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COMMISSION STAFF WORKING DOCUMENT

Better regulations for innovation-driven investment at EU level

Contents

1. Innovation and Better Regulation

Innovation is a necessary condition for sustainable growth for Europe. *'A growing body of evidence suggests a strong relationship between entrepreneurship, innovation, and economic growth'*[1], therefore '*action is needed to stimulate more and better investment in research and innovation.*'[2]

Innovation depends on a large number of systemic factors, including the incentives and obstacles set by the existing regulatory framework. A recent CEPS study[3] concludes that: *'EU regulation matters at all stages of the innovation process from R&D to commercialisation.'*

There is, however, no simple relation between innovation and the regulatory environment. For this reasons, the Commission is committed to evaluate the impact of existing or proposed EU regulation on innovation to maximize the way it can support innovation. The Commission Better Regulation procedures and its rolling REFIT programme provide a framework for this work, allowing it to enhance innovation-based opportunities for sustainable growth, jobs and competitiveness. A favourable regulatory framework would also enhance the impact of Horizon 2020 financing instruments, which support initiatives to tackle societal challenges and ensure industrial development, innovation and competitiveness in Europe.

Growth and job creation are top priorities of the Juncker Commission. Better Regulation, which helps unleash the full innovative potential of our firms and people, is central to the growth and jobs agenda. As President Juncker said[4]:

'Jobs, growth and investment will only return to Europe if we create the right regulatory environment and promote a climate of entrepreneurship and job creation. We must not stifle innovation and competitiveness with too prescriptive and too detailed regulations, ...“red tape” both at European and at national level that could be swiftly removed as part of my Jobs, Growth and Investment Package.'

As Vice-President Timmermans pointed out[5]:

'This Commission is determined to change both what the Union does and how it does it. Better regulation is therefore one of our top priorities. ... Better regulation is not about "more" or "less" EU rules, or undermining our high social and environmental standards, our health or our

[1] Working Papers 2010/03 Innovation, Entrepreneurship and Financial Market Cycles (Josh Lerner) http://dx.doi.org/10.1787/5kmjp6nt8rr8-en

[2] "Creating an innovative Europe", report of the Expert group chaired by Mr Esko Aho, following the Hampton Court Summit, http://ec.europa.eu/invest-in-research/action/2006_ahogroup_en.htm (2006)

[3] Does EU regulation hinder or stimulate innovation?, J. Pelkmans & A. Renda, CEPS Special Report No. 96, November 2014

[4] A New Start for Europe: My Agenda for Jobs, Growth, Fairness and Democratic Change Political Guidelines for the next European Commission

[5] http://europa.eu/rapid/press-release_IP-15-4988_en.htm

fundamental rights. Better regulation is about making sure we deliver on the ambitious policy goals we have set ourselves in the most efficient way.'

Moreover, Europe's ability to attract inward investment requires a pro-innovation regulatory context. The Commission has recently further confirmed the importance of innovation through:

- The 'Single Market Strategy' highlighting the need to assess the possible impacts on innovation of new policy proposals and to identify existing barriers and possible ways to remove them.

- The third strand of the 'Investment Plan for Europe' devoted to providing greater regulatory predictability and removing barriers to investment, thereby making Europe more attractive and thus multiplying the impact of the Plan.

The Commission's Open Innovation agenda aims at enhancing the regulatory framework for innovation. As Commissioner Moedas put it[6]:

'Open innovation is about involving far more actors in the innovation process, from researchers, to entrepreneurs, to users, to governments and civil society. We need open innovation to capitalise on the results of European research and innovation. This means creating the right ecosystems, increasing investment, and bringing more companies and regions into the knowledge economy.'

1.1. Innovation is key for growth, jobs and addressing societal challenges

Today, Europe is lagging behind its major competitors, especially in the share of private investment in R&I. It is therefore important to see if more appropriate framework conditions would allow, on the one hand, maximising the impact of public spending and, on the other hand, increasing the incentive for the private sector to invest, thereby creating more sources of employment and income[7].

Productivity is a key driver[8] for competitiveness, investment and growth. The link between innovation and productivity is well established[9] through the impact of R&D investment on productivity[10]. Europe faces a productivity gap[11] when compared with its main competitors. Since the outbreak of the 2007 financial crisis, the annual productivity rate per person employed in Europe has been less than a quarter of the US level and even far lower compared with China or

[6] http://europa.eu/rapid/press-release_SPEECH-15-5243_en.htm
[7] In 2015, EU GDP per head of population equals only around 50% of US levels in real terms and only slightly above 80% of levels in Japan or South Korea. Source: Eurostat and DG ECFIN. Data in PPS EURO at 2005 exchange rates.
[8] The Future of productivity, http://www.oecd.org/economy/the-future-of-productivity.htm
[9] E. Edworthy & G. Wallis, R&D and a value creating asset, UK Office of National Statistics, 2010
[10] J. Stancik and F. Biagi, Characterizing the evolution of the EU-US R&D intensity gap using data from top R&D performers (2012), European Commission IPTS-JRC, Seville
[11] EU productivity gap is driven by lower levels of capital investment and by lower multifactor productivity (MFP), the latter being the major explanatory factor of the gap of EU towards US and South Korea and Japan over the period 2007-2011. In addition, D. Andrews, C. Criscuolo (Knowledge-Based Capital, Innovation and Resource Allocation, OECD Economics Department Working Papers No. 1046) shows that MFP drives cross-country differences in GDP per capita.

South Korea. Such a gap creates loss of investment interest and market shares in global trade. The shortfall of investment over the past few years, with a drop of around EURO 430 billion since its peak in 2007[12] is likely to continue to hamper job creation and have a negative impact on the capacity for the EU to remain competitive in the long term.

The EU and the Member States also need to ensure that the conditions necessary for the competitiveness of the Community's enterprises exist, including facilitating adjustment to structural changes, encouraging a favourable environment for entrepreneurship and SMEs, encouraging an environment favourable to enterprise cooperation, and fostering better exploitation of the innovative potential of enterprises.

Another factor is the ability to generate fast growing firms that bring innovation on a large scale to the market. The capacity of an economy to create jobs in fast growing firms[13] in the most innovative sectors is the main source of GDP Growth[14]. During the period 2001–13, the most effective Member States enjoyed an annual growth rate of their GDP that triple of the rate of increase in GDP of the other EU Member States (and twice the EU average, the US or the Japan) over the period 2001-2013[15].

On the European level, the Lead Market Initiative for Europe (LMI)[16] constituted a test bed to support markets that are highly innovative, provide solutions to broader strategic, societal, environmental and economic challenges, have a strong technological and industrial base in Europe, and rely more on the creation of favourable framework conditions through public policy measures.

1.2. Regulation as part of the framework conditions for innovation

Innovation depends on a large number of systemic factors[17]. Barriers to the internal market, language barriers, and the weak presence of macro-clusters with different public and private stakeholders that would enable working on common solutions to new needs on a pan-European scale, all hinder the development of innovative companies. Only a small percentage of such companies reach a sufficiently significant size to establish themselves for the long term in the global market. Due to this lack of a sufficiently integrated system of innovation, too often innovations launched in Europe remain marginal, leaving competitors to impose their norms or business cases, ultimately leading to European companies disappearing or being left with a secondary role.

The importance of a high quality and cost-effective regulatory framework has been confirmed for fast growing firms[18] as well as for the innovation behaviour of traditional firms[19]. The Commission

[12] http://www.eib.org/about/invest-eu/index.htm
[13] Although direct comparison between countries should be avoided, the concept gives significant insights on the economic gains that these countries get from innovation.
[14] Report of the High-level Panel on the Measurement of Innovation chaired by Pr Andreu Mas-Colell (2010), https://ec.europa.eu/research/innovation-union/pdf/elements-for-the-setting-up-of-headline-indicators2013.pdf
[15] Their annual GDP growth rate was 1.65% against 0.77%. Data: Eurostat, OECD, Unesco,
[16] COM(2007) 860 final and its supporting document SEC (2007) 1729
[17] OECD Oslo Manual: Guidelines for collecting and interpreting innovation data, 2005
[18] http://ec.europa.eu/research/innovation-union/pdf/high_growth_p2-ki0115557enn.pdf#view=fit&pagemode=none . The survey analyse data on fast growing firms in the most innovative sectors in eight countries: Germany, France, United Kingdom, Poland, Switzerland, USA, South Korea and Japan.
[19] https://ec.europa.eu/research/innovation-union/pdf/KI-04-13-129-EN-N-RegulatoryScreening.pdf : Screening of regulatory framework, Final Report, 13 November 2013 (Technopolis Group)

worked from 2007 to 2012 on the reduction of the main administrative burdens imposed by EU legislation. It moved on to identify the main regulatory barriers faced by SMEs and developed its Regulatory Fitness and Performance Programme to encourage business and other stakeholders to identify how to reduce regulatory burden and increase the efficiency and effectiveness of EU regulation and its implementation in protecting the public interest, ensuring growth, jobs and a competitive economy.

The REFIT programme and broader Better Regulation Agenda have been further developed through the Communication in May 2015 on *'Better regulation for better results*' and the further REFIT initiatives announced by the Commission Work Programme for 2016, adopted in October 2015. The Single Market Communication[20] in October 2015 highlighted that the *'Commission Better Regulation framework sets out the tool needed to assess the possible impacts on innovation of new policy proposal and to identify existing barriers and possible ways to remove them'.*

While these actions are important at the EU level, the efficiency and effectiveness of national, regional and local regulation and administration can also have an important impact on economic performance and innovation.

1.3. Interaction between innovation and regulation

A recent CEPS study[21] concludes that: *'EU regulation matters at all stages of the innovation process from R&D to commercialisation. Individuals, firms and governments, when deciding on whether to engage with innovation, incorporate in their decisions general rules that shape the business environment, rules affecting market size (including, critically, also free movement, directly from the treaty), innovation-specific rules, but also sectoral rules and even rules that affect the later stages of the innovation process, e.g. rules on consumer protection.*'

There is no simple relation between innovation and the regulatory environment. No strict rules can be set on an optimal level of numbers of regulations in a domain, on their level of stringency[22] and on their stability over time[23]. The absence of generic criteria based on evidence makes it necessary to examine different parts of regulatory regimes to identify which parts – such as procedures for marketing authorisation – need to be stable and which parts – such as accommodating new production techniques or materials – need to be open to development. The relationship between regulation and innovation, therefore, needs to be examined on a case-by-case basis.

It is obvious that *'In highly regulated environments, the positive effect of regulation on innovation is more important in activities using or producing high technology'* [19]. A number of examples have been identified to illustrate such positive impact:

[20] http://ec.europa.eu/DocsRoom/documents/14007?locale=en (page 6)
[21] Does EU regulation hinder or stimulate innovation?, J. Pelkmans & A. Renda, CEPS Special Report No. 96, November 2014
[22] This point is worth underlining: the assessment of the impact of regulation on innovation is not a call for reducing the stringency of regulation when justified by public interest.
[23] "A clear taxonomy determining the direct and indirect innovation effects of a given regulation does not exist. How regulations affect innovation processes is, to a large extent, unknown" (ibidem).

- ✓ In the study[19] mentioned earlier, the Water Framework Directive, the Directives concerning Drinking Water, Groundwater, IPPC and Urban Wastewater as well as the Blueprint to safeguard Europe's Water are highlighted.

- ✓ From the same study: '*An instructive example of the positive interaction between EU regulation and innovation is found in energy efficiency regulation of household equipment, other small, e.g. office, equipment and cars. The general purpose of this category of EU regulation is to reduce energy consumption for a given use of equipment or of cars, in the light of the overall EU climate strategy to cut greenhouse gas emissions. An associated EU benefit of such regulation is the positive effect on energy security. Three regulatory instruments are of importance: consumer friendly colour labels, mandatory energy limits and credible compliance.'*

- ✓ Similarly, '*The End-of-Life Vehicles Directive 2000/53 and subsequent (comitology) regulations and decisions on regular updates of technical Annex II (the last in 2013),… aim to reduce waste arising from end-of-life vehicles (ELV) for cars and light commercial vehicles, … has had and still has a significant impact on innovation in the car and car related industries. … Altogether, ELV regulatory regimes are a powerful stimulant of innovation, beyond what market incentives combined with environmental rules may achieve.'*

- ✓ In addition, the Global System for Mobile telephones (GSM) is cited *'as a successful example of a European standard stimulating a breakthrough (disruptive) technology in mobile at the time, with a highly positive (though temporary) impact on the EU mobile equipment industry's competitiveness. It is the 'standard adoption strategy' that rendered GSM so special, with various pre-commitment mechanisms agreed and intensified over time. There was a Memorandum of Understanding in 1987 between telecoms operators with detailed principles of joint pro-competitive procurement, cross-border roaming and planning. The EU enacted directives on frequencies, on competition in telecoms terminals (such as handsets) and on mutual recognition of conformity of telecoms terminals, in addition to a recommendation and, later, a Commission mandate for ETSI to take over the technical standard issues.'*

Other examples include the 'centralised procedure' for authorising medicinal products laid down in EC Regulation 726/2004[24]. Allowing faster market authorisation than 28 separate Member State procedures and the 'orphan designation' for medicines was introduced by EC Regulation 141/2000 including a number of incentives for drug developers to develop medicines with small target populations.

Legislation can also hinder innovation if it is technically prescriptive, or limits the speed of technological progress, or creates uncertainty for investments[25]. It may favour existing technologies by diverting R&D resources from innovation to compliance tests[26], or discourage new firms as

[24] The centralised procedure, which came into operation in 1995, allows applicants to obtain a marketing authorisation that is valid throughout the EU. http://ec.europa.eu/health/authorisation-procedures-centralised_en.htm

[25] Knut Blind: The Impact of Regulation on Innovation, Nesta Working Paper 12/02 (2012)

[26] E.g. in the case of pesticides: Innovation And Regulation In The Pesticide Industry, Ollinger, Michael and Fernandez-Cornejo, Jorge (1998); similarly in the case of water quality standards, the pulp and paper industry may shift resources

compared to large firms that can afford the additional costs[27]. The lack of regulation in a given sector may also hinder innovation.

Regulatory bottlenecks can arise in the following situations:

I. The regulatory framework (i) is *de jure* or *de facto* prescriptive in technology choice and discourages different solutions and new entrants; (ii) establishes a level of stringency which is inconsistent with available cost-efficient technology, hence delaying investment and deployment of solutions or (iii) allows too frequent changes in standards which may also limit the incentive for investment if a technology is relatively recent. Examples[28] for possible further examination in the Annex are:

- Road vehicle automation,
- Aircraft products certification

II. Regulatory frameworks not sufficiently friendly for innovation can be identified when**:** (i) the regulatory environment is not fully interoperable across sectors and blocks co-operation and the development of open innovation based on multi-technology sourcing; (ii) regulations which are technology specific are not adapted in a timely way to technological progress or (iii) inconsistencies between regulations give rise to legal uncertainties and unnecessary additional compliance costs. Stakeholders view the following as possible examples of the above (see Annex):

- Health technology assessment,
- Nanomaterials: Towards a unified definition,
- Energy-efficient buildings.

III. Problems in the implementation of innovation-friendly regulations can also discourage investment and limit the marketing of innovative products, when: (i) legislation is not uniformly or not appropriately implemented across Member States; or (ii) European and National legislation duplicates, overlaps or is not fully consistent or repetitive controls and authorisation procedures are maintained. The examples indicated by stakeholders presented in the Annex as areas where implementation is a key issue are:

- Eco-design for resource efficiency,
- Energy-efficient buildings,
- Electrified vehicles.

IV. Gaps**:** If no EU legislation exists in a given field, barriers to the internal market may arise or there may be uncertainty for investment in innovation. Examples of this indicated by stakeholders (see Annex) are:

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away of radical innovation towards more incremental changes, according to an article by Norberg-Bohm & V., Rossi, M in 1998 (The Power of Incrementalism: Environmental Regulation and Technological Change in Pulp and Paper Bleaching in the US).

[27] European Commission, The Impact of EU Regulation on Innovation of European Industry: Regulation and Innovation in the Chemical Industry, Fleischer, M., Kelm, S., Palm, D (2000)

[28] As described in the Annex, all examples are the result of an initial stakeholder consultation.

- Road vehicle automation,
- Health technology assessment,
- Low carbon hydrogen in transport.

The conclusion of analyses carried out so far is that the key issue lies in the substance of regulation rather than its mere existence. Although clear and simple rules are generally recognised as being supportive for entrepreneurship[29], the relationship of regulation / innovation issue is more complex. Less regulation does not necessarily equal more innovation and nor is the reverse true. A thorough analysis of business needs in specific regulatory contexts linked to innovative solutions with appropriate risk management[30] is necessary to identify possible improvements in the impact of regulation on innovation and growth**.**

The relation between innovation and regulation needs be further investigated both at the horizontal level and from sectorial perspective, in order to identify and reduce bottlenecks and to find ways to improve opportunities for innovation.

[29] Communication on Entrepreneurship 2020 Action Plan (COM(2013) 795 final), especially section 3.6 on "regulatory burden: clearer and simpler rules".
[30] European Risk Forum think-tank position paper 'Fostering Innovation: Better Management of Risk' (March 2015).

2. An innovation-friendly regulatory framework

The Better Regulation Agenda and the third strand of the Investment Plan for Europe constitute comprehensive packages of various instruments with mutually reinforcing impact. They respond to the need to examine possible ways:

- To further improve the design of existing and future regulations as regards their impact on innovation;
- To achieve an optimal balance between predictability of the regulatory environment and adaptability to technological and scientific progress;
- To ensure an overall approach to the assessment of the combined impact of regulations that impact multi-technology and multi-domain innovations, with a view to simplifying and increasing the effectiveness and coherence of the regulatory framework;
- To check implementation issues that can affect outcomes, including at national, regional and local levels of administration, increasing dialogue with stakeholders to identify problems and seek solutions;
- To search for future proof, more forward-looking and innovation-friendly approaches.

The Commission's Better Regulation Agenda and the REFIT programme, in particular, provide a framework for further work on innovation. The 'Lighten the load' website and REFIT Platform provide for input from business and other stakeholders on regulatory burdens, inefficiencies and obstacles. The Better Regulation Guidelines (May 2015) provided a dedicated 'Research and Innovation Tool' which guides as to how to evaluate the positive and negative innovation implications of options for new legislative proposals. This is in line with the concept of an 'innovation principle'[31] that anticipates impacts on innovation to be assessed and addressed in policy or regulatory proposals. The Better Regulation tools also allow identifying cumulative burdens or inefficiencies of EU regulation and assessing impacts on competitiveness, all relevant to innovation.

There is an increased commitment to transparency throughout the regulatory cycle and public consultations allow for increased stakeholder input. Stakeholders need to bring forward perceived obstacles to innovation in their contributions to ex-post evaluations, the mid-term reviews of EU funding programmes (including Horizon 2020) and independently through the 'Lighten the load' website.

More specifically, as indicated in the Single Market Communication[32], the Commission will ask the REFIT Platform to launch a call for input from business on the impact of EU and Member State implementing regulation and administration on innovation to contribute to the identification of key areas for further work.

[31] https://www.businesseurope.eu/sites/buseur/files/media/imported/2015-00536-E.pdf
[32] http://ec.europa.eu/DocsRoom/documents/14007?locale=en (page 7)

3. Openness to innovation through Innovation Deals

A further approach to be explored is that of Innovation Deals. They will address regulatory uncertainties identified by innovators, which can hinder innovation within the existing legal framework. In cases where a regulatory obstacle can only be addressed at EU level, the European Commission could help national, regional or local authorities to identify and make use of existing flexibility in the EU legislative framework or to implement specific legal provisions appropriately by providing clarification. In this way, potential barriers to innovation can be addressed, whilst fully respecting EU law, without any derogation from the existing regulatory framework, unless specifically foreseen in the latter instruments. The involvement of all levels of government and administration would be ensured.

The Innovation Deals are inspired by the 'Green Deal' Programme[33] of the Government of the Netherlands, where a large number[34] of Green Deals were completed and proved successful in supporting the national Green Growth policy by providing regulatory clarity for innovative solutions.

Innovation Deals would not support 'normal' business activities, but would be restricted to innovative initiatives that have only a recent and limited or even no access to the market with the potential of wide applicability. Through involvement of the European Commission and the relevant Member State authorities, together with stakeholders Innovation Deals would seek to find ways to avoid potential innovation barriers arising from existing EU law or Member State implementation. They may concern actions which EU law already allows, but where confirmation or clarification of the legal position is sought, for example exploring existing flexibility within the legislative framework, eventually leading to testing and/or application of the innovation, fully complying with existing legal requirements. The outcome of Innovation Deals, therefore, will be considered by relevant Member State authorities for their policy and legislative actions, and will be monitored according to national schemes. Member State Authorities may be asked to report data in order to assess the impact of these Deals on economy, environment, growth and job creation.

If clarification, enhanced guidance, existing flexibility and/or demonstration of the innovative solution are not enough, and the existence of a regulatory barrier were to be confirmed as an obstacle to innovation and does not infringe or jeopardise any environmental, social or competition requirements, the Commission may consider initiating legislative amendments, subject to any further evaluation or Impact Assessment. This work would take place within the overall framework of the REFIT Programme.

As a first step, a pilot action in the Circular Economy is foreseen to help innovators facing regulatory obstacles by setting up agreements with stakeholders and public authorities[35]. If this is successful, Innovation Deals could be extended to other areas with demand driven requests in any possible area being considered on a case by case basis.. This would be in accordance with the principles of Better Regulation which encourage the involvement of stakeholders in making suggestions for more efficient EU regulation as for example through the REFIT platform[36].

[33] http://www.greendeals.nl/english/
[34] Up to now, 185 Green Deals have been concluded.
[35] http://ec.europa.eu/priorities/jobs-growth-investment/circular-economy/docs/communication-action-plan-for-circular-economy_en.pdf
[36] http://ec.europa.eu/priorities/democratic-change/better-regulation/feedback/index_en.htm

4. Conclusions

- A growing body of evidence suggests a strong relationship between investment in research and innovation, and economic growth. Therefore, opportunities need to be systematically sought to encourage and support innovation for sustainable growth, jobs and competitiveness.

- The regulatory environment may constitute enabling factors or perceived or real regulatory bottlenecks – barriers, frameworks not sufficiently friendly for innovation, implementation problems or gaps – to innovation. Business, other stakeholders, EU institutions and Member State authorities should work together to ensure an optimal regulatory framework to foster innovation.

- The systematic use of the Better Regulation Guidelines to assess key areas of innovation where the design and implementation of EU regulation is considered to have an important influence and can help dismantle barriers to growth, employment and competitiveness of EU business.

- A forward-looking regulatory approach within the framework of the Better Regulation Agenda could help to increase the level of investment in Europe through innovation, thereby supporting the priorities of the Juncker Commission:
  - ✓ Boost jobs, growth and investment
  - ✓ An internal market with a strengthened industrial base
  - ✓ A stronger Digital Single Market
  - ✓ A more efficient and effective energy union
  - ✓ An accelerated climate change policy

- The Commission services will further develop the preliminary analysis already undertaken, working together with the Presidency of the Council in the first half of 2016 to collect further suggestions on the relationship between innovation and regulation, indications of regulatory barriers to innovation and suggestions for simpler, clearer and more efficient regulation supporting growth and jobs. The Commission will consider asking the REFIT Platform to examine the resulting case studies and collect further evidence on a wider range of issues concerning the relationship between existing regulation and innovation.

- The concept of Innovation Deals will be further assessed, following the pilot action in the Circular Economy, to ensure increased opportunity for innovation within the existing regulatory environment at EU, national, regional and local levels.

Annex

All cases in this document are the result of an initial stakeholder consultation. They are based on common principles to allow thorough presentation and systematic comparison. Each case contains a concrete example about a potential barrier signalled by stakeholders. To ensure a wide collection of information, a large number of stakeholders have been contacted:

- all European Joint Technology Initiatives,
- the European Technology Platforms,
- the European Innovation Partnerships,
- Horizon 2020 contractual Public Private Partnerships,
- Member States through ERAC and
- Selected leading innovative companies.

Most of these stakeholders are umbrella organisations with extensive connections to those economic players who have experience and knowledge, and could provide concrete examples on missed or hindered investment opportunities.

The cases present a first and useful input, but a comprehensive assessment of all the factors that need to be taken into account when considering the overall effectiveness and efficiency of any particular piece of legislation is still necessary. They are valuable inputs to on-going, planned or possible future assessment of existing legislation and, potentially, future policy initiatives. Further preparatory work and wider stakeholder consultations, among others with the civil society, would always be needed before any conclusion is drawn.

All stakeholders were asked to identify and analyse potential barriers to and drivers for innovation according to their understanding of how regulation affects the given innovation-driven investment. They were expected to provide rationale for each case, to identify the regulations involved and to propose solutions. Since their views may be biased towards their own interests or be based on a limited perspective, an initial internal analysis was carried out to identify valid cases. The services and/or products concerned were linked by their NACE codes[37].

Overall, stakeholders highly appreciated the initiative; however, their responsiveness varied largely. The suggestions put forward varied in their technical content, clarity and detail. For some areas, converging inputs have been received, possibly pointing towards weaknesses in the underlying legislation. The link to research and innovation was not always explicit, in which case there was no follow-up given. A number of important sectors contributed to the exercise, with the most prominent being energy-, environment- and health-related.

Examples, as views on potential obstacles to innovation, have been selected from more than 60 possible cases from stakeholder input. The initial analysis concentrated only on the most pertinent elements with particular attention to the main economic indicators. A more thorough analysis will be undertaken once a selection of the areas most appropriate for follow-up has been confirmed. Further analytical work and empirical evidence gathering is planned in 2016[38] in this respect..

[37] European statistical classification of economic activities: http://ec.europa.eu/eurostat/web/nace-rev2/overview .
[38] A Commission study has been launched on 'Assessing the impacts of EU regulatory barriers on innovation' (expected results in 2016).

A.1. Road vehicle automation

ISSUE AT STAKE

Road vehicle automation is one of the major trends expected to shape the future of road transport and of mobility. It holds the promise of helping to address many of the major challenges of today's transport system, such as user safety, energy efficiency, air quality and traffic congestion, and to enhance drivers' individual comfort and convenience.

At the same time, it represents a critical testing ground for the ability of the European automotive industry to preserve and consolidate its international competitiveness. Car manufacturers are competing in a worldwide race towards vehicle automation and connectivity with new players from the IT sector (Google, Apple and Tesla). Automakers around the world are unanimous in predicting the emergence of systems for automated driving as a major market opportunity in the reasonably near future. Automated and connected driving has a huge market potential, not only for the European car manufacturers and suppliers, but also for the ICT industry and mobility service providers in Europe. There will be strong global competition in a sector occupied by many large companies with extensive resources and R&D potential.

Road vehicle automation can strongly contribute to three of the ten priorities identified by President Juncker:

- *A new boost for jobs, growth and investment – strengthen the competitiveness and mobilise private investment in innovation*
- *Digital Single Market*
- *A Resilient Energy Union with a Forward-Looking Climate Change Policy*

Road vehicle automation technologies encompass passenger, public and freight transport. They include all advanced vehicle systems that can assist or replace the tasks of the driver. Today, many vehicles are equipped with Advanced Driver Assistance Systems (ADAS) with 'function-specific automation', such as Adaptive Cruise Control, Lane Keeping Assist or Automated Braking. Current technology is expected to evolve from 'driver assistance' further towards 'partial automation' and eventually towards 'fully automated driving', completely piloting a vehicle on highways and in urban environments.

PROBLEM DEFINITION

- **Legal framework prevents the use of higher degrees of automated driving in Europe**

A potential barrier for the successful introduction of automated driving systems is the legal framework, which prevents higher degrees of automated driving in Europe. The rapid development of automation technologies resulted in an amendment of Article 8 of the 1968 Vienna Convention (Convention on International Road Traffic) in March 2014. According to this recent amendment, the driver still has to be present and be able to take over the steering wheel at any time. It allows the car to drive itself only as long as the automated driving system 'can be overridden or switched off by the driver' at any moment. All 72 countries that are party to the convention have to incorporate

the new rules into their laws. The convention covers most European countries and Mexico, Chile, Brazil and Russia. Similar rules are applied by the United Kingdom, United States and Japan (1949 Convention on road traffic). Although the amendment of the Vienna Convention therefore allows a certain degree of automation, it specifically precludes fully automated systems. This means that the convention could, if not further amended and once technology for fully automated driving is available, limit the take-up of fully automated systems.

Before highly and fully automated driving functions can enter the market, existing legislation on vehicle approval would have to be amended. According to UN/ECE regulation UN-R 79, 'Uniform Provisions Concerning the Approval of Vehicles with regard to Steering Equipment', automated commanded steering function is currently only permitted up to a speed of 10 km/h. A draft amendment, which allows the use of more innovative automated driving functions at higher speeds, is being discussed in the framework of the UN/ECE.

- ***Missing framework for large scale testing of automated vehicle technologies in Europe***

Technology development in the area of road automation is in such an advanced state that there is now a need to demonstrate the technological readiness, reliability and safety of the automated driving functions in large-scale pilots. Several Member States (e.g. France, Finland and the Netherlands) adopted the necessary legal framework to enable the testing of automated cars on public roads in 2015. Other Member States have introduced special exemption procedures (e.g. Germany, Sweden) or developed a non-regulatory 'Code of Practice' to allow testing on their roads. There is a risk that the fragmented solutions with different ways of allowing testing in each country will lead to amendments of Member State national traffic laws that are not harmonised across the EU. A common European framework for large-scale testing approach could be considered to stimulate testing and take-up of automated vehicles technologies in Europe, in line with the objectives of the EU 'Single Market Strategy'[39].

Mr Samuelsson, President and Chief Executive of Volvo Cars, said[39]: '*the US is currently the most progressive country in the world in autonomous driving (AD), but … this position could be eroded if a national framework for regulation and testing is not developed… Europe has suffered to some extent by having a patchwork of rules and regulation.'*

FORWARD LOOKING CONSIDERATIONS

Ideas, which need further examination, include:

- **Harmonised regulatory framework for the use of higher degrees of automated driving in Europe**

Current technology for automated driving is rapidly evolving and highly or fully automated vehicles are expected to become available in the next ten years. The regulatory framework needs to be established before these vehicles are ready for deployment.

[39] http://ec.europa.eu/growth/single-market/index_en.htm
[40] http://www.volvocars.com/intl/about/our-innovation-brands/intellisafe/intellisafe-autopilot/news/volvo-cars-responsible-for-the-actions-of-its-self-driving-cars

Further amendment of the Vienna Convention could be supported when necessary to maintain the pace of innovation in this area, e.g. to allow for fully autonomous vehicles or driverless cars.

The Commission, as a member of the World Forum for Harmonisation of Vehicle Regulations (WP 29) of the United Nations Economic Commission for Europe ("UNECE"), is in a position to advocate that the regulations should not hamper innovation and to promote the possibility for amendments of UN/ECE regulation (UN-R 79). In this respect, a step-by-step and flexible approach could be followed, which would allow the early approval of some specific automated driving technologies before implementing a blanket set of rules.

- **Temporary ad hoc permits for testing automated vehicles and European 'Code of Practice'**

The Commission could explore, together with the national authorities of those Member States interested in testing automated vehicle technologies and industry stakeholders, how to develop a harmonised approach for the testing of automated vehicles. This could, for example, take the form of a non-regulatory European 'Code of Practice' which defines clear guidelines for framework conditions (e.g. requirements for test driver or recording of data, liability during testing, infrastructure requirements, cyber-security, public education of testing, cross-border testing, etc.) under which tests can be implemented.

- **Platform for sharing and exploiting collected data in National, European and International Field Operational Tests**

The Commission could, together with Member States look at the possibility developing a platform for sharing and exploiting collected data in National, European and International Field Operational Tests (FOTs). This would allow individual FOTs to benefit from others' learning experience, leading to an increased efficiency of these trials and better support awareness of and support for innovative solutions.

- **Guidance on existing regulatory framework conditions for automated driving**

The Commission could consider providing guidance on other important legal framework conditions (e.g. data protection, privacy, data sharing, liability, safety or cyber-security) for the deployment of innovative automated driving systems. Such guidance would make it easier for researchers or companies to take into account the various regulatory requirements related to automated technologies stemming from other regulatory areas.

With regard to the speed of development of automated vehicle technologies, further urgent consideration could be given to the relationship between technological development, commercial application and existing international, EU and national regulation.

ADDITIONAL SOCIO-ECONOMIC ELEMENTS

A government commitment to ensuring the timely adoption of a clear legal framework for the use of higher degrees of automated driving could help ensure private and public investment in innovative solutions in the area of automated and connected vehicles in a sufficiently flexible way to accommodate all technologies and potential applications currently being pursued. This would have a positive impact on the competitiveness of the European automotive and ICT industry.

An EU-level policy could ensure fair conditions of competition across the EU and create a level playing field for European car manufacturers/suppliers, the ICT industry and other investors. This will support the exploitation of the potential of the Single Market and contribute to the development and implementation of innovative solutions.

Consideration could be given to the adoption of a 'European Code of Practice' to allow testing of innovative solutions based on temporary ad hoc permits.

Sharing experiences and valuable datasets could yield further research results, create new collaborative options, generate financial and time savings in transport research and contribute to market introduction of improved vehicle ICT.

A.2. Health technology assessment

ISSUE AT STAKE

The healthcare sector is characterised by a high degree of regulation. On the one hand, EU legislation provides harmonised rules to ensure the quality, safety and efficacy of healthcare products which can be placed on the market in the European Union. On the other hand, healthcare expenditures are largely subsidised by national healthcare systems, responsible for assessing and regulating the pricing and reimbursement of healthcare products and the conditions of their public funding.

The price and reimbursement of healthcare interventions, including medical products like medicines and medical devices are largely defined by the health technology assessment (HTA) process that is performed by independent agencies. HTA analyses the medical, economic, social and ethical implications of the value, effectiveness, costs and impact of a health intervention. These analyses are not necessarily limited to healthcare products (medicines and medical devices) but may look at healthcare more broadly, i.e. including, for example, surgical procedures, radiation, prevention and screening.

With currently about 50 HTA agencies in Europe (including national and in some countries regional agencies) fragmentation is very high. The limited standardisation and coordination of the HTA process in Europe requires that healthcare manufacturers address multiple stakeholders and systems which apply varying requirements to secure access to their products for patients in the different Member State markets.

Improving framework conditions for the healthcare sector to enable innovative products and solutions to reach the European market can be considered relevant to two of President Juncker's priorities:

- *A new boost for jobs, growth and investment*
- *A deeper and fairer internal market with a strengthened industrial base*

While medicinal products and medical devices account for only approx. 20% of health costs, these industries are the two major pillars of the healthcare sector, accounting for more than 25% of all European private R&D investments annually.

These two sectors are affected differently by HTA: while drugs developed by the biopharmaceutical industry are assessed by HTA agencies, HTA is not required by EU legislation for medical devices, and most medical devices do not have to undergo HTA to reach the market, especially low risk devices. Some countries perform such assessment nevertheless. High-risk devices may have to go through an assessment usually performed by hospitals or clinics to which the industry provides about 80% of its products, technologies and services.

The following case study focuses on HTA of pharmaceuticals. Its industry has the highest R&D intensity of all sectors in Europe: R&D accounted for 14.4% of the net sales in 2012. The sector includes 40 global pharmaceutical companies and about 2,000 small and medium-sized healthcare

biotechnology companies. It has about 750,000 employees in Europe, of which 130,000 work in R&D. In 2012, the European pharmaceutical market is the second world market (27%) after the US (41%). Revenues in Europe reached EURO 180 billion for the same year.

PROBLEM DEFINITION

Each Member State carries out assessments individually, under different legal frameworks. The varying results between countries raise the question of objectivity and accuracy of assessments, which are necessary to reward health technology developers for true innovation. In particular, for medicines multiple assessments impose a high cost on the industry which needs to submit its application multiple times, according to varying requirements.

Compared to EU level, separate assessments by individual Member States mean duplication of work. In addition, shortcomings in HTA coordination between Member States, notably differing requirements made by HTA agencies, can have negative effects by delaying patients' access to innovative treatments. Paradoxically, while pre-market regulations (EU legislation on medicinal products, incl. clinical trials, and medical devices) provide the European Union with a robust framework to undertake R&D, complex and fragmented post-market approval processes and reimbursement decisions could have a restraining effect on research and innovation in the healthcare sector.

In a recent study[41], the cost for preparing and submitting an application for one full national HTA was estimated to be approximately EURO 100,000. The global HTA cost for a healthcare product at the EU level is significantly higher given the number of HTA agencies. Delays also affect companies' revenues which are closely linked to patent duration, a crucial period of time during which companies can recoup their R&D investments.

The Patients 'WAIT Indicator' produced by the European Federation of Pharmaceutical Industries and Associations (EFPIA) reports the average time between marketing authorisation and patient access for new medicines. This is measured by the number of days elapsing from the date of EU marketing authorisation to the day of completion of administrative post-marketing authorisation processes, including in most cases HTA, pricing and reimbursement processes.

The Indicator shows that delays in market access are extremely varied in Europe, depending on the country and the setting where the drugs are used. The Transparency Directive[42] has fixed a maximum of 180 days for both pricing and reimbursement decisions altogether and contributed to improve the situation with regard to delays for patients to access treatment. Still, delays vary significantly between EU Member States and most countries do not respect the maximum of 180 days.

While innovation in the pharmaceutical and medical technology industries is accelerating with the rise of **Personalised Medicine**, fragmented approaches from HTA agencies can have a negative impact on R&D investment in Europe.

[41] Study funded by DG SANTE:
http://ec.europa.eu/health/technology_assessment/docs/study_ecorys_european_cooperation_hta_en.pdf
[42] See : http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31989L0105

Personalised Medicine: The traditional approach to healthcare treatments relies on the 'one-size-fits-all' approach where one treatment is used for millions of patients. However, following the sequencing of the human genome, the understanding of diseases at molecular level advances and the taxonomy of diseases is being redefined. Diseases historically seen as one disease are in fact a collection of diseases influenced by different pathological mechanisms requiring different treatment strategies. The rise of Personalised Medicine will require new methodologies and approaches in HTA to assess targeted treatments to be used by smaller populations.

There are currently several on-going initiatives aiming at improving cooperation between HTA agencies at the European level. These initiatives have been jointly implemented by the appropriate Directorates-General of the Commission (EUnetHTA Joint Actions[43], EMA-HTA parallel scientific advice, EU projects on HTA methodologies[44]).

FORWARD LOOKING CONSIDERATIONS

Currently, there are a number of on-going pilot projects to address HTA fragmentation. These are, *inter alia*, conducted in the framework of the cross-border Healthcare Directive.

- **Pilot 1: EMA-HTA early parallel scientific advice: centralised at EMA**

In parallel, scientific advice on the appropriate tests and studies is being provided at EMA by experts from HTA agencies nominated by EU Member States, as a complement to the regulatory scientific advice performed by the respective Committees (e.g. the Committee for Medicinal Products for Human Use). Parallel scientific advice on both marketing authorisation and HTA can help reduce delays by providing companies with early advice from several HTA agencies on requested data that can help fine-tune their development plans[45].

- **Pilot 2: HTA early scientific dialogue: decentralised at Member States level**

An early scientific dialogue takes place between the developers and a group of HTA agencies supported by HTA agencies' staff in the premises of one of the Member States agencies. In this part of the process, the advice on HTA is separated from the regulatory advice. This pilot is implemented by the EUnetHTA JA and is currently financially supported by the EU Health programme, albeit only on a temporary basis[46].

- **Pilot 3: Development of a common HTA methodology**

[43] In 2010, the European Commission funded the EUnetHTA Joint Action 1 (2010-2012) regrouping HTA agencies. The current EUnetHTA Joint Action 2 (2012-2015) aims to strengthen the practical application of tools and approaches developed by the network.

[44] 4 HTA EU projects are currently funded through the Health programme of FP7 to broaden the methodology so far used to cover specific areas, such as the Integrate-HTA project for evaluating complex technologies or the AdHopHTA project for adopting hospital based HTA in Europe. The Innovative Medicines Initative Joint Undertaking (IMI) has also devoted significant resources to HTA-related activities, via for example the 'Get Real' project which involves the industry, the European Medicines Agency (EMA) and several HTA agencies.

[45] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000049.jsp&mid=WC0b01ac05800229b9

[46] http://www.earlydialogues.eu/has/

In this pilot, HTA agencies have successfully developed a methodological framework for shared production and sharing of HTA information (HTA Core Model®) through their collaboration under the EUnetHTA JAs. However, it remains challenging to develop a full common methodology since the scope and objectives of HTA agencies vary significantly from one Member State to another.

The results of these initiatives will serve as a basis for possible decisions regarding pathways to an improved coordination and mutualisation of the work of national HTA agencies, thereby potentially facilitating pharmaceutical/medical products innovation in the EU.

A.3. Nanomaterials: Towards a unified definition

ISSUE AT STAKE

Nanotechnology has been identified by the European Union as a key enabling technology (KET) providing the basis for further innovation and new products.[47] Nanotechnologies engineer matter at the nanoscale to take advantage of the size-specific, enhanced or new properties such as higher strength, lighter weight, increased control of light spectrum, or greater chemical reactivity. Nanotechnologies provide new opportunities in virtually all sectors: health, energy, water, construction, consumer goods and clean technologies, to name just a few.

The global market for nanotechnology products is estimated to have a compound annual growth rate of ~20% from 2014 to 2019.[48] The European Chemical Industry Council has calculated that by 2015 there will be around two million nanotechnology jobs worldwide, of which 300,000 to 400,000 will be in Europe. These are predominantly high-skilled jobs.

Nanotechnologies development includes both innovative nanomaterials and innovative uses of well-known nanomaterials. Nanomaterials have been used in a wide range of applications, such as carbon black in tyres, pigments in paints, silica in food and toothpaste, for decades. The use of nanomaterials is prevalent throughout industrial sectors, covering both high tech and traditional commodity materials.

Their benefits range from saving lives (e.g. targeted cancer drug delivery), breakthroughs enabling new applications or reducing significantly the environmental impact[49] (e.g. photovoltaic cells and batteries, light-weight and high-strength materials, reduction in raw material consumption leading, for instance, to smaller volumes in similar products, reduced transport costs and overall carbon footprint of a product, soil and groundwater remediation) to improving the function of everyday commodity products (e.g. carbon black in tyres, synthetic amorphous silica in polymers). [50]

The total annual quantity of nanomaterials on the market at the global level is estimated to be around 11 million tonnes, with a market value of roughly EURO 20 billion. In high tech applications, it can be shown that the value added can increase by several orders of magnitude when moving up in the value chain, from the primary nanomaterial to its final use, in e.g. a photovoltaic cell.

While offering significant innovation opportunities, nanomaterials may also cause health and environmental risks, which raise concerns among consumers and workers. In order to ensure the safety of the products using such nanomaterials and to gain acceptance for their use, consideration needs to be given to the regulatory framework for their use. On the one hand, the regulatory framework needs to be able to respond to new health and environmental hazards, including appropriate screening and information gathering on nanomaterials, making good use of nanosafety research. On the other hand, it must be lean and flexible enough to avoid unnecessary administrative burden. Good governance of nanotechnologies, and of nanomaterials in particular, and appropriate balance of risks and benefits are essential to secure what is already achieved and for

[47] http://ec.europa.eu/enterprise/sectors/ict/key_technologies/kets_high_level_group_en.htm
[48] BCC Research, Nanotechnology: A Realistic Market Assessment (2014).
[49] Commission Staff Working Paper: Types and uses of nanomaterials, including safety aspects. SWD(2012)288 final.
[50] SWD accompanying the Second Regulatory Review on Nanomaterials (SWD(2012)288)

nanotechnologies to deliver their promises. Transparent information to citizens, in the most appropriate and understandable form, will facilitate confidence in nanotechnologies. Products containing nanomaterial that are developed by the industry safely and sustainably, and are adequately controlled by the regulators will have high levels of acceptance with citizens.

The use of nanomaterials, as for any substance, is subject to environmental and health protection regulations, as well as worker protection. While the applicable legislation must ensure a high level of health, safety and environmental protection, **it should also allow innovative products to reach the market quickly and thus promote innovation and competitiveness**.

Ensuring a swift, safe and sustainable deployment of nanomaterials through a sound, science-based and balanced regulation, covering also nanomaterials, is relevant to the following priorities of the European Commission:

- *A New Boost for Jobs, Growth and Investment*
- *A Resilient Energy Union with a Forward-Looking Climate Change Policy*
- *A Deeper and fairer internal Market with a strengthened industrial base*

Nano-innovation is driven by the constant and rapid development of new nanoforms with new or improved functionalities and their subsequent use in a wide range of innovative sectors and applications. A 2012 study estimated that the number of nanomaterials on the market lies between 500 and 2,000. Each of those has potentially numerous nanoforms[51]. Many are used in innovative applications, such as catalysts, electronics, solar panels, batteries and biomedical applications including diagnostics and tumour therapies. These applications will be essential for the competitiveness of a wide area of EU products in the global market. There are also many newly founded SMEs and spin-off companies in this high technology area. The market relevance of properly addressing nanomaterials in the regulatory framework is therefore considerable.

There is a broad range of legislation relating to nanomaterials. Early on, concerns about the safety of nanomaterials were raised[52], leading the European Commission and the EU legislators to react at different levels[53] and to introduce specific provisions on nanomaterials in the corresponding regulations. The regulations, listed below, target some or all of the following elements: (i) risk assessment (clarifications on requirements and/or new requirements), (ii) notification and authorisation procedures and (iii) 'nano-labelling':

- **Regulation (EC) 1907/2006 REACH** (through the Impact Assessment of the possible amendment of its annexes, currently on-going)
- **Regulation (EU) 1223/2009 on Cosmetics Products**

[51] A study to support the Impact Assessment of relevant regulatory options for nanomaterials in the framework of REACH, Matrix, 31 March 2014

[52] Nanoscience and nanotechnologies: opportunities and uncertainties, Report of the Royal Society and the Royal Academy of Engineering, July 2004 ; European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials (2008/2208(INI))

[53] Communication from the Commission - Towards a European strategy for nanotechnology (COM(2004) 338) ; Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee - Regulatory aspects of nanomaterials (COM(2008) 366) ; Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, Second Regulatory Review on Nanomaterials, (COM/2012/0572)

- **Regulation (EU) 528/2012 concerning the making available on the market and use of biocidal products** (BPR)
- **Food contact materials: Regulation (EU) 10/2011 'on plastic materials and articles intended to come into contact with food'** and **Regulation (EU) 450/2009 'on active and intelligent materials and articles intended to come into contact with food'**
- **Regulation (EU) 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control**
- **Regulation (EU) 1169/2011 on the provision of food information to consumers** (FIC)
- **Proposal COM/2013/0894 for a Regulation on Novel Foods**
- **Proposal COM/2012/542 for a EU Regulation on Medical Devices**

In areas such as REACH and worker protection, guidance documents on nanomaterials have been issued and the addition of specific nano provisions is under discussion in a new legislative proposal in development, replacing the EC Directives 98/24/EC and 2004/37/EC. In addition, the Commission is currently working on an **Impact Assessment on Transparency Measures on Nanomaterials on the Market**, as a follow-up to the second regulatory review and the explicit request from the European Parliament. This impact assessment evaluates different options to increase information on nanomaterials on the market, including a Nanomaterials Observatory and different forms of registries for nanomaterials and products containing nanomaterials.

Importantly, such **concerns are global** and are being addressed worldwide, in particular in the United States. **International dialogue and collaboration**, in particular with major trade partners, is key to avoiding unnecessary divergences and to stimulating the development and commercialisation of nanotechnology-enabled applications and industries.

PROBLEM DEFINITION

The underlying issue is having multiple and inconsistent definitions of 'nanomaterial' in the EU regulatory measures. This point affects all legislation addressed in the previous section.

The legally binding definition of "nanomaterial" varies across different EU regulations. The intention of the EC Recommendation[54] is to harmonise the definition of nanomaterial to avoid a situation where the same material could be a nanomaterial under one regulation and not considered a 'nanomaterial' in another. The present situation, in which the EC Recommendation has not yet been used in several EU regulations, could create some uncertainty in the area.

In part, the several definitions are due to legislative acts prior to the EC Recommendation (2011) (e.g. Cosmetics, food additives), but the complexity of amending a regulation also plays a role (e.g. rejection of the Food Information to Consumers (FIC) delegated act, the novel food proposal). This regulatory complexity (e.g., when the same (nano)material is categorised differently under different legislative measures) may act as a deterrent to investments. At the same time, as the Commission Recommendation on the definition of nanomaterial recognises, there may be valid reasons to

[54] The European Commission Recommendation 2011/696/EU on the definition of nanomaterial is foreseen for revision by 2016. The intention of the EC Recommendation is to harmonise the definition of "nanomaterial" across legislations. The scope of the targeted nanomaterials may however vary across specific sectorial legislation (e.g. limiting the scope to manufactured/engineered nanomaterials).

introduce or maintain specific elements in relation to a definition in sectorial legislation, also for the purpose of managing sector-specific risks in the most proportionate manner.

There is also a lack of validated or standard methods and reference materials to assess whether a material is a nanomaterial.

Based on a survey that aimed to collect feedback from key actors (authorities/agencies, industry associations, trade associations, NGOs, academic/research organisations) on their experience with the implementation of the definition, the recent JRC policy paper[55] reported that industry and trade associations '*would welcome a better harmonisation of the definitions of nanomaterials across legislation and with the EC definition. There are also concerns regarding non-harmonised national regulations based on different definitions. For example, if a nanomaterial is covered by several sector specific Regulations, e.g. by REACH (as a chemical substance) and by the Cosmetic Products Regulation (as ingredient,) different definitions would apply which would cause confusion.*'

The overall regulatory framework, including its implementation, for nanomaterials deserves careful consideration.

FORWARD LOOKING CONSIDERATIONS

Ideally, all EU legislation addressing nanomaterials would use a coherent and implementable definition for nanomaterials to allow for a coherent approach to the risk and safety assessment in different specific applications. One coherent definition or a framework to ensure the coherent development of the definition of nanomaterials would provide clarity on regulatory implementation and it would be beneficial for industry, encouraging innovation and investment decisions and increasing competitiveness. Any definition should allow for consistent implementation and effective application within the legislative framework, such as under health and safety at work and the OSH legislative framework. Undertaking regular reviews of the definition on nanomaterial in the light of scientific progress would be advisable.

With regard to the applicability of the definition, it should be noted that a review of the EC recommendation **2011/696/EU** on the definition of nanomaterial is currently on-going and that an FP7 project, NanoDefine,[56] is working specifically on the development of an integrated approach based on validated and standardised methods to support the implementation of the EC recommendation. The detection and identification of nanomaterials in complex matrices, which is challenging and acts as a major hurdle for regulatory implementation, is also an issue being tackled by several ongoing research projects.

[55] JRC Scientific and Policy reports (2014), 'Towards a review of the EC Recommendation for a definition of the term nanomaterial. Part 1: Compilation of information concerning the experience with de definition', Part 2: 'Assessment of collected information concerning the experience with the definition', Part 3: 'Scientific-technical evaluation of options to clarify the definition and to facilitate its implementation'.
[56] www.nanodefine.eu

ADDITIONAL SOCIO-ECONOMIC ELEMENTS

A harmonised definition of nanomaterial for innovative solutions across EU legislation could have the following impacts:

- Reduce uncertainty for all stakeholders.

- Avoid the need to multiply characterisation and evaluation costs for each different definition. As the number of candidate nanomaterials in different forms to enter the market could increase rapidly and have applications in several sectors, having multiple definitions could become unaffordable even for bigger industries and greatly delay entry into the market. Such a situation could have a dissuasive effect on investment decisions.

- Allow for pragmatic and affordable methods to implement a given definition (i.e. reduced analytical costs and legal acceptance of the material's classification and, subsequently, lead to the identification of hazardous properties and possible threshold limit values).

- Have an overall positive impact on the ability of European small businesses to compete in the nanomaterial market, as they are more vulnerable and disproportionately affected by regulatory requirements, because of their limited resources.

A.4. Aircraft products certification

ISSUE AT STAKE

For new aircraft products, operations and services certification is the gateway from research & development to market uptake, as a compulsory guarantee of safety and environmental compliance. The cost, time and uncertainty related to certification are important factors in preparing new products and services. The European Aviation Safety Agency (EASA) is in charge of certification in Europe, including for technologies developed in EU programmes. However, EASA participation in early R&D activities has been hindered due to the lack of dedicated resources. The solution has been addressed in the context of the revision of the EASA Regulation currently adopted by the Commission[57].

The issues and the measures to address them are outlined below as an illustrative case study of both the complexity of regulatory barriers to innovation and as a concrete example of the possibility of addressing them. The revision of EASA's Founding Regulation aims – amongst other things – to strengthen the Agency's work in the field of certification.

New aircraft development has strong contributions to at least two Commission priorities[57]:

- *A new boost for jobs, growth and investment*
- *A deeper and fairer industrial market with a strengthened industrial base*

It is important to shorten time-to-market and to decrease costs of the development and operation of new air transport products and services[58], notably for market-creating innovations. This would help increase the European share in the fast-growing global market despite increasing global competition.

The cycle from preparation to completion of certification tests for large aircraft can take more than 5 years. A 6-month delay in delivery to an airline can lead to penalties for the manufacturer of up to 2% of the price of each aircraft, or cancellation of orders to the benefit of competitors.

Development costs exceed EURO 10 billion for a new large aircraft. If a design issue is detected at a late stage of the certification process, the development costs can increase by 10%. The cycle design-build-test-redesign drives up costs and leads to delays.

The products and services concerned are:

- Manufacture of aircraft and related machinery (under NACE v2 code 30.30).
- Repair and maintenance of aircraft (under NACE v2 code 33.16).
- Passenger air transport (under NACE v2 51.10).
- Freight air transport (under NACE v2 51.21).

[57] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS: An Aviation Strategy for Europe" (ref. COM(2015) 598 final)

[58] As set out in 'Innovation Union' (commitments No 15 – Screen the regulatory framework in key areas; No 16 - Speed-up and modernise standard-setting) and 'Flightpath 2050 Europe's Vision for Aviation' (50% reduction in cost of certification; Europe leads the harmonisation of standardisation and certification processes globally).

Based on the forecast of sustained 5% air traffic growth, it is estimated that over the next 20 years worldwide, there will be more than EURO 4,000 billion of market opportunity for 30,000 new large/mid-size aircraft for passengers and freight[59].

In addition, it is estimated that there will be more than EURO 1000 billion market of opportunities over the next 20 years in other civil market segments (regional aircraft, helicopters, general aviation) and in emerging markets (un-manned aerial systems / 'civil drones' products & services, personal planes, high-speed/sub-orbital planes).

Following the R&D stage, all new aviation products and services need to be certified for safety and environmental compliance before market uptake. Therefore, EASA participation is needed in early R&D stages to avoid issues and delays later at the certification level.

Early preparation of certification is particularly important in EU programmes supporting aviation research & innovation, deployment and investment e.g. Horizon 2020 (including Clean Sky 2 and SESAR 2020 JTIs), Connecting Europe Facility (including Single European Sky Deployment) and Structural Funds (at least 20 EU regions include aeronautics among the targeted sectors)[60].

Research underpins the new certification processes and the new regulations, including those adopted internationally (United Nations' International Civil Aviation Organisation - ICAO), where EASA is called upon to play a more active role. The supporting technical evidence put forward firstly by one country (typically US) is influential in the final decision. The act setting up the US Federal Aviation Administration includes provisions not only for safety regulation but also for the promotion of aeronautics and air-transportation in such a manner as to best foster their development adapted to US commercial needs[61].

The improvement of certification with EASA participation in early R&D activities can also contribute to three other policy objectives of the Commission, namely:

- *Strengthening Europe's role as a global actor*, notably at United Nations International Civil Aviation Organisation (ICAO), where global regulations are discussed among aviation authorities on the basis of evidence collected e.g. from R&D programmes. Timely involvement of EASA in R&D activities could accelerate the pace of setting European regulations and standards, which could then become a reference at global level.

- *A resilient Energy Union with a forward-looking climate change policy*, as aviation is the fastest growing CO_2 emitting sector and earlier introduction of energy-efficient aircraft products, operations and services could help to mitigate this.

- *A Digital Single Market*, in relation to drones, aircraft connectivity and cyber-security by design.

[59] Airbus Global Market Forecast 2014-2033. 20 year related to average operation of aircraft and fleet renewal pace.
[60] More than 6 bEURO EU funding and 10 bEURO total costs of aviation-related EU programmes in the next 5 years.
[61] '- Competition to the extent necessary to assure the sound development of an air-transportation system properly adapted to the needs of the foreign and domestic commerce of the United States […] - The promotion, encouragement, and development of civil aeronautics.'

PROBLEM DEFINITION

The main issue relates to uncertainties in the timely and cost-efficient development and certification of innovative air transport products, operations and services if EASA is not involved at early stages of the R&I process. Certification issues increase costs and delays, put orders at risk, endanger market penetration, and reduce returns on investments for European companies. In a global market worth an estimated EURO 5000 billion over the next 20 years, each drop of 1% in market share equates to a potential loss of EURO 2.5 billion per year to the European industry.

A number of EU co-founded R&I projects address safety and certification related issues, in a broad range of areas from Human Factors (pilots' behaviour) to Fire on-board and Weather hazards. EASA involvement in R&I projects will, following adoption of the revised Founding Act, be improved through the re-orientation of its work from inception to regulation and certification issues. For example, regarding the ban on Lithium batteries transportation, recently decided at global level and affecting EU operators, the fire-risk evidence was based solely on information presented by US authorities taking into account US operators' needs.

Timely and cost-efficient safety and environmental certification require deeper and earlier involvement of certification authorities in the R&D stages of products and services, which increasingly include and integrate innovative technologies, processes and operations. Efficiency gains are possible by proactive early identification of issues in order to avoid redesigns at later stages.

National and intergovernmental aviation agencies in Europe (such as Eurocontrol) receive EU-grants in R&I projects, even if their regulatory competences are increasingly transferred to EASA, which is precluded from receiving EU grants. In the past, hand-in-hand involvement of those European agencies with companies and laboratories in EU R&I projects was instrumental in demonstrating at UN's ICAO that the Airbus' A380 did not need more flight distance separation than Boeing's B747, despite initial claims from US. If this had not been demonstrated, initial orders for Airbus A380 would have been severely compromised worldwide.

Increasing global demand, more emerging competition and growing safety and environmental requirements put pressure on European manufacturers and service providers to deliver quickly products that are more advanced and services with less development and operational costs. This trend has led to higher R&I in the European aviation sector in an effort to maintain or increase the global market share. Hence, consideration should continue to be given to possibilities to accelerate the pace of certification by EASA for new technologies incubated, matured and demonstrated in research programmes, not least because these new technologies may present new failure modes requiring new tests.

By increasing the speed and efficiency of the certification issue European air transport industry and service providers will benefit from decreasing time, cost and risks for entry into market of new services based on new, more efficient products or on new application of existing products.

Indirectly, passengers and airspace users will also benefit from earlier introduction of more efficient products and services in the market.

Timely and efficient certification will act as an enabler to secure part of the EURO 5,000 billion market opportunity in the next 20 years, to maintain the more than 500,000 direct jobs in the European Aeronautics industry and to achieve a good return on the investment of more than EURO 10 billion in EU innovation-related programmes planned over the next 5 years.

FORWARD LOOKING CONSIDERATIONS

Without prejudice to the need of a global and simple solution at EU level to allow relevant EU Agencies to bring their expertise into research programmes and use their participation in these in the context of their objectives including addressing regulatory barriers to innovation at early stages, the proposed revision of EASA Constituent Act, Regulation (EC) No 216/2008 (ref. COM(2015) 613 final) mandates and enables EASA to support and benefit from EU-funded programmes related to research & innovation.

- A dedicated article on Research and Innovation has been added to the EASA mandate to allow the Agency to participate in EU research programmes, to support the definition and accomplishment of the relevant Union framework programmes for research and innovation activities, including conducting evaluation procedures, reviewing funded projects and exploiting the results of research and innovation projects.

- A further specific article in the EASA mandate allows the Agency to receive grants for participation in EU programmes, without prejudice to other revenues for the Agency.

This will enable EASA to accelerate certification, which is a key factor ing maintaining the European competitiveness on the global market. It marks a significant step towards the aviation sector objective to achieve 50% reduction in development and certification costs by 2050[62]. It will assist in establishing Europe as a leader in the harmonisation of standardisation and certification processes globally, notably for market-creating innovations at UN's International Civil Aviation Organisation (ICAO), covering all elements of the industry through the entire life cycle from design through to disposal. It helps Europe to alleviate proactively market-entry barriers by third-country regulation and certification.

ADDITIONAL SOCIO-ECONOMIC ELEMENTS

Accelerated certification would have a positive impact on Europe's at least 40% share of the EURO 5,000 billion global market for new aviation products over the next 20 years[62]. Besides the positive impact on innovation in the sector, it may bring significant contribution to 'Flightpath2050' environmental goals (relative to the capabilities of typical new aircraft in 2000), namely 65% reduction of perceived noise emission of flying aircraft, 75% reduction in CO_2 emissions and a 90% reduction in NOx per passenger kilometre.

Faced with ever increasing competition, Europe can maintain and potentially increase competitiveness by ensuring faster entry into market of higher-performance products, by leading

[62] In line with Flightpath 2050, Europe's Vision for Aviation by The European High Level group on Aviation Research.

international standard-setting (notably at UN's ICAO) and by countering market-entry barriers by third-country regulations and certification.

Productivity of the European aviation sector should increase when new design and manufacturing techniques are aligned with new certification tests, rather than relying on compliance requirements based on previous products and services.

For SMEs, these competitive aspects are particularly relevant. For instance, in the case of market-creating innovations with lighter aircraft (e.g. drones, general aviation, personal planes), costs driven by certification are higher relative to the product value and to SMEs' financial capacity.

It could be expected that consumers will benefit from more affordable prices, safer, more secure, efficient and environmental-friendly products and services coming onto the market earlier.

A.5. Eco-design for resource efficiency

ISSUE AT STAKE

The Ecodesign legislation[63] provides EU-wide rules for improving the environmental performance of energy-related products, such as household appliances, information and communication technologies or engineering products, by setting out minimum mandatory requirements for energy efficiency of these products. Therefore, manufacturers do not have to navigate through multiple national regulations when launching their products on the market.

The result of current ecodesign requirements combined with energy labels has been estimated to be an energy saving of around 175 Mtoe by 2020, which is roughly equivalent to the annual primary energy consumption of Italy[64]. For consumers, this would mean a yearly saving of EURO 465 on household energy bills. Moreover, energy efficiency measures could create EURO 55 billion in extra revenue for industry, wholesale and retail sectors.

Ecodesign regulations have to date mainly addressed the use-phase energy consumption. There is, however, potential for reduction of other environmental impacts of energy-related products. A systematic integration of material efficiency requirements (e.g. product lifetime, recyclability, recycled content and/or design for higher efficiency in the use of Raw Materials) in the implementing measures of the Ecodesign Directive (2009/125/EC)[65] has the potential to drive innovation for circular economy business models through better product design. Ecodesign for resource efficiency can benefit consumers by making products more durable or easier to repair. It can help recyclers to disassemble products in order to recuperate valuable materials. It can contribute towards saving resources that are valuable for the environment and economy.

Market signals are, however, not always sufficient to make this happen, in particular because the interests of producers, users and recyclers are not necessarily aligned. It is, therefore, essential to promote and incentivise improved product design, while at the same time preserving the internal market and enabling innovation.

Adopting ecodesign implementing measures including material efficiency requirements for energy related products, developing European standards for material efficiency aspects and putting into place legislation on products other than energy-related ones can support the priorities of President Juncker on:

- *A new boost for jobs, growth and investment*
- *A deeper and fairer internal market with a strengthened industrial base*
- *A resilient Energy Union with a forward-looking climate change policy*

From the existing EU regulatory framework, the relevant legislation is the following:

[63] https://ec.europa.eu/energy/sites/ener/files/documents/list_of_ecodesign_measures.pdf.
[64] Ecodesign Impact Accounting Study, Van Holsteijn en Kemna B.V. (VHK), 2014; cited in the Ecodesign Working Plan, 2015
[65] OJ L 285/10, 31.10.2009

- **Ecodesign Directive for energy-related products (2009/125/EC), and its implementing measures;**

- **Directive 2010/30/EU of the European Parliament and of the Council of 19 May 2010 on the indication by labelling and standard product information of the consumption of energy and other resources by energy-related products.**

PROBLEM DEFINITION

The Ecodesign Directive was reviewed most recently in July 2015[66]. The impact assessment investigated why, to date, environmental impacts other than the use-phase energy consumption are not significantly addressed in the implementation of the Ecodesign Directive. One reason is that the use-phase energy consumption represented the most important contribution to the environmental impacts of the energy-related products. A second reason is that further modifications to the Methodology for the Ecodesign of Energy-related Products[67] ("MEErP') would be necessary to better fit the analysis of material impacts. In addition, to address more widely other environmental impacts, it would be necessary to regulate product groups other than energy-related products, as for such products environmental impacts other than use-phase energy consumption usually dominate.

Therefore, the problem that needs to be addressed is twofold. Firstly, there are potential untapped implementation opportunities for material efficiency (e.g. designing for circularity, recyclability benefit rates, recycled content, lifetime, and a critical raw material index) of energy related products which could be addressed through the implementation of the Ecodesign Directive, even though its implementing measures have so far focused on energy efficiency, with only a few exceptions. Secondly, no similar EU legislation exists for other types of products (e.g. furniture, textiles). The 2013 study on 'Screening of Regulatory Framework'[68] identified that regulatory measures can provide incentives for innovation in waste reduction and better use and recycling of materials. At the same time, market pressures such as growing material costs and consumers' environmental concerns provide incentives for companies to innovate. These drivers can be enforced via demand-side policies such as eco-efficiency standards in public-procurement, material input taxes, labelling systems, and technical standards.

Unilever designed new compressed deodorants that are smaller compared to the traditional diluted deodorants. In this way, it is possible to use half the propellant gas and on average 25% less aluminium in the compressed deodorants compared to the diluted ones. The reduced quantity of materials embedded in the products results in less weight and less volume that bring additional benefit in the supply chain. It has been estimated that simply increasing the number of cans in each load to be transported by trucks can result in a 35% less road usage. By the end of 2014 the combined sales of compressed aerosols (since launched) has reached over 106 million cans, resulting in aluminium savings of approximately 1,380 tons and CO_2 equivalent savings of approximately 16,600 tons.

[66] COM(2015) 345 http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015DC0345&from=EN
[67] http://ec.europa.eu/DocsRoom/documents/105/attachments/1/translations/en/renditions/native .
[68] http://ec.europa.eu/research/innovation-union/pdf/KI-04-13-129-EN-N-RegulatoryScreening.pdf

FORWARD LOOKING CONSIDERATIONS

The conclusion of the review of July 2015 of the ecodesign legislation was that environmental impacts other than energy in the use phase (e.g. durability, recyclability, reparability) could be taken up more systematically under ecodesign measures without the need to change the Directive. This could be achieved through implementing measures that include resource material requirements.

The environmental impacts of products other than energy-related ones represent a wider problem than the Ecodesign Directive, and there may be other ways to address some of them than to extend the scope of the Directive. The impact assessment for the review of July 2015 found that extending the scope of the Directives to cover all other product groups could potentially have twice as much environmental impact as at present. It concluded, however, that, because some of the environmental impacts of products other than energy-related ones are already addressed through other pieces of legislation, the potential of this extension of the scope of the Directive is actually smaller than expected at first sight. Therefore, there is no need to extend the scope of the Ecodesign Directive.

On the other hand, monitoring the implementation of the updated MEErP would help to assess the environmental impacts related to material efficiency parameters. The MEErP has been updated in December 2013 to include parameters such as reusability, reparability, and recyclability. These parameters, enabling further analyses of material efficiency aspects in products, have been shown to be fully functional and ready to be used in future ecodesign preparatory studies. Their introduction in the implementing measures would address the need to keep materials circulating in the economy and would offer a potential for innovating ecodesign of non-energy related products. Monitoring the implementation of the updated MEErP would show whether the impact categories, the characterisation factors, the inventory database and the assumptions in the modelling of the MEErP and its Ecoreport tool are appropriate for the analysis of material impacts.

Another issue for consideration is that resource efficiency requirements need measurement methods, which are usually developed by European Standardisation organisations in supporting EU product legislative requirements. A request to the European Standardisation organisations to draft European Standards with regard to ecodesign requirements for material efficiency aspects would support the legislative work.

The 2015 Circular Economy Package supports the development of material efficiency criteria in energy related products, including the forthcoming Ecodesign Working Plan 2015-2017.

ADDITIONAL SOCIO-ECONOMIC ELEMENTS

Integrating the material efficiency requirements in the Ecodesign Directive implementing measures would have substantial impact on innovative solutions, which, in turn, would bring additional economic, social and environmental impacts.

- Resource efficiency increase in the EU: the introduction of material efficiency requirements in products, including recycled content, lifetime, reparability, recyclability and a critical raw material index, would lead to saving in material use and reduction of waste generation.

- Opening the market for new products and circular economy models: the introduction of material efficiency requirements in products has an untapped potential for new opening new markets. It would facilitate the implementation of eco-innovative solutions for recovery of resources,

promote the use of secondary raw materials, minimise waste and facilitate the implementation of new business circular economy models.

- Reduction of CO_2 emissions and less pressure on the environment for raw materials: it is estimated that applying design solutions (like the use of more durable parts, or the reduction of product weight) for a restricted set of existing products (microwaves, LCD televisions, washing machines, tumble dryers, laptops, and refrigerators) in the UK could lead to Greenhouse Gas savings of about 400,000 tCO_2-eq/year and product material savings of about 170,000 t/y[69]. In the same way, by prolonging the lifetime of a set of products (laptop and printers from 3 to 5 years, and washing machines from 12 to 30 years) average greenhouse gas savings of about 1 million tCO_2-eq/year and savings in resource depletion of about 9,000 t Sb-eq/year[70] could be achieved in the EU.

- Creation of jobs: around 2 million additional jobs could be created in the EU with 2% Resource Productivity improvement per annum by 2030, partly from investment and partly from using market-based instrument revenues to reduce labour costs.

- Savings for end-users: it can provide consumers with more durable and innovative products that provide monetary savings and an increased quality of life.

[69] European Environmental Bureau, Delivering Resource-Efficient Products (2015): data extracted from WRAP
[70] In Life Cycle Impact Assessment methodology, one of the reference unit for Abiotic Resource Depletion is kg Antimony [Sb] equivalent.

A.6. Energy-efficient buildings

ISSUE AT STAKE

The energy efficiency potential of buildings is huge. Improved efficiency in buildings could cut Europe's total energy use by over 20%, reduce energy bills by EURO 270 billion and reduce CO_2 emissions by 460 million tonnes a year.

Buildings are a major target area for achieving the EU's energy efficiency goals, which are currently at least 27% improvement in energy efficiency by 2030. This will be reviewed before 2020, with a possible increase in the target to 30%. The Commission will pay particular attention to sectors with an important efficiency potential including buildings. The quest for better energy efficiency in buildings concerns new buildings as well as improvements for existing buildings, in both the public and private sector. The Communication on an Energy Union[71] foresees a review and possible revision of the Energy Performance of Buildings Directive 2010/31/EU (EPBD)[72] by the end of 2016.

The (re)construction of energy efficient buildings plays an important role in the priorities put forward in President Juncker's Political guidelines:

- *A new boost for jobs, growth and investment*
- *A resilient Energy Union with a Forward-Looking Climate Change Policy*

Buildings also consume other resources such as materials and water and they do so during their full life cycle, from extraction of materials, manufacturing of construction products, construction, use phase and end of life.

It is therefore important to be aware of the necessary trade-offs between different kinds of resource use in different stages of the life cycle. This will require a new approach, and build-up of reliable and comparable data. Those wider environmental impacts will have to be addressed via different policies, in order to obtain similar positive trends as those we see today for energy efficiency. Such policies would have to be based on a wider assessment of the environmental performance of buildings.

The Commission Communication on the 'Strategy for the sustainable competitiveness of the construction sector and its enterprises' (COM(2012) 433 final) aimed at facilitating sustainable growth and development in the construction sector. The 'Construction 2020' Action Plan that accompanied the Communication aimed to support the construction sector in adapting to key upcoming challenges, including the resource efficiency aspect. Among the REFIT actions planned for implementation during 2016 a fitness check (originally Cumulative Cost Assessment) of the most relevant EU legislation impacting on the construction sector will be conducted, in the areas of internal market, energy efficiency, health and safety and resource efficiency.

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71 http://ec.europa.eu/priorities/energy-union/index_en.htm

72 Directive 2010/31/EU of the European Parliament and of the Council of 19 May 2010 (recast)

The Strategy for the sustainable competitiveness of the construction sector and its enterprises was followed by a Commission Communication on 'Resource Efficiency Opportunities in the Building Sector' (COM(2014) 445final), which set out a route towards a common European approach to assess the environmental performance of buildings. Such a common approach targets a common language, increased transparency and support for the business case for buildings with a better environmental performance overall. Work is now ongoing to develop this approach further, in close co-operation with stakeholders, and a first framework with core indicators due by summer 2017.

A Public-Private Partnership (PPP) on Energy-efficient Buildings (EeB) was launched in 2008 and it continues under Horizon 2020. With nearly EURO 200 million for the 2014-2015 calls, the cPPP aims at developing affordable breakthrough technologies and solutions for building and building districts. The calls under the EeB PPP were complemented by the Energy Efficiency 2014-2015 calls under the societal challenge 'Secure, Clean and Efficient Energy'. The Energy Efficiency calls are focused on removing existing market barriers by building capacity, providing support for sustainable energy policy implementation and fostering the uptake of innovative technologies and solutions.

The European construction sector including its extended value chain (e.g. material and equipment manufacturers, construction and service companies) registered a yearly turnover of around EURO 162 billion in 2013 (8.8% of EU's GDP).

The sector is crucial for job creation: every job created in construction sector generates two further jobs in related sectors. In 2013, there were 13.9 million direct jobs (6.4% of total employment and 29% of industrial employment). The building area represents 79% of activities and civil engineering represents 21%. In addition, the sector is a key employer at regional and local level since by its nature construction of new buildings and retrofitting of existing stock are geographically distributed activities. The skills upgrading in the building construction workforce to deal with the challenges of improved energy performance and renewable energy integration is also being supported under the Horizon 2020 societal challenge 'Secure, Clean and Efficient Energy' within the 'BUILD UP Skills' initiative.

Regulation, including internal market, health, safety, energy and environment-related, affects and guides every activity and aspect of the construction sector. Construction is influenced by a number of regulations that govern products and processes, as well as by planning and environmental regulations governing finished products. Innovation in the construction sector is generally characterised by the adoption of new practices and advances in both technological and business processes. The introduction of performance requirements as in the area of energy efficiency paves the way for long-term investment and encourages building designers to make better choices and incorporate innovative solutions.

Thus, coherent standards and regulations should be explored, enabled by effective metrics that would be difficult to develop at the level of single Member State or with a market push by industry alone.

Energy efficient buildings can also contribute to other Commission policy objectives, namely:

- *A Deeper and Fairer Internal Market with a strengthened industrial base*
- *Energy 2020: A strategy for competitive, secure and sustainable energy*
- *A Digital Single Market, the internet and digital technologies are transforming the way the 'house of the future' will be built. ICT offers a major opportunity to reduce emissions from the construction sector, by 15% in 2020*

The following EU regulations have been identified as relevant for the uptake of innovation in the sector:

- **Energy Performance of Buildings Directive (2010/31/UE) recast**

Review date: The directive shall be evaluated by 1 January 2017 at the latest. This review is currently ongoing. The evaluation roadmap was published in July 2015[73]. It is accompanied by a public consultation[74] which was open until 31 October 2015, which will provide the basis for the Impact Assessment of policy options in the framework of the EPBD review and its possible revision.

The 2010 EPBD (replacing Directive 2002/91/EC) sets the framework to improve the energy efficiency of EU buildings. It requires Member States to set minimum performance standards for buildings; to apply energy performance certificates to buildings; and to ensure that, from the end of the decade, only "nearly zero energy buildings" (NZEB) are built. Besides the 2018 and 2020 NZEB targets, the EPBD requires support policies to refurbish the existing building stock to the same "nearly zero-energy" levels. This obligation is complemented by the strategies to mobilise investment in renovating the building stock in line with the EED. The EPBD provides general EU principles and objectives for a system of energy performance requirements, leaving flexibility to Member States to define national implementation in accordance with local and regional conditions.

The EPBD introduced a benchmarking system ('cost-optimal methodology') to increase the level of ambition of the efficiency requirements in the national or regional building codes, while ensuring that these are set at the best value for money but also encouraging innovative solutions. Whilst the Eco-design Directive regulates the placing on the market of individual products, the EPBD sets requirements for their performance as part of the technical systems serving a building. Overall, the EPBD offers a performance-based framework and reference that is open to innovation at different integration levels (e.g. building/system/product).

- **Construction products Regulation (305/2011)**

Review date: April 2016 (plan for Report on CPR implementation - Assessment of the application of the CPR in Member States).

The Construction Products Directive is an internal market Directive with the primary purpose of overcoming technical barriers to trade when different Member States had different standards, testing and labelling approaches for the same construction products.

The CPR aims at ensuring reliable information on construction products in relation to their performance. By offering a 'common technical language' and a uniform assessment method of the performance of construction products this goal can be achieved.

- **The Energy Efficiency Directive (2012/27/UE)**

The Commission is required (Article 24 of the Energy Efficiency Directive) to review the implementation of Article 6 and Article 7 and to submit a report to the EP and Council in 2016.

[73] http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_ener_023_evaluation_energy_performance_of_buildings_directive_en.pdf.
[74] http://ec.europa.eu/yourvoice/consultations/docs/planned-consultations_en.pdf

The directive addresses one of the three key main pillars identified in the EU 2020 Strategy, a 20% reduction of energy consumption by 2020 compared to projections. The directive requires that Member States renovate every year at least 3% of buildings owned and occupied by central governments. Member States must draw-up long-term national building renovation strategies, which can be included in their National Energy Efficiency Action Plans. Article 7 of the directive requires Member States to set up an energy efficiency obligation scheme or to use alternative measures to ensure a reduction of at least 1.5% in energy sales to final customers. This Article is expected to deliver more than half of the energy savings required to reach the 2020 20% energy efficiency target.

- **Products legislation**

This framework is mainly composed of two directives, the Eco-Design Directive and the Energy Labelling Directive. It has the dual purpose of ensuring that the worst performing products are removed from the market (eco-design) while encouraging consumers to buy the most efficient products (energy labelling).

- **Eco-design Directive (2009/125/EC)**

Review date: Under article 21 of the Directive, the Commission was required to review, no later than 2012, the effectiveness of the Eco-design Directive and its implementation measures, and to assess the appropriateness of extending the scope of the directive to non-energy related products. However, the review showed that it was too early to assess certain aspects, including the effectiveness of implementing measures and harmonised standards, which were subsequently assessed during the review of the Energy Labelling Directive (see below). These reviews concluded that addressing environmental impacts other than energy in the use phase (e.g. durability, recyclability and reparability) can be taken up more systematically under eco-design measures without the need for changing the legislative framework and that scope extension beyond energy-related products is not appropriate at this time.

The Directive establishes a framework for the setting of eco-design requirements on Energy related Products (ErP) addressing all environmental aspects from a life cycle perspective. Examples of such energy related products include lighting equipment, motors, pumps, refrigerators, computers, TVs, air conditioning and ventilation systems or machine tools.

The Directive sets minimum efficiency standards for products used in the building sector (e.g. boilers, hot water, generators, pumps, ventilation, etc.).

- **Energy Labelling Directive (2010/30/EU)**

Review date: the Commission was to evaluate the effectiveness of the directive and submit a report to the European Parliament and Council by end of 2014.

The directive establishes a framework for product specific energy labels for a number of energy-related products, including products used in the building sector.

Based on the outcome of the evaluation, the Commission concluded that a revision was appropriate and it has proposed to replace the current Directive by a Regulation. The proposed Regulation establishes a framework for energy labelling, which has to be uniform across the EU given the internal market for products imperative. This is more likely to be achieved, whereas a Directive has to be implemented in national legal systems, leading to possible divergences.

The Commission proposed a new Energy Labelling Regulation on 15 July 2015. Its contribution to 'innovation' is foreseen as follows:

- *'Benefits outweigh the costs, both for businesses and for society as a whole. Energy labelling is a principal driver for innovation, alongside consumer demand and competitive positioning. The more ambitious the requirements are for the top classes, the more they give businesses the opportunity to positively differentiate their products, thereby stimulating innovation.'*

- *'To encourage technological progress and innovation and enable ever more efficient products to be recognised.'*

- *'Energy labelling allows consumers to make informed choices with regard to energy consumption of products and thereby promotes innovation.'*

- *'Improving the efficiency of energy-related products through informed consumer choice benefits the Union economy overall, drives innovation and will contribute to the achievement of the Union's 2020 and 2030 energy efficiency targets.'*

The energy efficient building sector is characterised by demand from different sources. Demand comes not only from the private sector for residential or office buildings but also from public infrastructure projects, which can be particularly important drivers of demand in the market. The public sector is a major client of the construction industry and is expected to boost further development by targeted and criteria-oriented procurement. Moreover, regulatory frameworks, e.g. in terms of energy performance, quality and environmental standards, have substantial impact on technological direction and sector-specific R&D activities, thus they may induce innovation in the construction sector and shift public and private demand to specific products and services.

PROBLEM DEFINITION

The replacement or renovation rate of the existing stock is very small (1-2% yearly) and acceleration is urgently needed. Innovative solutions have a role to play not only in facilitating renovation but also in developing new technologies and solutions for highly efficient new buildings. Innovation has a role to play in the full building value chain from design to end-of-life, which includes design and engineering services, manufacturers of construction materials and technologies, onsite construction companies, property developers and facilities managers, energy companies as well as building users. The building sector is still largely crafts-based. There is a huge potential to render the current cumbersome and lengthy renovation processes much more client-friendly through industrialisation, where applicable.

Feedback from industrial stakeholders does not report EU level regulatory barriers to innovation (also taking into account that the costs of investments play an important role in determining decisions) but acknowledges the differences that remain across Member States in this sector.

Some variations appear justified because of the geographic and climate situation, diversity in cultural aspects or traditions, the level of economic development, energy resource endowments and demographics of Member States that influence the energy needs of households. The outcomes from energy efficiency improvements depend greatly on the country context. For example, the need to cool buildings in hot countries should not be neglected, next to the heating needs in cold countries.

Stakeholders would nevertheless value better comparability of the energy requirements of buildings among Member States.

FORWARD LOOKING CONSIDERATIONS

- **The foreseen revision of EPBD**

Industry stakeholders have suggested the design and implementation default values for calculating energy efficiency characteristics of buildings based on 'geo-clustering'. In such an approach, countries or regions could be clustered based on their geographic, climatic and other key parameters determining the energy performance of buildings. The clustering approach was explored in the EU funded project 'GE2O70: Geo-clustering to deploy the potential of Energy Efficient Buildings across EU'. This project resulted in a mapping tool that considers local similarities across EU by combining single or multiple parameters and indicators organised in homogeneous layers and sub-layers. This approach should be in line with the CEN standards for a methodology calculating the integrated energy performance of buildings and promoting the energy efficiency of buildings, in accordance with the EPBD, which are under development and will be ready in early 2016.

This new set of EPBD standards will be a systematic, clear and comprehensive package for the benefit of professionals, construction industry, Member States and relations with third countries. The EPBD standards will also provide the underlying calculation methodology for the European Voluntary Certification Scheme in the non-residential sector, which is currently under development (as required by Article 11(9) of the EPBD). This will allow for the fair comparison of different buildings' energy use across borders.

- **The Report on CPR implementation - Assessment of the application of the CPR in Member States**

Other areas with innovation potential for the buildings sector (further data, input is expected from the EeB PPP) are the following:

- Impact of fire-testing regulations on the innovation potential for energy efficiency in buildings (addressing the need to consider fire safety requirements at an early stage e.g. of development of building materials, questions on EU-wide coherence of rules and related market potential).
- Regulatory requirements and incentives for recycling of aggregates ('urban mining' of demolished buildings).

- **Available framework with core indicators for the assessment of the environmental performance of buildings (summer 2017)**

Once the framework with core indicators for the assessment of the environmental performance of buildings is available, it would be worthwhile to consider how to incentivise its use in different building markets, via voluntary and mandatory policies.

A.7. Electrified vehicles

ISSUE AT STAKE

Electrified vehicles – mainly All-Battery Electric Vehicles (BEV) and Plug-in Hybrid Electric Vehicles (PHEV) – have the potential to help address many of the major challenges of today's transport system, such as energy efficiency, emissions reduction, noise and air quality. Supporting their deployment will help maintain and consolidate the industrial and technological global leadership of the European automotive industry.

The electrification of road transport is one of the most important technology paths towards achieving the goals of the European Commission's Transport White Paper[75], particularly the goal of halving the number of conventionally fueled cars in cities by 2030 and phasing them out by 2050, as well as a 60% reduction of GHGs by 2050 (compared to 1990), and achieving essentially CO_2-free city logistics of goods by 2030. At the same time, the electrification of transport offers a pathway to introduce renewable energy sources into the transport system.

The production and deployment of electrified vehicles has significant potential to contribute to four of the ten priorities identified by President Juncker:

- *A New Boost for Jobs, Growth and Investment*
- *A Resilient Energy Union with a Forward-Looking Climate Change Policy*
- *A Deeper and Fairer Internal Market with a Strengthened Industrial Base*
- *A Connected Digital Single Market*

The European Commission has funded research and development projects on electric vehicles since 2009 in the framework of the European Green Cars Initiative PPP (EGCI) and its successor in Horizon 2020, the European Green Vehicles Initiative cPPP (EGVI) which is focused on energy efficiency and alternative powertrains.

The target projected by industrial stakeholders of the EGVI sets a 10% market share of electric and plug-in hybrid passenger cars by 2025 (as compared to a market share of 1.2 % in 2013). The funding of research and innovation projects in the domains of energy storage, powertrain and system integration in the EGCI and EGVI is thus essential for achieving the objectives of the Transport White Paper to decrease transport emissions by 60% by 2050.

Amongst the high number of legislative measures relevant to electrified vehicles, **Directive 2014/94/EU 'on the deployment of alternative fuels infrastructure'** is the key to addressing barriers to innovation in this case, together with Regulation 443/2009 on CO_2 emission limits.

PROBLEM DEFINITION

Innovation in the field in Europe is hindered by market segmentation. As a result, compared to other regions of the world, Europe is lagging behind in the deployment of electrified road transport and in

[75] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011DC0144&from=EN

the industrialisation of some technologies. As of December 2014, the following fleets of highway capable rechargeable electrified vehicles have been registered: 291,322 in USA, 108,248 in Japan, 83,198 in China, 45,020 in the Netherlands, 43,605 in France, 43,442 in Norway and over 25,000 in Germany.

To reach the 10% market share target of electrified passenger cars stated in the EGVI, further measures will be needed to reduce market fragmentation and thereby boost innovation for competitive electrified vehicle production. In the following, two market barriers for innovation are discussed.

Technical interoperability at the level of connectors

The technical interoperability between electrified vehicles and recharging stations would avoid fragmentation and maximise the number of available and accessible recharging points in a given geographical area. Connectors will be standardised from 2017 at European level through the Directive 2014/94/EU 'on the deployment of alternative fuels infrastructure' (which also addresses natural gas and hydrogen supply for transport). However, there are other connections (EU standardised or non-standardised) used for fast charging, such as Chademo (from Japan) and Tesla (from the US), which are being deployed in parallel and are not compatible with each other. The date of November 2017 was requested by Member States to allow existing users of vehicles with other charging technologies able to charge their cars during the lifetime of their car. Customers will, nevertheless, continue facing a segmented market because even after 2017 the owner of an EV equipped with non-EU standards will only be able to recharge in a limited number of stations. This market segmentation is going to be reduced by the fact that many new fast charging stations being installed are dual standard (Combo 2/Chademo).

Tesla decided to deploy its own network across Europe with ultra-fast recharging to serve its customers. The network provides privileged access to their customers at their recharging stations. Tesla forecasts 448 stations by end 2015. However due to lack of interoperability and marketing reasons, these stations are only accessible for Tesla vehicle owners at the moment, which gives undue advantage to Tesla, because the users of Tesla cars can however access some other networks through the Type 2 plug and via an adaptor that allows the conversion to the Chademo plugs.

On the car side, at the end of last year there were about 10 models on the market capable of fast charging with Chademo (some European brands but based on Japanese models – only one with significant sales – Nissan Leaf), three with AC charging on the Type 2 plug and three with DC on Combo 2, while seven were not capable of fast charging at all. The poor interoperability of the network presents a negative image of electrified vehicles.

The electricity suppliers also recommend shifting over time to Mode 3 charging (IEC 61851) as the preferred solution for all types of locations. In Mode 3 charging, the vehicle is connected directly and can communicate with the electric grid (this is often the case for public charging spots, while at home this is not required but it is possible with an intelligent wall box) using an EV multi-pin socket with control and protection functions.

Electric vehicles and the corresponding charging infrastructure may therefore be part of the future smart home/smart building system that interacts with the electricity grid. E-mobility infrastructure that offers Mode 3 charging enabling communication or other smart charging solutions which open the way for smart load management will be required in an efficient electricity system and contribute to building-up the Digital Single Market. However, currently the electricity market does not allow such services to the grid being remunerated at this disaggregated level. New price signals are necessary at distribution level and the regulatory framework has to incite new business models taking advantage of this space. In the case of fast chargers such prices will be further increased and would need to incorporate other costs such as space occupation and local storage devices.

Free and easy access to all electricity networks

Market fragmentation is similarly severe regarding payments for recharging. Electrified vehicles are not able to recharge when the electricity providers promoting Mode 3 charging are not able to identify the driver as a registered end-user of an incumbent electricity or service provider. This occurs when travelling across different Member States or even across Regions. The problem is similar to what would happen when using mobile phones in different Member States if they didn't have the possibility both to access and pay for a service (which requires a payment system with technical and legal compatibility). The possibility to 'roam' between Member States with a single SIM card is one of the elements that determined the worldwide diffusion of the GSM standard, and at least a similar arrangement would be needed for cars.

The lack of accessibility to different charging 'brands' leads to a series of segmented subnetworks of smaller size. At national level the problem might be less acute, particularly in nations where the issue has been considered from the start (such as in Portugal, where a system has been set up to clear charging between different networks) or where a single actor has largely taken up the task of putting charging points in place along the main network (i.e. Ireland). The issue, however, becomes worse when crossing national boundaries, as some networks only exist at national level or have a limited number of international agreements in place or under negotiation. Roaming platforms are being set-up at EU regional level. However, the interoperability of the services they offer is a growing concern. Existing platforms initiated a Pan-European roaming platform to facilitate the recognition of the contracts at EU level and therefore allow better roaming services, but this is still not a reality.

The potential costs generated by roaming services could soon become a barrier to the take-up of the electro-mobility market. Common European identifiers as well as data Formats & Communication protocols to identify charging points and contracts can contribute to further overcome the barriers to the interoperability for EV services. Common rules to define the interoperability of charging systems are also necessary. This, however, is still more cumbersome than a simple on-demand payment at any charging point which should be the ultimate target to make the system as simple as fuel refilling is today.

The initial cost of setting up networks of fast chargers, while being a necessary enabler to wider adoption of electric vehicles, will probably not generate profits for a relatively long period, therefore it is also important to promote, in this initial phase, a burden sharing between operators in order to reach as soon as possible a critical mass along main roads. This implies an even stronger justification for easy cross-network access.

FORWARD LOOKING CONSIDERATIONS

The considerations which are described hereunder are based on the existing Directive 2014/94/EU *'on the deployment of alternative fuels infrastructure'* and aiming at exploring its full implementation before 2020.

- **Industry-wide standardisation of fast charging modes**

Cars sold in Europe should converge to a single fast-charging solution after a transition period, be it AC or DC, to facilitate both customer choice and the task of the actors deploying the infrastructure, reducing the need of costly duplications on the fast chargers (AC vs DC, Combo2 vs Chademo).

A convergence on DC (which already seems to be taking place) would mean that chargers are more costly but would save the cost of the charger on each electric vehicle, which in the long run would save money for the system as a whole. Moreover, in the transition period a DC charger could also have the possibility to charge AC vehicles at no additional cost.

A further issue is the lack of standardisation of communication protocols in the connectors, expected only for 2017, which on one hand hinders the development of services and on the other will require costly retrofits of already installed infrastructures. Charging technologies should be available at accessible cost by 2020 and should allow for payback for demand management.

- **Free and easy access to all electricity networks**

There are at least two possibilities to ensure that users of electrified vehicles are able to use all charging stations.

- **Roaming**

Today a subscriber to a given charging network can have problems accessing chargers belonging to other networks, be it across borders or even within the same country.

Electricity suppliers could accept users who are registered with another operator with no or minimal additional cost, over the whole EU territory (and possibly beyond), to ensure effortless and transparent e-mobility and full use of all installed chargers, particularly in these early phases of deployment. This would need the development of a unified identification system accepted by all operators through international agreements, preferably by recognizing the car and not requiring additional steps such as using a bank card.

This possibility resembles roaming in the telecommunication sector; therefore its introduction might re-create similar problems we face today in this respect if there were to be additional charges levied to the customers. However, roaming in recharging would represent a significant step towards a single market.

Also, common European identifiers as well as data Formats & Communication protocols to identify charging points and contracts would further overcome the barriers to the interoperability for EV services, as would common rules to define the interoperability of charging systems.

- **Payment on demand**

In this possibility, already covered by the Directive, recharge service providers should also sell electricity on demand with no or minimal additional cost and allow all common types of payment means, including upcoming ones based on mobile devices. This would require the deployment of meters on the charging stations and appropriate payment equipment. This possibility provides the most straightforward solution, similar to conventional refuelling, thereby ensuring a free and single recharging market for electrified vehicles, promoting competition, but likely increasing investment costs in charging points that currently are not profitable.

ADDITIONAL SOCIO-ECONOMIC ELEMENTS

Demand for electric vehicles is growing rapidly around the world with more than 320,000 new registrations in 2014 bringing the total market up to 740,000 vehicles. The overall global market saw a growth rate of ~76%, with EV registrations almost doubling, between 2012 and 2014.

The three countries with the highest increase rate are those that introduced supportive policies: USA, Japan and China. In most EU Member States, supportive policies are few or missing: be it economic incentives for buying such vehicles or complimentary local benefits such as free access to city centres or parking. Therefore, there is a real risk that the 10% market share of electric and plug-in hybrid passenger cars by 2025 will not be met. If owners of electrified vehicles have problems driving long distance or across borders and they have no access to recharging points at a reasonable distance, drivers will not opt for EVs and the present momentum for innovation could be lost. Innovative solutions, in turn, could bring positive environmental and economic impact.

Although there are no detailed studies specific to fast chargers, in their 'Consumers acceptance of Electric Vehicles in the US' 2012 presentation ICCT mentions a survey where "54% of surveyed consumers would not consider purchasing an EV until charging locations are widely available and as easy to locate as gas stations today". It is implicit that such an expectation is for fast chargers that are easy to pay and conveniently located on main roads. Being a US study, it most likely takes for granted the equally needed slow charger in the garage, which must in any case be the backbone of the charging infrastructure.

By 2020, 5 million vehicles (out of a total fleet in the EU of about 240 million vehicles) would be 2.5 times more energy efficient. The global impact on energy efficiency by 2020 would be limited, but if the move towards electrified vehicles is maintained or accelerated through the on-going research, innovation and new legislation, the present trend would lead to a substantial impact on energy efficiency by 2030: industrial members of the EGVI estimate an improvement of road transport energy efficiency by 50% by 2030, including 80% energy efficiency of urban vehicles and 40% energy efficiency of long-distance freight transport.

Electrified vehicles can deliver significant decarbonisation, depending on the generation of the electrical energy. This is particularly so when real-life driving is considered, as electrified vehicles

are less dependent on traffic conditions and driving styles. Polluting emissions and noise are similarly reduced, particularly locally. Where emissions are produced (at power generation plants) they can be located further from dense population centres and the pollution widely diluted by the time they spread over populated areas.

Supporting the deployment of electrified vehicles in Europe will help maintain the global leadership of European car manufacturers and suppliers in the automotive world market. European industry needs to be supported both through research and innovation and through measures to accelerate the uptake of electrified vehicles, in order to create critical-mass of internal EU demand. Otherwise, electrified vehicles might be imported from the USA and the Far East and jobs and competences would be lost (this is already happening in Norway, where the majority of vehicles are US and Japanese models). Research and innovation will be essential to adequately develop the technology. Important opportunities for innovative European vehicle SMEs, equipment suppliers, ICT industry and mobility service providers exist and could be captured with appropriate supporting measures.

A.8. Low carbon[76] hydrogen in transport

ISSUE AT STAKE

Building a resilient Energy Union in Europe with a forward-looking climate-change policy, will not be possible without promising technologies. Fuel Cells and Hydrogen could constitute a triple 'win' for Europe because they have the potential to enhance energy security (through superior efficiency and diversification of energy sources), environmental sustainability (through reduction of greenhouse gas emissions from both the energy and transport sectors) and simultaneously bring economic benefits. They contribute to the following key priorities identified by President Juncker:

- *A New Boost for Jobs, Growth and Investment*
- *A Resilient Energy Union with a Forward-Looking Climate Change Policy*
- *A Deeper and Fairer Internal Market with a Strengthened Industrial Base*

The emerging fuel cells and hydrogen sector represents a very significant economic potential. It is estimated that the total number of jobs in the sector in Europe has been increasing by about 6% annually since 2007, to around 4,000 full time employees in 2012 and turnover is expected to rise by on average 35% year on year towards 2020[77]. In the transport sector alone, the global demand for hydrogen fuel is expected to reach over 0.4 Mt/year by 2020, reflecting a 2010-2020 growth rate of 88%[78]. Worldwide, it is estimated that the manufacturing of fuel cells will experience exponential growth in jobs this decade; with almost 700,000 cumulative jobs created by 2020 (over a million total new jobs could be created when fuel cell installation, servicing and maintenance are considered[79]).

Although in recent years the fuel cell and hydrogen industry has moved into a new stage of commercial development, some important financial, economic, technical and societal challenges must be addressed before the technology can be deployed at a large scale.[80] High technology costs coupled with lack of hydrogen distribution infrastructure remain the key bottlenecks.[81] Sustained political support as well as industry commitment is crucial to ensure new investments in fuel cell and hydrogen technology that are necessary to trigger transition to mass production (to cut costs due to learning effects and economies of scale) and to consolidate this nascent industry with an important potential for supporting the European policy prerogatives.

For example, efficient integration of rapidly increasing renewables into European energy systems calls for increased system flexibility. One of the key options to bring more flexibility is through

[76] Also called clean/green

[77] Report commissioned by the Fuel Cells and Hydrogen Joint Undertaking 'Trends in investments, jobs and turnover in the Fuel cells and Hydrogen sector', 2013

[78] Pike Research, Fuel Cell and Hydrogen Industry: Ten Trends to Watch in 2011 and Beyond, 2011

[79] http://www.fuelcelltoday.com/news-archive/2010/january/fuel-cell-industry-could-create-700,000-green-manufacturing-jobs-by-2020

[80] Joan Ogden, Christopher Yang, Michael Nicholas, Lew Fulton: THE HYDROGEN TRANSITION, NextSTEPS White Paper, University of California, Davis, 2014

[81] To address these issues on the European level, the Fuel Cells and Hydrogen Joint Undertaking (FCH JU) has been set-up, as a unique public private partnership supporting research, technological development and demonstration (RTD) activities in these technologies in Europe.

energy storage to balance between the periods of fluctuating renewable energy sources and to deal with the geographical mismatch between locations of generation and demand. Various storage technologies have a wide range of technical and cost parameters that make them more or less suitable for the provision of various storage services. Hydrogen storage where renewable energy is used to generate low carbon hydrogen (through water electrolysis) emerges as an interesting option[82] because of high energy density, quick response times, and potential for use in large-scale energy storage applications. The hydrogen produced could be stored flexibly until it is needed in the power sector, gas grid, mobility or industry, contributing to the decarbonisation of these sectors. However, at the current state of art, this technology is less mature than other energy storage options.

As regards end-use markets today, a step towards market integration of low carbon hydrogen in the transport sector would contribute to cut GHG emissions of transport operations while traffic/freight volumes continue to grow and limited alternatives exist to fossil fuels.

These drivers have led to very ambitious policy objectives targeting decarbonisation of the sector in Europe, including:

- 60% GHG emissions reduction target by 2050 (vs. 1990 levels),
- CO_2 emission target of 95gr CO_2/km by 2021 (fleet average) and more stringent targets in discussion for 2025, and
- 10% share of renewable fuels in transport by 2020 (with a cap of 7% for first generation biofuels).

Reaching these goals will require transition to innovative, zero-emission technologies. Electric vehicles, be it battery or Fuel Cell can facilitate this transition but their effective GHG intensity depends on the energy source used[83]. Fuel Cell Electric Vehicles (FCEVs) convert the chemical energy in hydrogen to electricity with clean water vapour as the only exhaust emission, contributing to the improvement of the local air quality. They can also have more than twice the efficiency of traditional combustion technologies, which results in reduced fuel/primary energy consumption. The technology readily enables large vehicle size, long driving range and a fast refuelling time.

Fuel cells are very versatile and can power a range of vehicle types from passenger cars, through buses, trucks, marine vessels, trains, specialty vehicles, as well as provide auxiliary power to traditional transportation technologies. As such, they could be an important component of the portfolio of technologies that will enable transition to low-carbon mobility without compromising customer expectations once considerable costs breakthroughs materialise. This is confirmed by the International Energy Agency, according to which, eliminating fossil fuels in transport and industry without resorting to hydrogen in the very long term will be hard to achieve[84].

Globally, the refining, chemical and industrial gas industries use approximately 7.2 exajoules (EJ) of hydrogen per year[85]. Most of this hydrogen is mainly produced from fossil fuels (some 95% of global production), with commensurate generation of GHG emissions. Only around 4% of

[82] The Energy pillar of the FCH 2 JU programme supports related R&I projects.
[83] BEVs or FCEV are not per se zero emission technologies – only if 100% renewable energy/electricity is used – i.e. the CO_2 intensity of the current EU wide electricity mix according the JEC Well-to-Wheel analysis is 150g $CO_{2/MJ}$ (http://iet.jrc.ec.europa.eu/about-jec/downloads)
[84] IEA Energy Technology Perspectives 2012: Pathways to a Clean Energy System
[85] B. Suresh et al., Chemical Economics Handbook, IHS Chemical (2013),.

worldwide production is based on water electrolysis[86], which can be adapted to a CO_2-free pathway when using renewable electricity.

In the short term, using low-carbon hydrogen in the refining process of diesel/petrol could be an ideal market entry with substantial potential[87] for reducing GHG emissions of conventional vehicles. The technology is ready and it does not require significant technical or infrastructure modifications (both the refinery processes and end-products are identical). Given that hydrocracking uses 3-6 kg of hydrogen per barrel of oil with an additional 0.1-2.5 kg needed in hydrotreatment and with nearly 4 billion barrels imported to EU in 2013, there is potential demand for a very significant amount of hydrogen[88].

PROBLEM DEFINITION

The fuel cells and hydrogen sector struggles with market failure for first movers, deficient leveraging of available funding, fragmentation and lack of critical mass. Regarding market failure, the potentially important environmental and energy security benefits of fuel cells and hydrogen applications accrue to society and are difficult to be monetised by individual technology providers. At the same time, the technology must compete with well-established incumbents with existing infrastructures, which results in high financial risk for early movers, aggravated by lack of cash flow during the initial deployment phase. Furthermore, the sector is dispersed across different activity areas (energy, transport, industry etc.) and actors, which also hampers the build-up of critical mass needed for self-sustained activity.

Hydrogen produced from fossil fuels is typically available at relatively low costs. Low-carbon hydrogen is cost-wise uncompetitive at the current state-of-the-art, leading to very low uptake rates[89].

On the other hand, the direct demand for hydrogen in the transport sector remains marginal. Although in the longer term FCEVs are expected to be the biggest transport related outlet market for green hydrogen, lack of refuelling infrastructure in combination with low vehicle numbers and high costs prohibit commercialisation. This leads to a problem often referred to as a "chicken or egg" problem[90]: to get hydrogen cars on the road, a convenient network of filling stations is required - on the other hand, filling stations can only be operated economically if there are enough vehicles. Whereas the directive on the deployment of alternative fuels infrastructure (2014/94/EU) was designed by the European Commission to solve this problem, the finally adopted text falls short of the initial ambitions. For hydrogen, Member States are not only free to choose whether they wish to develop such infrastructure, but they also have the flexibility to define an "appropriate" number of refuelling points to be put in place by end of 2025. These indicative targets are unlikely to secure the necessary investments.

[86] R.Guerrero-Lemus & J.M. Martinez-Durant 2010 'Updated hydrogen production cost and parities or conventional and renewable technologies'. International Journal of Hydrogen Energy 35, 3929-3936

[87] Default value of the life cycle GHG intensity for hydrogen from fossil sources (104,3 gCO2/MJ) versus electrolysis (9,1 gCO2/MJ) according to Annex I of the Directive (EU) 2015/652

[88] An introduction to petroleum refining and the production of ultra-low sulphur petrol and diesel fuel, 2011

[89] The production costs are in the range of ~2 EUR/kg for fossil hydrogen (produced via steam methane reforming) and 5-6 EUR/kg for hydrogen produced via electrolysis according to the study "Development of Water Electrolysis in the European Union" financed by the Fuel Cells and Hydrogen Joint Undertaking

[90] In terms of which was the very first to exist, the chicken, coming from an egg, or the egg, laid by a chicken?

The relationship between government support for, and industry investment in, hydrogen in the transport sector should continue to be assessed. At present, European business incentives to build-up of the hydrogen-refuelling infrastructure, a prerequisite for hydrogen-based mobility, seem to be lacking. European car manufacturers, Daimler being the most prominent example, are delaying market introduction of fuel cell cars in spite of earlier launch date announcements, whereas in Japan Toyota has already commercialised its first fuel cell model in autumn 2014. This car is now being introduced in the United States and Europe.

FORWARD LOOKING CONSIDERATIONS

Hydrogen technologies, along with other solutions, could be an important component of a broader strategy towards the future renewable energy mix, including storage of renewable electricity. Hence, purpose-oriented coherent regulatory framework that would reduce the development times, offsets first-mover disadvantages, valorises the societal benefits and ensures a level playing field to enable wider uptake of fuel cells and hydrogen technologies would be helpful.

Identifying the scope for a specific policy promoting the use of low-carbon hydrogen deserves a broad review best placed in the context of research and innovation agenda and policies driving renewable energy across various end user markets. Any such review would need, *inter alia,* to develop an appropriately strong case for any specific incentives to be put in place for hydrogen technologies.

In order to begin to open up the market for green hydrogen, it could be a possibility to create new regulatory incentives for use of green hydrogen in industrial processes. For example, this is the case in California, where the revised 'Low Carbon Fuel Standard' includes a provision for 'Renewable Hydrogen Refinery Credit Pilot Program', in which a refinery may receive credits for GHG emissions reductions from using renewable hydrogen in the production of petrol/diesel. It could be considered that future incentives address low carbon hydrogen in a comprehensive manner and should not be limited only to hydrogen in refineries.

Achievement of these goals requires speeding up the pace of market uptake of various low-carbon technologies, which necessitates an equally ambitious and forward-looking policy framework with a view to proportionate adjustment of the risks of innovation.

In addition, monitoring the implementation of policies by Member States as regards the level of support granted to more innovative but less mature technologies, such as hydrogen and fuel cells**,** could be also an important factor in ensuring that the Members States take advantage of the opportunities created by the European framework. It would also seem relevant to assess the possibilities for increased coherence between various Member States related to the support measures applied, in particular for various advanced drive-train technologies.

ADDITIONAL SOCIO-ECONOMIC ELEMENTS

Besides the positive impact on innovation, a thorough impact assessment could be useful to define the precise cross-sectorial socio-economic and environmental impacts of increased support to low-carbon hydrogen and related fuel cell technologies.

Better reflection of the GHG emission savings of renewable hydrogen in refinery processes could allow build-up of larger capacities, bringing the cost down and catalysing wider uptake across various end-use sectors.

It could also render this pathway economically competitive vis-à-vis biofuels blending, triggering a transition away from first generation biofuels with considerable indirect land use change (ILUC) effects. This would create an additional value stream for hydrogen-based energy storage, bringing it one-step closer to positive business case and commercialisation.

It should also be acknowledged that, although the fuel cells and hydrogen sector is still relatively small, it is of strategic importance due to its potential knock-on effect on the European automotive industry. Given that Europe excels in auto technology, increased use on FCEV components could provide a boost to competitiveness in that area.

At the same time, wider adoption of low-carbon hydrogen could also bring environmental benefits resulting from GHG[91] and pollutant emissions reductions, displacing fossil hydrogen and replacing more ILUC intensive biofuels that are currently used to meet 2020 targets. This would also result in improvements in public health.

Innovation-wise, further assessment of actual GHG emissions generated through fuel production processes could lead to changes in the regulatory framework which would help to promote innovation and reward investments in improving the GHG intensity of fuels beyond business as usual, stimulating transition to next generation technologies.

[91] hydrogen produced by electrolysis emits only 9.1 g CO2/MJ versus 104.3 g CO2/MJ for hydrogen from fossil sources and ILUC for low carbon hydrogen is close to zero