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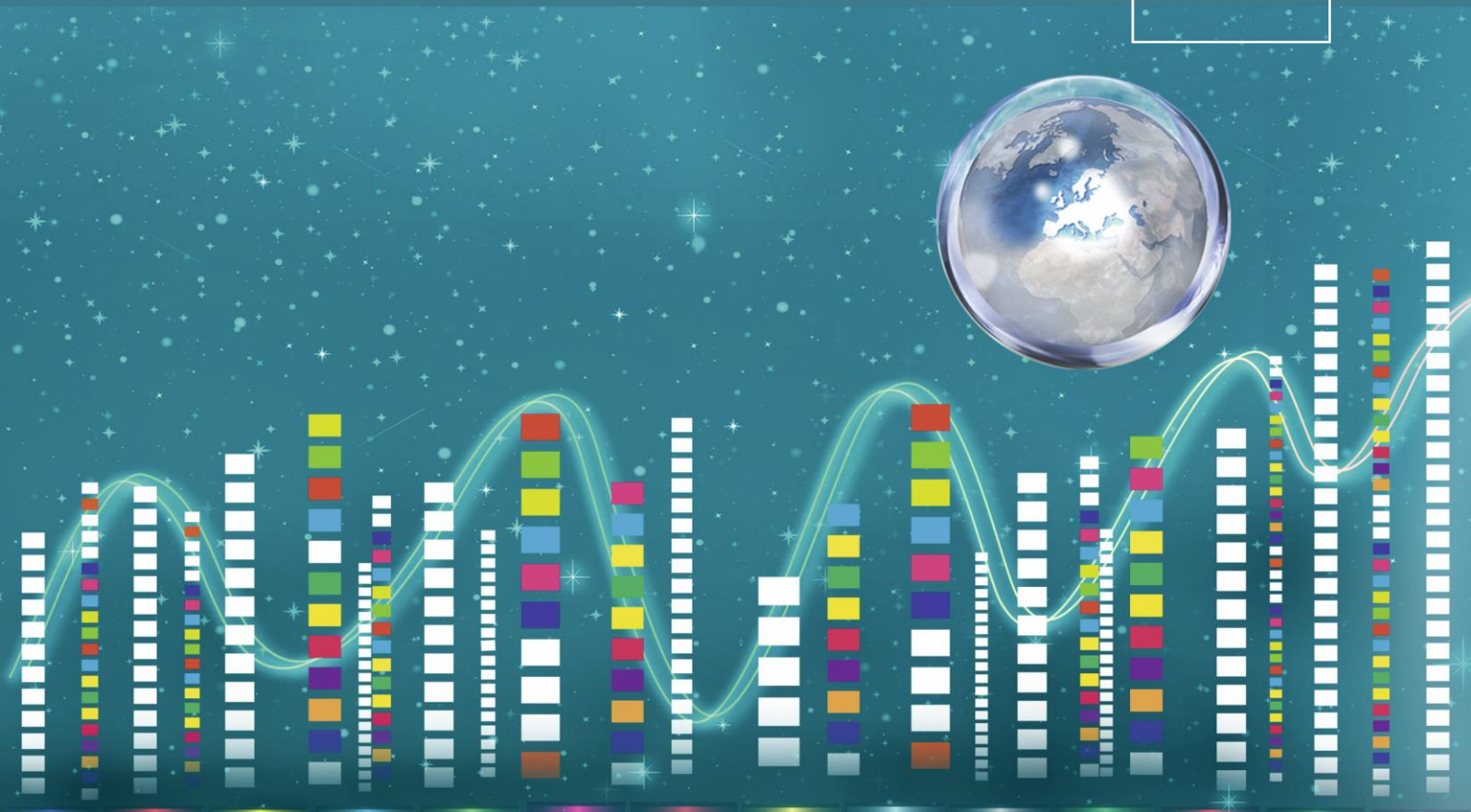
Study supporting the interim evaluation of the innovation principle

Final report

Independent Expert Report



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Study supporting the interim evaluation of the innovation principle

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EUROPEAN COMMISSION

Study supporting the interim evaluation of the innovation principle

Final report

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2019 Directorate-General for Research and Innovation

Table of contents

List of acronyms and abbreviations

AnMBR	Anaerobic membrane bioreactors
Better Regulation Guidelines	European Commission (2017), Better Regulation Guidelines, SWD(2017) 350, Brussels, 7 July 2017
Better Regulation Toolbox	Better Regulation Toolbox complementing the Better Regulation Guidelines
CEO	Chief Executive Officer
DG	Directorate General
DG ENV	Directorate General for Environment
DG GROW	Directorate General for Internal Market, Industry, Entrepreneurship and SMEs
DG RTD	Directorate General for Research and Innovation
EPSC	European Political Strategy Centre
EU	European Union
GDP	Gross Domestic Product
GII	Global Innovation Index
HTA	Health technology assessment
SME	Small and medium-sized enterprise
Study	Study Supporting the interim evaluation of the innovation principle
TFEU	Treaty on the Functioning of the European Union
Tool #21	Research and Innovation Tool included in the Better Regulation Toolbox
ToR	Terms of Reference
USA	United States of America

Executive summary

The European Commission has recognised the importance of **a more innovation-oriented EU *acquis***, gradually exploring the ways in which EU rules can support innovation. The 'innovation principle' was introduced to ensure that whenever policy is developed, the impact on innovation is fully assessed. However, as further discussed in this Study, the exact contours of the innovation principle have been shaped very gradually within the context of the EU better regulation agenda: originally advocated by industry in the context of the precautionary principle, the innovation principle has gradually been given a more articulate and consistent role, which aims at complementing the precautionary principle by **increasing the salience of impacts on innovation during all phases of the policy cycle**.

This Study presents **an evaluation of the current implementation of the innovation principle**, limited to two of its three components, *i.e.* the Research and Innovation Tool included in the Better Regulation Toolbox, and the innovation deals. As a preliminary *caveat*, it is important to recall that the implementation of the innovation principle is still in its infancy, and thus the Study only represents **a very early assessment** of the extent to which the innovation principle is being correctly implemented, and whether changes would be required to make the principle more effective and useful in the context of the EU better regulation agenda.

The main finding is that the innovation principle has the **potential to contribute to the quality and future-proof nature of EU policy**, but that significant changes and effort will be needed for this potential to fully materialise. The most evident areas for improvement are related to the lack of a clear legal basis, the lack of a widely acknowledged definition, the lack of awareness among EU officials and stakeholders, and the lack of adequate skills among those that are called to implement the innovation principle. As a result of these problems, the impact of the innovation principle on the innovation-friendliness of the EU *acquis* has been limited so far. The Commission should clarify in official documents that **the Innovation principle does not entail a de-regulatory approach**, and is not incompatible with the precautionary principle: this would also help to have the principle fully recognised and endorsed by all EU institutions, as well as by civil society, often concerned with the possible anti-regulatory narrative around the innovation principle in stakeholder discussions.

Apart from clarifications, and further dissemination and training, **major improvements are possible in the near future**, especially if the innovation principle is brought fully in line with the evolving data-driven nature of digital innovation and provides more guidance to the Commission on how to design experimental regulation, including *inter alia* so-called 'regulatory sandboxes'. Finally, the Commission should ensure that the innovation principle is given **prominence with the transition to the Horizon Europe programme**, in particular due to the anticipated launch of 'missions' in key domains.

1 Introduction

There is increasing awareness, among policymakers, of the importance of **well-designed regulation to promote innovation**. Scholars have clearly demonstrated that regulation, when featuring adequate levels of stringency and appropriate timing, can **steer innovation towards addressing societal needs.**[1] However, **badly designed regulation can also harm innovation**, for example by failing to reflect ongoing technological trends, failing to incentivise investment in research and development, hindering the emergence of alternative business models or imposing excessive red tape that ends up distracting resources from more productive uses. Over the past few years, the acceleration of digital innovation has created significant challenges for policymakers, starting with the so-called 'pacing problem', which calls for more agile, adaptive regulatory schemes, and more flexible and experimental approaches to regulation, aimed at testing solutions and accounting for ongoing technological and organisational changes.[2]

The European Commission has recognised the importance of **a more innovation-oriented European Union (EU) *acquis* in support of EU policy objectives**, gradually embracing the view that regulation can support innovation. The 2016 Commission Staff Working Document on "Better Regulation for Innovation-Driven Investment" already paved the way towards a **proactive use of regulation to remedy market failures and complete innovation ecosystems**, with several examples.[3] Since 2016, EU institutions have started to refer to the 'innovation principle' as a new approach, which would promote the consideration of innovation throughout the policy process, and ultimately comprising three main components: i) 'Foresight and Horizon Scanning';[4] ii) the Research and Innovation Tool included in the Better Regulation Toolbox;[5] and iii) the innovation deals.[6]

The innovation principle was originally described as an approach to policymaking "ensuring that whenever policy is developed, the impact on innovation is fully assessed".[7] Nevertheless, as further discussed in this Study, the exact contours of the innovation principle have been shaped very gradually within the context of the EU better regulation agenda: originally advocated by industry, and in opposition to precaution, the innovation principle has gradually been given a more articulate and consistent role, which aims at complementing the precautionary principle by **increasing the salience of innovation during all phases of the policy cycle**. As of today, as this Study demonstrates, the role of the innovation principle within the EU Better Regulation landscape would deserve a clearer definition: this is true for all three components of the innovation principle.

This Study was commissioned by the Directorate General for Research and Innovation (DG RTD) of the European Commission. It presents an **evaluation of the current implementation of the innovation principle**, limited to two of its three components,

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[1] Ashford, N.A. and Renda, A. (2016), *Aligning Policies for Low-Carbon Systemic Innovation in Europe*, CEPS and i24c Report.

[2] Renda, A. (2019), *Regulation and IRC: challenges posed by the digital transformation*, OECD.

[3] European Commission (2016), Directorate-General for Research and Innovation, Commission Staff Working Document, *Better regulations for innovation-driven investment at EU level*.

[4] For further details, please see: https://ec.europa.eu/jrc/en/research/crosscutting-activities/foresight

[5] *Tool #21 – Research and Innovation - Better Regulation Toolbox complementing Better Regulation Guidelines* (SWD(2017)350). It is worth mentioning that an earlier and different version of this specific tool (encompassing other activities) was already included in the 2015 edition of the Better Regulation Toolbox.

[6] For further details, please see: https://ec.europa.eu/info/research-and-innovation/law-and-regulations/innovation-friendly-legislation/identifying-barriers_en

[7] EPSC (2016), EPSC Strategic Note, *Towards an Innovation Principle Endorsed by Better Regulation*, Issue 14, 30 June 2016.

i.e. the Research and Innovation Tool included in the Better Regulation Toolbox (hereinafter also referred as 'Tool #21'),[8] and the innovation deals. While the innovation principle is not a policy *per se*, but rather a new approach that adds to the existing toolkit available to EU policymakers, this Study follows, to the extent possible, the structure of *ex post* evaluations recommended by the EU Better Regulation Guidelines.[9] Accordingly, the evaluation revolves around five criteria:

- **Relevance**, *i.e.* whether the rationale for introducing the innovation principle is still appropriate, or whether a revision would be advisable to account for changing needs and problems.
- **Effectiveness**, intended as the extent to which the current implementation of the innovation principle meets the original objectives it was intended to achieve, and generated the benefits it was intended to produce.
- **Efficiency**, which entails an assessment of the extent to which objectives are being met at the minimum possible cost.
- **Coherence**, *i.e.* whether the components of the innovation principle are being implemented in a consistent way (so-called 'internal coherence'), and in a way that is consistent with the EU policy framework at large (so-called 'external coherence').
- **EU-Added Value**, which reflects the appropriateness of introducing the innovation principle at the EU level, rather than leaving the issues addressed by the innovation principle in the hands of Member States.

The main purpose of this Study is to **identify areas for improvement** and **put forward policy and operational recommendations** to foster the proper implementation of the two components of the innovation principle under investigation as well as spur innovation in the EU. As a matter of fact, and as a preliminary *caveat*, it is important to recall that the implementation of the innovation principle is still in its infancy, and thus the Study only represents **a very early assessment of the extent to which the innovation principle is being correctly implemented**, and whether changes would be required to make it more effective and useful in the context of the EU better regulation agenda. More specifically, the Study focuses on the initial design of the innovation principle and its application to EU policy-making in 2017 and 2018.

The Study is structured as follows. **Chapter 2** presents the background of the intervention, the state of play and the *ex ante* design behind the innovation principle, including its rationale and expected results; it also provides an analysis of the application of the innovation principle so far. **Chapter 3** defines the main elements of the evaluation framework adopted for this evaluation and discusses the main findings by covering the five criteria listed above. **Chapter 4** illustrates key recommendations to improve the implementation of the innovation principle in the future. The Study also includes an **annex** detailing the main elements of the evaluation framework adopted for this evaluation.

[8] *Tool #21 – Research and Innovation - Better Regulation Toolbox complementing Better Regulation Guidelines, op.cit.*
[9] European Commission (2017), *Better Regulation Guidelines*, SWD(2017) 350.

2 The innovation principle

For the purposes of this Study, the following components of the innovation principle are taken into account:

- **The Research and Innovation Tool**, which provides guidance to assess the impacts of EU legislation on all forms of innovation.[10] More specifically, it includes four main activities:[11]
    - broadening stakeholder consultation to capture the research and innovation angle of EU initiatives;
    - assessing the potential impacts of EU initiatives on research and innovation;
    - considering the impacts of the legislative design on research and innovation; and
    - improving the design of EU initiatives to make them more innovation-friendly.

  Tool #21 is in principle applicable to *ex ante* impact assessment, as well as *ex post* evaluations and REFIT initiatives.[12] However, its wording in the Better Regulation Toolbox seems more apt for use in *ex ante* impact assessment.

- The **innovation deals**, which aim to remove perceived barriers to innovation arising from the implementation of existing EU legislation, by clarifying current rules and making use of existing flexibility in the EU legislative framework.[13] The innovation deals are a non-legislative tool relying on cooperation among the European Commission, the relevant Member State authorities and businesses to: i) identify regulatory obstacles hindering innovation; and ii) find solutions (if any) to remove such obstacles, while fully complying with EU and national law.[14] The innovation deals are activated on request by a specific group of stakeholders including businesses, public authorities and other interested parties.

The innovation principle also encompasses a third component, **'Foresight and Horizon Scanning'** (hereinafter also referred to as 'Horizon Scanning'). This is a technique for detecting early signs of potentially important developments through a systematic examination of potential threats and opportunities, with emphasis on new technology and its effects on the issues at hand. Horizon scanning is often based on desk research, but can also be undertaken by small groups of experts who are at the forefront in the area of concern.[15] Nonetheless, **the present Study does not cover Horizon Scanning**, as it was not part of the original request.

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[10] This applies to all EU initiatives for which an impact assessment is needed, i.e. those initiatives that are expected to have significant economic, social and environmental impacts.

[11] These activities correspond to the four steps of the "stepwise approach" described in Tool #21 of the Better Regulation Toolbox.

[12] For further details, please see: https://ec.europa.eu/info/law/law-making-process/evaluating-and-improving-existing-laws/refit-making-eu-law-simpler-and-less-costly_en

[13] If the existence of regulatory barriers is confirmed, the Commission may consider legislative amendments, subject to further evaluation.

[14] "The innovation deal cannot derogate from existing EU legislation but may make use of the possible flexibility already allowed in such legislation." (*The Joint Declaration of Intent for the Innovation Deal on sustainable waste water treatment combining anaerobic membrane technology and water reuse,* signed on 07 April 2017, p. 4, available at: https://ec.europa.eu/research/innovation-deals/pdf/jdi_anmbr_042017.pdf).

[15] For further details, please see: https://www.oecd.org/site/schoolingfortomorrowknowledgebase/futuresthinking/overviewofmethodologies.htm

2.1 Background

The need for an innovation principle in EU policymaking was first mentioned in October 2013 in **a letter sent by 12 Chief Executive Officers** (CEOs) **of multinational companies to the Presidents of the three EU institutions**,[16] which was followed up by another letter signed by an even larger number of CEOs (22) after the Juncker Commission took office.[17] The letters were **backed by a report of the European Risk Forum**.[18] The innovation principle was summarised as requiring that whenever the EU institutions consider policy or legislative proposals, the **impact on innovation is fully assessed and addressed**.[19] The letters sent by the CEOs expressed deep concern for the "negative impact of recent developments in risk management and regulatory policy on the innovation environment in Europe", and referred to the need to appropriately address "challenges such as food, water and energy security and sustainability" by developing a "balanced approach to risk management through a rigorous science-based approach and careful balancing of the principles of precaution and proportion in relevant regulation". The letters also argued that "the necessary balance of precaution and proportion is increasingly being replaced by a simple reliance on the precautionary principle and the avoidance of technological risk". This view was **criticised by civil society representatives** as purporting a **wildly deregulatory and too business-friendly approach.**[20]

During the same period, the European Commission started to look at possible ways to **strengthen the consideration of innovation throughout the policy process**. In 2014, a study by Pelkmans and Renda[21] for DG RTD explored the relationship between regulation and innovation, largely **rejecting the view that regulation is an obstacle to innovation**. The study, far from advocating a relaxation of regulatory standards, argued that regulation matters at all stages of the innovation cycle, from research and development, to diffusion, commercialisation, uptake, and beyond. It discussed options to place innovation in a more central position in the EU better regulation agenda, and in particular in the *ex ante* impact assessment of major new policy initiatives. Steps in this direction were later made with the introduction, in the new Better Regulation Toolbox of the European Commission, of a **Research and Innovation Tool** "for analysing the interaction between new or revised EU legislation (including spending programmes) and innovation".[22] Importantly, the tool emphasises the importance of **developing future-proof regulation and eliminate excessive compliance costs** where possible, but **does not entail a de-regulatory stance**. Rather, as also advocated by an EPSC strategic note in 2016, it refers to an innovation principle endorsed by better regulation.[23] The application of the innovation principle was also **supported by the Council of the EU** in

[16] For further details, please see:
http://www.riskforum.eu/uploads/2/5/7/1/25710097/innovation_principle_letter.pdf
[17] For further details, please see:
http://www.riskforum.eu/uploads/2/5/7/1/25710097/innovation_principle_letter_4_nov.pdf
[18] European Risk Forum, *Monograph on the Innovation Principle*, available at http://www.riskforum.eu/innovation-principle.html.
[19] *Ibid*.
[20] For further details, please see: Corporate Observatory Europe (2018), *The 'Innovation Principle' trap. Industries behind risky products push for backdoor to bypass EU safety rules*, available at https://corporateeurope.org/en/environment/2018/12/innovation-principle-trap.
[21] Renda, A. and Pelkmans, J. (2014), *How Can EU Legislation Enable and/or Disable Innovation*, European Commission.
[22] *Tool #21 – Research and Innovation - Better Regulation Toolbox complementing Better Regulation Guidelines*, op.cit., p.1 (146).
[23] *Towards an Innovation Principle Endorsed by Better Regulation*, *op.cit.*.

May 2016.[24] In a nutshell, originally the innovation principle was described as an approach to policymaking "ensuring that whenever policy is developed, the impact on innovation is fully assessed".[25] In May 2018, in its contribution to the Informal EU Leaders' meeting on innovation in Sofia, the Commission used the same description.[26]

The first conceptualisations of the innovation principle did not entail the deployment of additional instruments such as the innovation deals or Horizon Scanning. The **innovation deals**, originally inspired by the Dutch Green Deals,[27] were introduced for the first time by the Commission Communication on "Closing the loop – An EU action plan for the Circular Economy".[28] They require the voluntary cooperation of the European Commission, Member States and stakeholders to **find shared solutions aiming to provide regulatory clarity and reduce potential barriers to innovation** arising from EU law and its national implementation. A reference to this instrument, which allows for interpreting the current legislation in a way that fosters innovation, was also contained in: i) a study by Renda,[29] which analysed the experience of the USA with negotiated rulemaking, drawing recommendations for the European Commission's implementation of the innovation deals; and ii) the already-mentioned Strategic Note published by the EPSC.[30] In this context, **the Council of the EU** in its conclusions adopted in May 2016[31] suggested developing and implementing pilots for innovation deals to be evaluated by mid-2018. Two years after, the Commission concluded that the completed pilots "suggest the experience can provide useful feedback to improve regulation and promote innovation".[32]

Today, the innovation principle covers **Tool #21 of the Better Regulation Toolbox** and the **innovation deals**. In addition, as mentioned at the beginning of chapter 2, the European Commission has included the practice of **Horizon Scanning** in the tools associated with the innovation principle. For example, the Management Plan of DG RTD for 2019 mentions that "for 2019, there will be a stronger coordination of the regulatory-related work of DG RTD through the more coherent application of the innovation principle in all stages of the policy-making cycle, from horizon scanning in emerging areas where the Framework Programme is providing support, to the application of the Research and Innovation Tool of Better Regulation in impact assessments for legislation design or REFIT, and to the launch of new innovation deals to identify possible obstacles to innovation in existing legislation".[33]

In summary, the innovation principle is a relatively new feature in the landscape of EU policymaking. In addition, its first development was characterised by a degree of

[24] Council of the European Union, *Research and Innovation friendly regulation* - Council conclusions (adopted on 27/05/2016); Council of the European Union, *Better Regulation to Strengthen Competitiveness*, Press release (25/06/2016).
[25] *Towards an Innovation Principle Endorsed by Better Regulation, op.cit.,* p.1.
[26] European Commission (2018), Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions - *A renewed European Agenda for Research and Innovation - Europe's chance to shape its future* - The European Commission's contribution to the Informal EU Leaders' meeting on innovation in Sofia on 16 May 2018, COM(2018) 306 final, p.17.
[27] For further details, please see: https://www.greendeals.nl/english.
[28] European Commission (2015), Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, *Closing the loop - An EU action plan for the Circular Economy*, COM(2015) 614 final.
[29] Renda, A. (2016), *Regulation and R&I Policies. Comparing Europe and the USA*, European Commission.
[30] *Towards an Innovation Principle Endorsed by Better Regulation, op.cit.*
[31] *Research and Innovation friendly regulation, op.cit*.
[32] *A renewed European Agenda for Research and Innovation - Europe's chance to shape its future*, *op.cit*., p.10.
[33] DG RTD (2019), *Management Plan*, available at: https://ec.europa.eu/info/sites/info/files/management-plan-rtd-2019_en.pdf

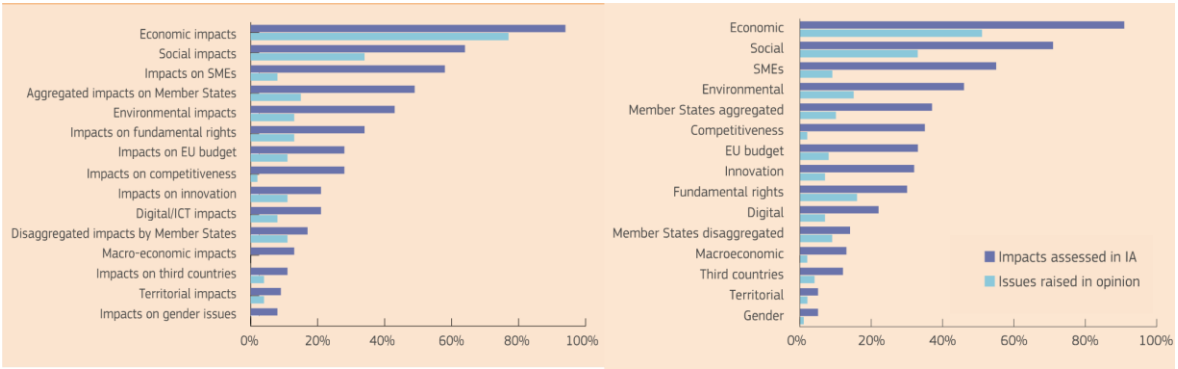
uncertainty, due to the origin of the term; nevertheless, **the underlying theoretical approach adopted by the European Commission did not automatically reflect the concerns expressed by some parts of the industry** on the excessive reliance on the precautionary principle featured by the EU *acquis*. As of today, as further discussed in this Study, **there is no universally acknowledged and agreed definition of the innovation principle**: the innovation principle is very often simply equated with Tool #21, and the fact that it comprises, besides the innovation deals, also Horizon Scanning is virtually unknown to most.

2.2 State of play

The Research and Innovation Tool was so far applied in a relatively small number of legislative[34] and policy[35] initiatives in order to assess their impact on innovation. Figure 1 below shows a comparison between the frequency of assessment of impacts on innovation in Commission impact assessments during 2017 and 2018, reflecting an **increased frequency of such assessment over time**.[36]

Figure 1 Assessment of impacts on innovation in 2017 and 2018

2017 **2017-2018**



Source: Regulatory Scrutiny Board Annual Reports, 2017 and 2018.

The recent Communication of the European Commission on "Better Regulation; Taking Stock and Sustaining Our Commitment" acknowledges the importance "to have regulation that fosters and, at the same time, harnesses innovation to the benefit of the environment, the economy and EU citizens" and mentions the innovation principle in a footnote, among "cross-cutting policy commitments".[37] This stocktaking Communication also refers to the

[34] For instance, legislative initiatives in the following topics were covered: coordinated health technology assessments; minimum quality requirements for water reuse for irrigation in agricultural areas; governmental satellite communication services; low-emission mobility action plan - post-2020 strategies on cars/vans and on lorries, buses and coaches; clean vehicles; and revision of drinking water directive.

[35] For instance, policy initiatives on the following topics were covered: strategy on plastics use, reuse and recycling; and fintech.

[36] European Commission (2018), *Regulatory Scrutiny Board. Annual Report 2017*, available at: https://ec.europa.eu/info/sites/info/files/rsb-report-2017_en.pdf; and European Commission (2019), Regulatory Scrutiny Board. Annual Report 2018, available at: https://ec.europa.eu/info/sites/info/files/rsb_report_2018_en.pdf

[37] European Commission, *Commission Staff Working Document: Taking Stock of the Commission's Better Regulation Agenda* accompanying the document Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions *Better regulation: taking stock and sustaining our commitment*, Brussels, 15.4.2019 SWD(2019) 156 final, p.7.

existing position of the European Risk Forum, which proposes to amend Tool #21. In this document, there is no mention of the innovation deals or the Horizon Scanning.

Despite the limited visibility of the innovation principle tools in the European Commission's official documents on better regulation, Tool #21 has had a **practical application in a number of legislative and policy initiatives** covered by the Commission Work Programme in 2017 and 2018. Moreover, **two pilots for the innovation deals** were initiated to date: one on e-mobility[38] and one on sustainable wastewater treatment combining Anaerobic membrane bioreactor technology (AnMBR) and water reuse [39]. The present Study is based on this empirical evidence, coupled with the results of a number of interviews with relevant stakeholders and Commission services (see chapter 3).

2.3 Ex ante design of the innovation principle

This section attempts to clarify **the design followed by EU decision-makers when proposing the introduction of the innovation principle**. As the innovation principle is not a policy initiative *per se*, but rather an approach, it was not accompanied by an impact assessment. Accordingly, this section is **based on information available in three documents published by the European Commission before the introduction of the innovation principle**: the 2014 report on regulation and innovation, which is directly mentioned as reference in Tool #21;[40] the 2016 Commission Staff Working Document on "Better regulations for innovation-driven investment at EU level", which paved the way for the introduction of the principle;[41] and the 2016 EPSC Strategic Note on the innovation principle.[42] These documents are used as a reference; however, research papers and strategic notes do not represent the official position of the Commission.

As a preliminary *caveat*, it must be recalled that most of these documents were not directly referred to the innovation principle as intended today, i.e. including three components. Therefore, the *ex ante* design presented below does not include Horizon Scanning.

2.3.1 Why did the EU establish the innovation principle?

The innovation principle was introduced for a number of reasons. First, there is ample evidence confirming the **strong positive relationship between investment in research and innovation** and gross domestic product (**GDP**) **growth**[43]; and more generally between innovation and growth.[44] These findings already suggest the need to promote innovation-friendly regulation, and thereby **strengthen the salience of innovation in the policy process**.

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[38] For further details, please see *The Joint Declaration of Intent for the Innovation Deal on From E-Mobility to recycling: the virtuous loop of the electric Vehicle*, signed on 12 March 2018 and available at: https://ec.europa.eu/research/innovation-deals/pdf/jdi_emobility_recycling_112017.pdf

[39] For further details, please see *The Joint Declaration of Intent for the Innovation Deal on sustainable waste water treatment combining anaerobic membrane technology and water reuse*, signed on 07 April 2017 and available at: https://ec.europa.eu/research/innovation-deals/pdf/jdi_anmbr_042017.pdf

[40] *How Can EU Legislation Enable and/or Disable Innovation, op.cit*.

[41] *Better regulations for innovation-driven investment at EU level*, *op.cit*

[42] *Towards an Innovation Principle Endorsed by Better Regulation, op.cit*.

[43] See for instance: Sokolov-Mladenović, S., Cvetanović, S. and Mladenović ì, I. (2016), *R&D expenditure and economic growth: EU28 evidence for the period 2002–201*2, Economic Research-Ekonomska Istraživanja, 29:1, 1005-1020.

[44] See for instance: Aghion, P. (2006), *A Primer on Innovation and Growth*, Bruegel Policy Brief 2006/06.

Second, past literature has shown the **complexity of the interaction between innovation and regulation**.[45] More specifically, the relevant literature[46] showed that: i) EU regulation matters at all stages of the innovation process, from research and development to commercialization; ii) regulation can be a powerful stimulus for innovation, but can also harm innovation when not properly designed; and iii) different types of regulatory approaches can have different impacts on innovation. Therefore, less regulation does not necessarily mean more innovation and the ultimate impacts of regulation on innovation should be carefully assessed on a case-by-case basis.[47]

Third, and importantly, both academics and policymakers have increasingly realised that **Europe is lagging behind when it comes to a number of innovation indicators**, such as business expenditure in research and development. In presenting a new agenda for research and innovation, the European Commission has observed in 2018 that "EU companies spend less on innovation than their competitors. Venture capital remains underdeveloped in Europe, resulting in companies moving to ecosystems where they have better chances to grow fast. Investment across the EU falls short of 3% GDP target. R&D intensity is still uneven among EU regions, with investment and research heavily concentrated in Western Europe. And 40% of the workforce in Europe lacks the necessary digital skills".[48] In charting Europe's performance in science, research and innovation, the Commission also emphasised the need to improve performance in digital innovation, and observed that "unfortunately, Europe has missed out on many of the opportunities created by digital innovations and it trails, not only vis-à-vis the United States but increasingly also vis-à-vis China, in transformational entrepreneurship".[49] Moreover, as highlighted by Ashford and Renda[50] and by the RISE group report[51], **Europe seems to experience a diffusion problem**, rather than an innovation deficit; this, in turn, calls into question the role of regulation in ensuring that innovation spreads throughout the economy and is made accessible and available to all citizens and businesses. Current evidence, unfortunately, shows that in many cases **only frontier firms catch up with innovation developments**, whereas laggard firms remain on the market without featuring the ability to catch up with innovation, and thereby failing to improve their productivity.

Fourth, there is evidence that **not all innovation is equally relevant for sustainable growth**.[52] Regulation, besides promoting innovation and its diffusion, can also provide direction to innovation, **steering it towards societal needs**. Good examples are environmental and data protection rules, which heavily affect the pace and direction of innovation in several domains.

Finally, it is widely acknowledged in academia and in international policy fora such as the OECD that **the 'pacing problem' created by the acceleration of innovation** generates

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[45] *Better regulations for innovation-driven investment at EU level, op.cit.*, p. 7 and p.9.
[46] See for instance: *How Can EU Legislation Enable and/or Disable Innovation, op.cit.*; and *Aligning Policies for Low-Carbon Systemic Innovation in Europe, op.cit.*
[47] *Better regulations for innovation-driven investment at EU level, op.cit.*, p.9.
[48] European Commission (2018), *Factsheet: A renewed European Agenda for Research and Innovation - Europe's chance to shape its future - The Commission's contribution to Leaders' agenda,* p.1 available at https://ec.europa.eu/commission/sites/beta-political/files/europe-chance-shape-future_en.pdf
[49] European Commission (2018), *Science, Research and Innovation Performance of the EU 2018 - Key findings,* European Union, p.9.
[50] *Aligning Policies for Low-Carbon Systemic Innovation in Europe, op.cit.*
[51] Research, Innovation and Science Policy Experts (RISE) High Level Group (2017), *Europe's Future: Open innovation, open science, open to the world*, European Commission.
[52] Leceta, J. M., Renda, A., Konnola, T. and Simonelli, F. (2017), *Unleashing Innovation and Entrepreneurship in Europe: People, Places and Policies*, CEPS Task Force Reports, Centre for European Policy Studies (CEPS); and *Europe's Future: Open innovation, open science, open to the world, op.cit.*

new challenges for regulators, requiring more flexible and experimental tools.[53] This calls for a **new set of tools** that can at once: i) strengthen the policymakers' ability to anticipate change (e.g. Horizon Scanning); ii) enable innovators to challenge existing legislation to obtain more clarity and, where possible, an acknowledgement of the viability of alternative modes of compliance (e.g. innovation deals); and iii) foster the development of experimental approaches to regulation, aimed at testing new solutions or alternative business models before admitting them to the market (e.g. regulatory sandboxes, and similar).

In summary, the innovation principle seems to have been inspired by the observation that Europe could perform better on innovation and its diffusion, that regulation can play a decisive role to this end, and that regulation needs to change and adapt to enable more evidence- and foresight-based policymaking. In the analysis of existing relevant documents, there was **no concrete evidence that the innovation principle was inspired by a pre-defined anti-regulatory stance**: interviews conducted with EU services have confirmed this. This is extremely important for the whole evaluation exercise, as it flags an important communication problem: civil society and even some policy-makers seem to consider the innovation principle as a tool aimed at reducing or weakening regulation.

In what follows, a more structured analysis of the rationale behind the innovation principle is offered, based on the needs, problems and objectives highlighted in the selected reference papers.

2.3.1.1 Ex ante needs and problems

Originally, the innovation principle was meant to contribute to addressing **the following needs**:

- The need to tackle the innovation deficit experienced by the EU and improve its innovation performance.[54]
- The need to bridge the productivity gap the EU faces *vis-à-vis* its main global competitors.[55]
- The need to maintain/ensure a competitive edge for EU enterprises.[56]
- The need to stimulate more and better investment in research and innovation in the EU.[57]

Among others, **the following problems** were affecting the satisfaction of these needs, and can be addressed by the innovation principle:

- The EU *acquis* is not sufficiently conducive to innovation, as suggested by the insufficient research and development investment observed in most Member States,

[53] Marchant, G. R., Allenby, B., and Herkert, J. (Eds) (2011), *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The Pacing Problem*, Springer Netherlands; and *Regulation and IRC: challenges posed by the digital transformation, op.cit.*

[54] *How Can EU Legislation Enable and/or Disable Innovation*, *op.cit.*, p.9; and *Towards an Innovation Principle Endorsed by Better Regulation*, *op.cit.*, p.4.

[55] *Better regulations for innovation-driven investment at EU level, op.cit.*, p.8.

[56] *Ibid, op.cit.*, p.8.

[57] *Ibid, op.cit.*, p.7.

and by the fact that many stakeholders perceive the lack of innovation-friendliness of parts of the EU *acquis*.[58]

- The process of developing legislation does not match the pace of innovation, therefore existing rules may slow down disruptive innovation (so-called 'pacing problem').[59]
- Problems in the national implementation of EU regulation can also discourage investment and limit innovation. This can be due to inadequate transposition or implementation of EU legislation, gold-plating, or to burdens or obstacles to innovation in the delivery phase of legislation.[60]

Going more in detail, **several elements contributed to these problems**:

- Despite the fact that regulation can be a very powerful stimulus for innovation, regulation creating excessive administrative burdens/compliance costs for businesses may curtail resources and times devoted to innovation.[61]
- Regulation may hinder innovation also if it is too prescriptive/inflexible, which limits the speed of technological progress or increases uncertainty for investment.[62]
- The efficiency and effectiveness of national, regional and local rules and administrations also have a significant impact on innovation.[63]

2.3.1.2 Ex ante objectives

The **objectives of the innovation principle** are presented in a hierarchical order, where the achievement of lower-level objectives is normally a precondition for attaining the higher-level ones. The **general objective** of the innovation principle is that of ensuring an optimal regulatory framework to foster innovation and ultimately improve overall societal well-being.[64]

The **specific objectives** of the innovation principle, as articulated *ex ante*, can be summarised as follows:[65]

- Improving the design of existing and future EU regulations with regard to their impact on innovation.
- Searching for future-proof, more forward-looking and innovation-friendly approaches to regulation.
- Achieving an optimal balance between predictability of the regulatory environment and adaptability to technological and scientific progress.
- Simplifying and increasing the effectiveness and coherence of the regulatory framework by ensuring an overall approach to assessing the combined impact of regulations affecting multi-technology and multi-domain innovations.[66]

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[58] For a comprehensive discussion on the topic, please see: *Better regulations for innovation-driven investment at EU level, op.cit.*; *How Can EU Legislation Enable and/or Disable Innovation, op.cit.*; and *Towards an Innovation Principle Endorsed by Better Regulation, op.cit*.

[59] *Towards an Innovation Principle Endorsed by Better Regulation, op.cit*., p.1

[60] *Better regulations for innovation-driven investment at EU level, op.cit.*, p.11.

[61] *How Can EU Legislation Enable and/or Disable Innovation, op.cit.,* p.20.

[62] *Better regulations for innovation-driven investment at EU level, op.cit.,* p.10; and *Towards an Innovation Principle Endorsed by Better Regulation, op.cit.*, p.4.

[63] *Better regulations for innovation-driven investment at EU level, op.cit*., p.9.

[64] *Better regulations for innovation-driven investment at EU level, op.cit.*, p.13; and *Towards an Innovation Principle Endorsed by Better Regulation, op.cit.*, p.4.

[65] *Better regulations for innovation-driven investment at EU level, op.cit.*, p.11; and *Towards an Innovation Principle Endorsed by Better Regulation, op.cit.*, p.7.

[66] In this respect, innovation can be also organisational, not only product- or process-oriented. In addition, user innovation also plays a role.

- Checking implementation issues that can affect innovation outcomes (including at national, regional and local levels of administration).
- Increasing dialogue with stakeholders to identify regulatory problems affecting innovation and seek solutions.

The **operational objectives** of the innovation principle, as articulated *ex ante*, include:

- Ensuring that the impact of existing or proposed EU regulation on innovation is adequately assessed.[67]
- Identifying existing barriers to innovation arising from EU regulation or Member State implementation of EU regulation and possible ways to remove such barriers.[68]

By achieving such objectives, the innovation principle is expected to contribute to **stimulating more and better private investment in research and innovation** and **fostering EU businesses' ability to innovate**, thus ensuring sustainable growth, jobs and competitiveness of EU businesses, while yielding social and environmental benefits.[69]

2.3.2 What are the expected effects stemming from the application of the innovation principle?

The expected effects of the innovation principle, as conceived initially, can be classified into three different categories (i.e. outputs, outcomes and impacts) based on the time frame and nature of their occurrence. At this stage, it is worth remarking that external factors and other EU policies may have influenced the performance of the innovation principle since its adoption. This section looks at the innovation principle by reconstructing an *ex ante* perspective.

The **expected outputs** of the innovation principle are its most immediate effects and reflect the operational objectives of the intervention. The following outputs were expected to stem from the application of the two components of the innovation principle covered by this Study:

- Innovation impacts are more often assessed in European Commission's *ex ante* impact assessments, *ex post* evaluations and REFIT initiatives.
- The adoption of more innovation-friendly policy initiatives by the European Commission, due to a systematic application of Tool #21 during the preparation of major policy initiatives.
- The identification of obstacles to innovation in the stock of existing legislation, due to the application of Tool #21 to *ex post* evaluations and REFIT initiatives.
- The identification of barriers, which potentially hamper innovative enterprises, through the innovation deal mechanism.

Moreover, in the medium-term, **the following outcomes,** as articulated *ex ante,* would be expected from a systematic application of the innovation principle:[70]

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[67] *Better regulations for innovation-driven investment at EU level, op.cit.,* p.11; and *Towards an Innovation Principle Endorsed by Better Regulation, op.cit.*, p.7.

[68] *Better regulations for innovation-driven investment at EU level, op.cit.,* p.12; and *Towards an Innovation Principle Endorsed by Better Regulation, op.cit.*, p.9.

[69] For a comprehensive discussion on the topic, please see: *Towards an Innovation Principle Endorsed by Better Regulation, op.cit.*; and *Better regulations for innovation-driven investment at EU le*vel, *op.cit.*

[70] *Better regulations for innovation-driven investment at EU level, op.cit*., p.11; and *Towards an Innovation Principle Endorsed by Better Regulation, op.cit.*, p.7.

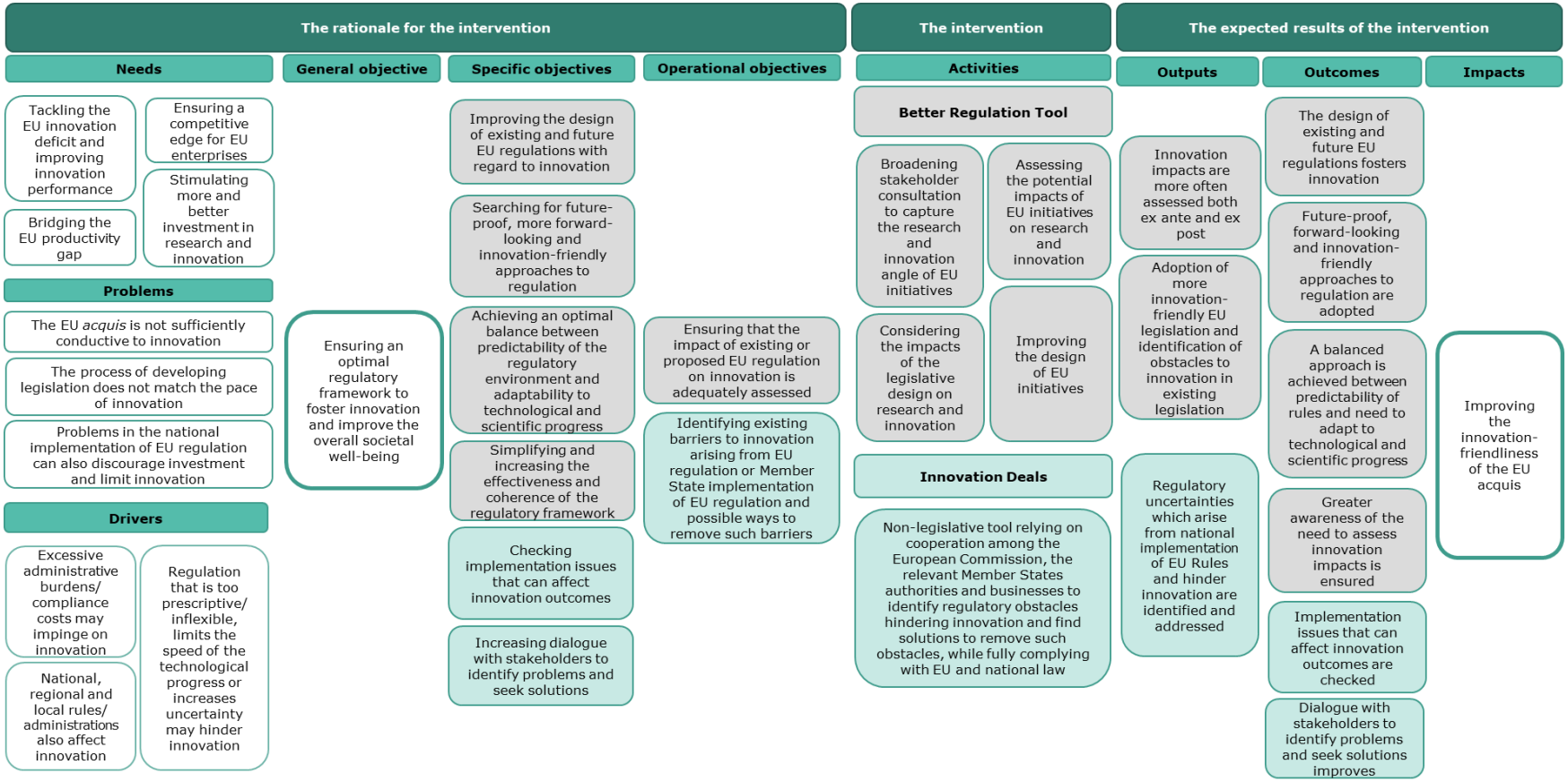
- The design of existing and future EU regulations fosters innovation in a way that is visible in indicators such as the European Innovation Scoreboard,[71] as well as in the perceptions of the relevant stakeholders.
- Future-proof, forward-looking and innovation-friendly approaches such as experimental and adaptive policymaking are adopted, becoming increasingly pervasive in the EU better regulation agenda.
- The awareness among EU officials of the need to assess innovation impacts is increased.
- A balanced approach is achieved between the predictability of the regulatory environment and the need to adapt to technological and scientific progress.
- Transposition and implementation issues that can affect innovation outcomes (including at national, regional and local levels of administration) are detected and addressed.
- The dialogue with stakeholders to identify regulatory problems affecting innovation and seek solutions is improved.

Finally, over a longer period, the appropriate and systematic application of the innovation principle is expected to generate an **improvement in the overall innovation-friendliness of the EU *acquis.***[72] Broader impacts, which are not directly linked to the innovation principle but benefit from its correct application, such as higher productivity and competitiveness, increase in employment, sustainable growth and improved societal well-being may also materialise.[73]

Figure 2 below provides a schematic illustration of the design behind the innovation principle.

[71] For further details, please see: https://ec.europa.eu/growth/industry/innovation/facts-figures/scoreboards_en
[72] *Towards an Innovation Principle Endorsed by Better Regulation, op.cit.,* p.10.
[73] *Towards an Innovation Principle Endorsed by Better Regulation, op.cit.*, p.1.

Figure 2 The design behind the introduction of the innovation principle



Source: Authors' elaboration on official documents published by the European Union.

2.4 An analysis of the current implementation of the innovation principle

2.4.1 Application of the Research and Innovation Tool

The application of the Research and Innovation Tool was evaluated by relying on the following activities:

- **A sample of 10 legislative proposals** where the Research and Innovation Tool was expected to be applied (Table 1) were scrutinised to develop a scoreboard on the quality of application.
- **A specific case study** was carried out on the Proposal of the European Parliament and of the Council on health technology assessment (HTA) and amending Directive 2011/24/EU.[74]

Table 1 Selected applications of the Research and Innovation Tool

Legislative proposal	Commission Work Programme
Proposal for a Regulation establishing the space programme of the Union and the European Union Agency for the Space Programme and repealing Regulations (EU) No 912/2010, (EU) No 1285/2013, (EU) No 377/2014 and Decision 541/2014/EU	2017
Proposal for a Regulation on health technology assessment and amending Directive 2011/24/EU	2017
Proposal for a Directive laying down rules relating to the corporate taxation of a significant digital presence	2018
Proposal for a Directive on the common system of a digital services tax on revenues resulting from the provision of certain digital services	2018
Proposal for a Directive on the reduction of the impact of certain plastic products on the environment	2018
Proposal for a Directive on the re-use of public sector information	2018
Proposal for a Regulation establishing a European Maritime Single Window environment and repealing Directive 2010/65/EU	2018
Proposal for a Regulation on promoting fairness and transparency for business users of online intermediation services	2018
Proposal for a Regulation on streamlining measures for advancing the realisation of the trans-European transport network	2018

Source: Authors' elaboration on publicly available publications and material received from DG RTD.

2.4.1.1 Scoreboard analysis of 10 legislative proposals

The scoreboard analysis aims to assess the extent to which the proposals under investigation complied with the guidance provided by Tool #21 of the Better Regulation Toolbox. More specifically, it checks **whether the 10 proposals listed in Table 1 relied upon the four steps proposed by Tool #21** to assess impacts on innovation:

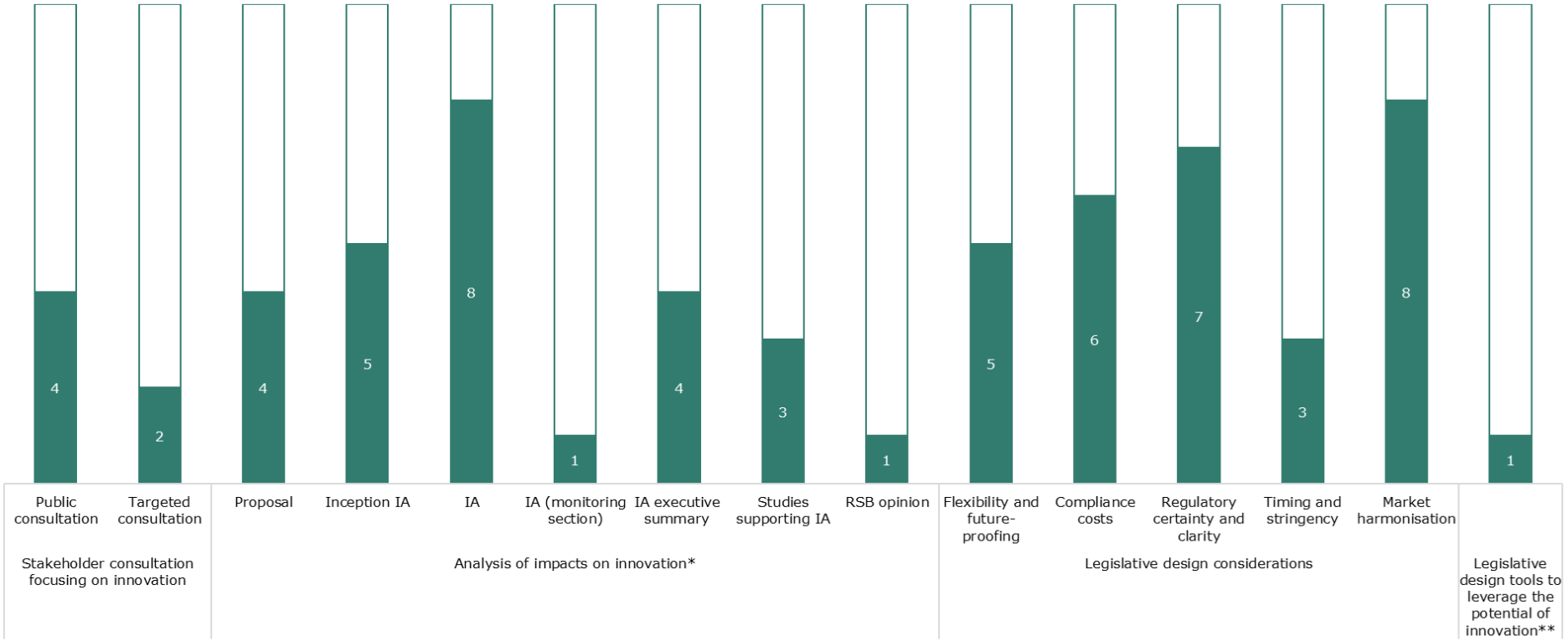
1. broadening consultation to capture the research and innovation angle;
2. assessing potential impacts on research and innovation;
3. addressing legislative design considerations; and

[74] European Commission (2018), *Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU, COM/2018/051 final.*

4. applying tools to leverage the potential of innovation and reduce negative impacts.

For each proposal, the following documents were reviewed, where available: i) inception impact assessments; ii) impact assessments; iii) executive summaries of the impact assessment; iv) studies supporting the impact assessment; v) public consultation reports; vi) Regulatory Scrutiny Board opinions; and vii) Commission's proposals. The results of this analysis are, therefore, entirely based on **desk review of official documents** that are publicly available. **Results are not necessarily representative**, as they rely on a small subset of the legislative proposals tabled by the Commission in 2017 and 2018. Figure 3 below summarises the main findings of the scoreboard analysis.

Figure 3 Application of the Research and Innovation Tool: analysis of 10 legislative proposals for innovation-friendly measures



*Notes: *The analysis of impacts is mostly qualitative. **In one case, outcome-oriented legislation was adopted. IA=impact assessment. RSB=Regulatory Scrutiny Board.*
Source: Authors' elaboration on public documents and material received from the Commission

In what follows, the main findings of the scoreboard analysis are detailed and complemented with relevant examples.

First step – Stakeholder consultation

- In four cases the questionnaire used for the **public consultation** included specific questions to capture the impact on innovation; this was, for instance, the case of the questionnaire used for the "Proposal for a Regulation on minimum requirements for water reuse".[75] Moreover, in two cases a **targeted consultation** with research and innovation players was conducted. A case in point is the stakeholder consultation that accompanied the "Proposal for a Regulation on promoting fairness and transparency for business users of online intermediation services",[76] which included focus groups with business users of platforms and with online platform companies.

Second step – Impact assessment

- In four cases impacts on innovation were **mentioned in the proposal**. For instance, the "Proposal for a Regulation on promoting fairness and transparency for business users of online intermediation services"[77] emphasised that online intermediation services are "key enablers" of innovation and that the rules underlying the proposal should safeguard the innovation potential of such services. In the same vein, Article 6 of the "Proposal for a Regulation establishing the space programme of the Union and the European Union Agency for the Space Programme"[78] listed the actions of the programme in support of an innovative Union space sector, such as the establishment of space-related innovation partnerships to develop innovative products or services.
- In five cases impacts on innovation were **mentioned in the inception impact assessment** and in eight cases they were **analysed in the impact assessment**. For example, Sections 6.6 and 7 of the impact assessment of the "Proposal for a Regulation establishing the space programme of the Union and the European Union Agency for the Space Programme"[79] discussed the impact of the proposal on innovation; this positive impact would occur through additional investment generated by the proposal, the development of the smart "EU GOVSATCOM Hub" and a better access to small and medium-sized enterprises (SMEs), which are considered as essential players for innovation. Similarly, Sections 6.2.3 and 6.3.3 of the impact assessment of the "Proposal for a Directive on the reduction of the impact of certain plastic products on the environment"[80] demonstrated that such legislation would be innovation-friendly as it would enhance the development of alternative business models, innovative product design and use of alternatives. However, **such impacts were not quantified** to

[75] European Commission (2018), *Proposal for a Regulation of the European Parliament and of the Council on minimum requirements for water reuse, COM/2018/337 final*.
[76] European Commission (2018), *Proposal for a Proposal for a Regulation of the European Parliament and of the Council on promoting fairness and transparency for business users of online intermediation services, COM/2018/238 final*.
[77] *Promoting fairness and transparency for business users of online intermediation services, op.cit.*
[78] European Commission (2018), *Proposal for a Regulation of the European Parliament and of the Council establishing the space programme of the Union and the European Union Agency for the Space Programme and repealing Regulations (EU) No 912/2010, (EU) No 1285/2013, (EU) No 377/2014 and Decision 541/2014/EU, COM/2018/447 final.*
[79] *Establishing the space programme of the Union and the European Union Agency for the Space Programme, op.cit.*
[80] European Commission (2018), *Proposal for a Directive of the European Parliament and of the Council on the reduction of the impact of certain plastic products on the environment, COM/2018/340 final*

compare policy options. In one case, the monitoring and evaluation section of the impact assessment includes an **indicator capturing future impacts on innovation**. In four cases impacts on innovation are **made prominent in the executive summary of the impact assessment**. In three cases an **assessment** (mainly qualitative) **of impacts on innovation was performed in external studies** supporting the impact assessments.

- Finally, in one case, the **Regulatory Scrutiny Board referred to impacts on innovation in its opinions**. In particular, the Regulatory Scrutiny Board emphasised the indirect positive impact of the "Proposal for a Regulation on promoting fairness and transparency for business users of online intermediation services"[81] on innovation via its positive effect on competition, which should lead to an increase in research, development and innovation investment by platforms.

Third step – Legislative design considerations

- In five cases, the proposals put forward **flexible provisions**, e.g. less detailed and prescriptive legislation such as automatic updates of proposed rules. For example, the "Proposal for a Regulation on promoting fairness and transparency for business users of online intermediation services"[82] set new requirements regarding the complaint-handling systems that ensure providers of online intermediation services a "reasonable degree of flexibility" in the operation of those systems. Similarly, the "Proposal for a Directive on the reduction of the impact of certain plastic products on the environment" [83] provided Member States with some flexibility with regard to the choice of the most appropriate specific implementation and data collection methods to meet the objectives of the Directive.
- In six cases, the proposals attempted to **eliminate excessive compliance costs**, thus also trying to avoid that such costs divert resources from research and innovation activities. This was the case of the "Proposal for a Directive on the reduction of the impact of certain plastic products on the environment",[84] which provided simple monitoring and reporting arrangements to eliminate excessive compliance costs for the Member States. In the same vein, the "Proposal for a Directive on the re-use of public sector information"[85] eliminated excessive compliance costs by focusing the policy intervention only on areas where change is necessary.
- In three cases, the proposals introduced **new requirements within a timeframe that was specifically set to be in line with market investments and the innovation cycle**. For example, the "Proposal for a Directive on the reduction of the impact of certain plastic products on the environment"[86] allowed sufficient time for the development of a harmonised standard, and for producers to adapt their production chains.
- In seven cases the proposals explicitly aimed to **create regulatory certainty and clarity**.[87] For example, the "Proposal for a Regulation on promoting fairness and

[81] *Promoting fairness and transparency for business users of online intermediation services, op.cit.*
[82] *Ibid.*
[83] *Reduction of the impact of certain plastic products on the environment, op.cit.*
[84] *Ibid.*
[85] European Commission (2018), *Proposal for a Directive of the European Parliament and of the Council on the re-use of public sector information (recast), COM/2018/234 final.*
[86] *Reduction of the impact of certain plastic products on the environment, op.cit.*
[87] The 'third step' under Tool #21 also looks at regulatory certainty and clarity since "regulatory uncertainty can hamper investment, including investment in R&I, because it increases risk and potentially also the cost of finance". Nonetheless, it acknowledges a trade-off "between the need to reduce regulatory uncertainty and the

transparency for business users on online intermediation services"[88] set common rules to enhance legal certainty for cross-border operations. Similarly, the "Proposal for a Council Directive laying down the rules relating to the corporate taxation of a significant digital presence"[89] aimed, *inter alia*, to provide taxpayers with additional legal certainty.

- Finally, eight of these ten proposals feature an **explicit aim to reduce market fragmentation** by e.g. fostering a harmonised approach across Member States when implementing the legislation. This was the case of Chapter III of the "Proposal for a Regulation on health technology assessment";[90] the Chapter established common rules for carrying out clinical assessments at EU and Member State-level, which should ensure a harmonised approach to clinical assessments across the EU. As another example, the "Proposal for a Directive on the reduction of the impact of certain plastic products on the environment" [91] established a harmonised legislative framework at the EU level to prevent and reduce marine litter.

Fourth step – Leveraging the potential of innovation

- Experimentation clauses, sunset clauses, tests of alternatives, top-runner approach, etc. were not used. In one case, both the proposals and policy options under assessment included **rules that are explicitly outcome-oriented**. In fact, the "Proposal for a Directive on the reduction of the impact of certain plastic products on the environment" [92] specified that "the transition towards alternatives should be outcome-oriented". The impact assessment accompanying this proposal assessed several measures that define specific targets (e.g. reduction targets for single-use plastic products where there are alternatives on the market: 30% by 2025 and 50% by 2030), without prescribing the exact mechanism by which the objective is to be achieved.

All in all, even when taking into account the fact that the Tool is still in the early phases of its implementation, these findings show **some potential for improvement**. A more thorough application of Tool #21 can be extremely useful in helping tackle the **challenges posed by new markets and technologies, and accelerating innovation.**

2.4.1.2 Case study: the Commission proposal on Health Technology Assessment

The case study on the Health Technology Assessment[93] relied on a **desk review** of the public documents associated with the proposal.[94] This set of documents includes: i) inception impact assessment;[95] ii) impact assessment;[96] iii) impact assessment executive

need to maintain flexibility" (*Tool #21 – Research and Innovation - Better Regulation Toolbox complementing Better Regulation Guidelines, op.cit,* p.150).

[88] *Promoting fairness and transparency for business users of online intermediation services, op.cit.*

[89] European Commission (2018), *Proposal for a Council Directive laying down rules relating to the corporate taxation of a significant digital presence, COM/2018/0147 final.*

[90] *Health technology assessment and amending Directive 2011/24/EU, op.cit.*

[91] *Reduction of the impact of certain plastic products on the environment, op.cit.*

[92] *Ibid.*

[93] *Health technology assessment and amending Directive 2011/24/EU, op.cit.*

[94] All documents are available at https://ec.europa.eu/health/technology_assessment/eu_cooperation_en

[95] European Commission (2016), *Strengthening of the EU cooperation on Health Technology Assessment (HTA).*

[96] European Commission. (2018), Commission Staff Working Document - *Impact Assessment – Strengthening of the EU cooperation on Health Technology Assessment (HTA)* – Accompanying the document: Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU.

summary;[97] iv) Regulatory Scrutiny Board opinion[98]; v) study supporting the impact assessment;[99] vi) public consultation report;[100] and vii) Commission's proposal.[101] Two interviews with Commission services were also performed.

The Commission proposal at hand aims to ensure **better functioning of the Internal Market** and **contribute to a high level of human health protection**. It intends to improve the availability of innovative health technologies for EU patients, ensure efficient use of resources and strengthen the quality of HTA across the EU, improve business predictability and generate efficiency gains. The proposal addresses the shortcomings of the current model of EU cooperation on HTA by promoting convergence through the use of common HTA tools, procedures and methodologies, by reducing duplication of efforts for HTA bodies and industry through the production of joint clinical assessments, and by ensuring the adequate uptake of joint outputs in the Member States. For example, Chapter III of the proposal lays down common rules for carrying out clinical assessments at EU and Member State-level. Moreover, the proposal is expected to encourage innovation and research on high-tech health technologies. For instance, it addresses the problem of impeded and distorted market access, which has negative effects on innovation in the long-run. Section 3 of Chapter II provides for an annual study on the identification of emerging health technologies.

When it comes to the application of the Research and Innovation Tool, **potential impacts of the regulation on research and innovation** are analysed in the inception impact assessment, impact assessment, impact assessment executive summary, and in the study supporting the impact assessment. It is worth mentioning that the inception impact assessment was prepared in 2016 before the current version of the Research and Innovation Tool was published. Therefore, the tool was not fully considered when planning the impact assessment and launching the supporting study. All policy options have nevertheless been assessed by considering, *inter alia*, their impacts on business predictability, research, innovation and competitiveness. However, the assessment is largely qualitative.[102] In the same vein, the questionnaire of the public consultation includes specific questions related to the impact of HTA on innovation; **innovation stakeholders** (large companies and SMEs in both the pharmaceutical and the medical devices industries) were also reached via targeted consultation activities and their concerns were accounted for when selecting the preferred option. The analysis of stakeholders' feedback, however, remains qualitative. The section of the impact assessment dedicated to monitoring and evaluation does not include indicators to measure future impacts on research and innovation. Nevertheless, the legislative design of the proposal tries to eliminate excessive **compliance costs and administrative burdens**

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[97] European Commission (2018), Commission Staff Working Document – *Executive Summary of the Impact Assessment – Strengthening of the EU cooperation on Health Technology Assessment (HTA)* – Accompanying the document: Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU.

[98] European Commission Regulatory Scrutiny Board (2017), *Impact Assessment / EU cooperation on Health Technology Assessment (HTA)*.

[99] European Commission (2017), *Study on impact analysis of Policy Options for strengthened EU cooperation on Health Technology Assessment (HTA) Final Report*.

[100] European Commission Directorate General for Health and Food Safety (2017), *Strengthening of the EU cooperation on Health Technology Assessment (HTA)*, Online public consultation report.

[101] *Health technology assessment and amending Directive 2011/24/EU, op.cit.*

[102] An exception is represented by Annex VIII of the impact assessment, which shows that one of the proposed policy options would speed up the market access process for innovative pharmaceuticals, thus leading to a 1% increase in the revenues for each innovative product launched (*Impact Assessment – Strengthening of the EU cooperation on Health Technology Assessment (HTA), op.cit.*, p.149).

and ensure that saved resources could benefit further research and innovation activities. It also aims to create regulatory certainty and clarity and introduces new requirements within a timeframe that is specifically set to be in line with market investments and the innovation cycle. Finally, the proposal clearly intends to reduce market fragmentation.

Interviewed stakeholders confirmed that the Research and Innovation Tool was used to properly assess the expected impacts **on research and innovation** of the different policy options while ensuring a high level of human health protection. They believe that **a joined-up Commission approach is needed to achieve better results**, especially when it comes to the quantification of impacts on research and innovation. **Ensuring inter-service coordination** in the inception phase of any proposal would help plan the proper application of the tool in all the steps leading to the preparation of legislative proposals. In this specific case, reportedly**, the tool was applied on an *ex post* basis** by relying on evidence already collected and identified policy options.

2.4.2 Application of the innovation deals

The pilot innovation deal on **sustainable wastewater treatment combining anaerobic membrane technology and water reuse** is the subject of this case study. The analysis relied upon interviews with three participants in the deal (the coordinator, a national authority and DG RTD); and a review of official documents (the joint declaration of intent, two reports prepared in the context of the innovation deal and the Commission's opinions on such reports).

This innovation deal involved several **entities representing the main interested parties**:

- European Commission services (DG RTD and DG ENV);
- Four national authorities (two from Malta, one from Portugal and one from Spain);
- Two regional authorities (both from Spain); and
- A consortium composed of three universities (one from Portugal and two from Spain), two research centres (both from France), two innovators (an SME from France and the entire grouping of entities involved in the H2020 SMART Plant Project) and one additional stakeholder (from Spain).

The joint declaration of intent for this innovation deal was signed in April 2017.[103] The declaration emphasised that **the instrument cannot lead to any derogation from existing EU legislation** but only make use of elements of flexibility (in particular, clarifications) to remove regulatory barriers hindering innovation. The deal focused on AnMBR, *i.e.* an innovative technology enabling the synergic application of water reuse and recovery of material and nutrients present in wastewater. It aimed to **identify regulatory barriers stemming from EU legislation that affect water reuse for agricultural purposes** and **propose solutions** to overcome the identified barriers, thus ultimately contributing to circular economy, climate resilience, resource efficiency, environmental protection and economic growth in the EU.

The innovation deal **lasted about 18 months** from the signature of the joint declaration of intent to its conclusion and was divided into three main phases:

[103] *The Joint Declaration of Intent for the Innovation Deal on sustainable waste water treatment combining anaerobic membrane technology and water reuse*, available at: https://ec.europa.eu/research/innovation-deals/pdf/jdi_anmbr_042017.pdf

- Early life (six months), to perform an assessment of the existing barriers;
- Intermediate review (six months), to develop and assess possible options to overcome the identified barriers; and
- Conclusions and outcomes (six months) to prepare a final report jointly accepted by all participants, including *inter alia* recommendations for follow-up actions.

All parties committed to participate in the innovation deal on a **voluntary basis** with **no funding** from the European Commission.

The innovation deal's output is a report providing an in-depth analysis of the regulatory problems impinging on the deployment of the AnMBR technology and proposed solutions to address such problems. The report is the result of a shared effort to identify and analyse the barriers perceived by the interested parties and propose solutions to overcome such barriers. Such a report could be considered a starting point to launch future evaluations and assessments of the impact of the identified barriers outside the framework or the innovation deal.

AnMBR present some **advantages when compared with conventional wastewater treatment technologies**. One of the main features of the technology is that nutrients (nitrogen and phosphorus) are not removed, therefore the reclaimed wastewater could be reused in agriculture for fertigation (i.e. irrigation and fertilisation) with benefits for farmers (cheaper fertilisers). However, the presence of nutrients in the reclaimed wastewater can also **pose an environmental threat** with adverse effects on the quality of soil, water and air, and on human health, especially in 'sensitive areas' or 'nitrate vulnerable zones' (which Member States can identify based on the provision included in the Urban Waste Water Treatment Directive[104] and Nitrate Directive[105]) where there is already a nutrient surplus. Therefore, **a wastewater treatment plant relying on the AnMBR technology cannot receive a construction or operation permit in 'sensitive areas' or 'nitrate vulnerable zones'**. In addition, the Water Framework Directive[106] seems to result in a water pricing policy for farmers that disincentives water reuse. Finally, some national rules setting standards for the quality of reclaimed water intended for irrigation further prevent the application of AnMBR.[107]

To overcome the detected regulatory barriers, the stakeholders participating in the innovation deal requested reviewing and clarifying certain aspects of the Urban Waste Water Treatment Directive[108] (or alternatively the Nitrate Directive[109]) and **bridge a regulatory gap** (namely the lack of a legal definition of 'discharge' and 'water reuse') in order to ensure a **special regime for the reclaimed wastewater used in agriculture**. This approach should be accompanied by the application of water reuse risk management practices and by changes in water pricing policies leading to a lower cost for reclaimed water for farmers.

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[104] *Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment*, Official Journal L 135, 30/05/1991

[105] *Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural* sources, Official Journal L 375.

[106] *Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy*, Official Journal L 327, 22/12/2000.

[107] Some technical obstacles to the application of the AnMBR technology have also been identified.

[108] *Urban Waste Water Treatment Directive* (91/271/EEC), *op.cit.*

[109] *Nitrates Directive (91/676/EEC), op.cit.*

In this context, the Commission emphasised that:

- The EU rules applying to AnMBR or other relevant technology to prepare water to be reused are technology-neutral.
- Stricter rules impinging on the adoption of the AnMBR technology apply only in certain, well-defined 'sensitive areas' or 'nitrate vulnerable zones'.
- In order for the AnMBR or other relevant technology to generate economic and environmental benefits, certain conditions must be met and it is unlikely that these conditions materialise in 'sensitive areas' or 'nitrate vulnerable zones' without any environmental risks.
- Allowing for the adoption of the AnMBR or other relevant technology for reclaimed water treatment in 'sensitive areas' or 'nitrate vulnerable zones' would require two elements: i) **precise balance of nutrient loads** in the agricultural field, where a fertigation could take place; and ii) **a shift of responsibility for control of nutrients from wastewater treatment plants to farmers**, thus making it more complex for national and regional regulators to enforce rules and increasing uncertainty about environmental benefits.

These points lead to the conclusion that the regulatory barriers detected in the current EU legislation were in place in order to **protect the environment and human health**. Therefore, the innovation deal team proposed to **consider the findings and arguments developed by the innovation deal in the ongoing evaluations of relevant legislation**. In addition, the Commission suggested relevant stakeholders **implement more EU-wide pilot projects applying AnMBR** or other relevant technology, where allowed (*i.e.* in so-called 'normal' or 'not-sensitive areas') by the current EU regulatory framework. Such pilots could better demonstrate opportunities for applying water reuse and bringing a stronger EU added value. They could also strengthen the cooperation between wastewater treatment plant operators and farmers to achieve economic benefits while ensuring a high level of environmental protection.

The innovation deal **enabled cross-border cooperation** among innovators, national authorities, regional authorities and Commission services. This helped to identify and frame the problem as well as suggest and discuss possible solutions to address it in the participating countries of the innovation deal. It shows a growing **EU added value** of this instrument and its potential **relevance** when it comes to addressing problems in the national implementation of EU regulation that can discourage investment and limit innovation as well as to identifying regulatory gaps stemming from old rules applying to innovative products/technologies. Nevertheless, the innovation deal so far **did not trigger regulatory changes.**

The innovators and public authorities participating in the innovation deal explained that the **process to perform the innovation deal was well structured and clear** from the very beginning. In addition, enough support was provided by the Commission to keep everything on track. Nevertheless, two missing elements limited the potential of the deal: i) there is no clear follow-up to the innovation deal, which may reduce the incentives for all parties to work on the deal; and ii) not enough emphasis is placed on the quantification of impacts, i.e. one of the main limitations of the final report, which falls short of monetising the missed opportunities in terms of net economic and environmental benefits. Some stakeholders also pointed at the need to account for all relevant policy areas (e.g. environmental policy, health policy, innovation policy) to improve the dialogue and address existing concerns about the perceived problem.

When it comes to the **efficiency** of the process, **coordination costs** appear to be the most burdensome part of the process. They materialise in the form of both out-of-pocket expenses for travelling or e.g. working on shared documents and difficulties to identify relevant stakeholders and convincing them to actively participate in the innovation deal. In this respect, coordination costs may be reduced by providing some reimbursement for out-of-pocket expenses as well as by **increasing the awareness of the instrument** at the national and regional level so that it becomes easier to identify and involve interested parties. The awareness of the instrument can be increased via improved communication and dissemination activities as well as by relying on success stories.

On a more general note, there is room to **improve the selection process for new pilots** to increase the **effectiveness** of innovation deals. First, selected pilots should focus on **major problems affecting a substantial number of innovators** (and a variety of technological solutions) and curtailing the overall economic, environmental and social benefits stemming from innovation (positive net benefits). This item is important to ascertain that the innovation deal has broad, positive impacts, beyond the direct interests of the stakeholders negotiating the specific deal. Second, the innovation deals should **look at barriers linked to the national implementation/application of EU legislation** that can be removed by improving the way rules are applied by national/regional authorities rather than amending existing EU rules.

3 Evaluation

In this chapter, the main findings of the **overall evaluation of the innovation principle** are reported. These findings are mostly based on a detailed **review of official documents and relevant literature**. Consulted documents include, *inter alia*, official documents (legislation, proposals and accompanying documents), studies and reports published by EU and national institutions, academic literature, 'grey' literature as well as any other document provided by DG RTD. All sources are referred to in footnotes. In addition, we carried out **11 in-depth interviews** with Commission officials, representatives of the business sector, representative of consumer organisations and civil society and innovators and authorities participating in innovation deals. In terms of interview techniques, we relied on semi-structured interviews. Interviews were conducted in English based on a written questionnaire that was shared with interviewees in advance.

Data collected have been validated via **triangulation** to ensure the robustness of the evidence. Triangulation allows for increasing confidence in collected data, revealing unique findings and providing a clearer understanding of the problem. In this respect, the Study relied on three different types of triangulation to provide a solid basis from which robust conclusions can be drawn: i) triangulation of data (collection of data from multiple sources and stakeholders); ii) triangulation of methods (collection of data via at least two methods among the following: desk research, interviews and case studies); and iii) triangulation of evaluators (answers to each question were reviewed by both co-authors of the report).

Based on data collected and validated, first, the indicators listed in the **evaluation framework** presented in Annex A were assessed. Then, indicators and other qualitative findings from data collection were arranged to match the evaluation criteria described in chapter 1 above. Evidence related to the various criteria were finally aggregated to provide a basis for answering the relevant questions.

The findings of the evaluation should be treated with caveats for two main reasons. First, the empirical data collection relied on a **limited number of interviews** (11). Therefore, results stemming from this consultation are not statistically representative. To the extent possible, interviews were conducted with experts of the topic, representing the interests of large and varied groups of stakeholders. A more robust future evaluation should include, broader consultation activities. Second, when considering the 'state of play', it is very **early to perform a robust evaluation of the innovation principle**, due to its very recent formalisation, as well as its limited application on the ground. The evaluation is therefore concentrated on detecting the first signs of expected outputs, rather than looking for medium-term outcomes or long-term impacts.

3.1 Relevance

HIGHLIGHTS

All the needs and problems originally addressed by the innovation principle are relevant: this means that the innovation principle can ultimately contribute to addressing them. Nonetheless, additional needs and problems have emerged and should be considered in the future. These include:

- More evidence-based and foresight-based policymaking. Tool #21 and the innovation deals could be based on more quantified data, whereas the

introduction of Horizon Scanning could significantly improve the ability of the Commission to engage in foresight-based policymaking.

- More guidance on experimental policymaking. Tool #21 could provide more detailed guidance to Commission officials to structure experiments such as regulatory sandboxes. The appointment of dedicated staff in charge of designing experiments would greatly improve the Commission's ability to craft robust rules in ever-changing environments.
- The fact that the Commission tends to choose soft policy options to address regulatory concerns in emerging technologies limits the extent to which the innovation principle can support policy choices in this field, since impact assessments on soft instruments are seldom conducted.
- A clearer definition of the innovation principle is needed, as most stakeholders would benefit from a better understanding of the concept behind the principle.
- A clearer legal basis for the innovation principle would also be helpful. The innovation principle should be defined in light of other existing objectives of EU law.
- Emphasis should be placed on fostering innovation that addresses societal challenges and on linking innovation to outcomes, e.g. sustainable development.
- The innovation principle should be linked to fundamental challenges for the EU innovation landscape, such as bridging the 'scale-up' gap, and promoting more investment in research and innovation.

The **relevance** criterion measures the extent to which the objectives that the innovation principle was meant to achieve are in line with the evolving needs and problems experienced by EU stakeholders when it comes to research and innovation. This criterion is translated into the **following questions**:

- Are the (original) objectives of the innovation principle relevant given the challenges it aims to address? How well do they (still) match the current needs and problems?
- To what extent is the innovation principle addressing stakeholder needs?
- What are the emerging needs the innovation principle does not cover?

As outlined in the Evaluation Framework (see Annex A Evaluation framework), these questions can be answered by relying on **two main criteria**:

- Degree of alignment between the original needs and problems identified in the *ex-ante* design and the current needs and problems.
- Degree of alignment between current needs and problems and the objectives identified in the *ex-ante* design.

Most of the interviewed stakeholders have confirmed that the **needs and problems** originally addressed by the innovation principle (see section 2.3) **are still relevant**. Some Commission officials pointed out that the EU *acquis* is already accounting for innovation relatively well and keeping the pace of innovation, especially when compared with rules enacted in other regions of the world. This conclusion is partially corroborated by the Global Innovation Index (GII),[110] which shows that some EU countries are leaders when it

[110] For further details, please see: https://www.globalinnovationindex.org/Home

comes to regulatory quality.[111] The average quality of EU rules, however, appears to be outperformed by leading innovators such as the USA, Japan and Israel.

Interviewed stakeholders also believe that by achieving its intended objectives (see section 2.3), **the innovation principle can ultimately contribute to addressing such needs and problems**. There are however a few exceptions. For instance, some stakeholders believe that the innovation principle can play a limited role when it comes to bridging the productivity gap the EU faces vis-à-vis its main global competitors, as innovation is only one of the many factors impacting productivity.[112] Nevertheless, the productivity gap is attributed by many scholars to the lack of innovation 'diffusion'.[113] Some other stakeholders, including representatives of the business sector, are more sceptical about solving the problems detected in national implementation of EU rules, especially because the innovation deals carried out so far have shown little effectiveness for solving issues identified at the national level (see section 2.4.2).

Most of the stakeholders believe that the needs and problems that the innovation principle is meant to address (see section 2.3) represent a fair picture of the research and innovation related obstacles that are impinging on the achievement of sustainable growth and jobs. Nonetheless, some **additional needs and problems** were identified, such as:

- The need for **more evidence-based policy-making**. For example, interviewed stakeholders observed that too little emphasis was placed on the quantification of impacts during the pilot phase of the innovation deals. This is an essential shortcoming, as it is more difficult to convince policy-makers to act and remove the detected barriers to innovation without a proper assessment of the costs and/or foregone benefits stemming from such barriers. Likewise, in the application of Tool #21, collecting evidence related to the lack of innovation incentives should occur more systematically.
- The need for **more foresight-based policymaking**. Especially when digital innovation is at stake, anticipating future trends and creating the preconditions for market monitoring over time becomes imperative for sound policymaking. In the future, Horizon Scanning could be used to strengthen the ability of the Commission to spot existing risks and trends and take appropriate mitigating and strategic actions.
- The need for **more guidance on experimental policymaking**. The need to structure experiments such as regulatory sandboxes properly is vibrantly emerging in the policy community. In the longer term, the appointment of dedicated staff in charge of designing experiments would greatly improve the Commission's ability to craft rules in difficult and ever-changing environments. The Commission could develop a multi-stakeholder community of practice to that effect. Such a community could be tasked with shaping a shared understanding of experimental policy-making at EU level.

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[111] The regulatory quality index is designed to capture the broader impact of regulation on the development of the private sector (for more details, please see: World Bank (2017), *Worldwide Governance Indicators*, available online at: http://info.worldbank.org/governance/wgi/index.aspx#home). As such, it is important to note that this analysis is only an approximation, as the index does not capture specifically the relationship between regulation and innovation.

[112] Research shows that productivity growth is impacted by a plethora of factors. One can differentiate between factors at the firm level and at aggregate factors. At the firm level, drivers include managerial practices, human capital quality, capital quality, research and development, product innovation, firm structure decisions. At the aggregate level, factors include, among others, competition, trade, and proper regulation. For further details, please see: Syverso, C. (2011), *What determines productivity?,* Journal of Economic Literature Vol. 49, Issue 2.

[113] See for instance: *Aligning Policies for Low-Carbon Systemic Innovation in Europe*, CEPS and i24c Report, *op.cit.* p. 7; *Europe's Future: Open innovation, open science, open to the world*, *op.cit.*, p.15; and *Unleashing Innovation and Entrepreneurship in Europe*, *op.cit.*, pp. 8-9.

- The fact that **the Commission tends to choose soft policy options** to address regulatory concerns in emerging technologies (e.g. through the appointment of High-Level Groups and calls for self-regulatory schemes) limits the extent to which the innovation principle can directly support legislative choices in this field, since no impact assessment is in principle carried out on soft instruments.
- The need to **foster innovation that addresses societal challenges**. As already recalled, not all innovation is equally useful for public policy purposes. Therefore, the Commission needs to ascertain that innovation is used for improving societal well-being. The innovation principle by itself only cannot fulfil this need but the combination with other tools and metrics spelt out in the Better Regulation Guidelines and Toolbox fully ensures such a well-rounded approach. In principle, legislative proposals are assessed with respect to a variety of monetary and non-monetary impacts; the innovation principle just contributes to ensuring that **impacts on innovation** are explicitly considered throughout the policy process.
- **The need to bridge the 'scale-up' gap**. Relevant literature points to the existence of a 'scale-up' gap in the EU in comparison to the USA.[114] This refers to the fact that the share of companies with high growth rates is smaller in the EU. The scale-up gap also has implications for productivity growth and job creation, as scale-up companies tend to be more productive than the average company and create many new jobs.[115]
- The problem of **insufficient investment in research and innovation as well as in new technologies and infrastructure**.[116] The innovation principle can contribute to solving this problem by: i) eliminating excessive regulatory costs borne by EU companies, thus freeing more resources for investment; and ii) reducing regulatory uncertainty, thus encouraging private investment attracted by more predictable exploitation of innovation results.

Importantly, the potential for the innovation principle to fully contribute to these needs is hampered by the **lack of a clear definition**, the **lack of a clear legal basis**, and the **insufficient awareness of its underlying rationale** among stakeholders. Stakeholders representing consumers and civil society argued in our interviews that:

- There is no legal basis for the innovation principle;[117]
- Innovation *per se* makes little sense, as not all types of innovation enhance societal well-being.[118] Hence, innovation should always be qualified to ensure that societal challenges are addressed, environmental and health protection is ensured and that societal well-being is improved.

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[114] For example, the Interim Evaluation of Horizon 2020 found that very few European start-ups survive beyond the critical phase of 2-3 years, and even fewer grow further. Less than 5% of European SMEs grow internationally. Venture capital in the EU is one-fifth the level of the USA. For further details, please see: https://ec.europa.eu/info/publications/interim-evaluation-horizon-2020_en

[115] Hoffman, A. (2016), *Scale-up Companies– is a new policy agenda needed?*, Expert report for the European Commission.

[116] In 2002, EU Member State agreed on the so-called Barcelona target and committed to invest no less than 3% of their GDP in scientific research and development. Nevertheless, the most recent figures show that only two Member States achieved this target. For further details, please see: Karakas, C. (2018), *Research and innovation in the EU - Evolution, achievements, challenges*, European Parliament.

[117] Some civil society stakeholders are concerned by the fact that the proposed regulation establishing the Horizon Europe programme is referring to the innovation principle in recitals, although such a principle finds no ground in the Treaties.

[118] The main example quoted by multiple stakeholders pertains to medicines. In this case, the EU seems to have made substantial investments in supporting the development of new products across the years. Nevertheless, some products supported by EU funding happened to be too expensive when commercialised. This is a case where innovation *per se* does not generate immediate societal benefits (See for instance: Van Hecke, M. and van Gils, B. (2019*), Médicaments: vous les payez deux fois*, Test Santé n°149).

- Tool #21 looks at the impacts of rules *on* innovation, rather than at the impacts *of* innovation on the economy, society and the environment: in other words, the Innovation principle is insufficiently oriented towards leveraging innovation for future societal well-being.

In this latter context, stakeholders representing consumers and civil society argues that it would be equally or even more relevant to introduce a 'climate change principle' or 'biodiversity principle' rather than an 'innovation principle', as there is a strong need to steer innovation in a direction that is worth for society. This is an important comment when it comes to the ongoing debate on the future of better regulation in the EU, in particular when it comes to the possible **mainstreaming of sustainable development goals** (Agenda 2030)[119] **in the EU better regulation agenda.**[120]

3.2 Effectiveness

HIGHLIGHTS

As the implementation of the innovation principle is still in early stages, it is possible to present only some preliminary results generated by the innovation principle.

With regard to the Regulation and Innovation Tool, most of the stakeholders interviewed are quite appreciative of the potential for it to achieve positive results. The most positive aspects include:

- The comprehensive "step-by-step approach" proposed by the tool.
- The improved dialogue with relevant stakeholders.
- The increasing attention paid by EU institutions to innovation-related impacts of regulation.

Nevertheless, stakeholders reported the following issues:

- A communication issue. The innovation principle has been misrepresented as a tool aiming to ensure that innovation *per se* becomes an objective of the regulatory agenda.
- A representation issue. Some of the stakeholders consulted believe that more should be done to consult innovators and to account for innovative solutions in legislative proposals. By contrast, stakeholders representing consumers and civil society believe that the business sector and innovators already have ample room to provide feedback in standard stakeholder consultations.
- An uptake issue. Policy-makers at all levels need to develop a common understanding of the innovation principle and consistently embed it in their policy-making practice.
- A skill and timing issue. Adequately applying the Research and Innovation Tool requires substantial investment in time, skills and knowledge, beyond the current effort.

[119] For further details, please see: https://www.un.org/sustainabledevelopment/sustainable-development-goals/
[120] See for instance: Renda, A. (2017), *How can Sustainable Development Goals be 'mainstreamed' in the EU's Better Regulation Agenda?*, CEPS Policy Paper 2017/12; and European Commission (2019), *Reflection Paper, Towards a Sustainable Europe by 2030*, COM(2019)22 of 30 January 2019.

Interviewed stakeholders observed that innovation deals contribute to:

- Identifying regulatory uncertainties arising from the national implementation of EU rules, which hamper innovation.
- Scrutinising implementation issues affecting innovation outcomes.
- Fostering dialogue with interested parties to identify regulatory problems in the field of innovation and seek solutions to address the detected problems.

Nevertheless, a number of issues were identified specifically for the innovation deals:

- Some stakeholders argued that the process put in place for innovation deals is too long and cumbersome.
- Getting stakeholders involved in innovation deals is quite challenging due to limited awareness, limited perception of benefits and lack of funding to participate in the process.
- According to the representatives of the business sector interviewed, one of the key limitations is linked to the fact that the innovation deals attempt to clarify rules, rather than change them and this may reduce the effectiveness of the instrument.
- Part of the problem may also be linked to the limited scope of the pilots conducted so far, which focus only on the circular economy, and hence may not show the full potential of this tool.

The **effectiveness** criterion assesses the extent to which the innovation principle has achieved its intended objectives and generated the expected results. Analysing the effectiveness of innovation principle requires answering three questions:

- What have been the main outputs and outcomes of the innovation principle so far?
- What are the expected outputs and outcomes that still need to materialise?
- What are the factors supporting or hindering the expected outputs and outcomes of the innovation principle?

In answering these questions, **two main criteria** are considered:

- Degree of alignment between actual and expected results of the innovation principle.
- Degree of alignment between the original objectives and actual results of the innovation principle.

At this stage, as already mentioned, it is difficult to assess the concrete results generated by the innovation principle.[121] Most of the proposals where the Research and Innovation Tool was applied are still being discussed by EU institutions. Few of them became legislative acts, and it is too early to assess full outcomes at this stage. Only two pilot innovation deals have been conducted so far.[122]

[121] Interestingly, between 2016 (before the innovation principle was applied) and 2018, a relatively short timeframe, there were small changes of the regulatory quality rankings in a positive direction, as compiled by the GII. There are fewer EU countries below rank 40, namely three Member States in 2018 in comparison to six in 2016. However, by relying only on this indicator, it is not possible to conclude that the innovation principle generated so far substantial changes in the EU regulatory framework affecting innovation. For further details, please see: https://www.globalinnovationindex.org/Home

[122] It is worth mentioning that the innovation deals are inspired to the Dutch Green Deals (introduced in 2011). The Netherlands Environmental Assessment Agency (PBL) conducted an evaluation of the Green Deals to assess

3.2.1 Effectiveness of the Research and Innovation Tool

Most of the stakeholders interviewed are quite appreciative of the potential for Tool #21 to achieve positive results. The most positive aspects of the early implementation of the innovation principle show that:

- The **comprehensive "step-by-step approach"** proposed by the tool seems adequate to achieve its objectives.
- The **dialogue with relevant stakeholders has improved**, leading to more involvement of start-ups in the consultation phase. This dialogue can be extremely useful in identifying regulatory problems affecting innovation and seeking ways to address them via both public and targeted stakeholder consultation activities.
- Improvements have been experienced in the **attention paid by EU institutions to innovation-related impacts of regulation**. According to some of the interviewees, the Commission is seen as more attentive to impacts on innovation, also due to the fact that DG RTD has set up an internal task force whose members are called to ensure the proper implementation of the innovation principle; and that staff members of DG RTD participate in impact assessment steering groups to emphasise the importance of innovation impacts throughout the *ex ante* impact assessment process. Also, the Council of the EU has officially endorsed the innovation principle;[123] and the European Parliament is showing a growing interest in understanding the Research and Innovation Tool and how to apply it for better regulation purposes.[124]

Interviewed stakeholders, however, saw the following issues:

- There is a **communication issue**. The innovation principle has been misrepresented as a tool aiming to ensure that innovation *per se* becomes an objective of the regulatory agenda. This is not the case, as the innovation principle does not operate in a vacuum, and an economic, social and environmental impact assessment of proposed rules is always needed to ensure a sound, comprehensive analysis, thus ascertaining that the EU will foster innovation to address societal challenges.
- There is a **representation issue**. Some of the stakeholders consulted believe that, despite efforts to involve start-ups and other relevant stakeholders, more should be done to consult innovators and to account for innovative solutions in legislative proposals. By contrast, stakeholders representing consumers and civil society believe that the business sector and innovators already have ample room to provide feedback in standard stakeholder consultations and that they tend to be better organised and vocal than other stakeholders' groups. Hence, there is no need to give them another opportunity to state their views. They also emphasised that more civil society engagement may be required when designing the research and innovation agenda.[125]
- There is an **uptake issue**. So far EU institutions have made little use of the Research and Innovation Tool. A joined–up approach would be advisable to ensure that the tool

primarily their role in paving the way towards a circular economy. Among others, they noted that while Green Deals do add value to green innovation, they do not automatically lead to environmental gains and other policies are also necessary. For further details, please see: Ganzevles, J., Potting, J. and Hanemaaijer, A. (2017), *Evaluation of Green Deals for a Circular Economy*, PBL Policy Brief, PBL Netherlands Environmental Assessment Agency.

[123] *Research and Innovation friendly regulation*, op.cit.

[124] Based on information gathered in stakeholder interviews for this Study.

[125] While there are public and targeted consultations focusing on citizens, consulted stakeholders argue that there is no way to check whether respondents really represent the interests of citizens.

is applied not only for Commission's proposals but also when Parliament and Council discuss possible amendments, or when Member States transpose legislation.

- There is a **skill and timing issue**. Commission services face constraints to adequately apply the Research and Innovation Tool since its proper application requires substantial investment in time, human resources and knowledge building. In fact, while the tool includes a detailed list of questions to ensure that all impacts on innovation are considered and improved, some of the interviewees explained that: i) the questions need to be adapted to specific sectors/topics; and ii) answering such questions is not an easy task, especially when it comes to the quantification of impacts. In a number of cases, the innovation principle is not applied simply because of limited awareness of the tool. In this respect, several Commission officials stressed: i) the need for DG RTD to ensure early and active participation in inter-service steering group for proposals with expected impacts on innovation; ii) the need for an improved coordination between different EU policy domains; and iii) the need to ensure that Commission staff called to apply the innovation principle holds the right set of skills (e.g. knowledge of the policy context, subject matter specific expertise, better regulation expertise, decision-making process expertise, etc.). At present this knowledge seems to exist in organisational pockets.

3.2.2 Effectiveness of the innovation deals

Interviewed stakeholders observed that the innovation deals carried out so far have provided a **significant contribution in identifying regulatory uncertainties** arising from the national implementation of EU rules, which hamper innovation. Innovation deals appear very useful when it comes to **scrutinising implementation issues** affecting innovation outcomes as well as **fostering dialogue with interested parties** to identify regulatory problems in the field of innovation and seek solutions to address the detected problems. In addition, one of the pilots has also allowed **identifying regulatory gaps** that increase uncertainty and reduce incentives in investing in research and innovation. Potentially, innovation deals may also contribute to **increasing the effectiveness and coherence of the *EU acquis***.

Against this background, a number of challenges were identified specifically for the innovation deals.

- Some stakeholders argued that the process put in place for innovation deals is **too long and cumbersome**, in both the preparation phase (signing the joint declaration of intent can take about six months) and execution phase (18 months, including several meetings between the consortium members and the Commission as well as the creation of an *ad hoc* inter-service steering group). Reportedly, while preparing a proposal for an innovation deal is relatively easy, putting together a convincing group of stakeholders representing all the relevant parties in multiple Member States is the most challenging task.[126]
- It seems also that getting stakeholders involved in innovation deals (especially national authorities and SMEs) is quite challenging due to **limited awareness**, **limited perception of benefits** and **lack of funding to participate in the process**. Interviewed stakeholders had limited understanding of the potential scope and outcomes of innovation deals. The business sector sees a strong need for more success stories to make this instrument more appealing for innovators.

[126] Innovation deals applicants should ideally have: i) a sufficient knowledge of the EU legislation under analysis; and ii) enough evidence (preferably quantitative in nature) that the detected barriers impinge on innovation.

- According to the representatives of the business sector interviewed, one of the key limitations is linked to the fact that the innovation deals **attempt to clarify rules, rather than change them** and this may reduce the effectiveness of the instrument. In fact, innovation deals cannot lead to an outright change in existing rules (contrary, for example to Negotiated Rulemaking schemes in the United States or Green Deals in the Netherlands). When it comes to changing rules, the viewpoint expressed by an innovation deal represents the interest of a specific group of stakeholders: a broader consultation and impact assessment are required to grasp the scale of the problem and overall impacts of the requested improvements.[127]
- Part of the problem may also be linked to the **limited scope of the pilots conducted so far**, which focus only on the circular economy. In this respect, a continuous "call for proposals", open to a larger number of topics, could allow to improve the selection process and make sure that the innovation deals look at barriers to innovation that can be removed by improving the clarity of legislation rather than by changing legislation, thus making the instrument more effective.

3.3 Efficiency

HIGHLIGHTS

- Based on data collected via interviews, the application of the Research and Innovation Tool requires between 2-3 days to 3-4 months in full-time equivalent for Commission staff.
- The expected impacts of the different policy options on innovation should be assessed by any external study supporting the Commission's impact assessments.
- More attention is needed to consider impacts on innovation, especially when it comes to the legislative design and the quantification of impacts.
- The innovation deals negotiated so far required 2-3 months in full-time equivalent for Commission staff and about three months in full-time equivalent for other stakeholders participating in the deal.
- Stakeholders are primarily asking to make the innovation deals more effective rather than to reduce participation costs.
- With regard to stakeholders targeted by the innovation principle, more should be done to ensure a coherent vision of the need to consider impacts on innovation throughout the policy process between all EU institutions.
- The Research and Innovation Tool contributed to ensuring that innovators are consulted when preparing new legislative proposals. The innovation deals conducted so far have reached innovators, national and regional authorities and relevant Commission services in the field of circular economy.

The **efficiency** criterion relates to whether the innovation principle's objectives are achieved at the minimum cost. This evaluation criterion includes two questions and one sub-question presented in the ToR:

[127] Due to their negotiated nature, innovation deals may suffer from an 'incumbency' problem. For further details, please see: Renda, A. (2016), *Regulation and R&I Policies – Comparing Europe and the USA*, European Commission.

- To what extent are the personnel and administrative costs linked to the innovation principle justified, given the observed and expected outputs and outcomes it has or still aims to achieve?
- To what extent is the innovation principle reaching the target group envisaged? What are the barriers and what could be improved?

To answer these questions, **two main criteria** have been taken into account, in line with the Evaluation Framework (see Annex A Evaluation framework):

- Cost-effectiveness analysis to assess the ratio between allocated resources and actual results of the innovation principle.
- The degree of alignment between target groups and groups that are benefitting from the innovation principle.

Interviews with Commission officials led to quite **different estimates of the time spent** to perform a proper implementation of the 'step-by-step' approach envisaged by the **Research and Innovation Tool,** ranging from **2-3 days** in full-time equivalent to **3-4 months** in full-time equivalent. Differences may be linked to the complexity of the Commission's proposal, the number of policy options to be assessed, different understanding of the activity at hand and the salience of expected innovation impacts. In addition, the Commission generally relies on external service providers to perform studies accompanying impact assessments, who should ideally identify and quantify the expected impacts of the different policy options on innovation; this request should be part and parcel of the ToR for studies accompanying the impact assessments of proposals with potential impacts on innovation. Consulted stakeholders believe that **more resources should be invested to consider impacts on innovation**, especially when it comes to the legislative design (e.g. definition of policy options), as the impact of the design has been largely overlooked so far, and the quantification of impacts on innovation (see section 2.4.1). It would be important to construct policy options or sub-options using innovation and new technologies as part of the solution.

Stakeholders participating in the pilots of the **innovation deals** have explained that while the proposal phase required about **one week** of work in full-time equivalent, about **three months** in full-time equivalent were required to perform the entire process. In proportion, a larger share of such time was invested by the stakeholders in charge of coordinating the innovation deals. Efforts by Commission officials to complete the process were estimated in the area of **two to three months** in full-time equivalent. Stakeholders **do not perceive this process as particularly burdensome** for two main reasons: i) some of the activities performed to participate in the innovation deal represent 'business as usual' for them; and ii) as they are expert of the topic, they do not spend an excessive amount of time to contribute to the deal. In fact, participants in the negotiation process include not only universities and research centres with deep knowledge of the technical issues at hand but also representatives from companies and public authorities that usually have "hands-on experience" of the topics under investigation.[128] This also explains why so far there was **no need to rely on external service providers** to complete the process. Travel and accommodation costs to participate in the meeting with the Commission represented the main out-of-pocket expenses. According to participants, some travel funding would make a difference, as the lack of dedicated budget for travels may affect the ability of some

[128] Nonetheless, it is worth remarking that in the two innovation deals conducted so far, stakeholders appeared to have a limited understanding of the full body of EU and national rules relevant to the deals. Therefore, the identification of regulatory barriers and solutions to overcome such barriers required some extra efforts.

consortium members to participate in the relevant meetings. The number of face-to-face meetings could also be reduced, but this may have a negative impact on the effectiveness of the instrument, by leading to a suboptimal level of coordination among stakeholders and EU institutions. Reportedly, some efficiency gains may stem from **streamlining the preparation of the joint declaration of intent**, which took up to six months in the two pilots and required large efforts from all parties (estimated in about 25% of the entire time spent on the innovation deals), mostly due to administrative work.

Against this background, it is still **early to measure the cost-effectiveness of the innovation principle**, as both instruments under evaluation have not generated yet the expected results (see section 3.2). In this respect, stakeholders are asking to **make the instrument more effective rather than to reduce participation costs**.

Finally, with regard to **targeted stakeholders**, the Research and Innovation Tool is meant to support the work of all Commission officials preparing impact assessments of proposals that are expected to affect research and innovation activities in the EU; it could also guide the work of the European Parliament and the Council when carrying out impact assessments in relation to their substantial amendments to Commission's proposals[129]. In this respect, a **coherent vision of the need to consider impacts on innovation throughout the policy process** between all EU institutions would be needed. So far there has been no explicit application of the innovation principle in the other two institutions, although its role has been officially acknowledged by the Council.[130] When it comes to target groups that are indirectly affected by the Research and Innovation Tool, it appears that so far **the tool contributed to ensuring that innovators are adequately consulted** when preparing new legislative proposals. In the same vein, the innovation deals conducted so far have reached the main stakeholders targeted by this instrument, i.e. innovators, national and regional authorities and the Commission. Nonetheless, innovation deals did not adequately involve end-users and representatives from civil society.

3.4 Coherence

HIGHLIGHTS

Strong synergies between the Research and Innovation Tool and the innovation deals confirm the high internal coherence of the innovation principle. While the two components aim at the same general objective, i.e. ensuring an optimal regulatory framework to foster innovation and improve overall societal well-being, they intervene in different phases of the regulatory process:

- The Research and Innovation Tool looks at the preparation and adoption stage, as well as in the *ex post* evaluation of legislation.
- Innovation deals look at the implementation and application phases of the EU policies.

When it comes to the external coherence, the innovation principle is characterised by:

[129] See Interinstitutional Agreements, *Interinstitutional agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-making*, Interinstitutional agreement of 13 April 2016 on Better Law-Making

[130] *Research and Innovation friendly regulation*, op.cit.

- Important synergies with the overall EU research and innovation agenda, some specific Horizon 2020 projects (where the Research and Innovation Tool may be applied) and other tools of the Better Regulation Toolbox ('Sectoral Competitiveness' - Tool #20 - and 'SME Test' - Tool #22-).
- Potential synergies with the application of the 'Foresight and Horizon Scanning' and the EU 'lighten the load' initiative.
- A more complex interaction with the precautionary principle. In this respect, the proper application of the EU better regulation agenda allows precaution and innovation to coexist, and enhances societal well-being by finding innovative solutions to key societal challenges.

The **coherence** criterion encompasses two main dimensions: the 'internal coherence' looking at the interaction between the Research and Innovation Tool and the innovation deals and the 'external coherence' assessing interactions with other EU level interventions. In this context, the coherence criterion is translated into two questions spelt out in the ToR:

- To what extent do the components of the innovation principle relate to and support each other?
- To what extent is the innovation principle coherent with wider EU policy?

Therefore, to assess both the internal and the external coherence of the innovation principle, the following criteria are considered in the Evaluation Framework (see Annex A Evaluation framework):

- Degree of coherence between the two components of the innovation principle (internal coherence).
- Degree of coherence between the measure and other EU initiatives (external coherence).

Consulted stakeholders identify **high synergies between the two instruments under analysis**. In fact, while they aim at the same general objective, i.e. ensuring an optimal regulatory framework to foster innovation and improve overall societal well-being (see section 2.3), they intervene in different phases of the regulatory process.[131] The Research and Innovation Tool looks at the preparation and adoption phases and ensures that rules are more innovation-friendly; and potentially intervenes in the *ex post* evaluation stage (although this possibility has not been explicitly used by the Commission to date). This may also reduce the likelihood that innovation barriers are created by Member States in the implementation and application phases and, in turn, the need to rely on innovation deals. In fact, innovation deals look at the implementation and application phases of the existing EU legislation. They may also initiate the preparation of new legislative proposals aiming, *inter alia*, to remove regulatory barriers, thus leaving again the floor to the Research and Innovation Tool. However, for the time being, the innovation deal concluded in the field of wastewater management did not trigger a legislative change (for further details, see section 2.4.2), thus showing that **existing synergies between the two instruments can be reinforced**.

[131] The regulatory process includes four main phases: proposal, adoption, implementation and application. For further details, please see: Renda, A. *et al.* (2014), *Assessing the Costs and Benefits of Regulation*, European Union.

When it comes to the external coherence, it is worth distinguishing between existing synergies, potential synergies and areas where synergies need to be further developed and contradictions reduced.

- With regard to **existing synergies**. Consulted stakeholders confirmed that the innovation principle is well aligned with the **overall EU research and innovation agenda**. It also interacts with a number of **Horizon 2020 projects** that are expected to deliver concrete policy results, where the Research and Innovation Tool could be applied.[132] It has strong synergies with other tools of the Better Regulation Toolbox. Two cases developed by DG GROW are particularly relevant, namely the **'Sectoral Competitiveness' tool** (Tool #20) and **the 'SME Test'** (Tool #22). Step six of the analysis requested by the 'Sectoral Competitiveness' tool involves assessing how EU rules impact the capacity of enterprises to innovate. While an initial assessment is conducted as part of Tool #20, the Better Regulation Toolbox emphasises that a more thorough analysis should be carried out using the Research and Innovation Tool, once a significant effect is detected. In the same vein, the 'SME Test' also requires assessing the potential impact on innovation of proposed measures. To this end, also Tool #22 references the Research and Innovation Tool.
- **Potential synergies** are expected to materialise with the application of the '**Foresight and Horizon Scanning'**,[133] an instrument looking into the longer-term impact of policies and technologies to anticipate emerging societal challenges. As discussed, this can be considered the third component of the innovation principle, although it is not in the scope of this evaluation. In the same vein, both the stakeholder consultation envisaged under the 'first step' of the Research and Innovation Tool and, even more, the stakeholder dialogue facilitated by the innovation deals may complement the **EU 'lighten the load' initiative**.[134]
- By contrast, some stakeholders argue that the innovation principle is incompatible with **the precautionary principle.** There is a difference in the legal status of the two principles.[135] The precautionary principle is a Treaty-based principle, defined under Article 191 TFEU, whereas the innovation principle is part of innovation policy, having been *ex post* derived from various Treaty provisions.[136] The concept behind the innovation principle has been supported, *inter alia*, by the European Risk Forum,[137] BusinessEurope[138] and Industry4Europe,[139] arguing that the principle would stimulate investments in innovation and improve regulatory efficiency. This group of stakeholders identified complementarities between the two principles. In contrast, the

[132] The following Horizon2020 project represents a potential example: "Design and development of a tool to support and improve the decision making process of investors for financing high-growth potential innovative SMES". From the perspective of the Better Regulation Toolbox, this would imply using Tool #22 to analyse the impact on SME, but also potentially Tool #21, since the focus is particularly on innovative SME, giving grounds for assuming that an assessment of the impact on innovation is also needed. For further details about the project, please see: https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/innosup-09-2018

[133] For further details, please see: https://ec.europa.eu/jrc/en/research/crosscutting-activities/foresight

[134] This initiative allows EU citizens to indicate existing rules that could be made more effective and efficient. Suggestions are reviewed by the REFIT platform and may be reflected in the recommendations of the platform to the Commission. For further details, please see: https://ec.europa.eu/info/law/better-regulation/lighten-load_en

[135] Garnett, K., Van Calster, G. and Reins, L. (2018), *Towards an Innovation Principle: an industry trump or shortening the odds on environmental protection?,* Law, Innovation and Technology, Volume 10, Issue 1.

[136] *Towards an Innovation Principle Endorsed by Better Regulation, op.cit.*

[137] European Risk Forum (2015), *Fostering Innovation - Better Management of Risk*, The ERF Study.

[138] BusinessEurope (2015), *Fuelling EU policies with an Innovation Principle*

[139] Industry for Europe (2018), *For an ambitious EU industrial strategy*

European Consumer Association BEUC[140] and Corporate Europe Observatory[141] have positioned themselves against the innovation principle, pointing to the contradiction between the precautionary principle and the innovation principle, the different legal status of the two, and the potential environmental and health risks that could arise through the application of the innovation principle.[142] In this debate, the EPSC proposes that the precautionary and innovation principle could, in fact, work together, as the management of risk looks at the costs and benefits of both action and lack of action.[143] Garnett *et al* further elaborate on this idea;[144] they propose the introduction of a "qualified innovation principle", which ensures that precaution is taken into account and incorporates "consumer and environmental safeguards".[145] Overall, many stakeholders (including those representing business and, with some caveats, civil society) believe that **the precautionary principle can coexist with the innovation principle**, and the case studies presented above (see section 2.4) confirms this finding. Consumers and civil society representatives seem not to be against a more systematic approach to assessing impacts on innovation; however, this should foster only **innovation improving societal well-being and ensuring environmental protection**. Indeed, the current Better Regulation Guidelines and Toolbox require assessing all social, environmental and economic impacts of proposed legislation. Policy options are usually compared by accounting for a variety of monetary and non-monetary impacts. In addition, the Regulatory Scrutiny Board provides central quality control for Commission impact assessment, thus helping protect Europeans against poorly conceived laws.[146] Against this background, the proper application of the EU Better Regulation agenda[147] ensures a sound, evidence-based analysis of policy choices in impact assessments.

3.5 EU added value

HIGHLIGHTS

The innovation principle has the full potential to create EU added value.

The Research and Innovation Tool:

- Ensures a consistent approach across all EU policies and institutions when it comes to assessing impacts of EU rules on innovation.

[140] Bureau Européen des Unions des Consommateurs BEUC (2018), *Precautionary principle under attack: please delete so-called 'Innovation Principle' from Horizon Europe research funding programme.*
[141] Corporate Europe Observatory (2018*), The "Innovation Principle": Industry's attack on EU environmental and public health safeguards.*
[142] In fact, they argue that the innovation principle is expected to encourage risk-taking behaviour; by contrast, the precautionary principle only allows to take risks when this means not harming society. This aspect is quite important because: i) often revenues stemming from innovation and risks stemming from innovation are not equally distributed between the business sector and the civil society; and ii) the jury is still out when it comes to the most adequate methodology to assess risks, which may materialise even many years after the introduction of a new product.
[143] *Towards an Innovation Principle Endorsed by Better Regulation, op.cit.,* p. 3.
[144] *Towards an Innovation Principle: an industry trump or shortening the odds on environmental protection?*, op.cit.
[145] *Ibid*, p. 13.
[146] For further details, please see *Annual Report 2018, op.cit*.
[147] For further details, please see: https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en

- Contributes to the innovation friendliness of the entire *EU acquis* in support of the underlying objectives of the legislation.

The innovation deals:

- Enable stakeholders from all Member States to rely on the same process to identify and address regulatory barriers to innovation.
- Encourage cross-border cooperation among innovators, public authorities, researchers and users to identify barriers and suggest harmonised solutions.
- Facilitate the identification and adoption of best practices and solutions already adopted in other Member States.
- Allow to identify and solve problems that cannot be addressed solely by Member States, as they require an EU intervention.

The **EU added value** dimension captures the additional impacts generated by intervening at the EU level, as opposed to leaving the issues addressed by the innovation principle solely in the hands of Member States. This evaluation criterion seeks to answer the following questions listed in the ToR:

- To what extent has the innovation principle so far demonstrated added value at European level if compared to similar national or regional initiatives?
- What is the additional value from the application of innovation principle compared to similar national or regional initiatives?
- Is there already an outstanding example of EU added value provided by the innovation principle based on the evidence at hand and relating to effectiveness, efficiency or coherence?

In line with the Evaluation Framework (see Annex A Evaluation framework), answering these questions requires the analysis of two criteria:

- Achievement of results that could not be otherwise attained via national or regional initiatives.
- Achievement of results at a cost lower than what could be attained via national or regional initiatives.

Consulted stakeholders are of the opinion that **Member States** by their own initiative may be able to identify and address regulatory uncertainty and obstacles hindering innovation that stem from the implementation of EU rules. In the same vein, Member States may try to improve the dialogue with national stakeholders to identify such obstacles and remove them. In this respect, Member States' initiatives can **complement and strengthen EU initiatives in the field**. By contrast, national initiatives play a limited role when it comes to making sure that EU rules are innovation-friendly. In addition, a piecemeal approach to fostering innovation by Member States may result in additional barriers to the functioning of the Internal Market with a negative impact on scaling-up opportunities: for example, inconsistent applications of research and development tax credits can lead to arbitrage across Member States, and industrial policy initiatives involving only a subset of Member States could hamper the possibility to create more pan-European synergies. Interestingly, national public authorities seem to be more optimistic than other stakeholders when it comes to the role played by the Member States in ensuring the innovation friendliness of the overall EU legal framework. In fact, they believe that Member States play a key role

in the legislative process in the Council of the EU and that they have proven to be a forerunner by officially endorsing the application of the innovation principle.[148]

Against this background, most of the stakeholders consulted for this Study are of the opinion that the innovation principle has the **full potential to create EU added value**.

- The **Research and Innovation Tool**: i) ensures a consistent approach across all DGs of the Commission and (possibly) EU institutions when it comes to assessing impacts of EU rules on innovation; and ii) contributes to the innovation friendliness of the EU *acquis*. This is an important source of EU added value because once EU rules hindering innovation are adopted, Member States may have little room of manoeuvring to fix issues in the implementation and application phases. In addition, EU rules that are innovation-friendly reduce market fragmentation potentially generated by multiple initiatives at the Member State level. In this respect, any adaptation required at the national level would inflate implementation costs and may hamper the functioning of the Internal Market.
- The **innovation deals**: i) enable stakeholders from all Member States to rely on the same process to identify and address regulatory barriers to innovation, irrespective of the salience given to innovation in the national policy debate, thus contributing to a level playing field for all EU innovators; ii) encourage cross-border cooperation among innovators, public authorities, researchers and users to identify barriers and suggest harmonised solutions, thus contributing to removing not only obstacles to innovation but also to the functioning of the Internal Market, with positive spillovers in terms of opportunities for innovators to scale up internationally; iii) facilitate the identification and adoption of best practices and solutions already adopted in other Member States; and iv) allow, in some circumstances, to identify and solve problems that cannot be addressed solely by Member States, as they require an EU intervention via e.g. guidelines or other 'soft law' instruments or by initiating the legislative process. Cross-border and cross-sectoral coordination generates also economies of scale, as the detected problem is solved once for all EU stakeholders, thus leading to regulatory cost savings.

[148] *Research and Innovation friendly regulation*, op.cit.

4 Concluding remarks

This Study looked into the implementation of two of the three main components of the innovation principle, i.e. the Research and Innovation Tool and the innovation deals. The results of the evaluation are combined below with an assessment of the strengths and weaknesses of applying the innovation principle in EU policy-making in 2017 and 2018.

The main finding of this Study is that the innovation principle has the **potential to contribute to the quality and future-proof nature of EU policy**, but that **significant changes will be needed** for this potential to fully materialise.

The most evident **areas for improvement** are:

- lack of a clear legal basis;
- lack of a widely acknowledged definition;
- insufficient awareness among EU officials and stakeholders; and
- limited skills and expertise in research and innovation for better regulation initiatives.

As a result of these problems, the impact of the innovation principle on the innovation-friendliness of the EU *acquis* has been limited so far.

General remarks

- There is a lack of clarity as regards the relation between **the precautionary principle and the innovation principle**: this is extremely important since the precautionary principle is based on EU Treaties. The relationship between the two should be clarified once and for all as being a complementary one: the academic literature has amply confirmed that regulation, if well-designed and adequately stringent, is a driver of innovation rather than an obstacle thereof.149 And while there are examples of cases in which regulation has become an obstacle to innovation, there are equally important examples of cases in which regulation has been essential to steer innovation towards the public good.150 The case studies presented in this Study (sections 2.4.2 and 2.4.3) show that innovation and precaution can coexist and reinforce each other.
- The Commission should make sure that the innovation principle is given more prominence with the **transition to the Horizon Europe programme**, and in particular due to the anticipated launch of a number of "missions" in key domains. These missions will focus on societal challenges (rooted in the sustainable development goals) and shall incorporate research, innovation, education and policy aspects, leading to a unique opportunity to identify possible legislative changes that would further promote sustainable innovation. According to the second ESIR Memorandum[151], missions shall follow a cycle of road mapping, consultation, planning, experimentation, monitoring, evaluation, learning and feedback. **Mission-Oriented Innovation Policy** should lead to extensive experimentation of possible solutions to the problem identified. Mission-oriented

[149] *Aligning Policies for Low-Carbon Systemic Innovation in Europe*, *op.cit.*
[150] Wiener, J. B. (2011), "*The Real Pattern of Precaution*" in *The Reality of Precaution: Comparing Risk Regulation in the United States and Europe*, ed. Jonathan B. Wiener, Michael D. Rogers, James K. Hammitt and Peter H. Sand, 519-565. Washington, D.C.

[151] ESIR Expert Group (2018), *ESIR Memorandum II, Implementing EU Missions*, European Commission.

agencies should be able to contribute to policy reforms by engaging in experimental policymaking and inspiring legislative proposals that would allow making the most of promising solutions. Future input to policymaking could take the form of a 'wishlist' submitted for inclusion in the Commission Work Programme.

Remarks on the Research and Innovation Tool

- The **timing of the application** of the Research and Innovation Tool throughout the policy cycle seems critical to effectiveness. The tool's usefulness is limited if applied after the alternative policy options have been identified, as a final check to an impact assessment that has largely been finalised. It would be advisable to: i) start applying the Research and Innovation Tool when the impact assessment is at the inception stage and is subject to a 12-week consultation; or even ii) transform the innovation principle into an input in the Commission's agenda, by directly selecting proposed regulations on the basis of their prospective impact on innovation. The timing issue can lead to a situation in which the innovation principle is applied in cases where innovation is not likely to be massively affected by the proposal at hand. This, ultimately, may also affect **compliance with the principle of proportionate analysis**, which would recommend that the investment in policy evaluation be proportionate to the extent of the problem. In the case at hand, this would require that the innovation principle be applied to those cases in which the impact on innovation is expected to be strongest; or, alternatively, when the risk of stifling innovation appears greater. A better timing of application would also make it possible to perform a **quantitative assessment** of the impacts on innovation. **Additional guidance and training** on the innovation principle would increase both the versatile skills required to apply Tool #21 and the awareness and 'ownership' of the innovation principle across all Commission services.
- The current scope of the Research and Innovation Tool is not fully in line with the **evolving data-driven nature of innovation**, especially in the digital sphere. This applies in particular to: i) the choice of policy alternatives; and ii) the approach to monitoring and evaluation in impact assessments. On the choice of policy alternatives, Tool #21 appears to lack indications on how to craft policies that are **adaptive and flexible** enough to accommodate for fast technological change; in this respect, guidance on how to make rules flexible enough to account for fast-evolving technologies and fast learning and reform is missing. Additionally, the emergence of solutions that dramatically reduce administrative burdens, such as **RegTech or SupTech**,[152] needs reflection. These solutions are based on the creation of information exchanges between regulators and regulated entities, aimed at enabling zero-contact monitoring of compliance and thereby effective market supervision.[153] Early applications of these approaches can be found, for example, in the Second Payment Services Directive (PSD2),[154] which was adopted without applying the innovation principle.
- Since impacts on innovation are mostly uncertain at the moment of policy design, it is of utmost importance that impacts on innovation are included in the section on **monitoring and evaluation of the impact assessment**, with an adequate

[152] See for instance: Armstrong, P. (2018), *Developments in RegTech and SupTech*, ESMA, available at: https://www.esma.europa.eu/file/49790/download?token=IzOilcfr.
[153] The Institute of International Finance (IIF) defines RegTech as "the use of technologies to solve regulatory and compliance requirements more effectively and efficiently".
[154] Directive (EU) 2015/2366 of the European Parliament and of the Council of 25 November 2015 on payment services in the internal market, amending Directives 2002/65/EC, 2009/110/EC and 2013/36/EU and Regulation (EU) No 1093/2010, and repealing Directive 2007/64/EC (Text with EEA relevance).

choice of indicators and a data collection and management plan that will enable adequate *ex post* analysis. This seems to be missing in the current practice.

- The innovation-friendliness of the proposed policy solutions could also be improved if the Commission decided to strengthen its approach to designing **experimental regulation**, including so-called regulatory sandboxes. In areas such as FinTech, blockchain/distributed ledger technologies, artificial intelligence, the Internet of things, etc. experimental regulation is essential in order to prevent pre-mature market exclusion for emerging business models that do not comply with existing regulatory frameworks without giving these models an opportunity to prove that they can offer adequate levels of protection of users. In this respect, applying the innovation principle would intuitively need to go hand-in-hand with reflecting on and developing experimental regulation.
- The Commission should clarify that the innovation principle, and in particular the Research and Innovation Tool, apply not only to *ex ante* impact assessments but also to ***ex post*** **evaluations.** If every relevant *ex post* evaluation contained an application of Tool #21, the ability of the European Commission to spot cases in which innovation is being jeopardised would significantly increase. This result would be even more magnified if **REFIT initiatives** encompassing entire policy domains could focus on the need to mobilise innovation as a way to improve societal well-being.

Remarks on the innovation deals

- The Commission should clarify that the potential of the **innovation deals** compared to the original Dutch Green Deals is different, due to the fact that **the Commission cannot commit to changing legislation** in the innovation deal, but rather to clarifying the content of rules and their application. When compared to similar processes, such as the United States Negotiated Rulemaking, it seems that the innovation deals could profit more from focusing on alternative modes of compliance with legislation.[155]
- The **procedure for activating innovation deals** appears still cumbersome and lengthy, and the incentive to apply for deals is undermined by the fact that even if a policy change is needed, a complex policy process must follow for rules to be amended. In this respect, innovation deals should become more transparent and widely disseminated (to attract more proposals), as well as more targeted and evidence-based (i.e. innovation deals should be selected in cases in which regulatory barriers can be effectively removed by clarifying rather than amending existing rules).
- Innovation deals appear to be less compelling for innovators due to the fact that the **Commission is not in charge of implementing EU rules.** In this respect, it has proven to be quite challenging to put together innovation deal teams representing all the relevant stakeholders, including national administrations. Attracting more stakeholders would require, *inter alia*, **increasing the awareness of the instrument** at the national and regional level.

[155] See for instance: Ashford, N. A. and Caldart, C. C. (1999). *Negotiation as a Means of Developing and Implementing Environmental and Occupational Health and Safety Policy* Harvard Environmental Law Review, 23(1):141-202, 1999; Ashford, N. A. and Caldart, C. C. (2008). *Environmental Law, Policy, and Economics: Reclaiming the Environmental Agenda*, MIT Press, 2008, 1088 pages; Coglianese, C. and Nash, J. (2014), *Performance Track's Postmortem: Lessons from the Rise and Fall of EPA's "Flagship" Voluntary Program*, Faculty Scholarship. Paper 1233; and *Regulation and R&I Policies – Comparing Europe and the USA, op.cit.*

- The lack of a clear path into an experimental phase such as a sandbox scheme limits the usefulness of the deals. A possible change in this respect would lead applicants for innovation deals to be admitted, where appropriate, to an experimental scheme in which proposed legislative changes are tested, and their overall impact is assessed prior to any further policy initiative. In addition, the Commission could develop a multi-stakeholder community of practice tasked with shaping a shared understanding of experimental policy-making at EU level.
- The current nature and scope of innovation deals make them **ill-suited for more disruptive, systemic innovation**. As a matter of fact, due to their negotiated nature innovation deals can suffer from a "path dependency" problem, and as such would lend themselves more easily to incremental innovation, rather than substantial market re-shuffling. In this respect, again the selection process to activate innovation deals could be improved to focus on major barriers to innovation affecting a variety of stakeholders and clearly showing the contribution of innovation to the societal well-being. The more the process is lengthy and cumbersome, the more it becomes difficult for non-established players to bear the burden of going through the process: this potentially leads to under-use of the deals, or to use of the deals primarily by incumbents.

Annex A Evaluation framework

Evaluation criteria	Evaluation questions	Success criteria	Indicators	Data sources	Data collection / analysis methods
Relevance	• Are the (original) objectives of the innovation principle relevant given the challenges it aims to address? How well do they (still) match the current needs and problems? • To what extent is the innovation principle addressing stakeholder needs? • What are the emerging needs the innovation principle does not cover?	• Degree of alignment between the original needs and problems identified in the intervention logic and the current needs and problems. • Degree of alignment between current needs and problems and the objectives identified in the intervention logic.	• Gaps between current needs and problems suggested by stakeholders and/or identified via desk research and the original needs and problems addressed by the innovation principle. • Gaps between current needs and problems suggested by stakeholders and/or identified via desk research and the original objectives targeted by the innovation principle.	• Primary information from stakeholders. • Secondary information from official documents and relevant literature.	• Desk research. • Interviews with stakeholders. • Qualitative assessment of data and information collected via desk research. • Qualitative assessment of responses to interviews.

Evaluation criteria	Evaluation questions	Success criteria	Indicators	Data sources	Data collection / analysis methods
Effectiveness[156]	• What have been the main outputs and outcomes of the innovation principle so far? • What are the expected outputs and outcomes that still need to materialise? • What are the factors supporting or hindering the expected outputs and outcomes of the innovation principle?	• Degree of alignment between actual and expected results of the innovation principle. • Degree of alignment between the original objectives and actual results of the innovation principle.	• Assessment of the contribution of the two components of the innovation principle to the achievement of its objectives. • Success stories • Quantitative impacts on innovation measured in impact assessments and accompanying studies • Number of indicators to measure the impact on innovation included in the "monitoring and evaluation" section of impact assessments • Gaps between actual and expected results of the innovation principle. • Gaps between original objectives and actual results of the innovation principle. • Assessment of the internal factors supporting or hindering the results of the innovation principle. • Assessment of the external factors supporting or hindering the results of the innovation principle.	• Primary information from stakeholders. • Secondary information from official documents and relevant literature.	• Desk research. • Interviews with stakeholders. • Case studies. • Qualitative assessment of data and information collected via desk research. • Qualitative assessment of responses to interviews. • Qualitative assessment of lessons learnt from case studies. • Multi-criteria analysis.

[156] The effectiveness criterion does not aim to evaluate the achievement of expected impacts of the innovation principle, as such impacts are expected to materialise only in the long-term.

Evaluation criteria	Evaluation questions	Success criteria	Indicators	Data sources	Data collection / analysis methods
Efficiency	• To what extent are the personnel and administrative costs linked to the innovation principle justified, given the observed and expected outputs and outcomes it has or still aims to achieve? • To what extent is the innovation principle reaching the target group envisaged? What are the barriers and what could be improved?	• Cost-effectiveness analysis to assess the ratio between allocated resources and actual results of the innovation principle. • Degree of alignment between target groups and groups that are benefitting from the innovation principle.	• Assessment of regulatory costs (mainly administrative burdens) to apply the innovation principle. • Gaps between the originally targeted groups and groups that are benefitting from the measure. • Assessment of the barriers affecting the ability of the innovation principle to reach the target group envisaged.	• Primary information from stakeholders. • Secondary information from official documents and relevant literature.	• Desk research. • Interviews with stakeholders. • Case studies. • Qualitative and quantitative assessment of data and information collected via desk research. • Qualitative and quantitative assessment of responses to interviews. • Qualitative and quantitative assessment of lessons learnt from case studies. • Cost-effectiveness analysis.
Coherence	• To what extent do the components of the innovation principle relate to and support each other? • To what extent is the innovation principle coherent with wider EU policy?	• Degree of coherence between the two components of the innovation principle (internal coherence). • Degree of coherence between the measure and other EU initiatives (external coherence).	• Assessment of synergies/overlaps between the two components of the innovation principle. • Assessment of synergies/overlaps between the objectives of the innovation principle and other relevant EU initiatives, especially other relevant tools of the Better Regulation Toolbox.	• Primary information from stakeholders. • Secondary information from official documents and relevant literature.	• Desk research. • Interviews with stakeholders. • Qualitative assessment of data and information collected via desk research. • Qualitative assessment of responses to interviews.

Evaluation criteria	Evaluation questions	Success criteria	Indicators	Data sources	Data collection / analysis methods
EU added value	• To what extent has the innovation principle so far demonstrated the added value at European level if compared to similar national or regional initiatives? • What is the additional value resulting in the application of innovation principle compared to similar national or regional initiatives? • Is there already an outstanding example of EU Added Value provided by the innovation principle based on the evidence at hand and relating to effectiveness, efficiency or coherence?	• Achievement of results that could not be otherwise attained via national or regional initiatives. • Achievement of results at a cost lower than what could be attained via national or regional initiatives.	• Assessment of the need for an EU intervention to achieve expected results. • Assessment of the ability of an EU intervention to achieve expected results at a cost lower than costs of national or sub-national interventions.	• Primary information from stakeholders. • Secondary information from official documents and relevant literature.	• Desk research. • Interviews with stakeholders. • Qualitative assessment of data and information collected via desk research. • Qualitative assessment of responses to interviews. • Qualitative assessment of lessons learnt from case studies.

Source: Authors' elaboration on ToR.

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The Commission has recognised the importance of a more innovation-oriented EU acquis, gradually exploring the ways in which EU rules can support innovation. The innovation principle was introduced to ensure that whenever policy is developed, the impact on innovation is fully assessed. As further discussed in this Study, the exact contours of the innovation principle have been gradually shaped within the context of the EU better regulation agenda: the innovation principle has been given a more articulate and consistent role. This study presents an evaluation of the innovation principle so far, limited to two of its three components: *i.e.* the Research & Innovation Tool included in the Better Regulation Toolbox, and the innovation deals.

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