

# Assessment of the State of Play of the Innovation Principle in the Preparation of EU Legislation

**Independent Expert Report**



## Assessment of the State of Play of the Innovation Principle in the Preparation of EU Legislation

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# **Assessment of the State of Play of the Innovation Principle in the Preparation of EU Legislation**

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## Executive summary

Introduced in the EU better regulation toolbox since 2016, the innovation principle requires that the innovation dimension is considered when preparing and implementing EU legislation, while upholding Europe's rigorous standards to meet societal needs. It is anchored in the EU Better Regulation Guidelines and Toolbox, notably in Tool #22 "Research and Innovation", which promotes the consideration of research and innovation impacts throughout the policy process, comprising three main components: (i) foresight and horizon scanning; (ii) preparation of EU legislation, including stakeholder consultation, impact assessment and experimentation clauses; and (iii) the implementation phase, focusing on evaluations and the so-called "innovation deals".

This study assesses the extent to which the innovation principle adequately promoted the preparation of innovation-friendly policies during the 2020-2025 period, and recommends possible improvements. It builds on a previous study (Simonelli and Renda 2019) and significantly expands the methodology, providing also nine case studies. It also examines the principle's coherence with the other Better Regulation tools and initiatives, especially the Competitiveness Check and the SME Test, as well as the Omnibus regulations. The assessment is based on a desk review of 219 impact assessments conducted between 2020 and 2025, including a more general, horizontal assessment and in-depth illustrative case studies. Within this sample, impact assessments that were particularly relevant for the application of the innovation principle can be found in areas such as environmental and climate regulation; energy markets and infrastructure; digital and data-related legislation; and chemicals, industrial, and product regulation.

### Overall assessment

The study found evidence of implementation of some of the instruments included in Tool #22, such as foresight and regulatory sandboxes; as well as several impact assessments in which research and innovation impacts were part of the analysis (even if they were most often qualitatively assessed). More specifically:

- **Foresight, horizon scanning, scenarios or megatrends are explicitly referred to in 66 impact assessments (30% of the sample)**, mostly to contextualise long-term environmental or technological trends rather than to frame the core problem definition. Only **15–20% of IAs used foresight-related concepts to shape baseline scenarios or the design of policy options**.
- **40 impact assessments (18% of the sample) explicitly assessed research and innovation impacts**, a decrease from the 35% reported by the Regulatory Scrutiny Board (RSB) in 2017-2018. In its opinions on impact assessments, **the RSB highlighted innovation-relevant shortcomings with respect to 54 out of the 219 IAs**, particularly in relation to market dynamics and technological change.
- **Experimentation clauses, pilot schemes or regulatory sandboxes appear in approximately 10–15% of impact assessments, primarily in digital, financial, and emerging technology policy areas**. Regulatory sandboxes (covered also by Tool #69 of the toolbox) appear to have permeated more than other tools the better regulation agenda of the European Commission. Pilot schemes are fewer, including the Disability Card Pilot Scheme and the system for greenhouse gas emission allowance trading.
- A well-established approach at the EU level, **co-regulation** via harmonised standards/presumption of conformity is present in the 219 IAs, as well as "outcome/performance-based" regulation where results are measured and methods left flexible.

As regards the coherence of the innovation principle with other Better Regulation tools, it is important to note that the Competitiveness Check, introduced in 2023, covers questions related to innovation. Both the Competitiveness Check and SME Test refer to Tool 22 for assessing impacts on innovation. Out of 219 impact assessments, 80 were conducted after 2023 when the **Competitiveness Check** was introduced – and out of those, 29 IAs applied this check, whereas a broader set of 59 IAs considered impacts on competitiveness without necessarily conducting a standalone test. **Only 13 IAs (6.2%) explicitly integrated R&D or innovation indicators into their competitiveness analysis.**

The **SME Test** is also rather widespread, appearing in 33.5% of the sample. However, **only 5 IAs (2.4%) explicitly linked the SME test results to innovation capacity.**

Our analysis also highlighted **a few good practices among Member States**, including in Finland, Denmark, Germany and the Netherlands. The OECD reports that about a third of its members address innovation in impact assessment guidance or by encouraging instruments like experimentation/regulatory sandboxes and more outcome-oriented approaches.

The study revisits the findings of an earlier report by Simonelli and Renda (2019) and finds the related recommendations to be still largely relevant. These recommendations pointed at the lack of a clear legal basis and a widely acknowledged definition; insufficient awareness of the principle among services; lack of institutionalisation of support for implementation; as well as limited skills and expertise in appraisal of R&I impacts. Simonelli and Renda (2019) also highlighted the need to link the principle to experimental governance approaches; the critical role of timing and proportionate analysis; the need for updating the approaches included in the Tool (e.g. RegTech, SupTech, “open API”); a lack of implementation of the Tool especially in monitoring and evaluation sections of impact assessments; and the lack of uptake of the innovation deals.

### **Main recommendations**

The study offers two sets of recommendations. The first set refers to incremental reforms aimed at improving the effectiveness, coherence, relevance and EU added value of the principle as it stands. The second set requires a more thorough reform, including a refocusing and repositioning of the principle in the overall better regulation agenda of the European Commission.

*First set of recommendations – incremental improvements to the current innovation principle*

- R1. Reinforce the innovation principle through more structured guidance and capacity-building by a dedicated service in the Commission.** Translate the principle into concrete operational steps and create a dedicated support service to help DGs quantify R&I impacts, provide training, integrate innovation into monitoring indicators, and publish an annual report on R&I policy impacts.
- R2. Bring foresight and horizon scanning more deeply into ex ante impact assessments.** Move beyond simple references to foresight reports by incorporating multiple future scenarios into impact assessments and using back-casting to identify policies needed to reach preferred futures.
- R3. Clarify and review the scope of the innovation principle, updating it with new tools.** Consolidate existing guidance on innovation-friendly regulation into a single framework that integrates current tools and expands to include new data- and AI-enabled regulatory approaches.
- R4. Build a repository of international good practices, and explain the factors for the success of given regulatory approaches.** Compile international success stories and analyse the institutional conditions that make approaches such as regulatory sandboxes or policy dialogues effective.

- R5. Deepen the guidance given to Commission services.** Provide more detailed technical guidance and training on implementing complex regulatory approaches—such as APIs or algorithmic oversight—while addressing capability gaps and risks of informational asymmetry.
- R6. Give more focus and a clearer label to the tool, also to distinguish it from the competitiveness check.** Clarify that innovation policy goes beyond competitiveness, also addressing societal challenges, resilience, and security, and therefore requires a distinct policy tool focused on R&I.
- R7. Support the innovation principle with a more data-driven analysis.** Expand the use of economic complexity analysis, modelling tools, and R&I ecosystem data to strengthen evidence-based impact assessments and improve projections of policy effects on innovation.
- R8. Revamp and recast the “innovation deals” instrument.** Redesign the instrument to enable stakeholders to propose regulatory reforms and pilot adaptive regulatory approaches through structured dialogues, hubs, testbeds, or similar initiatives.
- R9. Introduce better guidance to adaptive regulation.** Equip Commission services with guidance on designing flexible regulatory options that account for uncertainty, including reversible or incremental measures and built-in review points.
- R10. Include guidance on ex post evaluations.** Strengthen guidance on assessing R&I impacts in ex post evaluations and improve transparency by making evaluations publicly accessible to enhance learning for policymakers and stakeholders.

*Second set of recommendations – thoroughly reforming the current innovation principle*

- R11. Replace the application of the innovation principle to individual ex ante impact assessment with comprehensive reports per policy domains or sectors.** Produce regular sector- or domain-level analyses (e.g. through the SRIP) to assess R&I ecosystems and future scenarios, enabling DGs to use this shared evidence base to guide legislation, policy priorities, and monitoring indicators.
- R12. Reconsider fitness checks and cumulative cost assessments rather than applying the innovation principle for each individual legislative proposal.** Use sector-wide cumulative cost assessments and policy-domain fitness checks to analyse the combined effects of legislation, helping identify regulatory improvements, simplification opportunities, and impacts on competitiveness and innovation.
- R13. Transform the Better Regulation Toolbox into real-time, interactive, AI-assisted guidance for services.** Develop an AI-based system—built on curated datasets and overseen by human experts—to guide Commission services in drafting legislation and conducting impact assessments using the most appropriate tools and methods.

# Introduction

The “innovation principle” is relatively recent in the EU regulatory context. Its gradual introduction dates back to the early 2010s, when a group of industry CEOs started evoking the introduction of the principle in letters sent to European Commission presidents Barroso (in 2013) and Juncker (in 2014). Their claim was that innovation was not sufficiently considered when preparing, designing and implementing EU legislation, and that too often precaution would prevail over innovation when deciding over new rules. The innovation principle has thus been compared to, and sometimes contrasted with, the more established precautionary principle, which is however anchored in EU law<sup>1</sup>. While the CEO letters in 2013 and 2014 appeared to undermine the importance of regulation for meaningful innovation, around the same time scholarly work nested the consideration of innovation into the broader better regulation agenda, under the premise that **well-timed, well-designed, adequately stringent regulation can be a blessing for innovation, rather than always constituting an obstacle**. The work of academics like Nicholas Ashford,<sup>2</sup> Michael Porter,<sup>3</sup> Jonathan B. Wiener<sup>4</sup> and, in the EU context, Pelkmans and Renda<sup>5</sup> and Ashford and Renda<sup>6</sup> shed light on the conditions under which regulation positively contributes to innovation, and paved the way for a more comprehensive understanding of the ways in which an ambitious regulatory agenda can be made compatible with pro-innovation stances.

The introduction of the innovation principle in EU better regulation was the result of this stream of scientific work, leading to guidance on **how to make regulatory measures more attentive to innovation stances and dynamic efficiency in markets, rather than paving the way for a massive deregulation** wave as industry representatives would have wanted. The 2015 Commission Staff Working Document on “Better Regulation for Innovation-Driven Investment”<sup>7</sup> laid the foundations for a proactive use of regulation to remedy market failures and complete innovation ecosystems. The introduction and application of the innovation principle was also supported by the Council of the EU in 2016.<sup>8</sup> Since then, 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; ii) the preparation of EU legislation including stakeholder consultation and impact assessment; and iii) implementation, focusing on evaluations and the so-called “innovation deals”.<sup>9</sup>

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<sup>1</sup> e.g., Article 191(2) TFEU): this principle holds that in case of risk of serious or irreversible harm, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures.

<sup>2</sup> Ashford, N.A., C. Ayers and R.F. Stone (1985), “Using Regulation to Change the Market for Innovation”, Harvard Environmental Law Review, 9(2), summer, pp. 419-466 (<http://hdl.handle.net/1721.1/1555>)

<sup>3</sup> Porter, M. and C. van den Linden (1995), “Towards a New Conceptualization of the Environment Competitiveness Relationship”, Journal of Economic Perspectives, 9(4):97-118.

<sup>4</sup> Hammitt, J.K., Wiener, J.B., Swedlow, B., Kall, D. and Zhou, Z. (2005), Precautionary Regulation in Europe and the United States: A Quantitative Comparison. Risk Analysis, 25: 1215-1228. <https://doi.org/10.1111/j.1539-6924.2005.00662.x>.

<sup>5</sup> Pelkmans, J. and A. Renda (2014), Does EU Regulation Hinder or Stimulate Innovation? (November 19, 2014). CEPS Special Report No. 96. Available at SSRN: <http://ssrn.com/abstract=2528409> (with Jacques Pelkmans). And Pelkmans, J. and A. Renda (2025), “EU regulation, hindering or stimulating innovation?”, in Braunjerhelm et al. (Eds.), Handbook of Innovation and Regulation, Edward Elgar.

<sup>6</sup> Ashford, N. and A. Renda (2016), Aligning policies for low-carbon systemic innovation in Europe, Centre for European Policy Studies and i24c, November 2016, ISBN 978-94-6138-543-7.

<sup>7</sup> SWD(2015)298, <https://data.consilium.europa.eu/doc/document/ST-15392-2015-INIT/en/pdf>.

<sup>8</sup> 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).

<sup>9</sup> 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. The

**These developments also led the European Commission to gradually clarify how greater attention to innovation translates into specific approach to regulatory design.** According to the Directorate-General for Research & Innovation of the European Commission, “EU policy and legislation should be developed, implemented and assessed in view of encouraging innovations that help realise the EU’s environmental, social and economic objectives, and to anticipate and harness future technological advances.” The aim of the innovation principle is to ensure that regulation becomes an enabler of beneficial innovation rather than an inadvertent barrier. This reflects a shift away from purely risk-avoidance or status-quo regulation toward regulation that also consciously looks at how novel solutions can contribute to societal goals (environmental, social, economic) and how emerging technologies and research trends might shape the future regulatory environment. It also reflects a vision of innovation that supports the achievement of the EU’s long-term goals in economic, social and environmental terms.

**Since the introduction of the innovation principle, the role of research and innovation seems to have become even more central in the overall agenda of the European Commission,** and the EU as a whole. In inaugurating her second mandate as President of the European Commission, Ursula von der Leyen made it clear that her agenda would entail a very significant focus on research and innovation. Already in the [political guidelines](#) of her candidacy, she observed that “Europe’s competitiveness – and its position in the race to a clean and digital economy – will depend on starting a new age of invention and ingenuity”, and that “This requires putting research and innovation, science and technology, at the centre of our economy”. A concept that she repeated in her [inaugural speech](#), as well as in the [Mission Letter](#) for the Commissioner on Startups, Research and Innovation. Since then, innovation has remained at the centre of the EU action, very often in combination with one of the “North Stars” of the current Commission, boosting European competitiveness and operationalising the many recommendations contained in the [Draghi report](#) on the issue.

Against this background, **the role of the innovation principle is to help the European Commission services design and implement regulatory interventions in a way that promotes research and innovation.** This, based on the existing literature, requires much more than simply reducing regulatory burdens, or repealing (partly or entirely) existing legislative measures, a goal that is being pursued *i.a.* through a series of *Omnibus* regulations often accompanied by a quantification of the impact on administrative burdens. The innovation principle entails developing and gradually mainstreaming in the whole European Commission, and possibly in Institutions that act as co-legislators and in Member States, a richer and more granular view of available policy approaches and alternative regulatory (or non-regulatory) options, which have proven to be compatible with the promotion of research and innovation. It also entails a variety of approaches, beyond the incorporation of specific “screens” in the *ex ante* impact assessment process, but also opening avenues for experimentation and overall management of the regulatory stock, with a view to adopting a more responsive, “customer-centric” (or CX) and adaptive approach to regulatory interventions.

In a nutshell, **properly implementing the innovation principle would not imply always the elimination or simplification of regulation: this can be done by looking at other instruments,** such as “one-in-one-out” or more generally, the measurement of administrative burdens and/or substantive compliance costs (Renda 2019). The innovation principle is also not directly related to the setting of innovation as one of the general or specific objectives of a given legislative intervention – even in the absence of a dedicated principle, the political decision to propose an Artificial intelligence Act, or a new package on Pharmaceutical Legislation (to name just a few examples) would entail measuring impacts of alternative policy options on innovation. The existence of the innovation principle adds to the already strong emphasis on innovation a more sophisticated and possibly effective approach to regulatory design, and to the use of tools

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innovation deals are activated on request by a specific group of stakeholders including businesses, public authorities and other interested parties.

that have demonstrated the potential to boost innovation, and increase the agility and effectiveness of the administration that propose them.

In this study, we assess whether the innovation principle, as nested in Tool #22 of the European Commission Better Regulation Guidelines, is adequately serving this purpose, and formulate recommendations on possible improvements to be considered in the near future. The study is divided in four main Sections. Section 1 below illustrates the results of an AI-assisted analysis of 219 *ex ante* impact assessments completed by European Commission services in the five years between 2020 and the end of 2025. Section 2 focuses on selected case studies, by providing a more in-depth view of the way in which research and innovation impact have been sought by the Commission services in specific regulatory initiatives. Section 3 takes stock of the previous two sections and provides an overall assessment of the current effectiveness, coherence and relevance of Tool #22. Section 4 concludes by outlining a number of policy recommendations. Annex 1 then contains the guidance we used for the scoring of the 219 impact assessments; Annex 2 contains the list of 219 impact assessments used for our study. Annex 3 contains the guidance document used by the team for completing the case studies.

## 1. The implementation of Tool #22 in 2020-2025

The innovation principle was introduced in the Better Regulation Toolbox<sup>10</sup> with a specific tool (#21, later renumbered as #22), which explicitly addresses “Research and Innovation” as one of the impact categories to be considered in *ex ante* impact assessments, as well as in *ex post* evaluations.<sup>11</sup> The purpose of Tool #22 is to guide Commission services (and those involved in policy or legislative design) in identifying, assessing and integrating impacts on research and innovation within impact assessments, evaluations, fitness checks and other better regulation instruments. The tool covers in principle both the *ex ante* phase (impact assessment of new initiatives) and the *ex post*/review phase (evaluation of existing legislation or regulatory frameworks), although in practice the guidance provided mostly refers to the *ex ante* phase only (a point that will be considered in more detail in Section 3).

Tool #22 prompts policy-makers to ask questions such as whether the policy/regulation will affect the conditions for research and innovation; what are the potential innovation barriers and drivers; what impacts can be identified for different types of innovators (large firms, SMEs, start-ups); whether the initiative provides space for new technologies and business models to emerge, or whether it is likely to stifle or encourage innovation; whether there are unintended consequences for innovation (e.g., regulatory burdens, reducing flexibility, deterring investment in R&D); how will the impact on innovation evolve over time (not only the short term, but medium-/long-term technological change); and whether there are alternative policy instruments or more innovation-friendly options than the *status quo*. It also focuses on how monitoring and evaluation can capture innovation-relevant indicators or metrics, potentially enabling stronger learning along the policy cycle. However, while there are questions explicitly asking to assess the impact on companies, the tool does not explicitly ask to assess how the proposed legislation affects other stakeholders that are key in the innovation ecosystem (e.g. universities, technology transfer offices / incubators, financial investors, buyers, end-users/citizens).

The tool also contains guidance on approaches that facilitate the assessment of innovation impacts, pointing at:

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<sup>10</sup> [https://commission.europa.eu/law/law-making-process/better-regulation/better-regulation-guidelines-and-toolbox\\_en](https://commission.europa.eu/law/law-making-process/better-regulation/better-regulation-guidelines-and-toolbox_en)

<sup>11</sup> Tool #22 is part of Chapter 3 of the Better Regulation Toolbox (“Identifying impacts in evaluations, fitness checks and impact assessments”). As listed in the toolbox contents it sits alongside other impact categories (SME test, competition, internal market, digital-readiness etc).

- **Qualitative methods** such as stakeholder consultation with innovators, R&D actors, industry, start-ups; workshops, focus groups; horizon scanning.
- **Quantitative methods**, including indicators of innovation (R&D spending, patents, new products, business model uptake, diffusion rates), though the tool acknowledges that innovation is not always easily quantifiable and may need qualitative assessment.
- **Consideration of the innovation ecosystem**: for instance, access to finance, technology transfer, regulatory sandboxes, standardisation, infrastructure, international cooperation.
- **Scenario analysis**: considering how different regulatory options might affect innovation trajectories (for example, option A might lock in current technology, option B might create space for emerging tech).
- **Checking for regulatory “lock-in”**: ensuring that regulation does not prescribe a specific technology or business model in a way that prevents future innovation.
- **Considering disruptive or breakthrough innovation**: which may require more flexible regulatory approaches, experimentation, “safe-spaces” (e.g., pilot regulation), regulatory sandboxes.

The tool also emphasises the need to include innovation-related indicators in monitoring and evaluation sections; to evaluate ex post whether barriers to or enablers of innovation materialised; and to build feedback loops so that regulation can be adapted if it is found to be hindering innovation.

Tool #22 focuses on key aspects of the policy cycle, including the **agenda-setting phase**, for which a greater and more systematic use of foresight and horizon scanning are sought.<sup>12</sup> The Commission announces in Tool #22 the **creation of a Regulatory Advice Mechanism (RAM)** in DG Research and Innovation to provide support for this and other phases of the analysis. The most substantive part of Tool #22 is then dedicated to the **ex ante impact assessment phase** of the policy cycle, with emphasis on stakeholder consultation and on a checklist that can guide administrations in identifying key questions to ask and spot relevant impacts of alternative policy options. Importantly, apart from addressing specific questions, the Tool devoted attention to the issue of legislative design, venturing into very advanced notions of adaptive and future-proof regulation, but also the reduction or minimisation of compliance costs, the promotion of regulatory certainty and stability, and the need to avoid unnecessary regulatory fragmentation across the Single Market.

The tool also focuses on **approaches that can leverage the potential of innovation and reduce negative impacts**, including experimentation clauses, outcome- (or performance-) oriented legislation, sunset clauses, tests of alternatives, and top-runner approaches. Some of these tools were rather new to the EU *acquis* at the time of the introduction of Tool #22, whereas others had already been experimented with on several occasions (e.g. outcome-oriented legislation, which is the core of consolidated approaches of the EU such as the New Approach to standardisation). Finally, **the Tool introduces so-called Innovation Deals**, *i.e.* cases in which innovators encounter a perceived regulatory problem and approach the European Commission with an identified solution, to be validated and appraised by the Commission, leading to clarifications or modification of the legislation.

**Although tool #22 contains useful guidance, it is not mandatory for Commission services.** Commission services are therefore not required to assess the potential impacts of

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<sup>12</sup> As specified below, the foresight and horizon scanning methods to be used in impact assessments and evaluations are the subject of a dedicated tool in the Toolbox (#20). In Tool #22, the Commission explains that “While having primarily an anticipatory function, horizon scanning can also relate to other stages of the policy-making cycle, including evaluation. For instance, its findings can be used in evaluations preceding legislative reviews, if horizon scanning results point to an important development that could affect the functioning of existing legislation.” That said, this paragraph does not refer directly to Tool 20.

proposed legislation on innovation through public consultations, ex-ante or ex-post impact assessments, fitness checks etc.

Importantly, **Tool #22 is not the only innovation-related section in the Toolbox**. Already **Tool #18**, in listing the key impacts to assess, lists *i.a.* relevant categories such as sectoral competitiveness; innovation (productivity and resource efficiency); research (academic and industrial); intellectual property rights; technological development/digital economy; and the position of SMEs (likely to be extended to small mid-caps). Other complementary tools include *i.a.* **Tool #20** (Strategic foresight for impact assessments and evaluations); **Tool #21** (Sectoral competitiveness), which deals with the capacity of enterprises to innovate as part of competitiveness-proofing; **Tool #23** (or the ‘SME test’), which considers innovation in the context of small and middle-size enterprises; **Tool #24** (Competition) which addresses the link between market competition and innovation; and **Tool #28** (Digital-ready policymaking) deals with impacts related to information and communication technologies as well as digital policy aspects. In addition **Tool #69** (Emerging methods and policy instruments) deals with regulatory sandboxes, and is therefore directly related to innovations in regulatory design.

## 1.1. Past reports and data on the implementation of the innovation principle

A previous study supporting the interim evaluation of the innovation principle (Renda and Simonelli 2019) reviewed the first few years of its implementation, finding a significant potential for the tool to improve the quality and future-proof nature of EU policymaking, but also several areas for improvement. Since then, the tool has been slightly modified and coupled with other screens and *ad hoc* tools, aimed at capturing various aspects of innovation and one of most prominent priorities of the current European Commission, *i.e.* competitiveness.

**The 2019 Study acknowledged the innovation principle’s potential to contribute to the quality and future-proof nature of EU policy, but also observed that significant changes would be needed for this potential to fully materialise.** Most evident areas for improvement were the lack of a clear legal basis; the lack of a widely acknowledged definition; the insufficient awareness among EU officials and stakeholders of the principle and the lack of institutionalisation of administrative and scientific support for its implementation; and the (consequent) limited skills and expertise in the appraisal of research and innovation impacts across the services of the Commission. As a result of these problems, the authors concluded that the innovation principle had exerted a very limited impact on the innovation-friendliness of the EU *acquis*. The authors also observed a **lack of clarity as regards the relation between the precautionary principle and the innovation principle**; the need to link the Principle to **experimental governance approaches emerging (at the time) in the Horizon Europe programme**, and particularly the Missions; the critical role of the **timing of the application of the Principle**, which often seems to be implemented as an afterthought rather than a foundational tool in the design of regulatory alternatives; the need for a reflection on the correct application of the **principle of proportionate analysis**; the need for updating the approaches included in the Tool, to reflect the pervasiveness of digital technologies, leading to **new frontiers such as RegTech, SupTech, “open API”, etc.** (see Section 4 in this study); a critical **lack of implementation of the Tool especially in the monitoring and evaluation** sections of impact assessment; and the **lack of uptake of the innovation deals**, which the authors also related to fundamental aspects of their design as well as their governance in the European Commission.

Since then, there has been limited coverage in the scientific literature of the uptake of the innovation principle in the better regulation agenda. That said, the European Commission’s independent “watchdog” for better regulation, the Regulatory Scrutiny Board, has kept track of the cases in which innovation impacts are considered in European Commission’s impact assessments (IAs) and ex post evaluations. Figure 1 below, from the RSB’s Annual report

2023<sup>13</sup>, shows the RSB's estimate of the number of IAs that assessed impacts on economic, social and environmental innovation<sup>14</sup>.

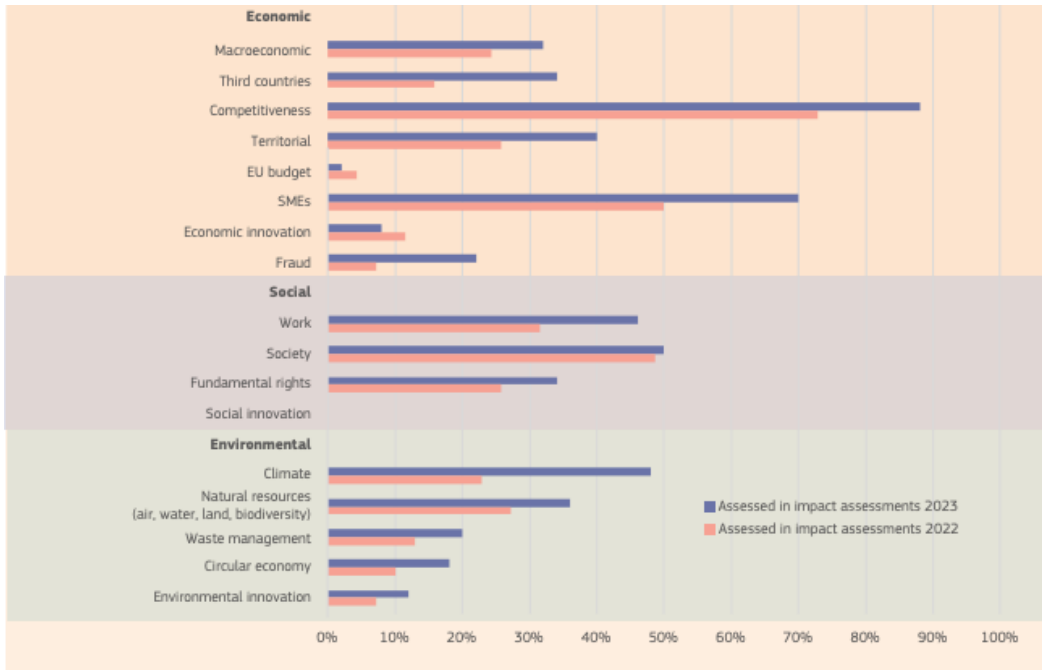


Figure 1 – Number of impact assessments scrutinised by the Regulatory Scrutiny Board and specific impacts covered in 2022 and 2023 (Source: RSB Annual report 2023)

<sup>13</sup> [https://commission.europa.eu/law/law-making-process/regulatory-scrutiny-board\\_en](https://commission.europa.eu/law/law-making-process/regulatory-scrutiny-board_en)

<sup>14</sup> In 2024, only three IAs were scrutinised by the RSB, reflecting the transition between the first and the second Von der Leyen Commission.

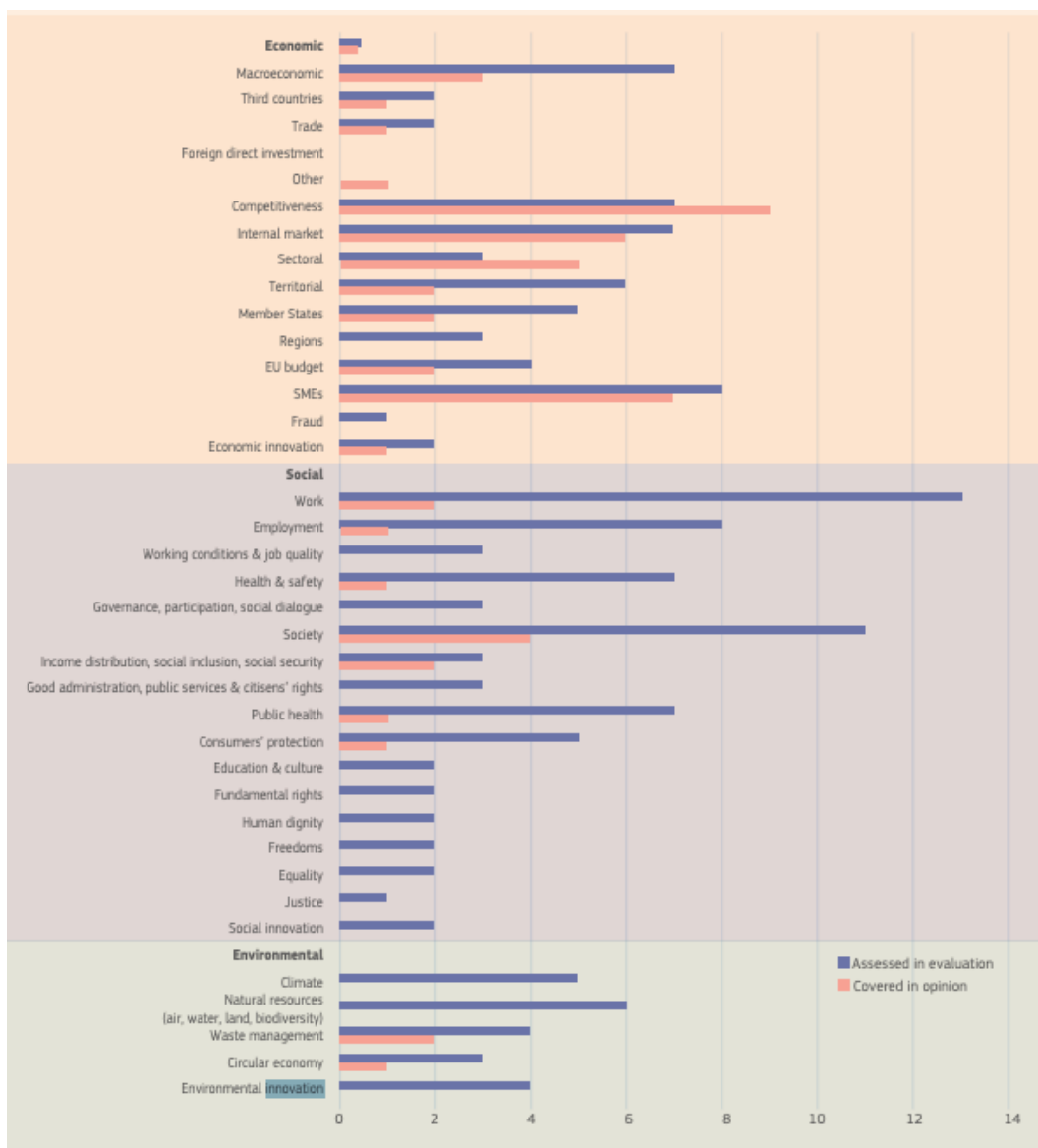


Figure 2 – Number of ex post evaluations scrutinised by the Regulatory Scrutiny Board and specific impacts covered in 2024 (Source: RSB Annual report 2024)

The European Parliaments Research Service (EPRS) also published in 2025 a [report](#)<sup>15</sup> analysing 143 IAs of the European Commission in the period 2019-2024. The study found that 24 IAs assessed economic innovation impacts (while another 33 partially assessed them), 21 assessed environmental innovation impacts (while another 14 partially assessed them), and 4 assessed social innovation impacts (with 5 others partially taking them into account). The study also found “a positive trend in the assessment of the competitiveness dimension, with share of the IAs that assessed impacts on competitiveness in detail increasing from around 47% in 2020-2022 to 67% 2023-2024. This was attributed to the Commission's renewed focus on

<sup>15</sup> [https://www.europarl.europa.eu/RegData/etudes/STUD/2025/765770/EPRS\\_STU\(2025\)765770\\_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2025/765770/EPRS_STU(2025)765770_EN.pdf). EPRS\_STU(2025)765770\_EN.pdf

competitiveness and a growth-promoting regulatory framework, and to the newly introduced “competitiveness check” requirement, added to the Better Regulation Toolbox in 2023, with the aim to provide an integrated competitiveness analysis and greater visibility for the competitiveness dimension in all IAs and covering four key elements: cost and price, innovation, SMEs and international competitiveness.

**The 2023 update of the Better Regulation Toolbox expanded the potential consideration of innovation in the context of the EU better regulation instruments:** for example, **Tool #17 on the choice of policy instruments** provides detailed guidance on self- and co-regulation, defined as policy approaches where private actors help set and apply rules<sup>16</sup>, as potentially innovation-friendly options. It also created a **greater overlap between Tool #22 and the competitiveness check**, leading to the question of whether a stand-alone tool on research and innovation would be required (see on this, Section 4).

## 1.2. An analysis of 219 impact assessments

This section examines how the innovation principle, as operationalised through Tool #22 of the European Commission’s Better Regulation Toolbox, has been applied in practice across **219 European Commission impact assessments (IAs) and their associated Regulatory Scrutiny Board (RSB) opinions**.

During the period 2020-2025, the **European Commission published 219 IA documents**, with a prevalence of initiatives led by the Directorate-Generals for Financial Services (FISMA, 12%), Justice and Consumers (JUST, 11%); Internal Market, Industry, Entrepreneurship and SMEs (GROW, 10%), as shown in Figure 3a.<sup>17</sup> Figure 3b also shows the number of IAs per year, reflecting the oscillations of the policy cycle, with the highest number of IAs released in the years 2021, 2022 and 2023, and a slowdown in 2024 related to the end of the legislature and the European Parliament elections in 2024. At the same time, the number of IAs released by the European Commission was also lower than it could have been, due to frequent reliance on fast-track procedures, which ended up in the Commission not releasing a (fully fledged) IA document in support of legislative or non-legislative measures (on this, see Sections 3 and 4).

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<sup>16</sup> See: European Commission, Better Regulation Toolbox, Tool 17, Section 3.1, p. 124.

[https://commission.europa.eu/document/download/c0561a9c-d112-4d20-b1ec-145748e2c61c\\_en?filename=BRT-2023-Chapter%202-How%20to%20carry%20out%20an%20impact%20assessment\\_0.pdf](https://commission.europa.eu/document/download/c0561a9c-d112-4d20-b1ec-145748e2c61c_en?filename=BRT-2023-Chapter%202-How%20to%20carry%20out%20an%20impact%20assessment_0.pdf)

<sup>17</sup> [https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/impact-assessments\\_en](https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/impact-assessments_en).

Consider that the actual names of the DGs have been slightly changed with the transition to the second von der Leyen Commission.



### 1.3. Explicit mentions of Tool #22, or the innovation principle in the analysed impact assessments

Our analysis revealed **only one reference to Tool#22** (at the time numbered #21) in the 219 impact assessments, i.e. in the IA on the Artificial Intelligence Act<sup>19</sup>, while only two IAs make a direct, explicit reference to the innovation principle<sup>20</sup>.

Based on this finding, one could argue that the **explicit mainstreaming of the innovation principle, or the related Tool #22**, in the language used by the Commission services in drafting their impact assessments **has been extremely limited** in the past five years. This finding, of course, does not lead to concluding that the innovation principle has not had any impact on the European Commission better regulation agenda; in order to give an answer to this question, it is important to assess whether the individual approaches and solutions outlined by Tool #22 have been taken up by the services in approaching their policy problems from an ex ante perspective.

The **RSB frequently highlights innovation-relevant shortcomings**, particularly in relation to market dynamics and technological change. This occurred with respect to opinions (normally one, in some cases more than one) related to **54 of the 219 IAs analysed**, a finding that is consistent with the analysis reported in the Annual Reports of the RSB (see figure 1 above). But in none of these circumstances the RSB explicitly referred to the innovation principle.

### 1.4. Use of foresight and future-oriented analysis

As mentioned above, the use of foresight and horizon scanning in the agenda-setting phase of the policy cycle is recommended in Tool #22 as a way to promote the consideration of research and innovation impacts. We carried out a text analysis to test the frequency of consideration of foresight in the 219 IAs. Variables for this category record the use of foresight tools, including scenarios, horizon scanning, megatrends, or structured treatment of uncertainty. A score of 1 indicates explicit and substantive use of foresight that informs analytical choices, such as problem definition, baselines, or option design. A score of 0.5 indicates descriptive or contextual reference to future developments without structured analysis. A score of 0 indicates no evidence of foresight. Separate variables distinguish between foresight in problem definition, baseline construction, option design, and uncertainty analysis.

**Explicit references to foresight, horizon scanning, scenarios, or megatrends are identified in 66 impact assessments (30% of the sample)**. Where present, foresight is most often used to contextualise long-term environmental or technological trends rather than to frame the core problem definition. When looking at references to foresight or horizon scanning in different sections of impact assessments, we found that **only around 15–20% of IAs use foresight-related concepts to shape baseline scenarios or the design of policy options**. One good example is the impact assessment<sup>21</sup> on the Proposal for a Regulation of the European Parliament and of the Council on standards of quality and safety for substances of human origin

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<sup>19</sup> The other two references to Tool #22 found in the text are related to the SME test, which had that number in the previous iteration of the Better Regulation guidelines.

<sup>20</sup> The first one is the impact assessment supporting the Commission Delegated Regulation supplementing Regulation (EU) 2020/852 by establishing the "technical screening criteria for determining the conditions under which an economic activity qualifies as contributing substantially to climate change mitigation or climate change adaptation and for determining whether that economic activity causes no significant harm to any of the other environmental objectives". The second one is the impact assessment on the participation of the Union in the European Partnership on Metrology.

<sup>21</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC. SWD(2022)190.

[EUR-Lex - 52022SC0190 - EN - EUR-Lex.](#)

intended for human application and repealing Directives 2002/98/EC and 2004/23/EC. There, the document refers to horizon scanning carried out by the EMA, which “indicates an increase in borderline therapies for which it is not clear which is the applicable legal framework and/or which multiple legal frameworks will need to be applied”. Such a reference is however not sufficient to conclude that horizon scanning has played a major role in the whole impact assessment process. Likewise, **the impact assessment on the proposed directive on industrial emissions**<sup>22</sup> (integrated pollution prevention and control) and regulation on reporting of environmental data from industrial installations and establishing an Industrial Emissions Portal – mentions that, with respect to one of the proposed measures, that “the European Commission will produce guidance for horizon scanning for potential issues”. This indicates that horizon scanning did not contribute to agenda-setting, the baseline option of alternative policy options, but rather constitutes a (rather minimal) part of one of the many policy measures prospectively envisaged.

**Several IAs refer to (strategic) foresight, but many of them simply make reference to the annual Strategic Foresight Report** of the European Commission JRC to support observations, claims or reported data. For example, **the impact assessment on key information documents for packaged retail and insurance-based investment products**<sup>23</sup> observes that “to meet the objectives of the European Green Deal and RepowerEU alone, additional investments of about EUR 620 billion annually between 2023 and 2030 will be needed, which amounts to 3.7% of the EU’s 2023 GDP”, and quotes the 2023 Strategic Foresight report as a source. **The impact assessment on the Union Civil Protection Mechanism**<sup>24</sup> frequently mentions the need to promote more strategic foresight to strengthen preparedness, but does not rely on strategic foresight as basis for the assessment. **The impact assessment the on Proposal for a Directive on improving and enforcing working conditions of trainees and combating employment relationships disguised as traineeships**<sup>25</sup>, refers to the Strategic Foresight Report 2023 to infer that the identified “structural drivers will continue to play a significant role, and to the extent that they can drive a skills-based competition among traineeship providers, they should not be underestimated”.

**Cases in which foresight contributed to the analysis and evolution of the problem** notably include the **revision of the roadworthiness package**<sup>26</sup>, in which an *ad hoc* section states that

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<sup>22</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Directive of the European Parliament and of the Council amending Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) and Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste and Proposal for a Regulation of the European Parliament and of the Council on reporting of environmental data from industrial installations and establishing an Industrial Emissions Portal. SWD(2022)111. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022SC0111&qid=1772056214248>.

<sup>23</sup> Commission Staff Working Document Impact Assessment Report accompanying the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2019/2088 on sustainability-related disclosures in the financial services sector (SFDR), Regulation (EU) No 1286/2014 on key information documents for packaged retail and insurance-based investment products (PRIIPs) and repealing Commission Delegated Regulation (EU) 2022/1288. SWD(2025) 838. [EUR-Lex - 52025SC0838 - EN - EUR-Lex](#)

<sup>24</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council on a framework of measures for the establishment of the Union Civil Protection Mechanism and for health preparedness and response repealing Decision 1313/2013 (Union Civil Protection Mechanism). SWD (2025) 545. [EUR-Lex - 52025SC0545 - EN - EUR-Lex](#)

<sup>25</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Directive of the European Parliament and of the Council on improving and enforcing working conditions of trainees and combating employment relationships disguised as traineeships and Proposal for a Council Recommendation on a reinforced Quality Framework for Traineeships and replacing the Council Recommendation of 10 March 2014 on a Quality Framework for Traineeships. SWD (2024) 67. [EUR-Lex - 52024SC0067 - EN - EUR-Lex](#)

<sup>26</sup> Commission Staff Working Document Impact Assessment Report on the revision of the Directives of the Roadworthiness package Accompanying the Proposal for a Directive of the European Parliament and of the Council amending Directive 2014/45/EU on periodic roadworthiness tests for motor vehicles and their trailers, and amending Directive 2014/47/EU on the technical roadside inspection of the roadworthiness of commercial vehicles circulating in the Union Proposal for a Directive of the European Parliament and of the Council on the

“the analysis incorporates throughout all its dimensions relevant foresight tools. It does so to anticipate trends and issues that may affect the initiative and build a robust, future-proof evidence base for its likely impact”; and that the baseline “incorporates foresight megatrends and developments captured in the 2022 Strategic Foresight Report”. The incorporation of megatrends in the baseline has become increasingly common in some DGs. examples include **the impact assessment on the Proposal for a Directive on harmonised river information services (RIS)**<sup>27</sup> on inland waterways in the Community (quoting the megatrends identified in the Strategic Foresight Reports 2021 and 2022, and also long-term population projections from Eurostat and GDP growth from the Ageing Report 2021 by DG ECFIN). A similar reliance on megatrends is found in **the impact assessment on the enforcement of passenger rights in the Union, and passenger rights in the context of multimodal journeys**<sup>28</sup>. The 2021 Strategic Foresight Report is also evoked by DG JUST in **the impact assessment on measures to facilitate consular protection and the EU Emergency Travel Document**<sup>29</sup>, concluding that “the need for consular protection is likely to increase as foresight studies suggest that large disruptions to travel and other human activities are likely to increase further, resulting from either man-made events (such as wars, conflicts or social unrest), phenomena linked to global warming (such as fires or floodings) or large-scale health crises and epidemics”.

**DG MOVE’s impact assessment of a support framework for intermodal transport of goods**<sup>30</sup> goes beyond reference on megatrends (which is present in the document), to build on the EU Reference scenario 2020 (REF2020), allowing for the inclusion of the ‘Fit for 55’ package proposal and the REPowerEU package. This is a very promising feature, although not directly overlapping with the use of foresight:<sup>31</sup> it makes use of broader studies and allows for the incorporation of cumulative and interactive effects in the projection of the baseline and alternative policy options into the future. In DG MOVE, foresight considerations in Impact Assessments are generally included in the chapters on problem definition, which includes a subsection on “how likely is the problem to persist?”; and in the sections on “what are the available policy options?”, and “analytical methods”. DG MOVE refers to foresight in other IAs, such as the one on the **maximum authorised dimensions and weight of certain vehicles in international traffic**<sup>32</sup>, where the analysis “incorporates throughout all its dimensions relevant foresight tools ... to anticipate trends and issues that may affect the initiative and build a robust, future-proof evidence base for its likely impact”; and “the megatrend ‘climate change and

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registration documents for vehicles and vehicle registration data recorded in national vehicle registers, and repealing Council Directive 1999/37/EC. SWD (2025) 96. [EUR-Lex - 52025SC0096 - EN - EUR-Lex](#)

<sup>27</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Directive of the European Parliament and of the Council amending Directive 2005/44/EC on harmonised river information services (RIS) on inland waterways in the Community. SWD(2024)15 [EUR-Lex - 52024SC0015 - EN - EUR-Lex](#)

<sup>28</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 261/2004, (EC) No 1107/2006, (EU) No 1177/2010, (EU) No 181/2011 and (EU) 2021/782 as regards enforcement of passenger rights in the Union Proposal for a Regulation of the European Parliament and of the Council on passenger rights in the context of multimodal journeys. SWD (2023) 386 [EUR-Lex - 52023SC0386 - EN - EUR-Lex](#).

<sup>29</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Council Directive amending Directive (EU) 2015/637 on the coordination and cooperation measures to facilitate consular protection for unrepresented citizens of the Union in third countries and Directive (EU) 2019/997 establishing an EU Emergency Travel Document. SWD(2023)941. [EUR-Lex - 52023SC0941 - EN - EUR-Lex](#).

<sup>30</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Directive of the European Parliament and of the Council amending Council Directive 92/106/EEC as regards a support framework for intermodal transport of goods and Regulation (EU) 2020/1056 of the European Parliament and the Council as regards calculation of external costs savings and generation of aggregated data. SWD(2023)351. [EUR-Lex - 52023SC0351 - EN - EUR-Lex](#).

<sup>31</sup> Foresight and the EU Reference Scenario are different workstreams, with the latter not using foresight methods. Mid-to long-term assumptions are made in the REF2020, but they do not originate from foresight methods or results (e.g., megatrends).

<sup>32</sup> Commission SWD Impact Assessment Report Accompanying the Proposal for a Directive of the European Parliament and of the Council amending Council Directive 96/53/EC laying down for certain road vehicles circulating within the Community the maximum authorised dimensions in national and international traffic and the maximum authorised weights in international traffic. SWD(2023)445. [EUR-Lex - 52023SC0445 - EN - EUR-Lex](#).

environmental degradation’ is relevant for the problem related to the low uptake of zero-emission heavy-duty vehicles and energy saving technologies and schemes”. The impact assessment **on ship-source pollution** and on the introduction of penalties, including criminal penalties, for pollution offences<sup>33</sup> also makes extensive use of the Strategic Foresight report and related megatrends, while the **IA on rules on breaks and rest periods** rules in occasional bus and coach transport<sup>34</sup> takes a very similar approach. Moreover, the **IA on the accounting of the greenhouse gas emissions**<sup>35</sup> in transport features a dedicated chapter on foresight in the problem definition section.

DG EMPL made use of a CEDEFOP foresight analysis in four sectors in the **IA on establishing an EU Talent Pool**<sup>36</sup>: this is a case in which foresight seems to have had a more substantial impact on the shaping and analysis of the problem and its evolution. More generally, there is strong evidence of use of foresight in DG EMPL (see for example the impact assessment on cross-border associations<sup>36b</sup>).

A special mention can be reserved to the **IA** in our sample, led by DG SANTE, **on the proposed regulation on plants obtained by certain new genomic techniques and their food and feed**<sup>37</sup>, and amending Regulation (EU) 2017/625. In the context of that analysis, on 15 February 2022 the JRC Competence Centre on Foresight organised a specific Megatrends Analysis workshop, identifying megatrends on ‘Aggravating resource scarcity’, ‘Shifting health challenges’, ‘Climate change and environmental degradation’ and ‘Continuing urbanisation’ as highly relevant for the initiative.

Quantitative scenario simulation is also starting to be used in the context of ex-ante impact assessment, though not within the pool of our selected IAs. However, scenario simulation makes a strong complement to foresight, supporting quantitative simulation of future scenarios based on the introduction of different types of policy interventions. A main reference to it can be found in the European Competitiveness Fund IA (European Commission, 2025).<sup>38</sup>

**In the majority of cases, baselines extrapolate current trends without explicit consideration of technological disruption or uncertainty.** Moreover, **use of, or reference to, foresight for sensitivity or contingency analysis is very rare.** This represents a missed opportunity to test regulatory robustness under alternative innovation pathways.

**All in all, the uptake of foresight appears very significant,** and growing over the years in European Commission impact assessments. Most of this is due to the publication of Annual Strategic Foresight reports by the Joint Research Centre, which contribute both thematically (e.g. on strategic autonomy, resilience, etc.) and with the identification of megatrends. However, areas for improvement are also equally emerging. First, **horizon scanning, and particularly**

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<sup>33</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Directive of the European Parliament and of the Council amending Directive 2005/35/EC on ship-source pollution and on the introduction of penalties, including criminal penalties, for pollution offences. SWD(2023)159. [EUR-Lex - 52023SC0159 - EN - EUR-Lex.](#)

<sup>34</sup> Commission Staff Working Document Impact Assessment Report - Rules on breaks and rest periods rules in occasional bus and coach transport Accompanying the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 561/2006 as regards minimum requirements on minimum breaks and daily and weekly rest periods in the occasional passenger transport sector. SWD(2023)137. [EUR-Lex - 52023SC0137 - EN - EUR-Lex.](#)

<sup>35</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND THE COUNCIL on the accounting of greenhouse gas emissions of transport services. SWD(2023)441. [EUR-Lex - 52023SC0441 - EN - EUR-Lex.](#)

<sup>36</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and the Council establishing an EU Talent Pool. SWD(2023)717. [EUR-Lex - 52023SC0717 - EN - EUR-Lex.](#)

<sup>37</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625. SWD(2023)412. [EUR-Lex - 52023SC0412 - EN - EUR-Lex.](#)

<sup>38</sup> [EUR-Lex - 52025SC0555 - EN - EUR-Lex](#)

**the anticipation of specific trends (e.g. emerging technologies) seems to be practically absent** in our sample. Second, **foresight does not lead Commission services to develop alternative scenarios as opposed to a single baseline** and then test the robustness of the alternative policy options under alternative scenarios. **The absence of this approach limits the ability of the European Commission to engage in anticipatory governance**, and to award priority to more agile, adaptive regulatory solutions whenever the uncertainty of the outlook so suggests.

## 1.5. Innovation-friendly Regulatory Design

### 1.5.1. Experimental clauses, regulatory sandboxes, pilot schemes

Regulatory design variables capture consideration of instruments associated with innovation-friendly regulation, including outcome-based regulation, performance standards, experimentation clauses, regulatory sandboxes, flexibility mechanisms, sunset clauses, and review provisions. A score of 1 indicates explicit consideration of the instrument in the context of innovation or adaptability. A score of 0.5 indicates consideration for other reasons (e.g. proportionality or feasibility) with potential innovation relevance. A score of 0 indicates no consideration. Variables are coded separately for each instrument type to avoid aggregation bias. Our findings reveal that **explicit consideration of experimentation clauses, pilot schemes, or regulatory sandboxes appears in approximately 10–15% of impact assessments**, primarily in digital, financial, and emerging technology policy areas. We then proceeded to a more in-depth research without the support of AI text analysis.

Regulatory sandboxes appear to have permeated more than other tools the better regulation agenda of the European Commission. Key examples include the following:

- **In the IA on the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency**<sup>39</sup>, DG SANTE explores options that would allow the introduction of regulatory sandboxes by the EMA and the European Commission. Option C in the IA contains proposes a ‘quid pro quo approach’ with a modulated system of incentives combined with obligations: this option foresees the inclusion of a sandbox environment (i.e. a structured form of testing before formal regulation in the cases of the most innovative medicines that would otherwise challenge the system). It also accommodates innovation in breakthrough areas where the current framework does not sufficiently cater for this innovation, for example medicines for ‘unmet medical needs’ and rare disease medicines for ‘high unmet medical needs’. The IA states that SMEs should benefit in particular from the introduction of regulatory sandboxes to support development of innovative products and scientific support from the Agency, as well as fee reductions. This IA contains many provisions alongside regulatory sandboxes, which may be classified as innovative approaches to regulation – for example, transferable exclusivity voucher for novel antibiotics, which could be especially beneficial to SMEs; and adapted regulatory pathways, e.g. for less complex cell-based medicinal products. Regulatory Sandboxes are also included as indicator for monitoring and evaluation. Other examples include platform technology marketing authorisations which favour innovation and use of medicines with a

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<sup>39</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006. SWD (2023) 192. [EUR-Lex - 52023SC0192 - EN - EUR-Lex](#).

fixed and a variable component that is pre-defined. Adapted frameworks align the regulatory system with requirements tailored to the characteristics of certain innovative medicines.

- **The IA on the Artificial intelligence Act**<sup>40</sup> (see also section 3.6 below for a case study on this policy file), is the most comprehensive when it comes to the introduction of regulatory sandboxes. The proposed horizontal instrument would allow EU or national authorities to set up AI regulatory sandboxes where innovative AI systems can be tested under close regulatory supervision before entering the market. These sandboxes would help developers experiment for a limited time under a defined testing plan, with authorities providing guidance to support legal compliance and increase legal certainty. No exemptions from existing laws would be granted, but authorities would retain limited flexibility in applying legal requirements within their discretion. Strong safeguards would apply: any serious safety or fundamental rights risks identified during testing would require immediate correction or suspension of the system. Overall, the regulatory sandboxes aim to foster innovation and faster market access while protecting safety and fundamental rights. They would also give regulators practical experience, help identify emerging risks and high-risk AI use cases, and inform future updates to EU AI regulation and technical standards.

The IA also reports the results of a public consultation, in which at least 19 position papers discussed establishing regulatory sandboxes as one potential pathway to better allow for experimentation and innovation under the new regulatory framework, and adds that at least 12 Member States supported regulatory sandboxes in their national strategies, adding a reference to the Council Conclusion on regulatory sandboxes (13026/20) and observing that “regulatory sandboxes are increasingly used in different sectors, can provide an opportunity for advancing regulation through proactive regulatory learning and support innovation and growth of all businesses, especially SMEs”.

Sandboxes are also included in the monitoring and evaluation indicators (Table 13 in the IA). The RSB asked the Commission services to clarify “how regulatory sandboxes can alleviate burden on SMEs, given the autonomous dynamics of AI”; as a result, the IA added some clarifications and gave more evidence to the related submissions coming from the open stakeholder consultation.

- **IA on the Interoperable Europe Act**<sup>41</sup>, contains important provisions on regulatory sandboxes. To support innovative interoperability solutions, the governance set up by the Act can lead to the set-up of regulatory sandboxes in cross-border contexts. The use of the regulatory sandbox provision is also included in the monitor and evaluation indicators. The document also reports the results of an ex post evaluation (of ISA2 and the European Interoperability Framework), which highlighted the relevance of regulatory sandboxes testing solutions and getting better feedback.

Two other IA documents refer to regulatory sandboxes, but do not incorporate them in the assessment. The **IA on the Health Data Space**<sup>42</sup> extensively refers to regulatory sandboxes, particularly with reference to the AI Act. Under Policy Option 2, Health Data Access Bodies, along with Testing and Experimentation Facilities and regulatory sandboxes as foreseen under the AI Act, would aid in the implementation of the AI Act itself. Moreover, the **IA on the**

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<sup>40</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence and amending certain union legislative acts. SWD (2021) 84. [EUR-Lex - 52021SC0084 - EN - EUR-Lex](#).

<sup>41</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act). SWD (2022) 721 [EUR-Lex - 52022SC0721 - EN - EUR-Lex](#)

<sup>42</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. SWD(2022)131. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022SC0131&qid=1772055886866>.

**establishment of a common framework for media services**<sup>43</sup> in the internal market, reports the comments received by the Regulatory Scrutiny Board on the possible introduction of regulatory sandboxes in the text of the regulatory measure. The RSB had suggested that the IA report better assess the impact and effectiveness of some measures (e.g. non-binding Board opinions and regulatory sandboxes, etc); as a result, the role of board opinions was expanded, while regulatory sandboxes were excluded from the envisaged measures. Lastly, the revision of the EU Medical Devices Regulation and In-Vitro Diagnostic Regulation are worth mentioning, even though not included in the pool of analysed IAs. Regulatory Sandboxes are explicitly mentioned as an option to carry out supervised real-world testing of innovative medical technologies, while also letting regulators trial and evaluate alternative regulatory approaches—without allowing any non-compliant devices to be placed on the market (European Commission, 2025a)<sup>44</sup>.

When it comes to **pilot schemes**, a few examples are available from the 2020-2025 period. They include the **IA on the Disability Card Pilot Scheme**<sup>45</sup>, launched by the European Commission in 2016 as an EU-wide initiative to test a standardised card proving that a person has a recognised disability and to facilitate mutual recognition of disability status across participating Member States. It was implemented on a voluntary basis by eight countries (Belgium, Cyprus, Estonia, Finland, Italy, Malta, Romania and Slovenia), which issued the cards and recognised them within the pilot framework. The primary aim of the pilot was to make it easier for persons with disabilities to access benefits and preferential conditions when travelling in other participating states, especially in the areas of culture, leisure, sport and transport, by providing a common proof of disability that host organisations could recognise. Importantly, the pilot did not harmonise national eligibility criteria — each country retained the right to decide who qualified as disabled and how the card was issued, and the card did not automatically grant rights to benefits outside the issuing country unless local service providers chose to accept it. Participation by service providers in offering benefits or discounts was voluntary, which, together with limited geographical scope, meant that the card's practical impact varied and was in some cases limited. The pilot was formally evaluated by the Commission to assess its usefulness and cost-effectiveness in improving access to services and supporting the rights of persons with disabilities, with results feeding into future EU policy development. Based on the pilot's experience and the EU's Strategy for the Rights of Persons with Disabilities 2021–2030, the Commission proposed a Directive to establish the European Disability Card across all Member States, aiming for mutual recognition of disability status and equal access to preferential treatment EU-wide. Under that new legal framework adopted by the EU institutions in late 2024, Member States will have time to implement the card so that it becomes available EU-wide by around 2028. The card will complement national disability cards and allow holders to enjoy the same special conditions and preferential treatment offered to residents with disabilities when visiting other EU countries.<sup>46</sup>

Pilot schemes have also been considered in the context of greenhouse gas emissions. The **IA on a system for greenhouse gas emission allowance trading**<sup>47</sup> refers to one of the actions

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<sup>43</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council establishing a common framework for media services in the internal market (European Media Freedom Act) and amending Directive 2010/13/EU. SWD (2022) 286 [EUR-Lex - 52022SC0286 - EN - EUR-Lex](#)

<sup>44</sup> [health.ec.europa.eu/document/download/94299481-f705-4918-9c64-8fd1d2ac2cb5\\_en?filename=md\\_swd-2025-1050\\_en.pdf](https://health.ec.europa.eu/document/download/94299481-f705-4918-9c64-8fd1d2ac2cb5_en?filename=md_swd-2025-1050_en.pdf)

<sup>45</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Directive of the European Parliament and of the Council establishing the European Disability Card and the European Parking Card for persons with disabilities. SWD (2023) 290 [EUR-Lex - 52023SC0290 - EN - EUR-Lex](#)

<sup>46</sup> See also European Commission: Directorate-General for Employment, Social Affairs and Inclusion, EY and IRVAPP, Study assessing the implementation of the pilot action on the EU Disability Card and associated benefits, Publications Office of the European Union, 2021, <https://data.europa.eu/doi/10.2767/429261>.

<sup>47</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Directive of the European Parliament and of the Council amending Directive 2003/87/EC establishing a system for greenhouse

undertaken under the Green Deal (Key Action 7), which entails the development of a pilot scheme – preferably at EU level – for a Carbon Contracts for Difference programme, in particular to support the production of low carbon and circular steel, and basic chemicals. While the IA itself does not deal with that pilot, and there is not yet a single EU-wide statutory CCfD programme in force, the concept is embedded in broader EU industrial decarbonisation strategies (e.g., the Clean Industrial Deal) and reflected in discussion on designing CCfD mechanisms that could be funded through competitive auctions and instruments such as the Innovation Fund. National pilots are therefore providing practical experience and evidence to inform how such a mechanism might be scaled EU-wide to support low-carbon and circular production in steel and basic chemicals.

### 1.5.2. Co-regulation, outcome-based or performance-based regulation

Mapping the use of flexible regulatory options such as co-regulation, outcome- or performance-based standards or regulation is a complex exercise, which cannot be carried out easily through machine learning systems. As a matter of fact, several pieces of legislation at the EU level entail some form of co-regulation, and the EU approach to standardisation has established a widespread performance-based approach, which reverberates across EU legislation in various ways, without necessarily being labelled as outcome- or performance-based (e.g. the AI Act contains several provisions of this sort). Major examples of legislative initiatives adopting one of these innovation-friendly approaches include the following:

- **EU co-regulation via harmonised standards/presumption of conformity**, such as
  - Tyre Labelling Regulation (EU) 2020/740 — performance/outcome logic via measurable label classes/indices (e.g., rolling noise, grip indices) rather than prescribing how tyres must be engineered.
  - Commission Delegated Regulation (EU) 2022/30 (Radio Equipment Directive cybersecurity essential requirements) — a textbook co-regulatory move: the law “switches on” essential requirements and industry can rely on voluntary harmonised standards to demonstrate compliance.
  - General Product Safety Regulation (EU) 2023/988 — while not a CE/essential-requirements instrument in the same way as some NLF product laws, it is still standards-driven in practice: European standards are used as a key reference point for assessing product safety.
  - The Machinery Regulation (EU) 2023/1230 the Regulation sets essential requirements and relies on harmonised standards (and related “presumption” mechanisms) to operationalise compliance.
  - Batteries Regulation (EU) 2023/1542 — establishes detailed sustainability/safety/circularity obligations that are intended to be implemented and verified through common EU methods and standardisation routes (a co-regulatory implementation pattern in a highly technical area).
  - Ecodesign for Sustainable Products Regulation (EU) 2024/1781. Sets a framework for product performance/circularity outcomes (durability, repairability, recyclability, footprints, etc.), with operational detail largely delivered through subsequent implementing measures and standardisation. See IA134 for the related assessment (especially related to administrative burdens).

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gas emission allowance trading within the Union, Decision (EU) 2015/1814 concerning the establishment and operation of a market stability reserve for the Union greenhouse gas emission trading scheme and Regulation (EU) 2015/757. SWD(2021)601. [EUR-Lex - 52021SC0601 - EN - EUR-Lex](#)

- Cyber Resilience Act, Regulation (EU) 2024/2847 — sets “essential cybersecurity requirements” for products with digital elements and explicitly provides presumption of conformity via EU cybersecurity certification and (in practice) standards/specifications.
- AI Act, Regulation (EU) 2024/1689 — strong co-regulatory architecture: conformity is expected to be demonstrated through harmonised standards (and related guidance/codes), translating high-level legal requirements into testable technical specifications.
- **Co-regulation via “codes of conduct / codes of practice” anchored in law, for example in:**
  - Digital Services Act, Regulation (EU) 2022/2065 — explicitly encourages voluntary codes of conduct to support proper application of the Regulation, under EU-level governance/oversight.
  - European Media Freedom Act, Regulation (EU) 2024/1083 — includes supervised self/co-regulatory tools (e.g., codes/structured practices) as part of the governance model rather than pure command-and-control rules.
- **“Outcome/performance-based” regulation (results measured; methods left flexible), including:**
  - The Recovery and Resilience Facility (RRF), Regulation (EU) 2021/241 — EU payments are linked to completion of milestones and targets, not traditional cost reimbursement: classic performance-based public policy design.
  - CAP Strategic Plans Regulation (EU) 2021/2115 — shifts to a “delivery model” with a performance monitoring and evaluation framework (targets/indicators), focusing on achieved results rather than uniform input rules.
  - Common Provisions Regulation (EU) 2021/1060 (EU funds 2021–2027) — embeds output indicators, milestones and targets into cohesion policy programming and monitoring.
  - EU ETS revision (Directive (EU) 2023/959 and related ETS framework) — outcome-based environmental regulation: the system is built around an emissions cap trajectory (the outcome), letting the market decide how reductions happen.
  - NIS2 (Directive (EU) 2022/2555) — largely outcome/risk-based: it requires “appropriate and proportionate” risk-management measures and incident handling, leaving implementation choices to entities (within a minimum set of areas).
- **Co-regulation via delegated/implementing technical standards (“regulator + expert bodies” model), including:**
  - DORA (Regulation (EU) 2022/2554) — obligations are further specified through delegated and implementing acts / technical standards, i.e., a structured rule-completion layer under regulatory control (co-regulatory in how detailed requirements are produced).
  - Data Act (Regulation (EU) 2023/2854) — includes an explicit standardisation/interoperability agenda (a governance + technical standard-setting layer supporting the legal framework).

Below we highlight some important cases in which performance-based measures have been explicitly considered in European Commission IAs, without the ambition to be exhaustive.

- In the **IA accompanying the proposal for establishing the European Fund for economic, social and territorial cohesion, agriculture and rural, maritime, prosperity**

**and security for the period 2028-2034**<sup>48</sup>, one of the alternative options entails the transition from a cost-based to a performance-based delivery model, with a few variants when it comes to whether the governance of the model should be centralised at the EU level or partly left in the hands of Member States. The RHOMOLO model (Barbero et al., 2024<sup>32</sup>) was used to simulate the impact of cohesion policy interventions for the period 2021–2027 for all three options on the delivery model (Annex 11).<sup>49</sup>

- Also **IA on the European Competitiveness Fund**<sup>50</sup> refers to performance-based delivery models, but mostly reporting the results of the public consultation, without incorporating them in the alternative policy options. **Similar tools are the core subject in IA9 on establishing a budget expenditure tracking and performance framework** and other horizontal rules for the Union programmes and activities, which chiefly considers moving from a cost-based to performance-based tracking; **and in IA10 on establishing Global Europe**, which makes reference to the importance of strengthening performance-based financing to further align EU policy objectives and spending in the context of pre-accession.
- **The IA on methane emissions reduction in the energy sector**<sup>51</sup> reports that in the public consultation, a majority of responding NGOs highlighted that “prescriptive, ambitious and performance-based approaches are needed to achieve meaningful methane emissions reductions” and “responding public administrations were either in favour of performance-based requirements or sector-specific approaches”.
- **The IA supplementing Directive 2014/53/EU of the European Parliament and of the Council with regard to the application of the essential requirements for radio equipment**<sup>52</sup>, the preferred option (n. 5) entails harmonised standards that – as stated in the document – “will be performance-based and technology neutral. This will limit the risk of hindering innovation”. The IA on FuelEU Maritime<sup>53</sup> contains a section that compared goal-based with prescriptive policy approaches, describing the results of a public consultation. “For ships in navigation, 52 % of respondents preferred a goal-based approach, while 15 % preferred a prescriptive approach. However, during the interviews

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<sup>48</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council establishing the European Fund for economic, social and territorial cohesion, agriculture and rural, maritime, prosperity and security for the period 2028-2034 and amending Regulation (EU) 2023/955 and Regulation (EU, Euratom) 2024/2509. SWD (2025) 565. [EUR-Lex - 52025SC0565 - EN - EUR-Lex](#)

<sup>49</sup> The frontloading investments under a performance-based delivery model means the benefits to GDP of the interventions start to materialise earlier, leading to larger cumulative GDP gains over time.

<sup>50</sup> Commission Staff Working Document Impact Assessment Report on the European Competitiveness Fund Accompanying the Proposal for a Regulation of the European Parliament and of the Council on establishing the European Competitiveness Fund (“ECF”), including the specific programme for defence research and innovation activities, repealing Regulations (EU) 2021/522, (EU) 2021/694, , (EU) 2021/697, (EU) 2021/783, repealing provisions of Regulations (EU) 2021/696, (EU) 2023/588, and amending Regulation (EU) [EDIP] Proposal for a Regulation of the European Parliament and of the Council establishing Horizon Europe, the Framework Programme for Research and Innovation, for the period 2028-2034 laying down its rules for participation and dissemination, and repealing Regulation (EU) 2021/695 Proposal for a Council Decision on establishing the Specific Programme implementing Horizon Europe - the Framework Programme for Research and Innovation for the period 2028-2034, laying down the rules for participation and dissemination under that Programme, and repealing Decision (EU) 2021/764. SWD (2025) 555. [EUR-Lex - 52025SC0555 - EN - EUR-Lex](#)

<sup>51</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND THE COUNCIL on the accounting of greenhouse gas emissions of transport services. SWD (2023) 441. [EUR-Lex - 52023SC0441 - EN - EUR-Lex](#)

<sup>52</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Commission Delegated Regulation supplementing Directive 2014/53/EU of the European Parliament and of the Council with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of that Directive. SWD (2021) 302. [EUR-Lex - 52021SC0302 - EN - EUR-Lex](#)

<sup>53</sup> COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the Proposal for a Regulation of the European Parliament and of the Council on the use of renewable and low-carbon fuels in maritime transport. SWD (2021) 635. [EUR-Lex - 52021SC0635 - EN - EUR-Lex](#)

and the roundtable it became clear that there are diverging views on what this performance-based requirement should be.”

- **The IA<sup>54</sup> relating to technical screening criteria for determining the conditions under which an economic activity qualifies as contributing substantially to climate change mitigation or climate change adaptation** and for determining whether that economic activity causes no significant harm to any of the other environmental objectives. The IA compared approaches to screening, considering performance on the environmental objectives and “best in class” performance requirements.

**At least six Commission IAs in the 2020-2025 period explicitly considered co-regulation as a policy option.** These include the following:

- **IA on the safety, resilience and sustainability of space activities in the Union<sup>55</sup>** identifies co-regulation as “option 1”. Co-regulation is defined there as “the mechanism whereby a community legislative act entrusts the attainment of the objectives defined by the legislative authority to parties which are recognised in the field (such as economic operators, the social partners, non-governmental organisations, or associations).” In this specific case, co-regulation would have combined legislative and regulatory measures with actions taken by the actors most concerned, drawing on their practical expertise; and would have promoted the development by the industry of labels for safety/resilience/sustainability, under the assumption that 60% of the European satellite industry and 80% of the European launcher industry would comply with the non-binding measures through either the codified codes of conduct or the label.
- **IA on the AI Act considers as Option 3+ a form of co-regulation, through voluntary codes of conduct<sup>56</sup>.** The whole Act, as will be explained in more detail in Section 3 below, is based on outcome-based interventions (through conformity assessment), coupled with regulatory sandboxes and voluntary measures, which were further reinforced with the adoption of the Code of Conduct for General-Purpose AI Systems. The preferred option in this IA was the one (“3+”) entailing, alongside a regulatory framework for high-risk AI applications, the possibility for all non-high-risk AI applications to follow a code of conduct.<sup>57</sup>
- **IA on a Single Market for Digital Services (DSA)<sup>58</sup>** contains an extensive report on workshops and events organised to better define the problem, with references to co-regulatory measures discussed in those events. The European Commission itself coordinated several self-regulatory initiatives in related matters, including the Code of Conduct on Countering Illegal Hate Speech Online (DG JUST); the Code of Practice on Disinformation (DG CNECT); EU Internet Forum – terrorist propaganda (DG HOME); the INHOPE network of hotlines – child sexual abuse (DG CNECT); the Memorandum of

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<sup>54</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Commission Delegated Regulation (EU) .../... supplementing Regulation (EU) 2020/852 of the European Parliament and of the Council by establishing the technical screening criteria for determining the conditions under which an economic activity qualifies as contributing substantially to climate change mitigation or climate change adaptation and for determining whether that economic activity causes no significant harm to any of the other environmental objectives. SWD (2021) 152. [EUR-Lex - 52021SC0152 - EN - EUR-Lex](#)

<sup>55</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council on the safety, resilience and sustainability of space activities in the Union. SWD (2025) 335. [EUR-Lex - 52025SC0335 - EN - EUR-Lex](#)

<sup>56</sup> COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the Proposal for a Regulation of the European Parliament and of the Council LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS. SWD (2021) 84. [EUR-Lex - 52021SC0084 - EN - EUR-Lex](#)

<sup>57</sup> Interestingly, this option is referred to as co-regulation in the table of contents only, not in the title of the corresponding section.

<sup>58</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Regulation of the European Parliament and of the Council on a Single Market For Digital Services (Digital Services Act) and amending Directive 2000/31/EC. SWD (2020) 348. [EUR-Lex - 52020SC0348 - EN - EUR-Lex](#)

Understanding on the sale of Counterfeit Goods on the Internet (DG GROW); the Memorandum of understanding on online advertising and IPR (DG GROW); and the Product Safety Pledge - Voluntary commitment of online marketplaces with respect to the safety of non-food consumer products sold online by third party sellers (DG JUST).

- **IA on combating child sexual abuse and sexual exploitation and child sexual abuse material**<sup>59</sup> refers to the previous regime (the CSAE Directive) as leaving a too large margin of discretion due to a series of self or co-regulatory measures that vary considerably in scope, methodology, and legal certainty.

As a conclusion, **some of the more consolidated innovation-friendly regulatory approaches, such as co-regulation and performance-based regulation, appear to be firmly embedded in the way the European Commission prepares its regulatory measures.** That said, **this does not provide solid evidence that the presence of Tool #22 has made a difference** in guiding Commission services in their analysis.

### **1.5.3. Other forms of innovative regulatory design: open banking, API-based regulation**

Our sample of impact assessments contains also interesting cases in which the Commission services have considered very innovative forms of regulatory intervention, which are often included in the taxonomies of agile regulatory instruments. More specifically, of particular interest is the **IA on the open finance framework**<sup>60</sup>, which presents open finance as a competition- and innovation-enabling infrastructure, expected to reduce information asymmetries, facilitate switching, enable new financial products and business models, and improve outcomes such as personalised services, SME financing and investment advice. Regulatory design is central to the IA's treatment of open finance. The preferred option combines mandatory data access via APIs, the development of common standards through industry schemes, governance rules for data holders and users, compensation mechanisms for data access, and safeguards related to consent, liability and dispute resolution. The IA repeatedly emphasises that access to data is a precondition for innovation, echoing OECD and EU data-economy literature. Open finance is expected to unlock innovation by reducing information asymmetries, enabling advanced analytics and machine learning, and allowing new entrants—especially fintech firms and data intermediaries—to develop value-added services. These effects are presented as downstream innovation outcomes, driven by market uptake rather than by research programmes or experimentation frameworks. Importantly, the IA explicitly acknowledges that, because open finance is an enabling framework, quantitative predictions about innovation impacts are difficult and rely on proxies from the European Data Market Study and experiences with PSD2 open banking. Innovation is therefore discussed at an aggregate and systemic level, not through project-level R&D metrics or technology readiness pathways.

In contrast, the **IA on the review of the Payment Services/PSD2**<sup>61</sup> could have treated innovation in a more direct way. It focuses primarily on consumer protection, fraud, costs for

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<sup>59</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Directive of the European Parliament and the Council on combating child sexual abuse and sexual exploitation and child sexual abuse material, and replacing Council Framework Decision 2004/68/JHA (recast). SWD (2024) 33 [EUR-Lex - 52024SC0033 - EN - EUR-Lex](#)

<sup>60</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council on a framework for Financial Data Access and amending Regulations (EU) No 1093/2010, (EU) No 1094/2010, (EU) No 1095/2010 and (EU) 2022/2554. SWD (2023) 224. [EUR-Lex - 52023SC0224 - EN - EUR-Lex](#)

<sup>61</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council on payment services in the internal market and amending Regulation (EU) No 1093/2010 and Proposal for a Directive of the European Parliament and of the Council on payment services and electronic money services in the Internal Market amending Directive 98/26/EC

PSPs, legal clarity, and market functioning, and treats innovation effects as implicit spillovers, assumed to follow if open banking works better. There is no dedicated innovation-impact comparison across options, such as, and innovation is neither used as a decision criterion to rank options, or operationalised with indicators, scenarios, or assumptions in the way access, costs, or risks are. The RSB opinion criticised the draft IA for insufficient evidence that the proposed measures will actually revive open-banking-driven innovation, especially given low consumer trust and fraud concerns.

Likewise, the **IA on instant credit transfers in euro**<sup>62</sup> clearly links instant payments to innovation and open-banking dynamics, but it does not treat research and innovation as a standalone impact category, nor does it compare options primarily on innovation outcomes.

Other IAs consider directly the opening of Application Programming Interfaces (APIs) as regulatory options. A clear example here is the **IA on the Data Act**<sup>63</sup>, which attributes significant efficiency, productivity and innovation-related benefits to improved data access enabled by APIs, including reduced switching costs, increased competition in aftermarkets, and the emergence of new data-driven services. However, these benefits are assessed at a high level of aggregation, and APIs are treated as part of the enabling infrastructure rather than as a variable whose design choices (e.g. openness, governance, cost recovery) are systematically compared. There is no granular assessment of alternative API governance models or their differentiated effects on competition or innovation.

Similarly, the **IA on a European Single Access Point**<sup>64</sup> considers Open APIs as part of a broader architecture, without linking the use of this innovative form of enabling access to a structured analysis of innovation. That said, the preferred option does explicitly assume API-enabled access as a driver of lower search costs, automation, scalability and innovation in downstream services. The IA links APIs to indirect benefits such as the emergence of new digital services, improved analytics, and reduced reliance on proprietary data aggregators, but these effects are treated at a high level of aggregation and are not differentiated across alternative API governance models. Thus, while Open APIs are clearly decisive for the choice of the preferred option, they are treated analytically as part of the enabling architecture, not as a design variable whose openness, governance or pricing is itself compared in detail.

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and repealing Directives 2015/2366/EU and 2009/110/EC. SWD(2023)231. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023SC0231&qid=1772055764142>.

<sup>62</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) No 260/2012 and (EU) No 2021/1230 as regards instant credit transfers in euro. SWD (2022) 546. [EUR-Lex - 52022SC0546 - EN - EUR-Lex](#).

<sup>63</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Directive of the European Parliament and of the Council amending Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) and Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste and Proposal for a Regulation of the European Parliament and of the Council on reporting of environmental data from industrial installations and establishing an Industrial Emissions Portal. SWD (2022) 111. [EUR-Lex - 52022SC0111 - EN - EUR-Lex](#)

<sup>64</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council establishing a European single access point providing centralised access to publicly available information of relevance to financial services, capital markets and sustainability Proposal for a Regulation of the European Parliament and of the Council amending certain Regulations as regards the establishment and functioning of the European single access point Proposal for a Directive of the European Parliament and of the Council amending certain Directives as regards the establishment and functioning of the European single access point. SWD (2021) 344. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021SC0344&qid=1772039482012>.

#### 1.5.4. Other agile governance tools are not present in our sample

Renda (2025) maps the innovative, agile regulatory approaches that are emerging along the policy cycle, as shown in Figure 5 below. Many of these tools are not currently being used by the European Commission, and could be gradually included in Tool #22.

One important category concerns **agenda-setting and anticipatory governance**. While the Commission increasingly uses foresight and strategic scanning, Renda (2025) highlights **more advanced and continuous horizon-scanning systems, crowdsourcing of regulatory priorities, and mission-oriented backcasting**, tools that remain under-institutionalised at EU level. These approaches allow governments to detect weak signals of technological and societal change earlier and to translate long-term policy goals into concrete regulatory pathways. Embedding such tools more explicitly into the Better Regulation cycle would allow the innovation principle to operate upstream, shaping regulatory agendas before problems crystallise into rigid legislative responses.

A second cluster of underused tools relates to **ex-ante impact assessment and regulatory design**. Although the EU increasingly acknowledges **outcome-based regulation and co-regulation**, these approaches are not yet treated as default or systematically tested options within impact assessments. Outcome- or performance-based regulation, **“law as code” approaches, and open-API regulatory mandates** can significantly lower compliance costs and stimulate innovation by focusing on results rather than prescribing technical solutions. Similarly, **structured regulatory hackathons and TechSprints**, which bring regulators and innovators together to prototype compliance and supervisory solutions, are absent from EU impact-assessment practice despite their potential to reveal innovation-friendly regulatory designs at an early stage.

**Experimental policymaking tools** represent another area where EU practice remains comparatively cautious. Regulatory sandboxes are now recognised in specific sectors such as finance and AI, but the report documents a broader toolbox of **pilots, testbeds, living labs and innovation deals** that are used more flexibly elsewhere to test regulatory hypotheses under real-world conditions. These instruments can help regulators learn iteratively and reduce uncertainty before scaling rules across the internal market. Their systematic integration into the innovation principle could shift EU regulation away from one-off legislative interventions toward more adaptive, evidence-based regulatory pathways

The **implementation and enforcement phase** also offers underexploited opportunities. Tools such as **RegTech and SupTech, predictive analytics, negotiated rulemaking, and structured regulatory guidance to support compliance** are shown to be particularly effective in innovation-intensive sectors. While some of these tools exist in fragmented form at EU level, they are not yet framed as part of an innovation-supporting regulatory strategy. Integrating them into the innovation principle would acknowledge that innovation impacts depend not only on the substance of rules but also on how they are applied, monitored and enforced over time

Finally, Renda (2025) points to **innovative consultation and participation tools** that remain marginal in EU practice, such as **digital platforms for deliberative engagement and advanced text-analysis of consultation responses**. These tools can broaden participation, surface non-obvious innovation concerns, and reduce the risk that regulation reflects only incumbent perspectives. Incorporating them into the innovation principle would strengthen its legitimacy and practical effectiveness by ensuring that innovation impacts are identified from a wider range of stakeholders and business models

Overall, the report suggests that the innovation principle could evolve from a largely analytical “check” within impact assessments into **a more comprehensive framework for agile regulatory governance**. By selectively integrating these underused tools across the policy cycle, the European Commission could better align regulation with rapid technological change,

reduce unnecessary regulatory friction, and create a more predictable and innovation-friendly regulatory environment without lowering standards of protection.

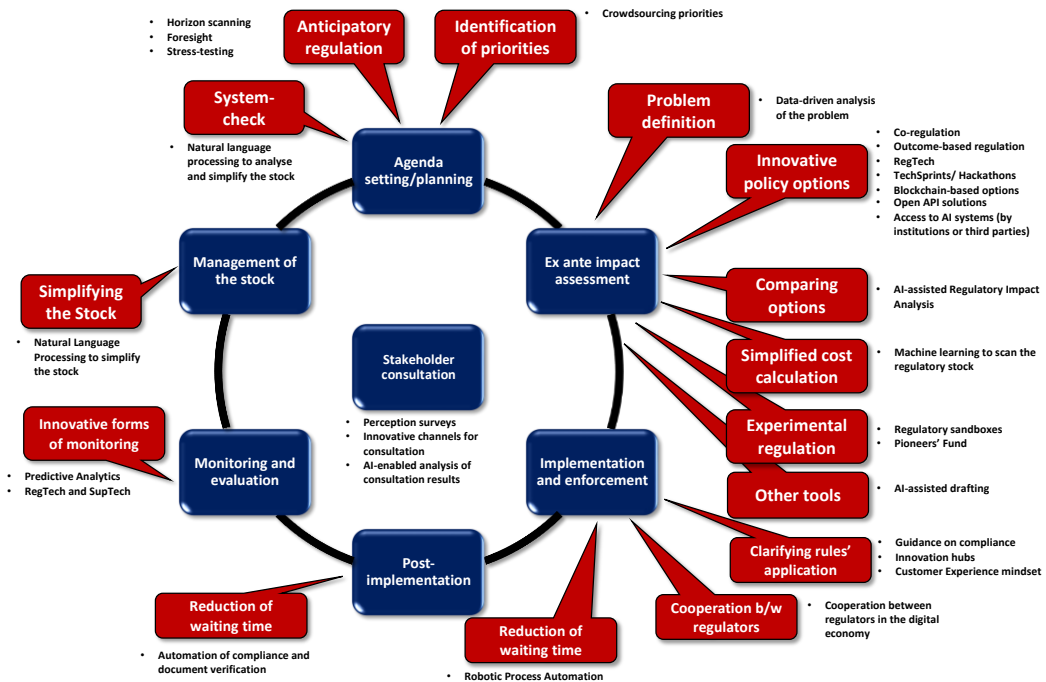


Figure 5 – New regulatory tools in the policy cycle (Source: Renda 2025, simplified)

## 1.6. Consideration of research and innovation impacts in impact assessments

Impacts on research and innovation are very often explicitly measured or considered in European Commission impact assessments. This, of course, does not mean that the assessment was conducted in partial or full respect of the guidance offered by Tool #22, but it helps establish the broader context in which such application could have occurred. Based on our data analysis, as many as **40 out of 219 IAs (18%) explicitly assess research and innovation impacts**. This is broadly comparable to the findings of the Regulatory Scrutiny Board Annual Reports as shown in Figure 1. It represents a decrease compared to the pre-2020 period, where up to around 35% of impact assessments examined by the Regulatory Scrutiny Board analysed impacts on innovation<sup>65</sup>.

More specifically, some form of assessment of research and innovation impacts was found in IAs carried out by several DGs, including the following cases.

<sup>65</sup> See for example Figure 13 in the 2018 Regulatory Scrutiny Board Report, [https://commission.europa.eu/document/download/58d24ca0-1c44-48ea-8111-13137f714c90\\_en?filename=rsb\\_report\\_2018\\_en.pdf](https://commission.europa.eu/document/download/58d24ca0-1c44-48ea-8111-13137f714c90_en?filename=rsb_report_2018_en.pdf).

## 1.6.1. DG CLIMA

**The IA on strengthening the CO<sub>2</sub> emission performance standards for new heavy-duty vehicles and integrating reporting obligations**<sup>66</sup> treats R&I mainly as an induced effect of stronger regulation, rather than as a separate policy objective. Stricter CO<sub>2</sub> standards for heavy-duty vehicles are presented as a technology-forcing signal that increases regulatory certainty and stimulates private R&D in zero-emission technologies, such as battery-electric and hydrogen drivetrains, energy-efficient trailers and related components. Innovation impacts are discussed primarily under competitiveness and industrial leadership, with the assumption that binding targets will channel investment into clean technologies and strengthen the EU's position in global markets. The IA does not quantify R&D spending or innovation outputs, but models innovation indirectly through market uptake and deployment scenarios. SMEs and smaller manufacturers are acknowledged as important innovation actors, but risks to them are addressed mainly through exemptions and flexibilities rather than targeted innovation measures. Innovation funding instruments (e.g. Innovation Fund, Horizon Europe) are mentioned only as contextual support, not as part of the regulatory design. The Regulatory Scrutiny did not dispute the role of regulation in driving innovation but questioned the realism of the underlying assumptions<sup>(66)</sup>. It highlighted insufficient analysis of risks linked to technology readiness, infrastructure availability and green electricity supply, which could delay innovation translating into market deployment. The RSB therefore called for better treatment of uncertainty and constraints, rather than additional innovation incentives as such.

**The IA on fluorinated greenhouse gases**<sup>67</sup> treats R&I mainly as a market-driven response to regulatory tightening, rather than as a separate policy objective. Innovation effects are discussed under macroeconomic impacts and competitiveness, with the IA expecting increased R&D activity and investment in alternative technologies and equipment manufacturing, particularly within the EU. Innovation impacts are not directly quantified. Instead, they are inferred from expected technology substitution, increased deployment of existing low-GWP alternatives, and strengthened industrial leadership. The IA emphasises that suitable alternatives already exist for most applications and frames innovation primarily as diffusion, incremental improvement and scaling, rather than as breakthrough research. Complementary R&I funding or support instruments are not analysed as part of the regulatory design, and risks for SMEs are addressed mainly through transitional measures and exemptions rather than innovation-specific tools. The Regulatory Scrutiny Board did not challenge the assumption that regulation can stimulate innovation, but it criticised unclear baselines, insufficient treatment of assumptions and feasibility, and limited discussion of trade-offs, which also weakens the credibility of claimed innovation and competitiveness benefits.

Finally, the **IA on the adaptation strategy**<sup>68</sup> treats R&I as a core enabling condition for effective climate adaptation, rather than as an indirect side effect of regulation. Innovation impacts are discussed primarily in terms of applied, solution-oriented innovation rather than frontier

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<sup>66</sup> Commission Staff Working Document Impact Assessment Part 1 Accompanying the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2019/1242 as regards strengthening the CO<sub>2</sub> emission performance standards for new heavy-duty vehicles and integrating reporting obligations, and repealing Regulation (EU) 2018/956. SWD (2023) 88. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023SC0088&qid=1772039712654>.

<sup>67</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014. SWD(2022)96. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022SC0096&qid=1772040043062>.

<sup>68</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions: Forging a climate-resilient Europe - The new EU Strategy on Adaptation to Climate Change. SWD (2021)25. <https://eur-lex.europa.eu/search.html?scope=EURLEX&text=SWD%282021%2925&lang=en&type=quick&qid=1772040180970>.

research. The IA emphasises innovation in areas such as climate services, risk assessment tools, nature-based solutions, resilient infrastructure design and water management. These impacts are not quantified as R&D outputs, but are embedded across multiple actions, including improved data systems (Climate-ADAPT), standardisation, climate proofing, and the Horizon Europe Mission on Adaptation, which is explicitly referenced as a vehicle for deploying and scaling innovative adaptation solutions. The Regulatory Scrutiny Board noted *i.a.* that the baseline was unclear regarding which existing R&I initiatives (such as Horizon Europe and other funding programmes) are already assumed, and that this weakens the credibility of claimed impacts, including innovation-related benefits. The RSB also highlighted uncertainty about implementation and uptake, which affects how effectively research and innovation would translate into real-world resilience outcomes.

### 1.6.2. DG CNECT

**The IA on setting up Agora EU for the 202-2034 period**<sup>69</sup> treats research and innovation as both a policy objective and an operational lever, particularly in education, skills, media, culture and civil society. Innovation is framed broadly to include pedagogical, social, cultural, digital and organisational innovation, rather than frontier R&D. EU funding is presented as enabling transnational cooperation that allows actors to test, transfer and scale innovative practices—for example through European Universities alliances, Centres of Vocational Excellence, innovative media business models, digital cultural tools, and new forms of civic participation. Innovation impacts are not quantified in terms of R&D spending or outputs, but are embedded across objectives, notably in addressing skills gaps, technological change (including AI), media viability, digital transformation of cultural and civic sectors, and reducing technological dependence on non-EU actors. The IA explicitly recognises underinvestment and market failures affecting innovation in media and cultural sectors and positions EU funding as a way to de-risk experimentation, build capacity and crowd in private investment, including through blended instruments. The Regulatory Scrutiny Board noted that innovation-related impacts are asserted without sufficiently clear baselines, SMART objectives, or evidence on magnitude, and that the relationship with other EU innovation instruments (notably Horizon Europe and Digital Europe) is insufficiently explained. This weakens the credibility of claimed innovation benefits and their contribution to policy outcomes. The RSB therefore called for clearer scope definition, stronger intervention logic and improved monitoring arrangements.

**The IA on horizontal cybersecurity requirements for products with digital elements**<sup>70</sup> argues that the Regulation will correct market failures and realign incentives, pushing manufacturers to invest more systematically in secure-by-design and secure-by-default development practices. Innovation is therefore framed largely as process and organisational innovation—notably improvements in secure development life cycles, vulnerability handling, software maintenance and update practices—rather than as frontier technological research. Innovation impacts are not quantified, and the analysis focuses more on compliance costs and risk reduction than on dynamic innovation outcomes. Potential negative effects on innovation—especially for SMEs and open-source developers—are acknowledged but addressed mainly through proportionality, risk-based requirements and reliance on harmonised standards, rather than through dedicated innovation support measures. The Regulatory Scrutiny Board issued a

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<sup>69</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council establishing the 'AgoraEU' programme for the period 2028-2034, and repealing Regulations (EU) 2021/692 and (EU) 2021/818 and Proposal for a Regulation of the European Parliament and of the Council establishing the Erasmus+ programme for the period 2028-2034, and repealing Regulations (EU) 2021/817 and (EU) 2021/888. SWD(2025)550. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52025SC0550&qid=1772040278863>.

<sup>70</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council on horizontal cybersecurity requirements for products with digital elements and amending Regulation (EU) 2019/1020. SWD(2022)282. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022SC0282&qid=1772040432717>.

positive opinion with reservations, without challenging the general innovation logic of the proposal. However, it implicitly cautioned that excessive or poorly calibrated requirements could affect market entry and innovation incentives, calling for clearer evidence, better differentiation by risk, and improved explanation of impacts.

**The IA on the AI Act**<sup>71</sup> addresses R&I as a key policy objective. Innovation is framed as central to the EU's ambition to build an “ecosystem of excellence and trust” for AI, where regulatory intervention should enable investment, uptake and innovation while addressing safety and fundamental rights risks. Innovation impacts are discussed mainly under competitiveness, investment certainty and market uptake, rather than through quantified R&D indicators. The IA assumes that a risk-based framework—limiting mandatory requirements to high-risk AI systems and prohibiting only a narrow set of practices—will preserve space for experimentation and innovation in low- and medium-risk applications. Regulatory sandboxes, harmonised standards and conformity assessment mechanisms are presented as innovation-enabling tools, particularly for SMEs, by reducing legal uncertainty, compliance learning costs and time to market (see Section 3.6 below). The Regulatory Scrutiny Board does not challenge the importance of innovation but repeatedly questioned whether the IA sufficiently demonstrated that regulatory costs would not deter innovation, especially for SMEs and new entrants. In its first (negative) opinion, the RSB highlighted insufficient clarity on costs, feasibility and the risk that high fixed compliance costs could act as barriers to innovation<sup>72</sup>. In its second (positive) opinion, the Board acknowledged improvements, while still flagging residual uncertainty around costs and their interaction with innovation-support measures such as regulatory sandboxes and reduced fees<sup>73</sup>.

**The IA on the Digital Markets Act**<sup>74</sup> includes innovation as a central policy objective, framing weak contestability and unfair gatekeeper practices as structural barriers that suppress innovation, market entry and scale-up, particularly for SMEs and start-ups. The DMA is explicitly justified as a means to restore competitive conditions that incentivise innovation, shifting firms' strategies away from rent-seeking, data hoarding and mergers towards product development, service quality and R&D investment. Innovation is thus conceived mainly as a dynamic market outcome of fairer competition, rather than as a direct target of regulatory intervention. Innovation impacts are discussed under competition, growth and productivity, and—unusually for an IA—are partly quantified. The IA uses economic modelling to estimate that increased market contestability would redirect significant resources from mergers and acquisitions to R&D, generating substantial long-term gains in innovation, entrepreneurship and consumer choice. However, these estimates rely on indirect assumptions about investment behaviour and spillovers, and do not distinguish between types of innovation (incremental vs. breakthrough) or sectoral effects within the digital economy. The Regulatory Scrutiny Board does not dispute the link between contestability and innovation, but questions the robustness of the underlying evidence and causal chains.

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<sup>71</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence and amending certain Union legislative acts. SWD (2021) 84. [EUR-Lex - 52021SC0084 - EN - EUR-Lex](#)

<sup>72</sup> Opinion of the Regulatory Scrutiny Board 1 SEC(2021)167. [Register of Commission Documents - SEC\(2021\)167](#).

<sup>73</sup> Opinion of the Regulatory Scrutiny Board 2 SEC(2021)167. [Register of Commission Documents - SEC\(2021\)167](#).

<sup>74</sup> Commission Staff Working Document Impact Assessment Report Accompanying the [Mandatory element] Digital Markets Act. SWD(2020)203. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020SC0203&qid=1772040623148>.

### 1.6.3. DG COMP

The IA on the revision of the Horizontal Block Exemption Regulations and Horizontal Guidelines<sup>75</sup> treats research and innovation as both a core justification and a sensitive risk area for competition policy. It frames R&D cooperation and specialisation agreements as generally innovation-enhancing, particularly for SMEs, by allowing firms to pool complementary assets, share risks, and undertake projects they could not pursue individually. The IA emphasises that clear and predictable competition rules are essential to enable pro-competitive R&D cooperation, reduce legal uncertainty, and avoid innovation delays or abandoned projects, especially for SMEs and research-intensive sectors. At the same time, the IA highlights the need to protect “innovation competition”, particularly in cases of R&D agreements concerning new products or undefined innovation spaces where market shares cannot be calculated *ex ante*. Innovation impacts are therefore discussed in a balancing framework: the preferred options aim to facilitate legitimate R&D cooperation while tightening scrutiny where cooperation could eliminate parallel innovation paths. Innovation benefits are not quantified directly, but are inferred through improved legal certainty, continued incentives to invest in R&D, and better alignment between antitrust and merger control approaches. The Regulatory Scrutiny Board argued that the first version of the IA did not convincingly demonstrate that current rules would insufficiently protect innovation competition, nor that SMEs would engage in harmful pre-market cooperation.

At DG COMP, also the IA on the regulation on foreign subsidies distorting the internal market<sup>76</sup> addressed research and innovation impacts by treating them as indirect but strategically important outcomes of restoring a level playing field in the internal market. Innovation is framed as being harmed by distortive foreign subsidies, which can crowd out more efficient and innovative EU firms, skew investment decisions, and facilitate subsidised acquisitions that transfer or concentrate advanced technologies without competition on merit. The IA argues that by addressing these distortions, the proposed instrument would preserve incentives for innovation, technology upgrading and efficient investment, particularly in capital- and R&D-intensive sectors such as semiconductors, steel, rail and advanced manufacturing. Innovation impacts are not analysed as a standalone category and are not quantified. Instead, they appear under broader headings such as competition, productivity and long-term growth. The IA assumes that reducing unfair subsidisation will foster dynamic competition, allowing innovative firms to scale through acquisitions and public procurement based on performance rather than state-backed financial strength. Potential short-term effects—such as reduced foreign investment or higher procurement prices—are acknowledged, but the IA emphasises that long-term innovation capacity and technological autonomy would benefit from more contestable markets.

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<sup>75</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Communication from the Commission - Approval of the content of a draft for a Communication from the Commission – Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements Commission Regulation (EU) .../... of XXX on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of research and development agreements Commission Regulation (EU) .../... of XXX on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of specialisation agreements. SWD(2023)0167. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023SC0167&qid=1772040723222>.

<sup>76</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council on foreign subsidies distorting the internal market. SWD(2021)99. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021SC0099&qid=1772040837190>.

#### 1.6.4. DG DEFIS

At DG DEFIS, innovation has been a salient feature of impact assessment work in support of new legislative initiatives. For example, the **IA on EU Space Law**<sup>77</sup> frames innovation impacts mainly in terms of industrial, technological and business-model innovation driven by the emergence of “New Space” actors and the rapid growth of commercial space activities. The IA argues that a clear and harmonised EU framework on safety, resilience and sustainability would reduce legal fragmentation and uncertainty, thereby encouraging private investment, supporting scale-up, and enabling innovative space technologies and services to move more quickly from development to deployment. Innovation impacts are discussed primarily under competitiveness and market development, not through quantified R&D indicators. The IA emphasises innovation in areas such as space safety technologies (e.g. collision avoidance, space situational awareness), cybersecurity solutions, environmental footprint methodologies (PEFCR for space activities), green propulsion, and new space services. Innovation is conceived largely as applied and incremental, responding to regulatory requirements and market demand rather than frontier research. The IA also highlights that regulatory clarity could unlock significant private investment in start-ups and SMEs, which are portrayed as key sources of innovation in the EU space ecosystem. The Regulatory Scrutiny Board opinion criticised the IA for insufficient substantiation of competitiveness and innovation claims, calling for a clearer analysis of impacts on innovative business models, proportionality for smaller actors, and international competitiveness, indicating concern that poorly calibrated rules could unintentionally constrain innovation rather than enable it<sup>78</sup>.

#### 1.6.5. DG EMPL

**The IA on the protection of workers from the risks related to exposure to carcinogens or mutagens at work**<sup>79</sup> addresses innovation explicitly. For each substance there is an analysis on the innovation capacity and impact on research and development with the most affected sectors identified (see pages 40, 49, 56, 59, 7, 183). The possible impacts on R&D are quantified. The IA assesses the impacts on the Directive’s main objective (health and safety of workers) as well as all other relevant impacts, including innovation. Besides, all impacts, including impacts on innovation, are taken into account when comparing the options. The requirement to assess spillovers and impact on new product development might not be proportional given the scope of the initiative and estimated negligible impact on innovation for most sectors.

#### 1.6.6. DG ENER

In the **IA on the revision of Ecodesign requirements for external power supplies**<sup>80</sup>, innovation impacts are not analysed separately or quantified. Instead, they are embedded in

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<sup>77</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council on the safety, resilience and sustainability of space activities in the Union. SWD(2025)335. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52025SC0033&qid=1772040898618>.

<sup>78</sup> Opinion of the Regulatory Scrutiny Board SEC(2025)335. [Register of Commission Documents - SEC\(2025\)335](#).

<sup>79</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. SWD(2020)183. <https://eur-lex.europa.eu/search.html?scope=EURLEX&text=SWD%282020%29183&lang=en&type=quick&qid=1772040968547>.

<sup>80</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Commission Regulation laying down ecodesign requirements for external power supplies, wireless chargers, wireless charging pads, battery chargers for portable batteries of general use and USB Type-C cables, pursuant to Directive 2009/125/EC of the European Parliament and of the Council and repealing Commission Regulation (EU)

assumptions about manufacturers' ability to comply through product redesign, component substitution and process optimisation. The IA presents the regulation as largely technology-neutral and innovation-following, accelerating the diffusion of existing best available technologies and harmonised standards rather than inducing new research efforts. Any positive innovation effects are implicit, such as increased demand for efficient power electronics, interoperable designs and durability-enhancing components, while potential risks of reduced product differentiation are acknowledged only indirectly. The Regulatory Scrutiny Board explicitly flagged insufficient analysis of impacts on competitiveness and innovation, in particular criticising the IA for not adequately examining how stricter and more harmonised requirements could affect firms' incentives to innovate, product differentiation, and the competitive position of EU manufacturers relative to third-country producers. The RSB therefore called for a clearer discussion of innovation trade-offs, including whether regulatory harmonisation could both stimulate efficiency-related innovation while constraining diversity and experimentation in product design<sup>81</sup>.

### 1.6.7. DG ENV

At least three IAs led by DG ENV analysed impacts on research and innovation. For example, the **IA on the revision of the End-of-Life Vehicles and 3R Type-Approval Directives – circularity requirements for vehicles**<sup>82</sup> argues that clearer and more stringent EU-level rules on design for dismantling, recycled content, information provision and treatment standards will steer innovation towards circular vehicle architectures, improved material recovery technologies (including for critical raw materials), and better integration of circularity into product development cycles. Eventually, innovation impacts are not quantified as R&D outputs and are discussed mainly under competitiveness, resilience and long-term efficiency of the automotive and recycling sectors. The IA emphasises incremental and diffusion-oriented innovation—such as improved dismantling techniques, post-shredder technologies, digital circularity passports and material tracking systems—rather than breakthrough research. Existing EU research programmes (Horizon, LIFE, JRC work) are referenced as background evidence and support, but innovation support is not embedded as a regulatory instrument within the preferred option. The RSB did not question the relevance of innovation considerations but criticised the IA for weak substantiation of competitiveness and dynamic effects<sup>83</sup>.

In the **IA on the revision of the Industrial Emissions Directive and the E-PRTR Regulation**<sup>84</sup>, research and innovation is treated as an explicit but supporting policy dimension, rather than as a primary objective. Innovation is framed mainly as applied, process- and technology-oriented innovation that enables industrial installations to comply more effectively with stricter environmental, resource-efficiency and decarbonisation requirements. The IA

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2019/1782. SWD(2025)288. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52025SC0288&qid=1772041017426>.

<sup>81</sup> Opinion from the Regulatory Scrutiny Board has not yet been published. Link with instructions to request the document - [Register of Commission Documents - SEC\(2025\)264](#)

<sup>82</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council on circularity requirements for vehicle design and on management of end-of-life vehicles, amending Regulations (EU) 2018/858 and 2019/1020 and repealing Directives 2000/53/EC and 2005/64/EC. SWD(2023)256. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023SC0256&qid=1772041112364>.

<sup>83</sup> Opinion of the Regulatory Scrutiny Board SEC(2023)292. [Register of Commission Documents - SEC\(2023\)292](#).

<sup>84</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Directive of the European Parliament and of the Council amending Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) and Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste and Proposal for a Regulation of the European Parliament and of the Council on reporting of environmental data from industrial installations and establishing an Industrial Emissions Portal. SWD(2022)111. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022SC0111&qid=1772041234643>.

identifies insufficient promotion of innovation under the current IED as a problem, arguing that the existing focus on compliance with Best Available Techniques (BAT) has sometimes led to lock-in rather than continuous technological upgrading. The proposed measures therefore seek to accelerate innovation diffusion, particularly through stronger BAT conclusions, performance-based environmental benchmarks (BAT-AEPLs), improved permitting, and enhanced transparency and reporting. Innovation impacts are discussed systematically but qualitatively. The IA emphasises incremental and deployment-oriented innovation in areas such as energy efficiency, low-carbon processes, pollution prevention technologies, digital monitoring, and data management. Innovation is expected to arise mainly through regulatory pull, encouraging operators to adopt and further develop available techniques rather than through frontier R&D. Dedicated “innovation” policy options are assessed, but the preferred package integrates innovation elements across effectiveness, circular economy and decarbonisation measures, rather than relying on stand-alone innovation instruments. The Regulatory Scrutiny Board recognised the relevance of innovation considerations but criticised the IA for weak substantiation of competitiveness and dynamic effects, which directly affects the credibility of innovation claims. The RSB questioned whether the first IA report adequately demonstrated that the proposed measures will stimulate innovation rather than merely increase compliance costs, especially for newly covered sectors and SMEs; hence it called for clearer evidence on how innovation-related benefits compare to costs and how regulatory ambition avoids discouraging investment or relocation, signalling concern that innovation effects may be overstated without stronger empirical support<sup>85</sup>.

The **IA on Ecodesign for Sustainable Products Regulation**<sup>86</sup>, argues that extending ecodesign beyond energy-related products and introducing durability, reparability, recyclability, recycled content and footprint requirements will steer innovation in product design, materials, production processes and business models, accelerating the diffusion of best and “best-not-yet-available” technologies across value chains. Innovation impacts are discussed qualitatively and across multiple policy options, yet not quantified as R&D outputs. The IA emphasises incremental and cumulative innovation—such as modular design, material substitution, circular business models, digital product passports and improved life-cycle assessment tools—rather than breakthrough research. Existing EU research and innovation programmes (Horizon Europe, EIT, JRC work) are treated as background enablers, while the ESPR itself is positioned as a horizontal framework that creates predictable demand for sustainable innovation through harmonised minimum requirements and standardisation. The RSB observed a weak substantiation of dynamic and competitiveness effects, and called for a clearer intervention logic<sup>87</sup>.

### 1.6.8. DG FISMA

In the **IA on the Listing Act – review of EU listing rules to improve access to public capital markets**<sup>88</sup>, research and innovation is indirectly treated but considered to be a strategically

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<sup>85</sup> Opinion of the Regulatory Scrutiny Board SEC(2022)169. [Register of Commission Documents - SEC\(2022\)169](#)

<sup>86</sup> Commission Staff Working Document Impact Assessment Accompanying the Proposal for a Regulation of the European Parliament and of the Council establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC. SWD(2022)82. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022SC0082&qid=1772041313880>.

<sup>87</sup> Opinion of the Regulatory Scrutiny Board SEC(2022)165. [Register of Commission Documents - SEC\(2022\)165](#).

<sup>88</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Directive of the European Parliament and of the Council amending Directive 2014/65/EU to make public capital markets in the Union more attractive for companies and to facilitate access to capital for small and medium-sized enterprises and repealing Directive 2001/34/EC Proposal for a Directive of the European Parliament and of the Council on multiple-vote share structures in companies that seek the admission to trading of their shares on an SME growth market Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/1129, (EU) No 596/2014 and (EU) No 600/2014 to make public capital markets in the

important outcome of more attractive and accessible public capital markets. Innovation is framed mainly in terms of firm growth, scale-up and long-term investment capacity, particularly for SMEs and high-growth companies. The IA argues that excessive regulatory burdens, legal uncertainty and limited flexibility in governance structures discourage companies—especially innovative and technology-driven firms—from listing in the EU, thereby constraining their ability to finance R&D, expand operations and commercialise innovation. Simplifying listing, prospectus and disclosure requirements is therefore presented as a way to unlock financing for innovative business models, rather than as a direct innovation policy. Innovation impacts are not analysed as a standalone category nor quantified as R&D outputs. Instead, they are embedded in assumptions about increased IPO activity, improved access to equity financing, and faster growth of listed companies. Innovation is thus treated as a downstream effect of improved market functioning and investment incentives. The RSB highlighted weak substantiation of causal links between regulatory simplification, increased listings and broader economic outcomes such as growth and innovation.

**The IA on the Basel III banking package<sup>89</sup> treats R&I** as indirect, second-order effects of a more resilient and stable banking system, rather than as policy objectives in their own right. Innovation is framed mainly in terms of financial intermediation capacity and long-term investment support, with the assumption that well-capitalised, trusted banks are better able to finance innovative firms, new technologies and the green and digital transitions. The IA therefore links innovation primarily to macro-financial stability and lending conditions, not to banks' own R&D activity or technological innovation. Innovation impacts are not analysed explicitly or quantified. They appear indirectly under sections on competitiveness, SME financing and sustainable finance, where the IA argues that smoother credit provision over the economic cycle will help innovative and growth-oriented firms avoid credit constraints. The introduction of ESG risk integration is discussed mainly as a risk-management and information issue, with any innovation effects (e.g. development of new data, models or analytical tools) treated as ancillary and compliance-driven rather than innovation-stimulating.

### 1.6.9. DG GROW

Not surprisingly, innovation is present and salient in many IAs completed by DG GROW: Below, we briefly describe some of the most representative examples.

**The IA on the Single Market and Customs Programme 2028–2034<sup>90</sup>** treats research and innovation as indirect, enabling outcomes of improved governance, cooperation and digital capacity in the Single Market and Customs Union, rather than as explicit policy objectives. Innovation impacts are not analysed separately or quantified. Instead, they are embedded in assumptions about improved market functioning, enhanced cooperation between national authorities, and stronger digital infrastructures in areas such as customs, taxation, market surveillance, competition, statistics and anti-fraud. The programme is positioned as a horizontal enabler of innovation, supporting evidence-based policymaking, regulatory enforcement and

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Union more attractive for companies and to facilitate access to capital for small and medium-sized enterprises. SWD(2022) 762. [EUR-Lex - 52022SC0762 - EN - EUR-Lex](#)

<sup>89</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 575/2013 on prudential requirements for credit institutions as regards requirements for credit risk, credit valuation adjustment risk, operational risk, market risk and the output floor Proposal for a Directive of the European Parliament and of the Council amending Directive 2013/36/EU as regards supervisory powers, sanctions, third-country branches, and environmental, social and governance risks, and amending Directive 2014/59/EU. SWD(2021)320. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021SC0320&qid=1772041692018>.

<sup>90</sup> Commission Staff Working Document Impact Assessment Report on the Single Market and Customs Programme Accompanying the Proposal for a Regulation of the European Parliament and of the Council establishing the Single Market and Customs Programme for the period 2028-2034 and repealing Regulations (EU)2021/444, (EU)2021/690, (EU)2021/785, (EU)2021/847 and (EU) 2021/1077. SWD(2025)592. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52025SC0592&qid=1772041750379>.

trust in the Single Market, while leaving direct R&D support to other instruments (e.g. Horizon Europe, Competitiveness Fund). Innovation is thus understood mainly as system-level and diffusion-oriented, rather than technology-pushing.

**The IA on the European Competitiveness Fund<sup>91</sup>** treats R&I as a central policy rationale but primarily through a systemic and financial lens, rather than through individual R&D instruments. Innovation is framed as the main driver of EU competitiveness gaps vis-à-vis the US and China, with underinvestment, fragmentation and weak scale-up support identified as core problems. Innovation impacts are not quantified in terms of R&D outputs but are analysed through expected improvements in funding continuity, scale, leverage and coordination. The IA emphasises system-level innovation effects, such as better translation of research results into marketable products, stronger support for strategic technologies, enhanced risk-sharing with private investors, and improved conditions for high-growth innovative companies. Horizon Europe, the EIC, IPCEIs and other innovation programmes are treated as core building blocks of the ECF architecture, but the IA focuses more on simplification, governance and financial design than on the substance of innovation activities themselves. Notably, the RSB was highly critical of the innovation analysis in the first version of the IA; it found that the IA did not sufficiently define competitiveness, failed to establish a clear and evidence-based intervention logic linking public funding to innovation outcomes, and inadequately demonstrated market failures justifying intervention at different stages of the innovation cycle<sup>92</sup>.

**IA on the revision of the Toy Safety Directive<sup>93</sup>, converting it into a Regulation**, frames innovation mainly as scientific, technical and compliance-related progress that allows toy safety regulation to be updated in line with new risks. Innovation impacts are therefore not analysed separately or quantified. Digital innovation appears mainly through the proposed Digital Product Passport, which is framed as an enforcement and information tool that may indirectly encourage better compliance processes and supply-chain transparency, rather than as a driver of product or technological innovation. Any dynamic innovation effects are clearly subordinated to health, safety and market surveillance objectives.

**The IA on the revision of the Supplementary Protection Certificate framework<sup>94</sup>** takes R&I as a core justification for the SPC system, framing innovation primarily through investment

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<sup>91</sup> Commission Staff Working Document Impact Assessment Report on the European Competitiveness Fund Accompanying the Proposal for a Regulation of the European Parliament and of the Council on establishing the European Competitiveness Fund ('ECF'), including the specific programme for defence research and innovation activities, repealing Regulations (EU) 2021/522, (EU) 2021/694, (EU) 2021/697, (EU) 2021/783, repealing provisions of Regulations (EU) 2021/696, (EU) 2023/588, and amending Regulation (EU) [EDIP] Proposal for a Regulation of the European Parliament and of the Council establishing Horizon Europe, the Framework Programme for Research and Innovation, for the period 2028-2034 laying down its rules for participation and dissemination, and repealing Regulation (EU) 2021/695 Proposal for a Council Decision on establishing the Specific Programme implementing Horizon Europe - the Framework Programme for Research and Innovation for the period 2028-2034, laying down the rules for participation and dissemination under that Programme, and repealing Decision (EU) 2021/764. SWD(2025)555. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52025SC0555&qid=1772041800270>.

<sup>92</sup> Opinion of the Regulatory Scrutiny Board SEC(2025)555. [Register of Commission Documents - SEC\(2025\)555](https://eur-lex.europa.eu/legislation/SEC(2025)555).

<sup>93</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC. SWD(2023)269. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023SC0269&qid=1772041895163>.

<sup>94</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast) and Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast) and Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013 and Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products. SWD(2023)118. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023SC0118&qid=1772041951071>.

incentives and legal certainty, rather than through direct R&D stimulation. Innovation impacts are discussed explicitly but mainly in qualitative and financial terms. The IA does not measure innovation outputs (such as R&D spending, pipelines or new products), but assumes that improving SPC efficiency, transparency and territorial coverage—especially through a unitary SPC—will increase expected returns on innovation and thereby support higher investment in novel medicines and plant protection products. Innovation is thus treated as investment-driven and IP-dependent, with benefits flowing from reduced red tape, lower legal costs and greater predictability, rather than from changes to the substance of innovation activity itself. The RSB repeatedly challenged the credibility and substantiation of innovation claims in this IA. The Board also questions whether the initiative's innovation rationale is sufficiently coherent with parallel reforms of pharmaceutical legislation that affect exclusivity periods. Overall, the RSB accepts innovation as a legitimate objective of the SPC framework but considers that the expected innovation impacts are plausible yet insufficiently demonstrated and require clearer intervention logic and monitoring indicators<sup>95</sup>.

As could be expected, the **IA on the Regulation on Standard Essential Patents**<sup>96</sup> treats research and innovation as a core justification for action, but frames innovation primarily through investment incentives, participation in standardisation and technology diffusion, rather than through direct R&D outputs. The IA argues that uncertainty, high transaction costs and litigation risks in SEP licensing undermine incentives to invest in standard-setting R&D, weaken EU firms' participation in global standardisation, and discourage SMEs and new entrants from implementing standardised technologies. Innovation impacts are discussed explicitly but mainly qualitatively and indirectly. The IA does not measure innovation outputs: innovation is thus treated as IP- and standards-driven, with benefits flowing from lower uncertainty, reduced negotiation costs and more predictable licensing outcomes, especially for SMEs and firms in emerging IoT markets. The RSB issued a positive opinion<sup>97</sup>, broadly accepting the innovation rationale, but raises concerns that indirectly qualify innovation claims. The RSB notes that the IA does not sufficiently set out how SME-supporting measures interact or their combined impact, and that links with parallel IP initiatives (notably SPC reform and compulsory licensing) are not fully reflected in the baseline. While the Board does not contest that improved SEP governance can support innovation and competitiveness, it signals that the magnitude and distribution of innovation benefits remain uncertain and require clearer articulation and monitoring.

**The IA on the revision of the Product Liability Directive**<sup>98</sup> argues that outdated liability concepts create uncertainty for innovative producers—particularly in software-intensive and circular business models—which may discourage the placing of innovative products on the market and slow adoption by consumers. Clearer and more future-proof liability rules are therefore presented as a supporting condition for innovation, rather than a direct stimulus to R&D. Innovation impacts are discussed qualitatively and defensively. The IA assumes that adapting liability rules to software, AI-enabled products and refurbished goods will improve legal certainty, ensure a level playing field and strengthen consumer trust, thereby facilitating innovation-friendly market conditions. At the same time, it stresses that the preferred option seeks to avoid overburdening innovators, especially SMEs and start-ups, by maintaining proportionality and relying largely on existing insurance mechanisms.

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<sup>95</sup> Opinion of the Regulatory Scrutiny Board SEC(2023)172. [Register of Commission Documents - SEC\(2023\)172](#).

<sup>96</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council on standard essential patents and amending Regulation (EU) 2017/1001. SWD(2023)124. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023SC0124&qid=1772042034363>.

<sup>97</sup> Opinion of the Regulatory Scrutiny Board SEC(2023)174. [Register of Commission Documents - SEC\(2023\)174](#).

<sup>98</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Directive of the European Parliament and of the Council on liability for defective products. SWD (2022)316. [EUR-Lex - 52022SC0316 - EN - EUR-Lex](#)

**The IA on EU geographical indication protection for craft and industrial products**<sup>99</sup>. Innovation impacts are discussed qualitatively and as part of broader economic and regional development effects. The IA assumes that EU-wide GI protection will strengthen incentives for producers—mostly SMEs and micro-enterprises—to invest in product quality, design, process improvements and marketing innovation by improving legal certainty, preventing free-riding and enabling price premiums. The RSB called for stronger analysis of innovation impacts, arguing that the draft IA insufficiently substantiated these effects and for weak comparison of options in terms of costs and benefits<sup>100</sup>.

Finally, the **IA on the “common charger”**<sup>101</sup> recognises the risk that regulatory intervention could hamper innovation if it locks in specific technologies too early. For this reason, innovation is addressed through the design of the intervention: by focusing on interoperability, performance requirements and information obligations rather than on regulating chargers themselves, the initiative seeks to reduce fragmentation while remaining technology-neutral and future-proof. In terms of impact appraisal, innovation impacts are not quantified or analysed as R&D outcomes. Instead, the IA assumes that most innovation in charging technologies has already occurred or is ongoing at global level, and that EU action will mainly steer diffusion and standardisation, rather than induce new research. Innovation is therefore treated as market-driven and standards-based, with regulation acting as a coordinating force to avoid inefficient divergence (e.g. proprietary connectors or protocols) while allowing continued development of faster or wireless charging solutions within common frameworks. The IA repeatedly stresses the need to avoid freezing innovation paths, especially in relation to fast charging and wireless technologies. The RSB explicitly criticised the IA for insufficient analysis of competition and innovation impacts. The Board called for clearer explanation of how innovation will be safeguarded over time, including how standards will be updated and how risks of constraining proprietary or emerging solutions are mitigated<sup>102</sup>.

## 1.6.10. DG HOME

The impact assessment IA29 on the establishment of the EU Talent Pool XXX<sup>103</sup> treats research and innovation as indirect but strategically important outcomes of addressing labour and skills shortages in the EU. Innovation is framed mainly in terms of the availability of human capital needed to sustain productivity, competitiveness and innovation across the economy, especially in sectors critical for the green and digital transitions. The IA repeatedly links unresolved skills shortages to risks for growth, productivity and innovation capacity, arguing that improving international recruitment through the EU Talent Pool would help firms—particularly SMEs—access skills they cannot find domestically and thereby avoid innovation bottlenecks and foregone investment. Innovation impacts are not analysed as a standalone category and are not quantified.

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<sup>99</sup> Commission Staff Working Document Impact Assessment Report on geographical indication protection for craft and industrial products Accompanying the Proposal for a Regulation of the European Parliament and of the Council on geographical indication protection for craft and industrial products and amending Regulations (EU) 2017/1001 and (EU) 2019/1753 of the European Parliament and of the Council and Council Decision (EU) 2019/1754. SWD(2022)115. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022SC0115&qid=1772054312618>.

<sup>100</sup> Opinion of the Regulatory Scrutiny Board, [Register of Commission Documents - SEC\(2022\)193](#)

<sup>101</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Directive of the European Parliament and of the Council amending Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment. SWD(2021)245. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021SC0245&qid=1772054435248>.

<sup>102</sup> Opinion of the Regulatory Scrutiny Board SEC(2021)318. [Register of Commission Documents - SEC\(2021\)318](#)

<sup>103</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and the Council establishing an EU Talent Pool; SWD/2023/717 final. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023SC0717&qid=1772054648099>.

## 1.6.11. DG JUST

**The IA on the Corporate Sustainability Due Diligence Directive**<sup>104</sup> argues that embedding sustainability and human rights considerations into corporate strategy can stimulate innovation in processes, products and business models, for example through cleaner production methods, more sustainable sourcing, traceability tools and risk-management practices. Innovation is thus understood largely as organisational, process and compliance-related, rather than as technological R&D in the narrow sense. The IA explicitly acknowledges risks to innovation, dynamism and agility. The Regulatory Scrutiny Board was particularly critical of the treatment of innovation impacts in the first version of the IA; it stated that the IA did not sufficiently assess impacts on innovation, agility and competitiveness, nor did it convincingly demonstrate that innovation-enhancing effects would outweigh the risks of reduced flexibility, increased litigation and compliance burdens<sup>105</sup>.

## 1.6.12. DG MOVE

At DG MOVE, consideration of innovation in IAs is relatively frequent. Notable examples include IA15 on the revision of the Roadworthiness Package). There, innovation is framed primarily in terms of digitalisation of inland waterway transport, including interoperable data exchange, digital navigation tools, automated reporting, corridor management platforms and the gradual integration of emerging technologies such as smart shipping applications and, in the longer term, automation. The IA argues that the existing RIS framework has failed to keep pace with technological progress, leading to fragmentation, outdated technical specifications and underuse of digital solutions. Revising the Directive is therefore presented as a way to remove regulatory bottlenecks that slow down innovation diffusion, rather than to directly stimulate new R&D

Another partly relevant IA from the standpoint of innovation impacts is **IA149 on the revision of the Intelligent Transport Systems Directive**<sup>106</sup>. There, research and innovation are treated as central enabling drivers, but not as autonomous policy objectives. Innovation is framed primarily in terms of digital, data-driven and systems innovation in transport, notably Intelligent Transport Systems (ITS), Cooperative, Connected and Automated Mobility (CCAM), Mobility as a Service (MaaS) and interoperable digital mobility services. The IA argues that slow, fragmented and uneven deployment of ITS across the EU is holding back the diffusion and scaling of innovations that are already technologically mature or emerging, rather than limiting upstream R&D. EU action is therefore presented as necessary to unlock innovation by improving interoperability, data availability, coordination and standardisation across borders and modes. Innovation impacts are discussed qualitatively and at system level, not measured in terms of R&D expenditure or technological outputs.

Finally, the IA on the **Regulation on the use of renewable and low-carbon fuels in maritime transport**<sup>107</sup> discusses innovation impacts explicitly and relatively prominently, though still

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<sup>104</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Directive of the European Parliament and of the Council on Corporate Sustainability Due Diligence and amending Directive (EU) 2019/1937. SWD(2022)42. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022SC0042&qid=1772054777778>.

<sup>105</sup> Opinion of the Regulatory Scrutiny Board SEC(2022)95. [Register of Commission Documents - SEC\(2022\)95](#).

<sup>106</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Directive of the European Parliament and of the Council amending Directive 2010/40/EU of the European Parliament and of the Council of 7 July 2010 on the framework for the deployment of Intelligent Transport Systems in the field of road transport and for interfaces with other modes of transport. SWD(2021)474. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021SC0474&qid=1772054900842>.

<sup>107</sup> COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the Proposal for a Regulation of the European Parliament and of the Council on the use of renewable and low-carbon fuels in maritime transport. SWD(2021)635. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021SC0635&qid=1772054946292>.

mainly in qualitative and system-level terms. The IA does not measure R&D outputs, but models how demand-side fuel requirements would accelerate learning effects, economies of scale and cost reductions for innovative fuels and propulsion technologies. Innovation is thus treated as deployment-driven and regulation-pulled, with the preferred option expected to result in significant penetration of innovative propulsion solutions by 2050, compared to negligible uptake under the baseline. R&I support via Horizon Europe and partnerships (e.g. Zero-Emission Waterborne Transport) is treated as complementary, while FuelEU Maritime itself focuses on creating lead markets rather than funding R&D. The Regulatory Scrutiny Board acknowledged that FuelEU Maritime can help create lead markets for innovative maritime fuels and technologies, and stresses that technology maturity, cost trajectories and innovation timing remain uncertain, and that innovation effects depend critically on coordination with ETS, RED and state-aid frameworks.

### 1.6.13. DG RTD

Research and innovation is inevitably tackled front and centre in the impact assessments led by DG RTD. In the IA on **Joint Undertakings under Horizon Europe**<sup>108</sup>, R&I impacts are the core performance yardstick for choosing how to organise and implement EU funding (traditional calls vs different partnership forms). The IA is structured around the Horizon Europe “necessity test”: institutionalised partnerships under Articles 185/187 TFEU should be used only if other delivery modes would not achieve the objectives or expected impacts, and only where a long-term perspective and high integration justify the added institutional complexity. In practice, this means R&I impacts are assessed comparatively across options (baseline traditional calls; co-programmed; co-funded; institutionalised), with emphasis on whether a partnership can deliver stronger integration of agendas, stronger commitments/resources, and faster translation from R&I to deployment than ad hoc project consortia. Within the thematic parts, the IA often supports expected R&I impacts with evidence from predecessor initiatives and interim evaluations—e.g. outputs and excellence indicators (high-ranked publications), innovation outputs (patents), and progress/uptake logic (e.g. demonstrators, TRL gains, industrial roll-out). For example, in the digital/semiconductor partnership logic, it cites concrete technological achievements and reports publication quality and patenting as markers of scientific and innovation impact, and frames the successor as building on these achievements while adapting to new technological/geopolitical realities. More broadly, the IA treats R&I impacts as system-level effects (reducing fragmentation, pooling investments, aligning EU/national/industry roadmaps, strengthening SME participation and openness) that are expected to be stronger under more integrated partnership forms than under the baseline of standard calls.

In the IA on the **European Partnership on Metrology**<sup>109</sup>, DG RTD frames metrology as a foundational enabler of scientific excellence, industrial innovation, standardisation and regulation across the EU economy, underpinning sectors such as digital technologies, health, energy, manufacturing and environmental monitoring. Innovation is understood broadly, encompassing upstream research, development of measurement capabilities, support to standard-setting, and downstream uptake in industrial processes and regulatory compliance. The IA argues that fragmentation of national metrology efforts, insufficient coordination and limited critical mass weaken Europe’s capacity to respond to emerging technological needs and global competition, thereby justifying EU-level intervention through a European Partnership. Innovation impacts are assessed comparatively across delivery modes, following the Horizon

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<sup>108</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe EU-Africa Global Health Partnership. SWD(2021)37. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021SC0037&qid=1772055007754>.

<sup>109</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Decision of the European Parliament and of the Council on the participation of the Union in the European Partnership on Metrology jointly undertaken by several Member States. SWD(2021)35. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021SC0035&qid=1772055110710>.

Europe “necessity test”. The IA systematically compares traditional Horizon Europe calls with co-programmed, co-funded and institutionalised partnership options, and concludes that only an institutionalised partnership can deliver the required long-term integration, stable governance and strategic alignment needed for high-impact metrology research. Innovation is framed primarily as systemic and cumulative, relying on coordinated Strategic Research and Innovation Agendas, shared infrastructures, European Metrology Networks and sustained public–public cooperation to translate research into standards, industrial applications and regulatory tools. While innovation outputs such as publications, patents, TRL progression and demonstrators are referenced, the emphasis remains on structuring effects—reducing duplication, pooling investments, aligning national agendas and accelerating uptake across Member States. The RSB opinion acknowledged the strong R&I logic of the initiative but challenged the clarity, balance and evidentiary strength of the IA’s innovation narrative<sup>110</sup>.

#### 1.6.14. DG SANTE

At DG SANTE, the **IA on revision of the Plant and Forest Reproductive Material**<sup>111</sup> legislation discusses innovation impacts qualitatively. The IA assumes that modernising registration, certification and marketing rules—such as allowing greater flexibility in variety testing, introducing dynamic references to DUS protocols, and easing rules for conservation varieties and heterogeneous material—will lower regulatory barriers to innovation, reduce time-to-market and support experimentation by breeders, SMEs and niche operators. Innovation is framed as regulation-enabled and diversity-enhancing, with expected benefits including broader genetic pools, more breeding activity targeting sustainability traits, and better alignment between innovation, standard-setting and climate adaptation needs. Direct impacts on R&D expenditure, patents or productivity are not quantified, and innovation benefits are largely embedded in avoided losses, resilience gains and long-term sustainability outcomes. The RSB noted that, despite repeated references to innovation, the IA does not sufficiently demonstrate how the proposed measures will affect competitiveness, innovation incentives and SME participation, nor how trade-offs between harmonisation and flexibility will play out in practice<sup>112</sup>. It also criticised the limited use of evaluation evidence and the weak quantification of impacts, which undermines claims that the preferred option will meaningfully enhance innovation while preserving diversity and food security. As a result, the RSB treats the expected innovation impacts as plausible but insufficiently substantiated, calling for clearer intervention logic, stronger evidence and better explanation of how innovation objectives are balanced against costs and regulatory burdens.

**The IA on the revision of the EU general pharmaceutical legislation**<sup>113</sup> (see also Section 3.1 below for a full case study) analyses innovation impacts comparatively across policy options,

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<sup>110</sup> Opinion of the Regulatory Scrutiny Board SWD(2022)42. [Register of Commission Documents - SWD\(2022\)42](#).

<sup>111</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031, 2017/625 and 2018/848 of the European Parliament and of the Council, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90 (Regulation on plant reproductive material) and Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of forest reproductive material in the Union, amending Regulations (EU) 2016/2031 and 2017/625 of the European Parliament and of the Council, and repealing Council Directive 1999/105/EC (Regulation on forest reproductive material). SWD(2023)414. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023SC0414&qid=1772055201543>.

<sup>112</sup> Opinion of the Regulatory Scrutiny Board SEC(2023)414. [Register of Commission Documents - SEC\(2023\)414](#).

<sup>113</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal

with explicit modelling of how changes in protection periods would affect expected revenues, return on investment and firms' capacity to finance future R&D. The IA acknowledges trade-offs: shortening baseline protection is expected to reduce originators' gross profits, while targeted extensions and transferable vouchers are intended to preserve incentives for priority innovation (e.g. novel antimicrobials, comparative trials, unmet medical needs). Innovation is thus framed in two modules; a baseline protection which is gauged to be internationally competitive and to maximise overall innovation volume, and a second part which is selective and conditional, with policy instruments designed to redirect R&D. The baseline innovation is further enhanced by horizontal simplification measures<sup>114</sup> which intend to enhance the innovation ecosystem and attractiveness of the EU as a destination for pharmaceutical R&D. However, quantification focuses on projected numbers of additional innovative medicines, changes in profits and dynamic effects on R&D investment, rather than on upstream research activity or spillovers. The RSB opinion identified significant weaknesses in how innovation impacts were evidenced and explained<sup>115</sup>.

**The IA on the revision of the EU legislation on substances of human origin – SoHO / blood, tissues and cells**<sup>116</sup> assesses innovation impacts explicitly and in a dedicated section, but mainly in qualitative and system-level terms. Key innovation-enabling measures include a risk-based, proportionate authorisation model for new or modified preparation processes (GAPP approach), clearer EU-level mechanisms to resolve borderline cases, and common IT tools to share assessments across Member States. These measures are intended to reduce duplication, shorten authorisation timelines and lower regulatory uncertainty, while still requiring clinical evidence proportionate to risk. Innovation is thus framed as regulated, incremental and safety-anchored, rather than disruptive or market-driven, and no attempt is made to quantify effects on R&D investment, patents or productivity. The RSB opinion explicitly recognises “supporting innovation” as one of the initiative's stated objectives, but it does not challenge the innovation rationale directly<sup>117</sup>.

Finally, in the **IA on the European Health Data Space**<sup>118</sup>, R&I impacts are treated as explicit and central, but primarily as enablers of efficiency, scale and data-driven innovation, rather than as stand-alone R&D policy objectives. The IA frames the EHDS as a foundational infrastructure initiative that lowers structural barriers to R&I by improving access to high-quality, interoperable health data across the EU. Innovation is understood mainly in terms of secondary use of health data for research, regulatory science, policy-making and the development of digital health solutions, including AI-driven tools, real-world evidence generation and personalised medicine. The IA repeatedly emphasises that fragmented national rules, limited interoperability and high transaction costs currently constrain researchers' and innovators' ability to exploit health data at scale, thereby weakening Europe's innovation potential in digital health and life sciences. Innovation impacts are analysed in a quantitative and system-level manner, focusing on

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products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006. SWD(2023)192. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023SC0192&qid=1772055317964>.

<sup>114</sup> See IA section 6.1.1.5.

<sup>115</sup> Opinion of the Regulatory Scrutiny Board SEC(2023)390. [Register of Commission Documents - SEC\(2023\)390](#).

<sup>116</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC. SWD(2022)190. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022SC0190&qid=1772055402861>.

<sup>117</sup> Opinion of the Regulatory Scrutiny Board SEC(2022)304. [Register of Commission Documents - SEC\(2022\)304](#).

<sup>118</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. SWD(2022)131. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022SC0131&qid=1772055495335>.

productivity gains and cost reductions rather than on upstream R&D incentives. The IA estimates significant efficiency gains for researchers and innovators from streamlined data access via national Health Data Access Bodies, reduced need for individual consent procedures, and harmonised governance and interoperability rules. These gains are translated into measurable economic benefits, including savings in data access costs and increased value creation from health data reuse, while innovation outputs (new products, services or therapies) are acknowledged but largely non-quantified due to evidence limitations. Innovation is thus framed as data-enabled and diffusion-oriented, with the EHDS acting as a horizontal accelerator of existing research and innovation activities rather than as a driver of additional R&D investment. The corresponding RSB implicitly treated the claimed innovation benefits as plausible but conditional on robust governance, trust and legal clarity rather than on technological progress alone<sup>119</sup>.

*Table 1 – Comparison of 41 selected IAs assessing innovation impacts*

IA # in the study sample	Initiative (short)	Main mechanism affecting innovation	Quantified?	Leading DG
IA83	CO <sub>2</sub> standards for HDVs	Regulation-induced pull (standards)	Partial	CLIMA
IA130	F-gas revision	Regulation-induced pull (phase-down, bans)	No	CLIMA
IA196	EU Adaptation Strategy	Coordination + platforms + mainstreaming	No	CLIMA
IA11	Post-2027 funding: education/youth/media/culture/values	Funding architecture + cooperation scaling	No	CNECT
A116	Cyber Resilience Act	Standards + essential requirements	No	CNECT
IA192	AI Act	Risk-based regulation + regulatory sandboxes/standards	No	CNECT
IA203	Digital Markets Act	Competition rules restoring contestability	Partial/Yes	CNECT
IA58	Horizontal Block Exemptions/Guidelines	Legal certainty + guardrails	No	COMP
IA191	Foreign subsidies instrument	Market fairness + merger/procurement scrutiny	No	COMP
IA13	EU Space Law	Harmonisation + safety/resilience standards	No	DEFIS
IA215	CMD amendment (carcinogens etc.)	OELs (technology-neutral)	No	EMPL
IA2	Ecodesign: external power supplies	Minimum performance requirements	No	ENER
IA40	End-of-Life Vehicles + 3R TA	Circularity requirements + info tools	No	ENV

<sup>119</sup> Opinion of the Regulatory Scrutiny Board SEC(2022)169. [Register of Commission Documents - SEC\(2022\)196](#).

IA87	CLP revision	Updating hazard classes/procedures	No	ENV
IA131	IED + E-PRTR revision	BAT evolution + permitting/data transparency	No	ENV
IA134	ESPR (Sustainable Products Initiative)	Framework + delegated measures + standards	No	ENV
IA98	Listing Act	Reduce burdens + governance flexibility	No	FISMA
IA167	Basel III package	Prudential stability → lending capacity	No	GROW
IA3	Single Market & Customs Programme	IT systems + cooperation + enforcement	No	GROW
IA8	European Competitiveness Fund	Integrated funding + simplification/leverage	No	GROW
IA38	Toy Safety Regulation	Updated chemical rules + enforcement	No	GROW
IA66	Detergents revision	Modernised rules + optional digital info	No	GROW
IA67	SPC reform (incl. unitary SPC)	Reduce fragmentation + unitary title	No	GROW
IA69	SEP framework	Transparency + essentiality checks + dispute resolution	No	GROW
IA111	Product Liability Directive	Framework clarity (avoid chilling innovation)	No	GROW
IA128	GI for craft & industrial products	Reputation/IP protection → investment	No	GROW
IA168	Common charger (RED amendment)	Standardisation + interoperability rules	No	GROW
IA29	EU Talent Pool	Matching platform → reduce shortages	No	HOME
IA139	CSDDD	Due diligence obligations	No	JUST
IA187	Consumer Credit Directive revision	Update rules to fit digital markets	No	JUST
IA15	Roadworthiness package	Modernised procedures + data	No	MOVE
IA21	River Information Services (RIS)	Update standards/specs + interoperability	No	MOVE
IA149	ITS Directive revision	Data sharing + specs + essential services	No	MOVE
IA181	FuelEU Maritime	Lead-market fuel standard + predictability	Partial	MOVE
IA197	Horizon Europe Joint Undertakings (institutionalised partnerships)	Partnership form choice (Art.185/187)	Partial	RTD

IA198	European Partnership on Metrology	Institutionalised partnership + long-term integration	Partial	RTD
IA49	Plant/Forest reproductive material	Regulatory flexibility + market access	No	SANTE
IA70	General pharmaceutical legislation	Adjust exclusivities/vouchers/conditions	Yes/Partial	SANTE
IA117	SoHO (blood/tissues/cells)	Proportionate authorisation + borderline clarity	No	SANTE
IA124	EHDS	Interoperability + access governance	Partial	SANTE
IA154	Anti-Coercion Instrument	Deterrence + countermeasures → reduced uncertainty	No	TRADE

## 1.7. Competitiveness checks, SME tests and other relevant impacts

The innovation principle seems to have been gradually flanked, if not superseded, by other tools in the better regulation agenda, including notably the competitiveness test, and the SME test. Our data analysis revealed that these forms of assessment have become much more common in IAs since 2024, and even more in 2025. A broad first analysis with AI-enabled tools suggested that **competitiveness impacts are assessed in over 70% of IAs, while SME impacts are assessed in around 60%**. A more refined analysis found that:

- Out of 219 IAs, 80 of which were completed after March 2023, Competitiveness Checks were performed in 29 IAs, whereas a broader set of 59 IAs considered impacts on competitiveness without necessarily conducting a standalone check.
- Only 13 IAs (6.2%) explicitly integrated R&D or innovation indicators into their competitiveness analysis. Examples include the IAs on the European Competitiveness Fund and the European Globalisation Adjustment Fund, where innovation capacity is treated as a fundamental driver of international competitiveness.

The SME Test is rather widespread, appearing in 33.5% of the sample. However, only 5 IAs (2.4%) explicitly linked the SME test results to innovation capacity. The IA on **“Business in Europe: Framework for Income Taxation”<sup>120</sup>** is a notable exception, discussing how compliance cost reductions directly release capital for SMEs to “invest in innovation”. Table 2 below shows our results for each of the 219 IAs.

Table 2 – Competitiveness checks, SME tests and innovation impacts in our sample of IAs

Year	IA_ID	Lead DG	Comp Check	Comp Impact	Comp Subsumes R&I	SME Test	SME Refers Inno
2025	IA1	FISMA	☑	☑	✗	☑	✗

<sup>120</sup> Commission Staff Working Document Impact Assessment Report Accompanying the Proposal for a Council Directive establishing a Head Office Tax system for micro, small and medium sized enterprises, and amending Directive 2011/16/EU. SWD(2023)302. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023SC0302&qid=1772055576160>.

2025	IA2	ENER	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2025	IA3	GROW	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2025	IA4	EUROSTAT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2025	IA5	EMPL	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2025	IA6	REGIO	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2025	IA7	TAXUD	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2025	IA8	GROW	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2025	IA9	BUDG	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2025	IA10	INTPA	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2025	IA11	CNCT	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2025	IA12	ECHO	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2025	IA13	DEFIS	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2025	IA14	FISMA	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2025	IA15	MOVE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2024	IA16	ENER	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2024	IA17	ENER	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2024	IA18	EMPL	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2024	IA19	CLIMA	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2024	IA20	HOME	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2024	IA21	MOVE	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2024	IA22	EMPL	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2023	IA23	JUST	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA24	SANTE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA25	JUST	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA26	JUST	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA27	MOVE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA28	ENV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2023	IA29	HOME	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2023	IA30	MOVE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA31	JUST	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2023	IA32	ENV	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2023	IA33	GROW	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA34	TAXUD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA35	EMPL	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA36	GROW	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA37	EUROSTAT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2023	IA38	GROW	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA39	ENV	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2023	IA40	ENV	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA41	ENER	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA42	JUST	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2023	IA43	MOVE	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA44	MOVE	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2023	IA45	MOVE	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA46	EUROSTAT	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2023	IA47	ENV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA48	SANTE	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA49	SANTE	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA50	ENV	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA51	FISMA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA52	FISMA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2023	IA53	FISMA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2023	IA54	TAXUD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2023	IA55	GROW	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2023	IA56	FISMA	X	X	X	X	X
2023	IA57	MOVE	X	X	X	X	X
2023	IA58	COMP	X	X	X	X	X
2023	IA59	MOVE	X	<input checked="" type="checkbox"/>	X	X	X
2023	IA60	MOVE	X	X	X	<input checked="" type="checkbox"/>	X
2023	IA61	MOVE	X	X	X	<input checked="" type="checkbox"/>	X
2023	IA62	JUST	X	X	X	<input checked="" type="checkbox"/>	X
2023	IA63	MOVE	X	X	X	<input checked="" type="checkbox"/>	X
2023	IA64	FISMA	X	X	X	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2023	IA65	TAXUD	X	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	X
2023	IA66	GROW	X	X	X	<input checked="" type="checkbox"/>	X
2023	IA67	GROW	X	X	X	<input checked="" type="checkbox"/>	X
2023	IA68	GROW	X	X	X	X	X
2023	IA69	GROW	X	<input checked="" type="checkbox"/>	X	X	X
2023	IA70	SANTE	X	X	X	X	X
2023	IA71	AGRI	X	X	X	X	X
2023	IA72	COMP	X	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	X	X
2023	IA73	FISMA	X	X	X	<input checked="" type="checkbox"/>	X
2023	IA74	ENER	X	X	X	<input checked="" type="checkbox"/>	X
2023	IA75	GROW	X	<input checked="" type="checkbox"/>	X	<input checked="" type="checkbox"/>	X
2023	IA76	JUST	X	X	X	X	X
2023	IA77	JUST	X	X	X	X	X
2023	IA78	GROW	X	X	X	X	X
2023	IA79	MOVE	X	X	X	X	X
2023	IA80	MOVE	X	<input checked="" type="checkbox"/>	X	<input checked="" type="checkbox"/>	X
2023	IA81	GROW	X	<input checked="" type="checkbox"/>	X	X	X
2023	IA82	CNCT	X	X	X	X	X

2023	IA83	CLIMA	✗	✗	✗	✗	✗
2023	IA84	EMPL	✗	✗	✗	✗	✗
2023	IA85	EUROSTAT	✗	✗	✗	✗	✗
2022	IA86	CNCT	✗	✗	✗	✗	✗
2022	IA87	ENV	✗	✗	✗	✗	✗
2022	IA88	HOME	✗	✗	✗	✗	✗
2022	IA89	COMP	✗	✗	✗	✗	✗
2022	IA90	COMP	✗	✗	✗	<input checked="" type="checkbox"/>	✗
2022	IA91	SANTE	✗	✗	✗	✗	✗
2022	IA92	HOME	✗	✗	✗	✗	✗
2022	IA93	TAXUD	✗	✗	✗	<input checked="" type="checkbox"/>	✗
2022	IA94	TAXUD	✗	✗	✗	✗	✗
2022	IA95	JUST	✗	<input checked="" type="checkbox"/>	✗	<input checked="" type="checkbox"/>	✗
2022	IA96	JUST	✗	✗	✗	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2022	IA97	FISMA	✗	✗	✗	✗	✗
2022	IA98	FISMA	✗	✗	✗	✗	✗
2022	IA99	CLIMA	✗	✗	✗	✗	✗
2022	IA100	ENV	✗	<input checked="" type="checkbox"/>	✗	✗	✗
2022	IA101	GROW	✗	✗	✗	<input checked="" type="checkbox"/>	✗
2022	IA102	DIGIT	✗	✗	✗	✗	✗
2022	IA103	GROW	✗	✗	✗	✗	✗
2022	IA104	GROW	✗	✗	✗	✗	✗
2022	IA105	HOME	✗	✗	✗	✗	✗
2022	IA106	ENV	✗	✗	✗	<input checked="" type="checkbox"/>	✗
2022	IA107	FISMA	✗	<input checked="" type="checkbox"/>	✗	✗	✗
2022	IA108	ENV	✗	✗	✗	<input checked="" type="checkbox"/>	✗
2022	IA109	ENV	✗	✗	✗	✗	✗

2022	IA110	COMP	✗	✗	✗	✗	✗
2022	IA111	GROW	✗	☑	✗	☑	✗
2022	IA112	EMPL	✗	✗	✗	✗	✗
2022	IA113	JUST	✗	✗	✗	✗	✗
2022	IA114	GROW	✗	✗	✗	✗	✗
2022	IA115	CNCT	✗	✗	✗	✗	✗
2022	IA116	CNCT	✗	✗	✗	✗	✗
2022	IA117	SANTE	✗	✗	✗	✗	✗
2022	IA118	SANTE	✗	✗	✗	✗	✗
2022	IA119	ENV	✗	✗	✗	✗	✗
2022	IA120	HOME	✗	✗	✗	☑	✗
2022	IA121	TAXUD	✗	☑	☑	✗	✗
2022	IA122	JUST	✗	✗	✗	✗	✗
2022	IA123	HOME	✗	✗	✗	✗	✗
2022	IA124	SANTE	✗	✗	✗	✗	✗
2022	IA125	HOME	✗	✗	✗	✗	✗
2022	IA126	HOME	✗	✗	✗	✗	✗
2022	IA127	HOME	✗	☑	☑	✗	✗
2022	IA128	GROW	✗	☑	✗	✗	✗
2022	IA129	CLIMA	✗	✗	✗	✗	✗
2022	IA130	CLIMA	✗	✗	✗	✗	✗
2022	IA131	ENV	✗	✗	✗	☑	✗
2022	IA132	AGRI	✗	✗	✗	☑	☑
2022	IA133	JUST	✗	✗	✗	✗	✗
2022	IA134	ENV	✗	✗	✗	✗	✗
2022	IA135	GROW	✗	☑	✗	✗	✗
2022	IA136	FISMA	✗	☑	✗	☑	✗

2022	IA137	JUST	X	X	X	X	X
2022	IA138	CNCT	X	X	X	X	X
2022	IA139	JUST	X	X	X	X	X
2022	IA140	DEFIS	X	X	X	X	X
2022	IA141	COMP	X	X	X	X	X
2022	IA142	HOME	X	X	X	X	X
2021	IA143	TAXUD	X	X	X	<input checked="" type="checkbox"/>	X
2021	IA144	ENER	X	X	X	X	X
2021	IA145	ENER	X	X	X	X	X
2021	IA146	ENER	X	X	X	X	X
2021	IA147	JUST	X	X	X	X	X
2021	IA148	MOVE	X	X	X	<input checked="" type="checkbox"/>	X
2021	IA149	MOVE	X	X	X	<input checked="" type="checkbox"/>	X
2021	IA150	HOME	X	X	X	X	X
2021	IA151	EMPL	X	X	X	X	X
2021	IA152	EMPL	X	X	X	X	X
2021	IA153	HOME	X	X	X	X	X
2021	IA154	TRADE	X	X	X	X	X
2021	IA155	HOME	X	X	X	X	X
2021	IA156	JUST	X	X	X	X	X
2021	IA157	FISMA	X	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	X
2021	IA158	FISMA	X	X	X	X	X
2021	IA159	FISMA	X	X	X	X	X
2021	IA160	JUST	X	X	X	X	X
2021	IA161	FISMA	X	X	X	X	X
2021	IA162	JUST	X	X	X	X	X
2021	IA163	SG	X	X	X	X	X

2021	IA164	ENV	✗	☑	☑	✗	✗
2021	IA165	GROW	✗	✗	✗	✗	✗
2021	IA166	ENV	✗	☑	✗	✗	✗
2021	IA167	FISMA	✗	✗	✗	✗	✗
2021	IA168	GROW	✗	☑	✗	✗	✗
2021	IA169	TRADE	✗	✗	✗	✗	✗
2021	IA170	FISMA	✗	✗	✗	✗	✗
2021	IA171	FISMA	✗	☑	✗	✗	✗
2021	IA172	JUST	✗	✗	✗	✗	✗
2021	IA173	TAXUD	✗	✗	✗	✗	✗
2021	IA174	CLIMA	✗	✗	✗	✗	✗
2021	IA175	CLIMA	✗	✗	✗	✗	✗
2021	IA176	MOVE	✗	✗	✗	✗	✗
2021	IA177	ENER	✗	✗	✗	✗	✗
2021	IA178	ENER	✗	✗	✗	✗	✗
2021	IA179	CLIMA	✗	✗	✗	✗	✗
2021	IA180	CLIMA	✗	✗	✗	✗	✗
2021	IA181	MOVE	✗	✗	✗	✗	✗
2021	IA182	MOVE	✗	✗	✗	✗	✗
2021	IA183	TAXUD	✗	✗	✗	☑	✗
2021	IA184	CLIMA	✗	✗	✗	☑	✗
2021	IA185	FISMA	✗	☑	✗	✗	✗
2021	IA186	JUST	✗	☑	☑	✗	✗
2021	IA187	JUST	✗	✗	✗	✗	✗
2021	IA188	FISMA	✗	✗	✗	✗	✗
2021	IA189	CNCT	✗	✗	✗	✗	✗
2021	IA190	HOME	✗	✗	✗	✗	✗

2021	IA191	COMP	X	X	X	X	X
2021	IA192	CNCT	X	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	X
2021	IA193	FISMA	X	X	X	X	X
2021	IA194	JUST	X	X	X	X	X
2021	IA195	CNCT	X	X	X	X	X
2021	IA196	CLIMA	X	X	X	X	X
2021	IA197	RTD	X	X	X	<input checked="" type="checkbox"/>	X
2021	IA198	RTD	X	X	X	X	X
2021	IA199	JUST	X	<input checked="" type="checkbox"/>	X	X	X
2021	IA200	ENER	X	X	X	X	X
2020	IA201	CNCT	X	X	X	X	X
2020	IA202	CNCT	X	X	X	X	X
2020	IA203	CNCT	X	X	X	X	X
2020	IA204	HOME	X	X	X	X	X
2020	IA205	ENV	X	X	X	X	X
2020	IA206	HOME	X	X	X	X	X
2020	IA207	JUST	X	X	X	X	X
2020	IA208	CNCT	X	X	X	X	X
2020	IA209	TAXUD	X	X	X	X	X
2020	IA210	EMPL	X	X	X	X	X
2020	IA211	FISMA	X	X	X	X	X
2020	IA212	FISMA	X	X	X	X	X
2020	IA213	FISMA	X	X	X	X	X
2020	IA214	FISMA	X	X	X	X	X
2020	IA215	EMPL	X	X	X	X	X
2020	IA216	COMP	X	X	X	X	X
2020	IA217	CLIMA	X	X	X	X	X

2020	IA218	FISMA	×	×	×	×	×
2020	IA219	TAXUD	×	×	×	×	×

## 2. Case studies

### 2.1. Case Study 1: Revision of the pharmaceutical regulation

#### 2.1.1. Context and relevance for the innovation principle

The general pharmaceutical legislation (introduced in 1965 and last revised in 2004), regulates the marketing authorisation, manufacturing, distribution and monitoring of medicines for human use, and provides for regulatory protection periods to reward pharmaceutical companies for their medicinal innovations. It consists of the Community code relating to medicinal products for human use, and the regulation on authorisation and supervision of medicinal products and establishing the European Medicines Agency. The specific pharmaceutical legislation includes the Paediatric Regulation which regulates medicines for children and obliges companies to screen new adult medicines under development for possible use in children, and the Orphan Regulation which provides for medical needs of people with rare diseases.

The legislative package on the revision of the EU's pharmaceutical legislation includes both the EU's general and specific pharmaceutical legislations. The current pharma package, comprises a proposal for a new [pharmaceutical directive](#) to replace the Community Code Directive 2001/83/EC and Directive 2009/35/EC, and incorporate relevant parts of the Paediatric Regulation; and a proposal for a new [pharmaceutical regulation](#) to replace Regulation (EC) No 726/2004 regarding medicine authorisation and supervision, and the Orphan Regulation, and repeal and incorporate relevant parts of the Paediatric Regulation (put forward by the Commission on 26.04.2023). The merger of the Orphan Regulation and the Paediatric Regulation with the legislation applicable to all medicinal products will allow for simplification and increased coherence. Those legislative proposals are accompanied by a [Commission communication](#) on measures addressing antimicrobial resistance (26.04.2023); as well as a [proposal for a Council recommendation](#) for action on antimicrobial resistance ([adopted](#) by the Council on 22.06.2023).

The proposed pharmaceutical legislation has a **strong innovation dimension** and is therefore **very relevant for the innovation principle**. As part of its four specific objectives, the [proposals](#) aim to “offer an attractive innovation-and competitiveness friendly environment for research, development, and production of medicines in Europe”. Across the proposed regulation and directive, it refers to “innovation” 93 times. The innovation dimension has been considered in the first two stages of the policy cycle (during the agenda-setting phase taking into account megatrends and the consultation of the diverse stakeholders (including the research and innovation communities), during the preparatory policy work, and during the legislation phase and as part of the impact assessments).

Negotiations of the legislative file were lengthy with Member States agreeing their position only in June 2025. More than two and a half years following the publication of the Commission's legislative proposal, it is now close to adoption: on 11 December 2025, the European Parliament and the EU Council have reached a [political agreement](#) on the EU's pharmaceutical legislation reform. The Council is now expected to formally adopt its position, which can then be endorsed by Parliament in second reading.

## 2.1.2. Impact assessments and RSB opinion

The legislative proposals were supported by **two impact assessments** prepared in parallel by the Commission's Directorate-General for Health and Food Safety (DG SANTE) and published together under SWD(2023)192 (on 26.04.2023), with the [Part I](#) accompanying the revision of the general pharmaceutical legislation and the [Part II](#) accompanying the revision of the medicines for rare diseases and children legislation. The problem definition of both IA parts builds on the results of the evaluation of the general pharmaceutical legislation ([Annex 5](#)).

While the IA does not include the checklist on "Impact on research and innovation", it duly considers qualitative and quantitative data including the stakeholder views to **assesses in depth the economic impacts of the alternative policy options, including impacts on research and innovation**: under the baseline situation, the IA assesses future impacts of incentives for innovation with i) incentives; ii) expedited regulatory schemes; and iii) repurposing as identified subthemes (the highly detailed impact analysis of all policy measures can be found in [Annex 11](#), including a qualitative multi-criteria analysis, and a cost-benefit analysis of the proposed horizontal measures). For the policy options A-C, the IA assesses of the proposed incentives for innovation, looking at i) expedited regulatory schemes; ii) repurposing; iii) incentives: adaptation of the period of regulatory protection. The IA also assesses the impacts on "Sectoral competitiveness, trade and investment flows" of the three policy options, as well as on "SMEs". Further, all three policy options are complemented by horizontal measures aimed at fostering innovation and "future-proofing" the regulatory framework for instance through the introduction of regulatory sandboxes.

However, impacts on innovation have not comprehensively considered in IAs from the outset: the **RSB's first opinion** in the written report received on 22 July 2022 ([SEC\(2023\)390](#)) **was negative**, highlighting "The report is not sufficiently clear on the impacts of options on innovation and competitiveness for the EU pharmaceutical ecosystem, including SMEs, and how this will affect access to and affordability of medicines for patients". DG SANTE subsequently addressed this notably in sections 6.1.2-4 and 7.1 where the impacts on competitiveness and SMEs were further elaborated and in section 6.1.1.2 where a subsection on RP reduction and the impact on EU competitiveness was added (see [Annex I](#)). Following these adjustments, the second RSB opinion was positive with reservations (noting for instance that there should be a better assessment of the impacts of reduced regulatory protection periods on the sectors capacity to finance future innovations and international competitiveness).

The specific objectives in general, and the innovation focused one mentioned above specifically, remain at a high level without further division into operational objectives with clearly defined deliverables (such as the SMART criteria as per tool#15). Nevertheless, several quantitative indicators included in the monitoring framework allow for measuring the implementation of the preferred policy option. For the specific objective on prompting innovation, in particular for UMN, seven relevant indicators are listed, including for instance the number of authorised medicines with new active substance or the number of regulatory sandboxes used. In the IA's Part II, indicators under this specific objective include another seven indicators among which for instance the number of research program financed by the EU concerning paediatric products addressing UMN.

Moreover, tool#22 suggests a non-exhaustive list of instruments and approaches that can be used to improve the design of your legislation to make it more innovation friendly, such as, the experimentation clauses that enable regulatory authorities to apply a degree of flexibility in relation to innovative technologies. Notably, the [political agreement](#) on 11 December 2025, in line with tool#22, puts a higher attention to EU pharma innovation, by proposing a different set of incentives for innovative products and adapting the Commission's proposal on regulatory sandboxes as a secure testing environment for truly novel medicines and adapted frameworks for certain non-standard treatments, like personalised therapies.

### 2.1.3. Stakeholder consultations

DG SANTE undertook **ample stakeholder consultation activities** to underpin the legislative proposal and IA. Overall, the preferred options in the IA are in line with stakeholders' views, for instance with stakeholders welcoming the proposal for more rapid regulatory pathways for new products, and more targeted incentives for companies to develop innovative medicines ([EURORDIS](#), [EPHA](#) or [EPF](#)), although the pharmaceutical industry expressed concerns regarding a potential modulation or shortening of incentives, as well as future attractiveness of investment in innovation in the EU ([EFPIA](#)).

Consultations activities related to the revision of the general pharmaceuticals legislation build on positions of Member State authorities in the context of its consultative committee, the [Human Pharmaceutical Committee](#), which met eight times since 30 March 2021, the moment when the Commission published its [Roadmap](#) for revising the general pharmaceutical legislation. The revision of the general pharmaceutical acts has always on committee's meeting agenda (with once a bit of a stronger focus around innovation). Further, the consultation included compiling 13 expert concept papers on technical aspects ([compendium](#)).

A [Public Consultation](#) was then launched from 28 September 2021 to 21 December 2021 with 478 responses received. **The questionnaire included questions taking into consideration an innovation dimension.** Only 16% of participants considered the pharmaceutical legislation has so far performed "very well" or "well" in terms of adapting efficiently and effectively to technological and scientific advancements and innovation, while 48% choose "Moderately" and 23% "Poorly" or "Very poorly". 68% considered it to be "Important" or "Very important" to make use of regulatory sandboxes in legislation to pilot certain categories of novel products/technologies. Other questions touched upon data and market protection periods' impact on innovation. Another [Consultation](#) was carried out focused on the revision of the orphan and paediatric legislation between 07 May 2021 and 30 July 2021 with 304 participants. The questions and responses had less of an innovation dimension.

In addition, the Commission organised Pharmaceutical Strategy for Europe [Workshops](#) between March to June 2021. To further stimulate innovation, participants suggested that the data protection period may be shortened, with longer protection only for new classes of medicinal product or breakthrough therapies. In a [Stakeholders' dialogue](#) on the pharmaceutical revision on 10 May 2023, 51 organisations and associations representing patients, healthcare professionals, industry and other relevant sectorial stakeholders were present discussed the proposal further, with researchers notably appreciating the provisions catering for innovation and incentives for academia.

In the context of the subsidiarity and proportionality in the IA, the Czech Chamber of Deputies adopted was the only member state to adopt a [resolution](#), asking specifically for clarification regarding the proposed transferable regulatory protection vouchers and regulatory sandboxes.

### 2.1.4. Regulatory sandboxes

[Part I](#) of the IA, accompanying the revision of the general pharmaceutical legislation, addressed the possibility of the introduction of regulatory sandboxes, their relevance for SMEs and stakeholder feedback: Under the comparison of the expected impacts of the options in terms of their effectiveness, the IA highlights for impacts on competitiveness that the horizontal measures on futureproofing of the legislation (e.g. flexibility of the framework, clarification of scope, sandboxes, codification of rolling reviews and PRIME) are applicable to all options. When it comes to effects on SMEs, it is noted that under Option C – the preferred option – regulatory sandboxes and the transferable exclusivity voucher for novel antibiotics could be especially beneficial to SMEs to support development of innovative products (ref. C.3.6.). Adapted regulatory pathways and regulatory sandboxes are expected to increase the chance of faster patient access to cutting edge medicinal products. It is also noted that one of the proposed

monitoring indicators under the specific objective of promoting innovation, in particular for UMN, is the ‘Number of sandboxes used’.

**Provisions on regulatory sandboxes were included** in the Commission [proposal](#) for the pharmaceutical regulation, which highlights that “regulatory sandboxes can provide the opportunity for advancing regulation through proactive regulatory learning, enabling regulators to gain better regulatory knowledge and to find the best means to regulate innovations based on real-world evidence, especially at a very early stage of development of a medicinal product, which can be particularly important in the face of high uncertainty and disruptive challenges, as well as when preparing new policies.” Article 133 of the proposal outlines that the Commission may set up a regulatory sandbox pursuant to a specific sandbox plan, based on a recommendation of the Agency.

## 2.1.5. Overall assessment

The pharmaceutical legislation is obviously very relevant from a research and innovation perspective. The proposed revision has a rather strong innovation dimension embedded – as reflected in its main objectives – and so does the IA. The IA demonstrates that an innovation dimension has been taken into account quite effectively across the first two stages of the policy cycle, including assessment of impacts on innovation of the different policy options. This has been reinforced following the RSB’s request to strengthen this part of the assessment. DG SANTE also defined innovation relevant indicators for monitoring purposes, and effectively captured stakeholders’ views including on research and innovation relevant aspects of the proposed legislation.

## 2.2. Case Study 2: The Digital Omnibus proposals

### 2.2.1. Context, objectives and relevance for the innovation principle

The Commission has presented ten [omnibus proposals](#) to the European Parliament and the Council since February 2025, as part of its [horizontal simplification agenda](#), as a response to the European Council conclusions ([March](#), [June](#), [October](#) 2025) calling for “simplicity by design” legislation; the Draghi and Letta reports (i.e. regulatory complexity as a drag on EU competitiveness) and stakeholder feedback. These proposals cover a wide range of policy areas, among them the Omnibus VII: digital (Digital Omnibus and Digital Omnibus on AI) and Omnibus V: defence (on which see, the Section 2.2.2).

The **Digital Omnibus** (November 2025) responds to concerns that the accumulation of EU digital legislation has increased compliance costs and reduced competitiveness. Without altering core objectives of EU digital legislation (e.g. fundamental rights, safety, trust), it introduces targeted technical amendments to this legislation to optimize its implementation and bring immediate relief to businesses, public authorities, and citizens. In parallel, the **Digital Omnibus on AI** (November 2025) applies the same simplification logic to AI-specific legislation proposing targeted amendments to the EU AI Act (Regulation (EU) 2024/1689). It aims to ensure timely, smooth, and proportionate implementation of the original AI Act, focusing on reducing administrative burdens, aligning timelines with available support tools, and providing more flexibility for operators. Together, the Digital Omnibuses aim to simplify the application of the EU digital acquis, lower regulatory complexity, reduce costs, and improve enforcement coherence.

**The Digital Omnibus** is strongly aligned with the innovation principle. It treats regulation as an enabler of innovation. Through a set of amendments to the digital legislative framework, the Regulation aims at providing immediate regulatory clarifications that stimulate innovation. It explicitly aims to ensure that rules remain “fit for supporting innovation and growth” while preserving high standards of protection. **The Digital Omnibus on AI** puts forward an explicit

aim to support the uptake of innovative AI applications by simplifying redundant or conflicting requirements. Its emphasis on regulatory coherence, legal certainty, and burden reduction aligns closely with innovation-enabling conditions identified by stakeholders.

### 2.2.2. Impact assessment of the legislation

The **Digital Omnibus Regulations** are not accompanied by a full standalone impact assessment, because the amendments put forward are targeted and technical and designed to ensure an efficient implementation of rules. The amendments do not involve multiple policy options requiring comparison in line with the Better Regulation guidelines but build on existing impact assessments of the amended acts. The Commission relies on a detailed [Staff Working Document](#) (accompanying both the Digital Omnibus and the Digital Omnibus on AI) explaining intervention logic, cost–benefit analysis and qualitative impact assessment, and previous evaluations and implementation experience.

Key impacts identified include significant administrative burden reduction for businesses and public administrations (with at least €5 billion in total savings by the end of 2029); reduced reporting duplication (notably through streamlined cybersecurity and incident reporting); expanded proportionality measures benefitting SMEs and small mid-caps (SMCs); improved legal clarity across overlapping digital instruments; and strengthened coherence in EU's digital regulatory framework. The Digital Omnibus on AI is projected to reduce regulatory compliance time for SMEs by up to 30%, supporting faster deployment of innovative AI applications. Innovation-related impacts are expected to arise from improved regulatory coherence and legal certainty, which reduce investment risk in emerging technologies, while lower compliance costs free up resources for innovation and simplified data rules facilitate data sharing, AI training, and switching between data processing and cloud services.

### 2.2.3. Stakeholder consultations

The **Digital Omnibus** proposal is underpinned by a broad consultation effort, involving a wide range of stakeholder groups, including businesses, civil society organisations, academics, public authorities, SMEs, Member States and individual citizens. Three public consultations and calls for evidence were launched in spring 2025 (AI strategy, Cybersecurity Act, European Data Union Strategy) and a dedicated [Call for Evidence](#) on the Digital Omnibus (Sept–Oct 2025) resulted in over 500 responses. In addition, consultations covered the implementation dialogues with Executive Vice-Presidents and Commissioners, SME Panel via the Enterprise Europe Network, and bilateral meetings, focus groups (“reality checks”), and Member State discussions.

While the stakeholder consultations did not explicitly refer to the innovation principle as such, both the consultation design and the submissions contained extensive innovation-relevant input. Most stakeholders strongly voiced support for the simplification agenda with some stakeholders explicitly suggesting future work on further harmonisation. Stakeholders repeatedly highlighted legal certainty, regulatory coherence, simplified data rules and reduced compliance costs as key conditions for investment in AI, data-driven services and other emerging technologies, which aligns closely with the objectives of the innovation principle. In the specific context of the Digital Omnibus on AI, multiple SME respondents expressed concerns about the impact of fragmented or duplicative rules on AI innovation. Consultations also highlighted the need for greater predictability in AI-related conformity assessments and encouraged expanded use of AI regulatory sandboxes.

### 2.2.4. Tool #22 and regulatory sandboxes

The **Digital Omnibus** makes no reference to Tool #22 but frames the proposal as a targeted, technical simplification exercise. Both the Regulations and the accompanying Staff Working Document refer to the use of such tools as calls for evidence, public consultations,

implementation dialogues and “reality checks” with stakeholders, and justify the absence of a full impact assessment.

The Digital Omnibus does not introduce new innovation-specific instruments such as regulatory sandboxes, but instead aims to enable innovation indirectly through simplification, reduced administrative burdens, improved regulatory coherence and greater legal certainty. While not explicitly referring to the Innovation Principle and the application of Tool #22, the Digital Omnibus on AI introduces targeted simplifications to make the AI Act more flexible and innovation-friendly, with a strong focus on AI regulatory sandboxes and real-world testing. It enables the European AI Office to establish an EU-level sandbox from 2028, complementing national sandboxes and providing priority access for SMEs and small mid-caps. Additionally, it broadens the ability to conduct real-world testing of high-risk AI systems outside sandboxes, aiming to make controlled experimentation more practical while maintaining safeguards and consistent enforcement across the EU. The accompanying Staff Working Document acknowledges stakeholder calls for risk-based approaches and exploratory tools, including regulatory sandboxes, particularly to support the development and deployment of artificial intelligence.

The proposal also positions the Digital Omnibus as a first step in an ongoing Better Regulation process, to be followed by a Digital Fitness Check of the EU digital acquis (analysis of the interplay between the rules and their cumulative impact on businesses), which would simplify the EU's digital rules, following the adjustments under the Digital Omnibus. This second step [stakeholder consultation](#) is open till 26 March 2026. In 2026 the Commission will organise other consultation activities in this context, including 'reality checks' and implementation dialogues, focusing on specific issues.

## 2.2.5. Overall assessment

In the Digital Omnibus and the Digital Omnibus on AI, innovation was considered primarily through the design of horizontal simplification measures that aim to reduce legal fragmentation, improve regulatory coherence, and lower compliance burdens—especially for SMEs and emerging digital actors. The Digital Omnibus on AI includes targeted adjustments to existing legislation that support the uptake of innovative AI applications, reinforce the effectiveness of AI regulatory sandboxes, and promote legal certainty. **Although the Innovation Principle is not named, these actions reflect its spirit** and are responsive to stakeholder feedback calling for more innovation-friendly frameworks.

**The initiative did not undergo full standalone impact assessments**, but the Commission provided justifications in line with Better Regulation principles, including stakeholder consultations and simplified impact analysis. The Digital Omnibus also initiates a broader Digital Fitness Check, which could provide a future opportunity to embed the innovation principle more formally.

## 2.3. Case Study 3: The Defence Omnibus

Proposed in April 2025 and adopted in December 2025, the so-called '[mini-Omnibus for defence](#)' is a package of legal changes aiming to make it easier for existing EU programmes to support projects with dual-use or defence applications. This is a key element in the implementation of the [ReArm Europe Plan](#) and a direct complement to the [Commission's Mid-Term Review \(MTR\) of Cohesion Policy](#) and the [Defence Readiness Omnibus](#).

The Defence Omnibus refers to a package of interrelated Commission documents, consisting of a policy Communication (Defence Readiness Omnibus (June 2025), reflecting the priorities set out in the [White Paper for European Defence-Readiness](#), and a package of legislative simplification proposals amending defence-related and horizontal EU laws (e.g. amending [defence procurement](#) or European Defence Fund Regulation). The primary goal is to accelerate

Member States' ability to scale up defence production and operations in the face of growing geopolitical threats. The accompanying Staff Working Document [Defence simplification omnibus](#) published few months later (November 2025) justify the legislative proposals demonstrating how simplification supports defence readiness, investment, and innovation.

Although the innovation principle is not explicitly referenced in the document, the initiative is closely aligned with its logic. The proposal aims to enhance the innovation capacity of the European Defence Technological and Industrial Base (EDTIB) by improving access to public procurement, streamlining European Defence Fund (EDF) procedures, and enabling the uptake of disruptive and dual-use technologies. Simplification is framed as a driver for innovation by reducing compliance complexity, improving access to finance, and accelerating research-to-market pathways.

### **2.3.1. Impact assessment of the legislation**

While a dedicated formal impact assessment was not conducted for the **Defence Omnibus**, the related [Staff Working Document](#) explains in details the necessity, proportionality, and expected effects of the Defence Omnibus in line with Better Regulation principles. It explains why two policy options were rejected (i.e. status quo and in-depth revision of legislation) and why the pragmatic simplification policy option was chosen to support Europe's defence readiness while improving innovation and efficiency in the short term. It includes a simplified cost-benefit analysis, estimated benefits of reduced administrative burden and compliance costs, indirect innovation impacts from improved legal clarity and access to funding, especially for SMEs, start-ups, and dual-use sectors. It highlights how faster and clearer rules will enable greater participation in collaborative R&D, support deployment of novel technologies, and reduce investment risk for innovative defence firms.

### **2.3.2. Stakeholder consultations**

The Defence Omnibus proposal is also supported by broad and detailed stakeholder consultations. More than 270 responses were collected via [public consultation](#), targeted consultations, workshops and high-level political dialogues. (with Commissioner Kubilius and President Von der Leyen). Stakeholders included Member States, defence companies, industry associations, financial actors, and civil society organisations. While the innovation principle was not directly referenced in the consultation design, innovation-related concerns featured prominently in responses. Stakeholders repeatedly cited regulatory fragmentation, excessive compliance costs, and lack of legal clarity as barriers to innovation and industrial agility. Several respondents called for easier access to R&D and innovation funding, stronger IP protection, and regulatory frameworks that support the scaling of emerging technologies and start-ups.

### **2.3.3. Tool #22 and regulatory sandboxes**

Tool #22 is not explicitly mentioned in the **Defence Omnibus**. However, the proposal includes a clear innovation logic, assessing how regulation affects research, development, and technological scaling, and addresses those impacts through targeted simplification. The document identifies innovation as a key enabler of defence readiness and justifies regulatory changes by their ability to unlock collaborative innovation, enable dual-use synergies, and support scale-up of disruptive technologies. Thus, while the formal tools were not used, their substance is reflected in the analytical and legislative design.

### **2.3.4. Overall assessment**

The Defence Omnibus focuses on removing regulatory bottlenecks that delay defence investment, joint procurement, and cross-border operations. Innovation was considered through

the lens of enabling the European defence industrial base to adopt and scale disruptive and dual-use technologies. The Staff Working Document accompanying the package includes a clear problem analysis, stakeholder input, and qualitative assessment of how simplification can boost innovation by reducing investment risk and improving access to funding, particularly under the European Defence Fund (EDF).

Here too, the initiative did not undergo a full impact assessment.

## 2.4. Case Study 4: The Net Zero Industry Act

Act adopted in 2024, examples of implementing acts could be interested to take into account for the assessment. The [Net-Zero Industry Act](#) (“NZIA”) came into force on the 29<sup>th</sup> of June 2024. This Regulation 2024/1735 of the European Parliament and of the Council provides a framework of measures to strengthen the European manufacturing ecosystem for net zero emission technologies. The Act also acts as an [amendment](#) of the Regulation (EU) 2018/1724 which established a single digital gateway to provide access to information, procedures, and assistance services with the aim to enhance the internal market by making it easier to trade, establish and expand businesses across the EU borders. The regulation [currently applies](#) to **19 key net-zero technologies**, ranging from solar and wind power to batteries, heat pumps and hydropower and energy-intensive industry decarbonisation projects that are part of a net-zero technology supply chain. Critical raw materials are covered by separate legislation (Regulation (EU) [2024/1252](#)).

The main aim of NZIA is to reduce the external dependencies in the EU of net-zero technologies and their supply chains, setting manufacturing capacity goals of at least:

- 40 % of the EU’s annual deployment needs for net-zero technologies by 2030; and
- 15 % of world production of net-zero technologies by 2040.

The [objectives](#) of NZIA include:

1. **Creating a favourable environment** through legislation that outlines measures to encourage the production, development and use of net-zero technologies. The measures include the creation of single contact points in each member state to facilitate the development of their own projects and the reduction of permit-granting processes for net-zero technology manufacturing projects.
2. **Setting targets for CO<sub>2</sub> injection** capacity to inject at least 50 million tonnes of CO<sub>2</sub> into storage sites, such as former oil and gas fields, by 2030 and stipulates that sites must be operational for at least five years; providing free and fair access. The Commission is expected to report on progress every 2 years while member states are expected to develop CO<sub>2</sub> transport infrastructure, publish annual public reports on CO<sub>2</sub> capture, storage and transport projects, support measures, national strategies and cross-border schemes.
3. **Developing net-zero acceleration industrial valleys.** These clusters of net-zero industrial activity are meant to make the EU a more attractive location for manufacturing activities and facilitates the streamlining of administrative procedures for setting up net-zero manufacturing.
4. **Boosting market access** by requiring national authorities to apply minimum environmental sustainability standards in public procurement and works contracts and contracts should include at least a social or employment, cybersecurity features or a financial penalty for non-delivery. They should also provide pre-qualification criteria, such as responsible business conduct and data security and develop financial and other incentives to encourage use of net-zero technology products.

5. **Developing skills, quality jobs and innovation** through the launch of European net-zero industry academies with training programmes and qualifications on the skills required in the development and use of the new technologies. Member States are required to designate a single contact point to handle all testing requests in a regulatory sandbox and provide small and medium-sized enterprises (SMEs) with priority access to a regulatory sandbox's testing facilities.

The regulation also [provides supporting mechanisms](#) such as:

- The [Net-Zero Europe Platform](#) to support the Commission and Member States with the development and use of net-zero technologies,
- A [Strategic Energy Technology Plan \(SET-Plan\) Steering Group](#) to strengthen research and innovation collaboration among Member States, industry, and academia to foster the development and deployment of clean energy technologies and;

A **Net-Zero Regulatory Burden Scientific Advisory Group** to assess the impact of regulation on industrial development.

### 2.4.1. Background Context and relevance of the innovation principle

In the backdrop of this regulation is the European Union's (EU) commitment to accelerate the decarbonisation of its economy and the rapid deployment of renewable energy sources, to achieve climate neutrality, namely net-zero emissions or emissions after the deduction of removals, by 2050. The Regulation is in alignment with policy instruments such as the European Green Deal; with the first pillar of the Green Deal Industrial Plan making provisions to develop and maintain an industrial basis for the provision of net-zero technology solutions to secure energy supply and achieve goals for climate neutrality. The regulation has also been motivated by security concerns caused by the Russian invasion of Ukraine. This invasion led to increases in energy prices and a wake-up call to the EU's over-dependence on fuel imports notably from Russia.

The innovation principle is central to this regulation because it is structured into seven pillars, with innovation as one of them. One of the core objectives of this regulation is to position the EU as the leading producer and market for net zero products and technologies. This requires innovation, keeping up with market demands and trends to gain and maintain a competitive edge. Innovation also provides for a secure and sustainable supply of net-zero technologies necessary to safeguard the EU's resilience to reach its climate neutrality targets and boosting the EU's competitiveness on a global level.

### 2.4.2. Stakeholder consultation

The formulation of the NZIA regulation did consider the input of various stakeholders. The first [stakeholder consultation](#) held in November 2022 was the Net-Zero Europe Platform hosted by the Commission, engaging 23 Member States and players in the net zero industry. The stakeholders highlighted the need to address lengthy processes in procedures for constructing or expanding net-zero manufacturing capacity, shortage of skilled workforce and an urgent need to increase the manufacturing capacity in response to Russia's aggression.

The [second engagement exercise](#) was through a survey targeted towards different players within the industry where they were requested to provide additional insights on bottlenecks for scaling up manufacturing capacity in key net-zero technology sectors. The questionnaire was divided into six sections namely, market size, industrial footprint, general bottlenecks (constraints and barriers), permitting, financing, and public procurement. The Commission also sought more input through existing [industrial alliances](#), such as in the Clean Hydrogen Alliance,

Battery Alliance, and the Solar PV Industry Alliance. These alliances mostly focused on bottlenecks and produced reports on barriers, such as for large-scale deployment of clean hydrogen in the EU.

These contributions have a biased approach towards identifying barriers to the growth of the net zero industry within the EU. Security is one of the key metrics also considered in response to the Russian aggression. The innovation principle has been adequately considered, a folly considering that the industries would need to constantly innovate to be competitive on a global scale. Addressing bottlenecks and bureaucracies alone will not achieve the goal to be more competitive if the industry is not innovating and producing products that address market needs.

### 2.4.3. The Impact Assessment

There was no formal regulatory impact assessment for the NZIA, but a Staff Working Document (SWD) has been published which acts as an analytical basis as stipulated by the Better Regulations framework. Some of the reasons provided by the Commission for not producing a formal impact assessment include:

1. The NZIA has been framed by the Commission as urgent and time sensitive to respond to the drastic changes in international industrial policy and to improve European competitiveness in clean technologies amid international dynamics like the U.S. Inflation Reduction Act. A full impact assessment would have delayed the response to these changes.
2. The Better Regulation framework has provisions that allow the Commission to provide supporting evidence in the form of SWDs if there are constraints to producing a full impact assessment. Considering the time constraints, the SWD was an adequate and legal way to provide an assessment to support the Regulation.
3. The NZIA is a *first-of-its-kind* legal framework with no prior evaluations to build on. Therefore, the SWD would be sufficient as there were no comprehensive ex-post evaluations or fitness checks of existing laws the Commission could use as benchmarks.

### 2.4.4. Tool #22 and Regulatory Sandboxes

The Regulation highlights the incorporation and consideration of the innovation principle throughout the process of preparation, review and revision of all policy initiatives within it. The Regulation also makes a provision of regulatory sandboxes which will provide for [experimentation spaces](#) as scientific outcomes need to be tested in a controlled real-world environment. Member States can establish sandboxes at their own initiative, collaborating with industry, research institutes and civil society. This provision and collaboration will ensure a holistic approach and considerations for the creation of the sandboxes; leading to successful testing of scientific outcomes.

[Additional innovation-friendly solutions](#) put forward include the setting up of an innovation hub within the industrial valleys to attract startups in the net zero industry. To promote design and production of more innovative and advanced renewable energy technologies, the sustainability contribution of bids should have award criteria that promotes the use of entirely new solutions or the improvement of comparable state-of-the-art solutions. Funding will be availed through the Innovation Fund to create cost efficient avenues to scale up manufacturing and deployment of clean hydrogen and other net-zero technologies in the EU. Lastly, coordination of research and innovation activities will be implemented through the Strategic Energy Technologies Plan Steering Group, as well as by use of pre-commercial procurement and public procurement of innovative solutions.

## 2.4.5. Overall Assessment

The Regulation **does, to a great extent, adequately consider innovation**. The Regulation starts by recognising that the nature of the industry, together with set goals for the industry to grow and to achieve climate neutrality, requires innovation to be central across the different facets of the regulation. The Regulation calls for the application of the innovation principle during preparation, review and revision of all policy initiatives guided by the Regulation. The limited emphasis placed on the application of Tool #22 diminishes its perceived significance, resulting in implementers overlooking considerations of innovation and instead prioritising alternative performance metrics.

**Innovation was adequately considered as also evidenced by supporting mechanisms that support innovation provided for by the regulation. These include the use of sandboxes, setting up of innovation hubs, access to funding through the Innovation Fund and the creation of the Strategic Energy Technologies Plan Steering Group to coordinate research and innovation initiatives.** However, there were **significant gaps** on considering the innovation principle during stakeholder engagements. The engagements prioritised streamlining of processes, expanding manufacturing capacity, developing required skills for the industry and identifying bottlenecks; with no mention of innovation. This was a missed opportunity to identify the challenges stakeholders face in innovating or emphasising innovation as a core element to achieve the goals of the Regulation.

## 2.5. Case Study 5: Implementing regulation on auctions for renewable energies

### 2.5.1. Context, objectives and relevance for the innovation principle

The [Implementing Regulation on auctions for renewable energies](#) (hereby, 'the Implementing Regulation') forms part of the [Net-Zero Industry Act](#) (NZIA). The NZIA aims to strengthen the EU internal market by establishing a framework to ensure secure and sustainable access to net-zero technologies. It defines a list of net-zero technologies, of which renewable energy technologies are a core component (Article 4). The NZIA also introduces measures to stimulate demand for sustainable and resilient net-zero technologies, including through public auctioning. Among the measures introduced by the NZIA, Article 26 set out specific requirements for the auctioning of renewable energy. It requires Member States to apply pre-qualification criteria<sup>121</sup> and award criteria when assessing auctions for certain renewable energy technologies. Accordingly, auctions shall promote innovation by providing entirely new solutions or improving state-of-the-art technologies. Article 26 also mandates the Commission to adopt an implementing act specifying these pre-qualification and award criteria by 30 March 2025.

In this context, the European Commission adopted the Implementing Regulation on 23 May 2025 to specify Article 26 of the NZIA. It aims to support the industrial basis needed for the production and deployment of renewable energy technologies, thereby securing the Union's energy supply and reducing dependencies in the supply of these technologies.

The Implementing Regulation is highly relevant for fostering innovation in renewable energy, as it addresses several structural barriers to market uptake. Many renewable energy technologies - such as floating offshore wind, ocean energy technologies (wave and tidal), and innovative solar applications - have yet to be deployed at scale. Even more mature technologies, including solar PV and onshore wind, continue to face cost disadvantages relative to fossil fuels. The

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<sup>121</sup> Related to responsible business conduct; cyber security and data security; and ability to deliver the project fully and on time.

ability to demonstrate a reliable and predictable market is critical to accelerating innovation and crowding in private investment. By establishing uniform pre-qualification and award criteria for renewable energy auctions, the Regulation enhances market certainty and reduces investor risk.

### **2.5.2. The impact assessment**

No impact assessment was conducted for the development of this Implementing Regulation. Under the Better Regulation Guidelines (Chapter IV, section I), an impact assessment is required for Commission initiatives if two conditions are met: i) the initiative would entail significant impacts or spending; *and* ii) the Commission has a choice of policy options. This requirement also applies to delegated acts and implementing measures, including implementing regulations.

However, in the case of the Implementing Regulation in question, the second condition was not met. Article 26 of the NZIA already set out the relevant policy option, which includes pre-qualification and award criteria for responsible business conduct, cyber security and data security, ability to deliver the project, and the sustainability and resilience contribution of auctions. As a result, through this Implementing Regulation, the Commission did not assess or develop alternative policy options, but instead specified the criteria already set out in Article 26 of the NZIA.

### **2.5.3. Stakeholder consultation**

A [public consultation](#) on the draft text of the Implementing Regulation was held between 24 January 2025 and 21 February 2025. Of the 121 responses, 17 (14%) referred to innovation, while none explicitly mentioned the innovation principle.

Of the 17 innovation-related response, six (35%) generally highlighted the importance of non-price criteria in fostering innovation and competitiveness of the EU renewable energy sector. Seven (41%) focused on the Regulation's requirement of on innovation criteria (Article 14 in the adopted text of the Regulation), in particular regarding the distinction between general auctions and pure innovation auctions (two responses) and issues related to technology neutrality (three responses). Two responses welcomed the requirement for auction participants to go beyond the state of the art of technologies. They consider this requirement as a driver of innovation in the sector. Finally, four other responses addressed issues related to technology maturity requirements, intellectual property protection, project description, and the role of the workforce in supporting sustainable technological progress.

### **2.5.4. Changes following innovation-friendly solutions in the legislation**

Article 26 of the NZIA features several innovation-friendly solutions, which are further specified in the Implementing Regulation. The list below examines the specific innovation-related instruments introduced under Article 26 of the NZIA and the Implementing Regulation. As both the NZIA and the Implementing Regulation were adopted recently (2024 and 2025 respectively), it is still early at the time of drafting to observe whether these innovation-promoted solutions have led to changes in the relevant provisions.

*Review provision:* Article 26 of the NZIA requires the Commission to conduct a comprehensive assessment of the impacts of the resilience and sustainability criteria applied in renewable energy auctions by 31 December 2027 and every two years thereafter. The assessment will examine, inter alia, the effects on the deployment of renewable energy sources. Its finding may inform adjustments to the annual auction volumes per Member State. An increase in the auction volumes would stimulate innovation in specific technologies.

*Distinction of pure innovation auctions.* Recital 29 and Article 14 of the Implementing Regulation distinguish two types of auctions: general auctions and pure innovation auctions. The latter are explicitly designed to promote novel renewable technologies. Recital 29 also provides examples of such technologies, including wave, tidal energy projects and kite-borne wind turbine projects. This provision is considered one of the most remarkable innovation-friendly instruments of the Regulation.

*Technology neutrality* is partially featured in several provisions of the Regulation.

- Recital 34 and Article 15 require that non-price criteria related to energy system integration be structured to ensure that all technologies and solutions capable of meeting the identified system needs can participate in auctions.
- Article 7 (on the resilience criteria of auctions) partially reflects the technology neutrality principle. It specifies the renewable energy technologies subject to the resilience requirement, namely solar PV technologies, onshore and offshore wind, electrolysers, and heat pumps. The scope for solar technologies is limited to PV, excluding other emerging technologies such as perovskites, solar thermal panels, and solar tiles. At the same time, Article 7 allows for the inclusion of additional technologies by referring to “all the net-zero technologies falling under the scope of Article 26 of NZIA”<sup>122</sup> other than those listed. However, the rules applicable to the explicitly listed technologies differ from those applied to the broader category of net-zero technologies covered by Article 26.
- Some stakeholder feedback on terminology affecting technology neutrality does not appear to have been taken up. For example, one stakeholder logging feedback to the public consultation pointed to the limitation of using the term ‘kite-borne wind turbine projects’ and recommended referring to ‘airborne wind energy projects’ instead better reflect the full spectrum of technologies within this sector. This comment appears not to be incorporated in the final text of the Regulation.

*Performance-based standards:* Recital 28 provides that the innovation criteria in renewable energy auctions should promote the development of cutting-edge technologies that go beyond the state-of-the-art solutions available in the market. Additionally, Recital 30 and Article 14 leverage the performance standard as instrument to promote innovation. Contracting authorities are required to assess candidate projects against minimum thresholds for key performance indicators, such as improvements in longevity, energy generation efficiency, recyclability, environmental impacts, or reduced dependence on raw materials. These improvements should exceed the state-of-the-art technology available on the market.

*Knowledge dissemination* is recognised as a key instrument for spurring innovation under Recital 31 and Article 14. Accordingly, authorities should include, as pre-qualification or award criteria, the sharing of results from winning bids through publications, conferences, open access platforms, or open-source channels. In addition, winning bidders are required to offer non-

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<sup>122</sup> They include:

- (a) solar technologies, including PV, solar thermal electric and solar thermal technologies;
- (b) onshore wind and offshore renewable technologies;
- (c) battery and energy storage technologies;
- (d) heat pumps and geothermal energy technologies;
- (e) hydrogen technologies, including electrolysers and fuel cells;
- (f) sustainable biogas and biomethane technologies;
- (g) carbon capture and storage technologies;
- (h) electricity grid technologies, including electric charging technologies for transport and technologies to digitalise the grid;
- (i) nuclear fission energy technologies, including nuclear fuel cycle technologies.

exclusive and non-discriminatory licences for protected research results at market prices, while ensuring appropriate safeguards for confidentiality.

*Regulatory flexibility:* Article 26 of the NZIA requires certain non-price criteria to be applied as pre-qualification criteria of auctions, while granting Member States *flexibility* to apply other criteria either as pre-qualification criteria, as award criteria, or as a combination of both. This flexibility is particularly important for innovation in the renewable energy sector. For example, technologies such as offshore wind, key project information – including details on suppliers and contractors - is typically available only at later stages of the tendering process. In such cases, Member States may choose to apply requirement related to suppliers and contractors as award criteria rather than as pre-qualification criteria.

In addition, Article 3 introduces flexibility to reflect technological progress by requiring that non-price criteria take into account the market maturity of the relevant technologies. It also allows these criteria to be developed with the involvement of key stakeholders, including developers, manufacturers, civil society representatives, and technical experts.

Finally, *policy dialogue* is also embedded in the Regulation. Article 16, which concerns the assessment of auctions, requires that bid evaluation methodology should be developed in consultation and cooperation with relevant stakeholders and experts.

### **2.5.5. Overall assessment innovation consideration and the innovation principle**

Overall, innovation is considered to be adequately integrated in the Implementing Regulation, albeit within a predefined framework set by Article 26 of the NZIA. The absence of an impact assessment reflects the limited discretion available to the Commission, as the core innovation-related policy choices had already been defined in Article 26 of the NZIA. As a result, innovation was considered mainly in terms of how to implement the legal mandate, not whether alternative innovation-supporting approaches could be pursued.

The innovation principle appears to have had an indirect influence on the drafting process. Many of the features embedded in the Implementing Regulation - such as dedicated innovation auctions, performance standards exceeding the state of the art, regulatory flexibility linked to technological maturity, and knowledge-sharing obligations - are highly consistent with the logic and objectives of the innovation principle.

The case study highlights several structural limitations in the current application of the innovation principle. *First*, the procedure illustrates the limited reach of the innovation principle in implementing acts, where policy discretion is constrained. The absence of an impact assessment, while formally justified, means that innovation instruments and impacts were not assessed in a structured, transparent, or comparative manner, especially when it comes to stakeholder consultation. This raises questions about whether the innovation principle should be more clearly integrated into situations where impact assessments are waived, for example through lighter-touch innovation checks or dedicated analytical sections. *Second*, findings from stakeholder consultation points to tensions around technology neutrality, such as the narrow framing of certain technologies. These issues suggest that the innovation principle could play a stronger role in flagging risks of technological lock-in or unintended exclusion of emerging innovations at an early stage. *Finally*, the lack of explicit reference to the innovation principle - both by stakeholders and institutions - suggests that it remains insufficiently operationalised and visible.

## 2.6. Case Study 6: The Artificial Intelligence Act

### 2.6.1. Context, objectives and relevance for the innovation principle

The long saga of the European Union Artificial Intelligence Act allows a long series of considerations with respect to the implementation of the innovation principle. Given the complexity and ever-changing nature of the subject matter, EU institutions have been challenged with revisiting their understanding of AI throughout the life of the legislative file, at least since 2018 and potentially until 2027, when some of the provisions of the AI Act shall eventually come into force.

In terms of agenda-setting, the European Commission decided to set up **two structured forms of consultation**, one with a large group of stakeholders (**AI Alliance**) and another more expert-led, in the form of the creation of an **independent High Level Expert Group on AI**, which was active in the period 2018-2020 and release ethics guidelines for trustworthy AI already in April 2019. In 2020, a **White Paper on AI** placed innovation as central objective of the EU's agenda in this domain, specifying the need to create both **an ecosystem of trust, and an ecosystem of excellence** for AI. An **open public consultation on the White Paper** then became the starting point for the impact assessment work, which was accompanied by a **long and detailed impact study** carried out by external experts.<sup>123</sup> Importantly, no foresight was carried out at that time, but the impact study incorporated assumptions on the future evolution of the AI market, which were essential to allow a quantification of the possible impact of introducing regulatory requirements for high-risk AI.

The public consultation on the White Paper [launched](#) in July 2020, and contained three sections: Section 1 referred to the specific actions for the building of an ecosystem of excellence to support the development and uptake of AI across the EU economy and public administration; Section 2 outlined a series of options for a regulatory framework for AI; and Section 3 referred to safety and liability aspects of AI. Especially the first section contained a focus on *i.a.* research on innovation, leading to three actions suggested by stakeholders: 86% of respondents said that the support of the existing networks of research and innovation centres is (very) important; 64% of respondents endorsed a new initiative for a world-class lighthouse research centre as (very) important; and 69% of respondents considered a public private partnership (PPP) for industrial research as (very) important.

Also, the role of Digital Innovation Hubs in supporting the uptake of AI by SMEs was highly appreciated by consultation participants. Knowledge transfer and the support of AI expertise for SMEs was seen as a (very) important task of Digital Innovation Hubs by 78% of respondents. In addition, 76% of respondents considered access to testing and reference facilities and SME partnerships with larger enterprises and academia as a (very) important contribution that Digital Innovation Hubs would have to offer.

Against this background, the AI Act was seen as mostly referred to the ecosystem of trust, rather than the ecosystem of excellence, the latter being the one most oriented towards innovation. This could have led to an insufficient emphasis on innovation in the impact assessment of the AI Act (IA192), even if the IA in fact contains several elements that could be implicitly or explicitly referred to the innovation principle.

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<sup>123</sup> Full disclosure: Andrea Renda at CEPS was the lead author of that study.

## 2.6.2. The impact assessment: innovation-friendly elements

The Commission proposal for an AI Act eventually saw the light in April 2021. It was accompanied by a detailed IA (IA192 in our sample), which contained several elements relevant for the innovation principle application. These included the following:

- In terms of regulatory design, the following elements in the AI Act were particularly important:
  - The choice of a **largely technology-neutral definition of AI**, rather than more specific definitions (e.g. machine learning). The definition was criticized for being too broad, but it referred to an Annex, which contained more specifications and could be amended more easily than the text of the Act itself: this, in and of itself, is a good practice in terms of adaptive regulation.
  - The **choice of a risk-based approach** to the regulation of AI, which some contrasted with an alternative “rights-based” approach, aimed at focusing regulatory efforts where they are most needed. It also led the European Commission to explicitly prohibit certain applications of AI.
  - The **focus on regulating high-risk applications on AI**, rather than on regulating the technology *per se*. The European Commission also clarified that it expected high-risk applications to represent at most 10% of AI application in the market.
  - The introduction of **more easily changeable lists** of high-risk AI applications and prohibited AI applications. The fact that the lists were included in Annexes, thus separate from the main text of the legislation, allowed for this update without requiring a new ordinary legislative procedure to be launched and completed.

At the same time, the Act appeared at once too prescriptive to be fully principles-based, and not specific enough to be actionable for each application it would apply to. This left ample space for interpretive guidance (e.g. on what human oversight, transparency, or high-quality data requirements would entail for autonomous vehicles as opposed to a triage system in a hospital, a fraud detection system in government, a mortgage eligibility algorithm in a bank, or a content moderation algorithm in a social network).

- In terms of regulatory options and measures, the following aspects were particularly important.
  - The choice of introducing a **principles-based, largely co-regulatory approach**: apart from cases in which AI was to be embedded in products subject to the EU product safety legislation, in all other cases the assessment of the conformity of a high- and limited-risk AI applications with the requirements of the AI Act is to be carried out through “internal checks”. More generally, the approach adopted by the AI Act is rooted in product safety, as such eminently co-regulatory; as well as in the overall approach of the General Data Protection Regulation, which is also based on self-assessment and subsequent monitoring by competent authorities.
  - The introduction of a **softer, innovation-friendly pathway for non-high-risk AI**: industry-led voluntary codes of conduct that adapt “trustworthy AI” requirements to lower-risk contexts. The IA explicitly rejects a separate voluntary label as potentially too complex/costly (especially for SMEs) and instead prefers codes as a lighter mechanism.
  - The introduction of **regulatory sandboxes**, designed to enable experimentation and testing of innovative AI systems *before market placement*, under a specific testing plan and direct supervision of competent authorities. Key design constraints are important: regulatory sandboxes would allow for no derogations or exemptions from applicable law (the regulatory sandbox is not a carve-out); authorities may use flexibility within

existing discretion (guidance on proportionality, robustness, transparency, etc.), but the legal requirements still apply.; they would lead to **immediate rectification/suspension** if significant safety or fundamental-rights risks emerge during testing. The IA explicitly claimed these regulatory sandboxes would foster innovation and increase legal certainty (hands-on guidance for compliance), speed up market access while minimising rights/safety risks, give regulators supervisory learning and early detection of emerging risks, and generate evidence that could inform updates to the list of high-risk use cases.

- The IA layered multiple **burden-reduction and capability-support measures** aimed at keeping compliance from chilling entry. First, the IA explicitly suggests priority access to regulatory sandboxes for SMEs/start-ups and other tailored support (awareness-raising, guidance). It also states that notified bodies should take SMEs' interests into account in fee setting and reduce fees proportionately. Moreover, a central claim is that harmonised standards reduce compliance design costs and help SMEs build trust without inventing their own governance/QA practices from scratch—supporting faster scaling and market acceptance.
- The IA points to Digital Innovation Hubs (DIHs) and Testing & Experimentation Facilities (TEFs) under the Digital Europe Programme as practical support, particularly to SMEs: training on requirements, technical/scientific assistance, and access to testing facilities (which matters particularly where physical infrastructure is costly).
- The launch of an **AI-on-demand platform + model compliance programmes**. The IA notes additional SME support through resources/services (AI-on-demand platform) and guidance/model compliance programmes—again framed as reducing barriers rather than funding R&D.

The IA's **monitoring framework is not focused on innovation**, but rather built around compliance, risk control and market functioning. Indicators are aligned with the specific objectives of the Regulation, which prioritises, safety and fundamental rights protection, legal certainty and harmonisation, and effective enforcement. As a result, monitoring focuses on inputs, processes and compliance outcomes, rather than on innovation outputs or dynamics.

### 2.6.3. Stakeholder consultations

There has been no shortage of public consultations, after the one already mentioned on the White Paper on AI in 2020. They include the following:

- **“AI Act: Have Your Say on Trustworthy General-Purpose AI”**. A multi-stakeholder consultation on General-Purpose AI models, including transparency, taxonomy and Code of Practice drafting. It opened on 30 July 2024 and closed: 18 September 2024. The main focus is on trustworthy GPAI criteria and draft Code of Practice content.
- **Consultation on High-Risk AI Systems Implementation**. Commission public consultation collecting input on how to implement rules on high-risk AI systems (classification, obligations). Launched June 2025 (duration varies by publication), it focused on practical examples and clarifications supporting future guidance on high-risk AI.
- **Consultation on Guidelines & Code of Practice for Transparent AI Systems**. Commission consultation to aid development of guidelines and a related Code of Practice under the AI Act, particularly for AI transparency obligations. Launched in early September 2025, focuses on transparency obligations and practice-oriented compliance support.
- **Consultation on Draft Guidance and Reporting Template for Serious AI Incidents**. A public consultation on draft guidance and a standard incident-reporting template under Article 73 (serious-incident reporting). It opened on 26 September 2025 and closed on 7

November 2025. The main focus is on clarifying incident definitions and interplay with other reporting regimes.

- **Consultation on Protocols for Text & Data Mining and GPAI Code of Practice**, to support the AI Act's obligations (including copyright-related reservation rights) and connected GPAI Code of Practice implementation. Opened on 1 December 2025, closed on 23 January 2026. The main focus is on technical opt-out protocols relevant to the GPAI Code of Practice.
- **Draft Implementing Act on AI Regulatory Sandboxes**. The Commission seeks feedback on the draft implementing act establishing common rules for regulated AI regulatory sandboxes under the AI Act. Open since 2 December 2025, it closed on 13 January 2026.
- **Consultation on the First Draft Code of Practice on Marking & Labelling AI-Generated Content**. A public consultation on the first draft of the voluntary transparency Code of Practice under Article 50. Opened on 17 December 2025, it closed on 23 January 2026. The main focus is on marking and labelling of AI-generated content and related transparency compliance.

Most of these consultations are directly related to the application of the rules, but leave very little space to innovation-related considerations. The table below offers a comparative analysis from this standpoint.

Table 3 – Recent stakeholder consultations on the AI Act

Consultation	Main Focus	Innovation Mentioned in Consultation Text?	How Innovation Appears (if at all)
Trustworthy General-Purpose AI models (GPAI Code)	Multi-stakeholder consultation on transparency, systemic risk taxonomy, and Code of Practice drafting. (Digital Strategy)	Indirectly / implied	Format invites industry and academic input on model obligations. It implicitly supports innovation by enabling compliant deployment and industry participation but doesn't explicitly ask about "innovation impacts." (Digital Strategy)
High-Risk AI Systems Implementation	Collect practical examples and clarify obligations under the AI Act for high-risk systems. (Digital Strategy)	Indirectly / contextual	Broader inclusion of developers, businesses and research institutions suggests relevance for innovation adoption and clarification of high-risk AI requirements, but text does not pose innovation-specific questions. (Digital Strategy)
Transparency Code of Practice	Draft guidelines and Code of Practice for transparent AI systems (e.g., labelling). (Digital Strategy)	Not explicitly	Focuses on compliance with transparency obligations. Discussion of innovation is assumed (e.g., better informed users, innovation in detection technologies) but not an explicit consultation topic. (Digital Strategy)
Protocol for TDM reservation rights & GPAI Code	Consultation on text and data mining opt-out protocols linked to the GPAI Code. (Digital Strategy)	Not explicitly	Technical focus on protocols; innovation emerges indirectly through enabling experiments with systemic GPT/AI models and rights management protocols, but innovation questions are not directly posed. (Digital Strategy)
Draft Implementing Act on AI Regulatory Sandboxes	Rules for establishment and operation of regulatory sandboxes. (Digital Strategy)	Implicit	Consultation mentions supporting AI innovation and compliance through regulatory sandboxes, but innovation is treated as a background objective of the sandbox regime, not as a distinct consultation theme. (Digital Strategy)

## 2.6.4. Implementation of Tool #22 and regulatory sandboxes

Several elements of the IA on the AI act could be related to innovation and the innovation principle, despite the absence of an explicit reference to the tool, or the principle itself. At the same time, the Commission could have incorporated more innovation-friendly elements early-on in the IA and the Act itself, such as the empowerment of an AI Agency for the gradual production of interpretive guidance, and a better coordination of regulatory sandboxes at the EU level. These provisions have gradually been added by the Commission and the co-legislators, as for example through the establishment of the central EU AI Office and its support functions like the AI Service Desk<sup>124</sup> and Compliance Checker, and by the recent Digital Omnibus, which aimed at streamlining further some of the provisions. Also, the implementation of the AI Act was made conditional on the existence of adequate standards, for which a mandate was given to CEN-CENELEC: while this standards-based enforcement approach is certainly pro-innovation, the standardisation process has proven to be too clumsy, leading the Commission to the decision to postpone the application of certain provisions of the AI Act to wait for the process to be completed.

On the other hand, the AI Act also rested on a comprehensive treatment of competitiveness and SME support. The IA includes an explicit competitiveness assessment, framed mainly in terms of the EU's position in the global AI market and the risk that regulation could undermine investment, market entry or scale-up. The IA argues that a harmonised, risk-based EU framework will ultimately enhance competitiveness by reducing fragmentation, increasing trust in AI, and facilitating cross-border market access. Competitiveness gains are therefore expected to arise indirectly, through higher uptake and legal certainty rather than through cost advantages. At the same time, the IA acknowledges potential negative competitiveness effects, notably: increased compliance and conformity assessment costs, risk of relocation or delayed deployment of high-risk AI, disproportionate impacts on smaller or less capitalised firms. These risks are discussed qualitatively and addressed through mitigation measures (standards, regulatory sandboxes, SME support), but the IA does not provide robust comparative evidence that EU firms will remain competitive vis-à-vis global rivals. The RSB explicitly criticised this weakness, noting that the IA does not convincingly demonstrate that the cost structure will not disadvantage EU innovators or new entrants.

The IA also contains a dedicated SME test, recognising that SMEs and start-ups are central to the AI ecosystem and may be disproportionately affected by fixed compliance costs. The IA identifies several SME-specific risks: limited legal and compliance capacity; higher relative cost of conformity assessments; difficulty navigating complex obligations for high-risk AI. To mitigate these impacts, the IA proposes a package of SME-targeted measures, including priority access to regulatory sandboxes, reduced conformity assessment fees, reliance on harmonised standards to lower design and compliance costs, access to Digital Innovation Hubs and Testing & Experimentation Facilities, and guidance and awareness-raising by competent authorities. However, the SME test remained largely qualitative. The IA does not quantify net cost reductions for SMEs, how many SMEs will realistically benefit from these measures, whether mitigation offsets fixed costs in practice. The RSB repeatedly flagged this as a major shortcoming, stating that the IA does not sufficiently demonstrate that SMEs will not be crowded out or discouraged from innovation.

## 2.6.5. Overall assessment

The AI Act was inevitably a significant testbed for the innovation principle. The overall impression is mixed: the presence of several innovative elements in the design of the regulation, the alternative policy options and the implementation measures, including the extensive guidance provided and consultation carried out, partly compensate for lack of adequate

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<sup>124</sup> [AI Act Single Information Platform | AI Act Service Desk](#)

foresight, as well as more dynamic, adaptive, agile provisions in the overall approach to the regulation of AI applications. Subsequent iterations, such as the extension of the scope to General Purpose AI Systems and the establishment of the AI Office in charge of centralised enforcement, were not originally envisaged by the Commission's proposal, and appear to have deviated from the original intent to refrain from regulating the technology *per se*.

Also, many provisions, including the ones regulatory sandboxes, will have to prove their worth on the market. The limited cases available to date (for example, in Spain) are not very reassuring on the value of regulatory sandboxes to test conformity with the Act. Most importantly, the Act ended up landing in between a very generic, principles-based piece of legislation, and a prescriptive one with provisions directly applicable to individual use cases. As a result, it falls short of providing the flexibility one would expect from a principle-based legislation, and the specificity and legal certainty one expects from a more detailed piece of legislation. The innovation community has flagged this as potentially providing a lack of regulatory certainty.

## 2.7. Case Study 7: Fit for 55: Intelligent transport systems; Emission Trading System and its extension to aviation

The Emissions Trading System (EU ETS) is the European Union's (EU) [tool](#) to reduce greenhouse gas emissions and achieve the body's climate goals of reducing net greenhouse gas emissions by at least 55% by 2030 and reaching climate neutrality by 2050. The EU ETS is part of the broader 'Fit for 55' package; a set of proposals to revise and update EU climate, energy and transport legislation. The EU ETS operates on a cap-and-trade system, with an established cap on the total amount of greenhouse gas (GHG) emissions that can be emitted by the targeted sectors. The cap is reduced annually to ensure a steady decline in emissions. The trade aspect refers to companies receiving or purchasing EU Allowances that permits them to emit one tonne of carbon dioxide (CO<sub>2</sub>); companies that manage to reduce their emissions can sell their excess allowances. The EU ETS will [apply](#) for intra-European flights, including departing flights to the United Kingdom and Switzerland.

The [main objectives](#) of the EU ETS extension to the aviation sector are to:

1. **Lower aviation GHG emissions** in alignment with EU's climate goals. The aviation industry has been identified as one of the biggest contributors to GHG emissions. This legislation ensures that aviation sector contributes fairly to this goal.
2. **Strengthen the “polluter pays” principle** and rules, with free allowances for airlines being phased out progressively (25 % in 2024, 50 % in 2025 and 100 % auctioning from 2026). This strengthens the economic incentive to reduce emissions and the urgency to innovate.
3. **Promote the use of sustainable aviation fuels (SAF)**. To achieve this, the EU ETS revision reserves 20 million allowances to help bridge the price gap between sustainable aviation fuels and conventional fuel.
4. **Improve emissions transparency and reporting** by introducing tighter rules on monitoring, reporting and verification, extending these rules to non-CO<sub>2</sub> climate effects like oxides of nitrogen (NOx) and contrails. These reports are meant to provide data that can be used to inform more comprehensive climate policy for the EU.

**Integrate, align and evaluate with global measures**, especially with international schemes such as the International Civil Aviation Organisation's (ICAO) Carbon Offsetting and Reduction Scheme for International Aviation (CORSIA). The Regulation makes a provision to revise and adjust EU policy if global action is insufficient to meet climate goals.

### 2.7.1. Background

Aviation emissions were rising too fast to meet EU climate targets and the free allowances under the ETS weakened incentives to reduce emissions. In response, the EU called for a global solution leading the adoption of CORSIA in 2016. However, CORSIA's climate ambitions were limited and did not align with the European Green Deal and later the Fit for 55 package and their commitment to mitigate climate change. To address this, the Directive 2003/87/EC (the ETS Directive) was revised and amended under the Fit for 55 legislative package. The revision included extending the legislation to the aviation sector, which had been identified as one of the biggest GHG emitters.

The EU ETS Directive aims to promote the use of SAF in the aviation industry. This objective makes innovation a core principle to consider, ensuring that the industry is creating solutions that lead to a quick adoption of SAF in support to the achievement of EU's climate neutrality goal. The monitoring and reporting aspects will require the adoption of innovative and efficient tools that ensure that the Commission gets accurate data and progress reports across the whole industry.

### 2.7.2. Stakeholder Engagement

Several stakeholder engagement initiatives were done during the different stages of the EU ETS for the aviation sector. Between October 2020 and January 2021, as part of the Fit for 55 legislative process, the Commission conducted an assessment of options for integrating the aviation sector in the EU ETS. This resulted in a [report](#) prepared by the Committee on Environment, Public Health and Food Safety (ENVI) proposing to expand EU ETS to cover not only intra- European Economic Area (EEA) flights but also flights to third countries departing the EEA. The report also proposed that revenues from auctioning go primarily towards greening the sector including for the development of sustainable aviation fuels. The Parliament adopted the report during the June 2022, plenary session with 479 votes in favour, 130 against and 32 abstentions, and referred to the ENVI with a mandate for trilogue negotiations. This highlights the difference in priorities amongst the stakeholders, with NGOs mostly preferring stricter measures while the industry players opt for leniency. Saliently, there was no consideration of innovation during the stakeholder engagement process.

In 2023, the Commission published a [call](#) for aviation experts to join an expert group to support the Commission in the implementation of the amendments regarding aviation's contribution to the EU's emission reduction target. The call was open to two groups of stakeholders, namely associations representing industries, sectors and solution providers related to the aviation sector, as well as non-governmental organisations and academic institutions with expertise in the aviation industry. The main areas of focus were new support mechanisms to speed up the use of the eligible sustainable aviation fuels (SAF), creating a new system for airlines to monitor, report and verify non-CO<sub>2</sub> effects of aviation and implementing the Carbon Offsetting and Reduction Scheme for International Aviation (CORSIA).

The Commission also launched an [open consultation](#) on the EU ETS calling upon stakeholders to provide feedback on how the ETS has been implemented and how it could be improved. The call advised stakeholders to use the Better Regulation framework with a special focus on potential economic, social and environmental impacts of possible amendments to the ETS Directive. The particular use of Tool 22 was not mentioned.

### 2.7.3. Impact Assessment of Legislation

An [impact assessment](#) on the ETS extension to the aviation sector was conducted and published in 2021. The [opinion](#) provided by the Regulatory Scrutiny Board (RSB), also does not refer to the use of tool 22 or mention the use of the Innovation Principle. The policy options were

evaluated using two metrics, environmental and economic impacts; also making no mention of innovation. A foresight scanning exercise was conducted to determine which policy options would be preferable, with a special consideration of the future evolution of fuel prices and future carbon values. The core themes highlighted in the assessment were:

1. Climate, with an emphasis on how stronger ETS provisions would raise the carbon price applied to aviation, incentivising emission reductions.
2. Market and cost implications and how they would affect the aviation sector, including the passengers.
3. Alignment with global schemes such as CORSIA and how the EU might extend ETS to extra-EEA flights if CORSIA proves insufficient.
4. Innovation, in relation to the adoption of SAF and different ways to support their production and use.

The impact assessment does not include policy options that can be considered as particularly suited to promote innovation such as regulatory sandboxes and co-regulation.

## **2.7.4. Overall Assessment**

The Regulation does, to a lesser extent, consider innovation. The core priority has been the creation of incentives for the aviation industry to reduce GHG emissions. Efforts have been centred on strategies to steadily reduce the cap-and-trade permits in ways that do not affect the industry and ultimately the customers and on extending this to flights going outside the EEA, so as to not be constrained by global standards by CORSIA which could hinder the EU's ambitious climate goals. Through this regulation, the Commission also seeks to promote the adoption of SAF, which requires the innovation and adaptability of players in the innovation industry. This will require that stakeholders in the aviation sector innovate and adapt their products and processes to make their fleets and operations emit less GHG. Finally, this regulation tasks the Commission to monitor and evaluate data on GHG emissions. This will require innovative and efficient systems to capture industry wide data that can be used to measure progress and inform policy.

## **2.8. Case Study 8: The Digital Services Act**

### **2.8.1. Context of the legislation, its objectives, and relevance for the innovation principle**

The [Digital Services Act](#) (DSA) was proposed by the European Commission in 2020 and was formally adopted in 2022. Together with other digital legislations, like the [Digital Markets Act](#) (DMA), it aims to update the regulatory framework around online platforms and intermediary services. Building on the [E-Commerce Directive](#) of 2000, the DSA responds to the changes of the last 20 years in the digital field. In particular, the DSA addresses challenges like the spread of illegal content, online disinformation, and the lack of transparency in platform moderation and advertising systems, with the objectives to create a safer digital space where users' fundamental rights are protected, to increase accountability and transparency of online platforms, and to establish clear responsibilities for digital services operating in the EU. At the same time, the regulation also seeks to maintain a functioning digital single market by applying proportionate obligations depending on the size and societal impact of platforms. Overall, the DSA represents a central pillar of the EU's strategy to regulate the digital economy and ensure that online platforms operate in a way that is transparent, responsible, and aligned with European values.

Although innovation is mentioned only a limited number of times in the regulation, it remains an important aspect of its design and objectives. From the outset, the regulation links the

governance of digital services with the promotion of innovation within the European digital economy: Article 1 states that the DSA aims to ensure the proper functioning of the internal market for intermediary services by introducing harmonised rules that create a safe, predictable, and trustworthy online environment, while also facilitating innovation and protecting fundamental rights, including consumer protection. In addition, Recital 4 highlights that the regulatory framework is designed to remain technology-neutral so that new technological developments are not restricted by overly rigid rules. By adopting this approach, the DSA seeks to balance stronger user protection and platform accountability with the need to support technological progress and the continued development of innovative digital services.

## **2.8.2. The impact assessment**

The impact assessment of the DSA is divided in two parts. In both parts, innovation is not framed in terms of “innovation principle”. Instead, ‘innovation’ is linked to the development of digital services, the functioning of the Digital Single Market, and the competitiveness of the EU digital economy.

The document highlights that legal fragmentation across Member States creates barriers for digital services, particularly for SMEs seeking to scale within the single market. Such fragmentation generates not only direct compliance costs but also opportunity costs by limiting potential business innovation (Part 1, 2.2.3). The EU intervention is therefore justified as a means to improve supervision of digital services and coordination between authorities, which is expected to enhance trust while supporting innovation and growth in the Digital Single Market (Part 1, 3.2).

The IA also connects innovation to the clarification of the intermediary liability regime. Increased legal certainty is expected to encourage investment, competitiveness, and innovation in digital services, particularly benefiting EU start-ups and scale-ups operating platform-based business models (Part 1, 6.1.2). At the same time, the assessment recognises that digital intermediary services are a major driver of technological innovation and digital transformation, while also creating new regulatory challenges such as illegal content and risks to fundamental rights.

Finally, the IA notes synergies with the Digital Markets Act (DMA), as both initiatives aim to strengthen the single market for digital services, improve opportunities for innovation, and enhance the supervision of digital platforms (Part 1, 7.1.3). Alternative regulatory approaches, such as a potential strict liability regime for platforms, were discarded because they were considered detrimental to innovation, competitiveness, and fundamental rights (Part 2, 3.5).

## **2.8.3. Stakeholder consultations**

The IA highlights extensive stakeholder engagement during the policy preparation process. The European Commission conducted open public consultations, targeted consultations with Member States, stakeholder workshops, and bilateral meetings with companies, organisations, and civil society actors active in the digital sector. These activities were used to gather evidence on market developments, the functioning of the E-Commerce Directive, and the challenges posed by online platforms and illegal content. During the consultation process, many respondents (particularly start-ups, SMEs, and business associations) warned that legal fragmentation and disproportionate compliance costs could hinder innovation and limit the ability of smaller companies to scale across the EU. As a result, the document emphasises the importance of a balanced regulatory framework that preserves the benefits of the internal market while introducing proportionate obligations, especially for smaller digital services, and addressing the risks associated with very large platforms.

## 2.8.4. Tool #22 and regulatory sandboxes

There are no explicit references to “regulatory sandbox” or Tool #22 in the DSA, which relies on traditional regulatory instruments rather than experimental governance tools.

However, as previously mentioned, the Regulation includes references to “vetted researchers”: researchers who can access certain platform data to study systemic risk. In Article 31 of the regulation, it is in fact stated that very large online platforms may be required to provide data access to qualified researchers for the purpose of analysing risks such as disinformation or manipulation of online systems. The Impact Assessment instead refers more generally to experts, academic research, and stakeholder input used to support the policy analysis.

In the impact assessment, in the methodology section, the document explains that the analysis relied partly on interviews with legal experts and judges involved in key cases, as well as on evidence gathered from academic research and expert commentary on digital technologies and online content moderation. These expert inputs helped inform the legal and economic analysis underlying the policy options considered in the IA.

## 2.8.5. Overall assessment

The DSA regulation was introduced to respond to the rapid digital and technological transformations of the last two decades and to update the regulatory framework governing online platforms and intermediary services. It aims to better address the societal challenges created by digital technologies and services while ensuring stronger protection of the fundamental rights of EU citizens. Ultimately, the DSA represents an attempt to balance stronger regulation of digital platforms with the need to maintain a dynamic and innovative digital ecosystem in the European Union, as also highlighted in the opinion of the [Regulatory Scrutiny Board](#).

## 2.9. Case Study 9: Markets in Crypto-assets

### 2.9.1. Context of the legislation, its objectives, and relevance for the innovation principle

The Regulation on Markets in Crypto-assets (MiCA) establishes the first comprehensive EU regulatory framework for crypto-assets and related services. It entered into force in 2023 and aims to address the risks related to the recent crypto asset market. It was created to bring more clarity and safety to the crypto market by regulating how crypto-assets are issued, traded, and managed. The regulation also aims to protect investors and create a clear legal framework for businesses operating in the digital asset sector.

The MiCA refers to innovation in several recitals when explaining the rationale for establishing a harmonised EU framework for crypto-assets. The regulation emphasises that EU financial legislation should be adapted to the digital age and enable the use of new technological solutions in financial services (Recital 1). It also recognises that crypto-assets may provide new and more inclusive ways of raising capital, particularly for SMEs (Recital 2). At the same time, MiCA notes that the previous absence of an overall regulatory framework across Member States created legal uncertainty for companies and weakened user confidence, potentially limiting the development of markets for crypto-assets and the emergence of new digital services, payment instruments, or funding mechanisms (Recital 5). For this reason, the regulation introduces a harmonised legal framework intended to support technological development and fair competition while ensuring investor protection and market integrity (Recital 6). The regulation also stresses that regulation in this field should remain adaptable and capable of keeping pace with technological developments (Recital 16), which is reflected in the requirement for the

Commission to assess whether additional emerging forms of crypto-assets should be included within the scope of the regulation in the future (Article 140q).

### **2.9.2. The impact assessment and Regulatory Scrutiny Board's opinion**

In the impact assessment, innovation is addressed since the beginning, as both as a premise and a policy objective, but also as something that requires a clear regulatory framework to develop safely. First, the IA frames crypto-assets and distributed ledger technology (DLT) as potentially beneficial for the economy. The document explains that these technologies could improve efficiency in financial markets, for example by enabling faster and cheaper transactions, reducing the number of intermediaries, improving transparency of records, and facilitating automation through smart contracts. These technologies could also support new forms of financing, such as token offerings, which may help start-ups and small companies access funding more easily.

Despite being defined as important innovations, these technologies remained constrained by legal uncertainty and fragmented regulation across Member States. In fact, several crypto-assets fall outside existing EU financial legislation or are interpreted differently by national authorities, companies face uncertainty about the applicable rules, leading Member States to legislate on their own, leading to a greater market fragmentation and weaker consumer protection.

The IA therefore presents the regulation as a necessary condition for crypto-assets, that “should support innovation and fair competition by creating a conducive framework for the issuance of, and the provision of services related to crypto-assets” (p. 31). By creating a harmonised EU framework, the proposed regulation aims to remove legal fragmentation, provide legal certainty for market actors, and allow innovative business models based on crypto-assets and DLT to develop within a safer and more predictable environment, while ensuring consumer protection and market integrity.

The Regulatory Scrutiny Board (RSB) issued a [positive opinion](#) with reservations. The RSB highlighted several aspects requiring clarification, including the scope of the proposed regulatory framework, the allocation of supervisory responsibilities between EU and national authorities, and the sequencing of political decisions. The Commission subsequently addressed these concerns by clarifying the scope of the proposal and providing additional explanations regarding the governance and oversight structure of the new regulatory framework.

### **2.9.3. Stakeholder consultations**

The IA relies significantly on stakeholder consultations. In particular, the European Commission organised a public consultation on “An EU framework for crypto-assets” between 19 December 2019 and 19 March 2020, which received 198 responses, through the Have Your Say platform, from a wide range of stakeholders, including financial institutions, crypto-asset service providers, technology firms, industry associations and public authorities. The consultation focused on three main issues: the classification of crypto-assets, crypto-assets currently outside the scope of EU financial services legislation, and crypto-assets potentially falling within existing frameworks such as MiFID II ([Markets in Financial Instruments Directive 2014/65/EU](#)) or EMD2 ([the Electronic Money Directive](#)). The results of this consultation were used as qualitative and quantitative evidence to support the analysis carried out in the IA.

Other important sources described in the annexes are expert advice from the European Securities and Markets Authority (ESMA) and the European Banking Authority (EBA), academic studies, other European institutions, and data collected from national authorities, international organisations and standard-setting bodies.

Together, these sources show that stakeholder feedback served primarily as empirical input for the policy analysis.

#### **2.9.4. Tool #22 and regulatory sandboxes**

In the regulation, Tool #22 and regulatory sandboxes are not mentioned, nor is there any reference to Better Regulation guidelines. However, the regulation introduces a requirement for the Commission to track the application of the regulation under Article 140, mainly regarding the functioning and scope of MiCA itself (for example, in relation to new types of crypto-assets and different data related to their use, among others). Although this does not constitute a regulatory sandbox, it makes the regulation capable of evolving in light of future developments and the possible evolution of the crypto-asset market and related technologies.

In addition, the IA discussed a pilot or experimental regime for DLT market infrastructures related to security tokens as a policy option “for crypto-assets that may qualify as financial instruments” (p. 35-36). This regime would allow certain market infrastructures using DLT to operate under controlled regulatory conditions and under the supervision of national authorities.

#### **2.9.5. Overall assessment**

Overall, although the regulation was not explicitly assessed through the innovation principle, innovation constitutes a central element of the MiCA regulation. Crypto-assets are described as ‘important financial innovations’, a point also acknowledged in the Regulatory Scrutiny Board’s opinion. In this context, ‘increased innovation’ is also identified as a potential indirect benefit of the initiative, as the establishment of a harmonised EU framework and a regulatory level playing field is expected to facilitate innovation by exposing market participants to EU-wide competition. The regulation clearly places innovation at the core of its rationale, while underlining the importance of strengthening market integrity, enhancing consumer protection, and ensuring the safe development of crypto-asset markets.

### **2.10. Comparison and synopsis of the case studies**

The case studies analysed in Section 3 reveal a heterogeneous and uneven application of the innovation principle across EU policy initiatives. While innovation is frequently acknowledged as an important objective, its translation into analytical practice and regulatory design varies substantially depending on policy area, legal form, and institutional context. Across the cases, innovation tends to be addressed implicitly through simplification, incentives or risk-based design rather than through the explicit application of Tool 22 or a structured innovation impact assessment.

The revision of the pharmaceutical legislation represents one of the most innovation-relevant cases examined. Innovation is embedded directly in the objectives of the reform, which explicitly aims to strengthen the EU’s attractiveness for pharmaceutical research, development and production. The accompanying impact assessments analyse impacts on innovation incentives, regulatory protection periods and market dynamics, and stakeholder consultations explicitly address innovation barriers and drivers. Innovation considerations are also integrated across agenda-setting and option assessment, and monitoring indicators related to innovation are identified. This case illustrates how innovation can be substantively integrated into the policy cycle by applying the innovation principle.

The Omnibus proposals, particularly the Digital Omnibus and the Defence Omnibus, represent a different regulatory logic. Here, innovation is not addressed through new regulatory instruments or explicit innovation analysis but is treated as an expected outcome of simplification, reduced fragmentation and lower administrative burdens. These initiatives did not undergo full impact assessments, yet the accompanying Staff Working Documents provide

qualitative analysis of innovation-related effects, especially for SMEs, start-ups and emerging technologies. Innovation is framed as a function of regulatory clarity, coherence and speed rather than experimentation or targeted incentives. While strongly aligned with the spirit of the innovation principle, these cases demonstrate its use primarily as a strategic narrative rather than an analytical tool.

The Net-Zero Industry Act stands out as one of the few cases that explicitly refers to the innovation principle in legislative text. Innovation is positioned as a core enabler of the Act’s objectives, and the Regulation introduces several innovation-supporting mechanisms, including regulatory sandboxes, innovation hubs and the use of non-price criteria in auctions to reward novel technologies. However, the explicit invocation of the innovation principle is limited, and Tool 22 is not systematically applied in impact assessment or stakeholder engagement. Innovation is strongly present in regulatory design but less so in analytical justification and consultation practice.

The implementing regulation on renewable energy auctions illustrates the challenges of applying the innovation principle in secondary legislation. Although innovation plays a central role in the substance of the measure—through auction design that rewards new or improved technologies—no impact assessment was carried out, and innovation considerations are confined to implementation details rather than explored through alternative policy options. Stakeholder input on innovation was present but limited in scope. This case shows how innovation-friendly outcomes can emerge even in the absence of explicit innovation analysis, but also highlights the missed opportunity for learning and evidence generation.

Finally, the Artificial Intelligence Act remains the most analytically mature case in terms of innovation considerations. Innovation is treated as a central dimension of the regulatory problem, with explicit recognition of risks to market entry, scaling and investment. The IA compares options with reference to innovation impacts, and the preferred option incorporates mitigation mechanisms such as risk-based regulation, harmonised standards and regulatory sandboxes. Although innovation is still framed largely as an indirect outcome of trust and legal certainty, this case comes closest to demonstrating how the innovation principle can meaningfully shape regulatory architecture and option selection.

Overall, the comparison shows that innovation is most effectively integrated when it is linked to core policy objectives and when regulatory design includes adaptive or experimental mechanisms. However, explicit and systematic use of Tool 22 remains rare. In most cases, innovation is either mainstreamed informally or treated as a by-product of other regulatory goals, limiting transparency, comparability and ex post learning.

*Table 4 – Comparison of case studies*

Case study	Reference to innovation / R&I	Use of innovation-friendly regulatory tools	RSB opinion	Overall assessment
Case Study 1: Revision of the pharmaceutical regulation	Strong – innovation is central to the reform’s objectives, with “innovation” mentioned 93 times in proposals; IA analyses impacts on innovation	Regulatory sandboxes, expedited regulatory pathways, repurposing frameworks; monitoring indicators for innovation defined; provisions on rolling reviews	Negative (first opinion); positive with reservations (second opinion) – RSB requested stronger analysis of innovation and competitiveness impacts	Innovation substantively integrated across the policy cycle; one of the most innovation-relevant cases examined; RSB reinforced the innovation dimension;

	incentives, regulatory protection periods, and R&D ecosystems in depth	and PRIME across all policy options		monitoring indicators for innovation included
Case Study 2: Digital Omnibus proposals	Innovation addressed as an expected outcome of simplification and burden reduction; Digital Omnibus on AI explicitly aims to support innovative AI applications and improve legal certainty	No formal IA; Digital Omnibus on AI strengthens and expands AI regulatory sandboxes at EU level; simplification as indirect enabler of innovation; Tool #22 not explicitly referenced	Not applicable (no formal IA conducted; supported by Staff Working Document)	Innovation not formally assessed through the innovation principle; treated primarily as an indirect outcome of simplification and regulatory coherence; Digital Fitness Check initiated as follow-up process
Case Study 3: Defence Omnibus	Innovation addressed through the lens of enabling the EDTIB to adopt disruptive and dual-use technologies; simplification framed as a driver of innovation and industrial agility	No regulatory sandboxes introduced; simplified cost-benefit analysis with qualitative innovation impacts; Tool #22 not explicitly referenced; collaborative R&D and EDF access improved	Not applicable (no formal IA conducted; supported by Staff Working Document)	Innovation considered indirectly through simplification of procurement and EDF access; no full impact assessment conducted; innovation addressed mainly as a by-product of regulatory simplification
Case Study 4: Net Zero Industry Act	Strong – innovation is one of seven regulatory pillars; regulation explicitly calls for application of the innovation principle during preparation, review and revision of all policy initiatives	Regulatory sandboxes, innovation hubs within net-zero industrial valleys, Innovation Fund, Strategic Energy Technology Plan Steering Group for R&I coordination; Tool #22 not systematically applied in IA	Not applicable (no formal IA; supported by Staff Working Document only)	Innovation adequately considered in regulatory design and supporting mechanisms; significant gap in stakeholder engagement on innovation; limited explicit use of Tool #22

				in analytical justification
Case Study 5: Implementing regulation on auctions for renewable energies	Innovation central to auction design – dedicated innovation auctions, performance standards exceeding state of the art, and knowledge-sharing obligations for winning bidders	Pure innovation auctions, performance-based standards, knowledge dissemination requirements, regulatory flexibility linked to technological maturity; no regulatory sandboxes; no standalone IA	Not applicable (no IA required; policy options predefined by NZIA Article 26)	Innovation adequately integrated within the predefined NZIA framework; limited policy discretion; no explicit use of the innovation principle; technology neutrality tensions identified in stakeholder feedback
Case Study 6: Artificial Intelligence Act	Innovation addressed explicitly – risk-based approach, ecosystem of excellence, competitiveness and market entry; White Paper on AI framed innovation as a central policy objective from the outset	Regulatory sandboxes, risk-based and technology-neutral regulatory design, SME-targeted support (DIHs, TEFs, reduced fees), voluntary codes of conduct for lower-risk AI; AI Office established for centralised enforcement	Positive with reservations – RSB criticised insufficient demonstration of competitiveness impacts and lack of robust SME analysis	Most analytically mature case for innovation considerations; mixed results overall; monitoring framework not focused on innovation; subsequent iterations (GPAI scope, AI Office, Digital Omnibus) gradually strengthened innovation-friendly elements
Case Study 7: Fit for 55 – ETS extension to aviation	Innovation considered indirectly through promotion of sustainable aviation fuels (SAF) and improved monitoring of non-CO <sub>2</sub> effects; no explicit reference to the	No regulatory sandboxes or Tool #22 application; 20 million allowances reserved to bridge price gap for SAF; progressive phase-out of free allowances as indirect innovation incentive	Positive – RSB opinion does not reference Tool #22 or the innovation principle	Innovation considered to a lesser extent; core priority is GHG emission reduction; SAF adoption and monitoring requirements provide some indirect innovation incentives; no

	innovation principle in the IA or RSB opinion			structured innovation assessment
Case Study 8: Digital Services Act	Innovation discussed indirectly through digital market development, legal certainty, and liability framework; DSA explicitly aims to maintain a dynamic and innovative digital ecosystem while protecting fundamental rights	No regulatory sandboxes or Tool #22 application; technology-neutral regulatory design; “vetted researchers” data access provisions; harmonised liability regime as indirect innovation enabler	Positive with reservations – RSB highlighted need to better balance platform regulation with innovation and competitiveness considerations	Innovation balanced with platform accountability and user protection; considered indirectly through harmonisation and legal certainty; no explicit use of the innovation principle or structured innovation impact assessment
Case Study 9: Markets in Crypto-assets (MiCA)	Strong innovation relevance – crypto-assets and DLT described as “important financial innovations”; harmonised framework designed to enable innovation through legal certainty and a regulatory level playing field	Pilot/experimental regime for DLT market infrastructures discussed as a policy option; Article 140 review mechanism enables framework to evolve with market developments; no explicit regulatory sandboxes	Positive with reservations – RSB highlighted need for clarifications on scope, supervisory responsibilities, and sequencing of political decisions	Innovation acknowledged and central to the regulation’s rationale; harmonised framework expected to facilitate innovation by exposing market participants to EU-wide competition; no explicit use of the innovation principle or Tool #22

### 3. Assessment of the state of play of the innovation principle: main findings

Below, we approach our assessment of the state of play in the implementation of the innovation principle by re-proposing the conceptual framework used in EU policymaking for legislative measures subject to ex post evaluation, based on the criteria of relevance, effectiveness, coherence, and EU added value. We will refer to the original intervention logic of the innovation principle (see figure 6 below) and provide an evaluation of the possible need for updating the principle, both in terms of the overall approach, but also with respect to the tools and alternative policy options that could be considered when it comes to innovation-friendly regulation (see Figure 5 above).

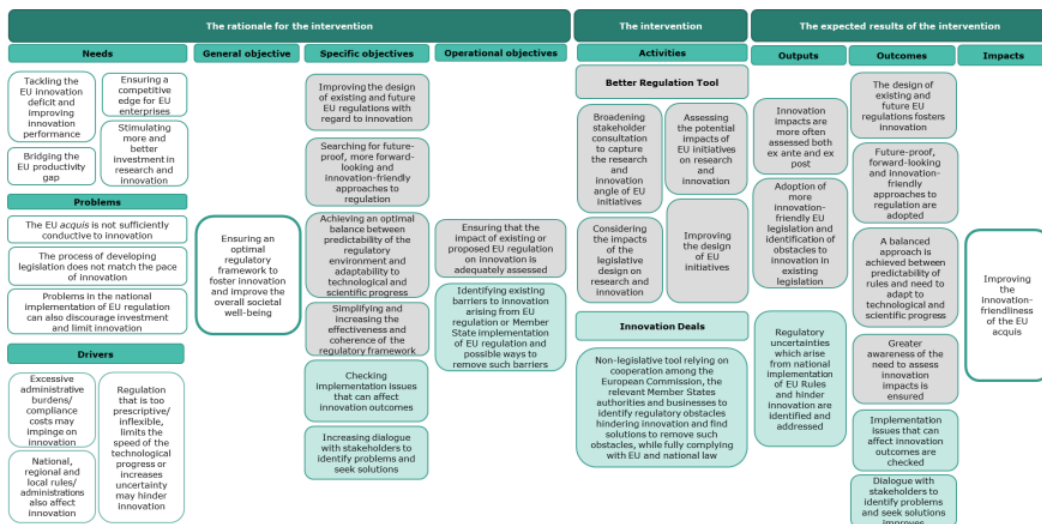


Figure 6 – The original “intervention logic” of the innovation principle (Renda and Simonelli 2019)

#### 3.1. How did the innovation principle evolve since 2019?

Since 2020, the EU’s Better Regulation framework has not introduced a new, standalone “innovation test” to replace or supersede the original innovation principle. Instead, innovation considerations have been progressively embedded and operationalised through a set of adjacent guidance tools and practices that shape how impact assessments are designed and scrutinised. This evolution is visible both in the formal updates to the Better Regulation Guidelines and Toolbox and in the way major post-2020 initiatives have been assessed and reviewed by the Regulatory Scrutiny Board.

The legacy innovation principle continues to operate mainly as a narrative framing device within impact assessments. In most post-2020 files, innovation is referenced in the problem definition or objectives as a desirable outcome, typically linked to legal certainty, trust in markets, or the completion of the internal market. However, it is rarely treated as an autonomous analytical category with its own indicators or metrics. Instead, innovation tends to appear as an assumed downstream effect of better regulation, rather than as an outcome that is explicitly tested or compared across policy options. The Regulatory Scrutiny Board generally accepts this framing but regularly challenges the absence of a clear causal chain or robust evidence supporting claims that proposed measures will in fact foster innovation.

**A major development since 2020 has been the formalisation and increased visibility of the competitiveness check within the Better Regulation architecture.** Since then, innovation is most commonly addressed through the lens of competitiveness, particularly in terms of firms' ability to enter markets, scale up, and compete globally. In practice, impact assessments often discuss innovation as an impact that may be hindered by high fixed compliance costs or regulatory fragmentation, or conversely supported by harmonisation and legal certainty. These analyses are largely qualitative and focus on risks to market dynamism rather than on positive innovation outcomes. The Regulatory Scrutiny Board has consistently pushed back against assumption-based claims that harmonisation automatically enhances competitiveness, asking instead for clearer baselines, international comparisons, and evidence that compliance costs will not undermine innovative capacity.

Closely linked to this is the strengthened role of the SME test and SME filtering mechanisms, which have become a near-standard feature of post-2020 impact assessments. Innovation concerns for SMEs are typically framed in terms of disproportionate burdens, limited compliance capacity, and the risk that fixed regulatory costs could deter entry or experimentation. Impact assessments usually respond by listing mitigation measures such as guidance, reduced fees, reliance on standards, or access to support structures. However, these measures are rarely quantified, and their effectiveness is largely assumed rather than demonstrated. The Regulatory Scrutiny Board has repeatedly highlighted this weakness, questioning whether SME-specific mitigation genuinely offsets compliance costs and warning that insufficiently substantiated SME analyses undermine claims of innovation-friendly regulation.

Another important shift has been the **growing emphasis on digital-ready and future-proof regulation, particularly in areas involving emerging technologies.** Rather than attempting to anticipate specific technological trajectories, impact assessments increasingly rely on technology-neutral requirements, standardisation processes, delegated acts, and guidance to ensure adaptability over time. Innovation is framed here as something that benefits from regulatory flexibility and the ability to evolve alongside technological change. At the same time, the Regulatory Scrutiny Board has cautioned that excessive reliance on future standards or guidance can create legal uncertainty, potentially undermining the very innovation benefits such approaches are meant to support.

**Regulatory sandboxes and experimentation mechanisms represent the most explicit post-2020 attempt to translate innovation-friendly rhetoric into concrete regulatory tools.** Following political endorsement at EU level, regulatory sandboxes have been incorporated into several legislative proposals, most notably in digital and emerging technology files. In impact assessments, they are typically presented as supervised environments for testing innovative solutions while learning about compliance requirements. Innovation support is thus framed in terms of regulatory learning and burden reduction rather than as a relaxation of legal obligations. The Regulatory Scrutiny Board has generally welcomed the concept but has remained sceptical about its practical effectiveness, repeatedly asking whether regulatory sandboxes genuinely reduce barriers for innovators or simply add another layer of governance.

Finally, **a prominent feature of post-2020 impact assessments is the treatment of innovation as a spillover effect of data access, interoperability and digital infrastructure.** In data, finance and digital market initiatives, innovation is increasingly linked to APIs, machine-readable formats, and reduced switching costs, rather than to direct support for research and development. Impact assessments often assume that improved access to data and interoperability will naturally lead to new products, services and business models. While this logic is broadly accepted, the Regulatory Scrutiny Board has frequently criticised the high level of aggregation of such claims and the lack of differentiation between policy options in terms of their actual innovation effects.

Taken together, these developments show that **innovation has become more systematically acknowledged within the EU Better Regulation framework since 2020, but mainly through indirect and instrumental channels.** Rather than being assessed as a standalone outcome,

innovation is embedded in competitiveness analysis, SME considerations, regulatory design choices and infrastructure-based approaches. The Regulatory Scrutiny Board's role has been less about questioning the relevance of innovation and more about challenging whether claimed innovation benefits are credible, proportionate and supported by evidence, especially in relation to costs and impacts on smaller and newer market participants.

## 3.2. Relevance

A key element in the assessment of existing instruments is that of relevance, which tries to capture whether the innovation principle is still fit-for-purpose after several years from its introduction, and in view of the shifting priorities of the European Commission, as well as technological development bringing innovations in public policy. Below, we tackle these questions in four separate sub-sections.

### 3.2.1. Is the current version of the innovation principle still fit-for-purpose given the evolving priorities of the European Commission?

**Broadly speaking, the current version of the innovation principle is still relevant for EU policy.** The introduction and consideration of foresight in shaping the policy agenda has become even more important, given the rise of the so-called poly-crisis world. One must, in this respect, consider that the innovation principle was introduced before the COVID-19 pandemic, which marked the rise of the poly- (or even perma-) crisis as a distinctive trait of current times.

Likewise, the consideration of research and innovation impacts in ex ante impact assessments is as important as ever, also given that President von der Leyen has repeatedly announced her intention to **place R&I at the heart of EU policymaking**. This extends to the emphasis on adopting innovative, agile instruments as preferred regulatory options: the goal is to strike the optimal balance between the need for regulatory intervention, the directionality offered by regulatory measures to innovation efforts, and the need to minimize regulatory burdens, another very salient goal in the current agenda of the European Commission.

To be sure, the European Commission has placed **huge emphasis on competitiveness as a "North Star"** (Renda 2024), also following the publication of the Draghi report, and the adoption of the Competitiveness Compass in January 2025. Innovation impacts are since then largely subsumed under the European Union's quest for competitiveness. However, **innovation goes beyond competitiveness, potentially serving other goals of the EU, such as security, safety, sustainability and strategic autonomy**.

In this respect, the **relevance of the innovation principle is not obliterated by the existence of competitiveness checks. Likewise, the SME test does not replace the innovation principle** as innovation, especially in the current context, may require larger corporations to reach a sufficient scale for the EU to boost its role in global markets and value chains, and to withstand competition from non-Eu players by seeking and achieving economies of scale. The recent boost to consolidation of telecommunications operators in the Single Market (following a recommendation of the Letta report), as well as the industrial policy measures adopted in domains such as defence and semiconductors, confirm that SMEs, however essential and predominant in the European industrial landscape, will have to co-exist and cooperate with larger companies if the European Commission is to recover its competitiveness in many sectors.

Even more importantly, **the Competitiveness Test and the SME tests are exclusively focused on regulatory impacts, rather than regulatory design**. On the latter, the innovation principle tool overlaps with other existing (and often more recently introduced) tools, such as **Tool #28** (Digital-ready policymaking) and **Tool #69** (emerging methods and policy

instruments). Here, a degree of consolidation would be needed to provide a single integrated source of guidance to services in charge of impact assessment (see below, Section 4).

Finally, **the innovation principle is not fully fit-for-purpose when it comes to five important aspects** of the Commission's better regulation agenda:

- *Horizon scanning.* While several IAs quote the JRC Strategic Foresight Reports, horizon scanning, particularly on technological developments, is not properly and regularly done in support of the translation of the *status quo* into a suitable baseline or “zero” option. This limits the ability of the Commission to engage on anticipatory governance and adopt future-proof solutions: most often, IAs simply rely on megatrends to prove the need for intervention.
- *Alternative baselines, strategic foresight and backcasting.* The poly-crisis age calls for a more thorough consideration of the need to adapt and change course in regulatory policy over time. As will be stated in more detail below, choosing only the “projected future” as baseline is in many cases almost preposterous, as the future will inevitably lead to disruptions and shocks that EU policies should be as resistant to as possible. Rather, exploring alternative futures (projected, likely, plausible, possible), choosing the preferred future and backcasting to identify the best course of action is likely to be the best way to address the problem of “which innovations” (and which policies) are needed to get the EU as close as possible to its intended goals. The academic literature on adaptive regulation also considers the age of poly-risk as a basis for adopting possible “maximin strategies” (see Sunstein 2021) and considering the reversibility and adaptability of alternative options as a criterion for choosing the preferred one.
- *Fast-track actions.* On several occasions, given emergency or urgency situations, the European Commission has decided to simplify or completely give up the drafting of a complete impact assessment document when adopting important pieces of policy or even binding legislation. Recent examples include the Competitiveness Compass, the Omnibus simplification measures, and more. The innovation principle tool does not provide a solution on how to consider innovation in those cases, for example through a post-implementation assessment to be carried out shortly after the entry into force of the regulatory measure.
- *Ex post evaluations.* Tool #22 says very little about ex post evaluations, despite clarifying that the innovation principle applies both in the ex ante and in the ex post assessment phases. Given the importance of managing the regulatory stock and assessing its cumulative impact on innovation, the lack of guidance in this respect is making the innovation principle unfit for the purposes of the current better regulation agenda (See below, Recommendations).
- *Interim evaluations and stress-testing.* Stress-testing has become almost an imperative for the European Commission, as key objectives such as resilience and economic security command a thorough review of the *acquis* in many domains. The EPRS developed a methodology on stress-testing for resilience (Fernandes and Heflich 2022), which could be usefully incorporated in the Tool going forward, and adapted to different policy objectives, beyond resilience.

### **3.2.2. To what extent are the (original) objectives of the innovation principle still relevant given the challenges it aims to address? How well do they (still) match the current political context, needs and problems?**

As said, **the objectives of the innovation principle are even more relevant today than they were in the mid-2010s**. Looking at the general, specific and operational objectives in Figure 6 above, one easily recognises the emphasis placed today on innovation. If anything, the need

for innovation-friendly and future-proof regulation is even stronger to ensure societal well-being, through a richer combination of intermediate objectives (Renda 2024), such as competitiveness, security, strategic autonomy, sustainability, etc. The type of innovation that should be unleashed or facilitated by regulatory and policy interventions is thus slightly different in terms of directionality, but the relevance of the objectives of the innovation principle cannot be questioned.

### **3.2.3. To what extent is the innovation principle addressing stakeholder needs, e.g. startups, midcaps and other innovative companies?**

The innovation principle is to a large extent addressing current needs of stakeholders, with a few exceptions that are listed below.

- **The need to accommodate the introduction of small mid-caps in the EU *acquis***, particularly through Commission Recommendation (EU) 2025/1099 (May 2025), which harmonises the definition for policy and statistical use, building on existing definitions embedded in the General Block Exemption Regulation and Risk Finance Guidelines, which used small mid-cap definitions for State aid purposes; and the Omnibus IV package which amends substantive EU rules (e.g., GDPR, Prospectus Regulation, MiFID) to include tailored provisions and reliefs for small mid-caps. This matters quite a lot for the innovation principle as operationalised in Tool #22 of the Better Regulation Toolbox, because the emergence of the small mid-cap (SMC) category fundamentally changes the baseline against which “innovation impacts” are assessed. In its original conception, Tool #22 (Research and innovation impacts) was implicitly built on a binary firm-size world: SMEs versus large enterprises. With the formalisation of small mid-caps, innovation impacts can no longer be assessed without addressing scale-up dynamics beyond SME status. Tool #22 will need to account for the fact that many of the EU’s most innovation-intensive firms sit precisely in the transition zone between SME and scaled-up enterprise. In practical Better Regulation terms, this may mean that innovation impacts under Tool #22 should increasingly be read together with the SME test and the competitiveness check, rather than in isolation. Where Tool #22 traditionally asked whether regulation supports or hinders innovation in general, the new policy reality requires asking where in the firm life-cycle innovation is most exposed to regulatory friction. The existence of SMC-specific reliefs and proportionality measures demonstrates that innovation risk is now explicitly recognised at the post-SME scaling stage, not only at market entry. The emergence of the SMC category strengthens the normative force of the innovation principle, even without a formal revision of Tool #22. It signals that innovation-friendly regulation is no longer only about not harming SMEs, but about designing regulatory regimes that allow firms to scale without innovation-killing discontinuities. If Tool #22 is applied seriously going forward, it will need to reflect this by systematically considering whether proposed measures create or mitigate scale-up cliffs—not just whether they affect SMEs or R&D spending in the abstract.

**Businesses and innovators, especially in deep tech areas, need the innovation principle to adopt more advanced and updated tools in regulation.** In particular, RegTech, Gov Tech and “law as code” solutions, among others, require more attentive guidance for Commission services to adopt them in full support of innovation. In this respect, Tool #22 would require an update and a consolidation with Tool #69, which covers many innovation-friendly instruments and agile regulatory approaches, without providing full guidance to services as to when and how to use them. Linking Tool #69 to innovation would already provide a great improvement in the quality of the guidance offered by the Toolbox.

### 3.2.4. What are the emerging trends and needs innovation principle does not cover?

Tool #22 has helped ensure that innovation considerations are not ignored in EU policymaking. However, experience since 2020 shows that important emerging trends and regulatory needs are only partially covered—or not covered at all—by the current framing of the innovation principle. These gaps have become more visible as EU regulation has increasingly targeted digital, data-driven and green technologies.

- First, the **innovation principle does not adequately capture scale-up and post-SME innovation dynamics**. It remains largely anchored in a dichotomy between SMEs and large enterprises and is primarily concerned with entry barriers and R&D incentives. Recent policy developments, particularly the introduction of the small mid-cap category, highlight that innovation constraints are often most acute once firms outgrow SME status. Issues such as regulatory cliff effects, cumulative compliance costs and the ability to scale innovative business models across borders fall outside the traditional scope of the innovation principle as currently applied.
- Second, the **innovation principle insufficiently addresses innovation as a system-level and infrastructure-driven phenomenon**. Many recent initiatives rely on data spaces, APIs, interoperability standards and shared digital infrastructures to stimulate innovation indirectly. The current toolset focuses on firm-level impacts and R&D activity, but does not systematically assess whether regulatory design choices enable or constrain innovation ecosystems, data reuse, platform-based innovation or network effects.
- Third, the **Principle does not fully reflect the growing importance of regulatory experimentation and learning**. Emerging technologies evolve faster than ex-ante regulatory analysis can capture. While regulatory sandboxes and experimentation clauses are increasingly used in legislation, the innovation principle does not explicitly guide policymakers on when experimentation is preferable to detailed rule-setting, nor how learning effects and iterative adjustment should be assessed as innovation-relevant outcomes.
- Fourth, the **innovation principle pays limited attention to innovation diffusion and adoption**, as opposed to invention. Many EU regulatory initiatives aim at accelerating uptake, trust and market deployment of new technologies. Impacts on time-to-market, standardisation speed, or cross-border scalability are rarely captured explicitly, even though they are critical for innovation performance in digital and green transitions.
- Fifth, the tool does not adequately account for **cumulative and cross-sectoral regulatory effects**. Innovation impacts are typically assessed initiative by initiative, without considering how overlapping requirements across digital, data, sustainability and competition frameworks may interact to shape firms' overall innovation capacity. This is particularly problematic for emerging technologies that cut across multiple regulatory domains.
- Finally, the innovation principle remains **weak on distributional aspects of innovation**, such as who innovates and who benefits. It does not systematically address whether regulation favours incumbent-driven innovation over challenger-led innovation, or how innovation impacts differ across firm sizes, sectors, or Member States.

### 3.3. Effectiveness

The effectiveness criterion refers to the extent to which the general and specific objective of the innovation principle have been achieved. We address this issue below, by answering three distinct questions.

### 3.3.1. What have the main outputs, results, impacts of the innovation principle been so far?

There is no doubt that innovation has become increasingly salient in EU legislation. Our data confirm that several IAs are related to subjects and problems that are relevant for research and innovation. This, of course, does not necessarily relate to the existence of Tool #22, and the introduction of the innovation principle in EU better regulation. To the contrary, our text analysis reveals that almost no IA completed between 2020 and 2025 refers to Tool #22 or the innovation principle, or explicitly follows the guidance contained therein.

That said, considering the more granular guidance contained in Tool #22, some clearly positive and some clearly negative results can be highlighted.

On the positive side, we noted:

- **The increased reliance on strategic foresight reports to include megatrends in the analysis of the problem.** This, however, has not yet translated into the use of foresight, horizon scanning and backcasting to distinguish between alternative futures and choose a preferred future.
- **Significant consideration of innovation impacts in Commission impact assessments and by the Regulatory Scrutiny Board.** That said, as explained above the assessment of these impacts is often too qualitative and not sufficiently inspired by in-depth analysis of the problems faced by European businesses, including SMEs and SMCs, in moving “from lab to market”, crossing the so-called “valley of death” and sufficiently leveraging the opportunities offered by the Single Market. The RSB has consistently challenged the lead Commission services to substantiate innovation impacts.
- **Growing use of innovative, experimental and agile tools, including co-regulation, third-party access to AI systems, regulatory sandboxes, open API, open banking solutions.** Brilliant examples have been summarised above, in Section 2.5, and include the “vetted researchers” and third-party audits and systemic risk assessment provisions in the Digital Services Act; the regulatory sandboxes introduced in the AI Act as well as in financial regulation; and open API frameworks *i.a.* in the Data Act and in PSD2. However, lack of sufficient emphasis on the implementation phase ended up weakening the potential of these provisions: open banking in PSD2 proved to be hardly successful in promoting entry; the rule on access for vetted researchers in the DSA have not produced sufficient scrutiny of content moderation by social networks (e.g. X) until now; and many regulatory sandboxes lack adequate design, as well as competent supervision by public authorities (Mifsud and Renda 2023).

On the negative side, apart from the shortcomings noted above, the following effects can be observed:

- **The EU still has a clear innovation lag *vis à vis* other parts of the world,** as highlighted *i.a.* by the Draghi report, but also by President von der Leyen in recent speeches (including the State of the Union 2025), in which she reiterated that Europe’s independence and future security is linked to its ability to innovate in key technologies such as digital and clean tech, and emphasised plans to boost research spending (including proposals to expand Horizon Europe and create a Competitiveness Fund).
- **The EU still suffers from regulatory hysteresis.** To the extent that simplification was part and parcel of the innovation principle, so far regulatory relief has not been observed at the EU level. If anything, the complexity of EU regulation has become even more unsustainable during the pandemic years, and one of the key priorities of the second von der Leyen Commission is to achieve radical simplification by placing the reduction of regulatory burdens very high up in the ranking of priorities. The Commission set out targets to cut administrative and regulatory burdens significantly — by 25 % overall and 35% for SMEs

— precisely to make business easier and cheaper, which in turn is expected to contribute to improved economic performance and help ease cost pressures. Independent economic analysis also supports the idea that regulatory complexity and legal fragmentation are deterrents to investment and economic dynamism in the EU, which can have inflationary effects by raising compliance costs and limiting productivity gains. For example, research on EU investment attractiveness highlights that complex and fragmented regulation increases legal and compliance costs and deters cross-border activity, which worsens the bloc’s competitive position relative to the United States — a key issue given Europe’s slower productivity and innovation growth relative to global peers.

**The “innovation deals” have fallen short of expectations, and have gradually been discontinued.** Announced by former Commissioner Moedas, the innovation deals had already proven difficult when Simonelli and Renda (2019) concluded their preliminary assessment of the innovation principle. Important shortcomings in their design and in the expectations associated with their implementation led to an early dismissal of a tool that may become more relevant, if thoroughly redesigned, today (see Recommendations below).

### **3.3.2. What are the expected impacts that still need to materialise?**

Most of the impacts sought by the innovation principle still need to materialise, and absent a thorough update of the principle it will be difficult to see them emerge in the coming years. If the innovation principle and Tool #22 of the Better Regulation Toolbox were applied fully and consistently across EU policymaking, the impacts would materialise less as a single, visible policy shift and more as a structural change in how regulation is designed, justified and adjusted over time. If the innovation principle and Tool #22 were fully implemented, the most important impact would be a shift from innovation as a narrative promise to innovation as a design constraint. Regulation would be more explicit about how it affects experimentation, scaling and diffusion, and more capable of supporting innovation across the full firm and technology life cycle—without weakening the EU’s core regulatory objectives.

The effects would span the quality of impact assessments, regulatory outcomes, market dynamics and institutional behaviour.

**At the level of policy design and impact assessments,** full implementation would fundamentally change the depth and discipline of analysis. Innovation would no longer appear mainly as a rhetorical benefit or a downstream assumption, but as a testable dimension of regulatory choice. Impact assessments would be expected to identify where innovation occurs along the life cycle—from research and experimentation to scaling and diffusion—and to assess how different options affect these stages differently. This would likely reduce reliance on generic claims that “legal certainty fosters innovation” and replace them with more explicit causal reasoning, including identification of scale-up barriers, time-to-market effects, and cumulative compliance burdens. Over time, this would raise the analytical standard of IAs and make innovation trade-offs more transparent to decision-makers.

**In terms of regulatory outcomes, a fully applied innovation principle would tend to favour more proportionate, adaptive and lifecycle-aware regulation.** Legislators would be more likely to design rules that avoid sharp threshold effects, such as regulatory cliffs at the SME boundary, and instead adopt graduated obligations that reflect firm growth and technological maturity. This would particularly benefit scale-ups and small mid-caps, which are often innovation-intensive but disproportionately affected by fixed regulatory costs. The result would not necessarily be lighter regulation, but regulation that is more continuous and predictable, reducing the risk that innovation stalls at specific growth stages.

**For emerging and fast-evolving technologies, full implementation would encourage wider and more systematic use of regulatory learning mechanisms,** such as regulatory sandboxes, experimentation clauses, staged obligations and review clauses. Innovation

impacts would be assessed not only ex ante but also in terms of how regulation can evolve as technologies mature. This would likely reduce over-specification in primary legislation and increase reliance on standards, guidance and iterative governance, with clearer justification of why such flexibility supports innovation rather than creating legal uncertainty.

**At the level of markets and firms, the cumulative effect would be a reduction in innovation-relevant frictions rather than a surge in R&D spending per se.** Firms would face fewer abrupt compliance shocks as they grow, more predictable regulatory pathways for scaling across borders, and clearer signals about how novel business models can be tested and brought to market. Innovation would be supported primarily through diffusion and scaling, rather than through direct subsidies or exemptions. This would be particularly relevant in data-driven and digital markets, where interoperability, access and regulatory continuity are decisive for innovation outcomes.

Institutionally, **full implementation would also reshape the role of the Regulatory Scrutiny Board and internal Commission dynamics.** The RSB would be more consistently equipped to challenge weak or generic innovation claims, because Tool #22 would provide clearer expectations about what constitutes an adequate innovation analysis. This would likely increase the number of revisions requested on grounds related to proportionality, scale-up impacts or cumulative burdens, but it would also gradually normalise higher-quality innovation reasoning across DGs. Over time, this could reduce friction between political ambition and analytical credibility by making innovation impacts a routine part of regulatory justification.

Finally, **at a more strategic level, full application of the innovation principle would help align EU regulation with broader competitiveness and growth objectives** without subordinating other public interests. Innovation would be treated as a systemic property of regulatory environments, not as an abstract R&D outcome or a slogan. This would make it easier to reconcile precaution, consumer protection, sustainability and innovation by clarifying where trade-offs genuinely exist and where they are assumed rather than real.

### **3.3.3. What are the factors supporting or hindering the expected outputs, results and impacts of the innovation principle?**

Several factors can be taken as potential enablers of the expected outputs, results and impacts of Tool #22 and, more generally, the innovation principle. They include the following.

- The **integration of the innovation principle into the Better Regulation framework**, notably through Tool #22 and its links with the competitiveness check and the SME test, is the most general enabling factor supporting the continued effectiveness of these tools.
- The **increased awareness and sense of urgency** related to issues such as scale-up and post-SME innovation challenges, including regulatory cliff effects and cumulative burdens. This sense of urgency is being further stimulated by the rather depreciable evolution of Trans-Atlantic relations at the outset of 2026, and the realisation of the need for Europe to invest in sovereignty and strategic autonomy, i.a. boosting domestic innovation.
- The **availability of regulatory learning tools**, such as regulatory sandboxes, experimentation clauses and review mechanisms, which provide practical feedback on innovation impacts.
- The **growing body of evidence and experience from digital, data and emerging-technology legislation on how regulation affects innovation, deployment and scaling.** This includes a rather substantial stream of academic literature, which shows that well-designed, adequately timed and proportionate regulation can promote meaningful innovation, adding directionality and certainty.
- The **stronger political focus on competitiveness, productivity and innovation**, reinforcing the relevance of innovation considerations in regulatory design.

Among the factors hindering the expected outputs, results and impacts, the following can be highlighted.

- The **conceptual breadth and lack of operational definition of the innovation principle**, leading to uneven and often superficial application. A sharper approach to innovation in regulatory design, as well as guidance on how to implement specific innovation-friendly regulatory measures, and better embedding of decision-making under uncertainty in the toolbox would mitigate this problem.
- The **lack of uptake and (possibly) acceptance of the innovation principle** in the services of the Commission, as well as in the RSB. The lack of explicit references, also by the RSB, is a possible sign of reluctance by services of the Commission to promote and acknowledge the institutionalisation and mainstreaming of the innovation principle and Tool #22 in the practical guidance used in approaching impact assessments.
- The **absence of dedicated innovation indicators and limited ex-post monitoring** of innovation outcomes.
- The **lack of public availability and overall methodological elaboration on ex post evaluations**, which remain very often unpublished, limiting the extent to which the “science” of monitoring innovation impacts could develop over time.
- The **tendency to treat innovation as an assumed downstream benefit of legal certainty** rather than a dimension to be tested across options.
- **Institutional constraints, including time pressure and political prioritisation** of other objectives (e.g. competitiveness, safety, strategic autonomy, economic security, etc.)
- **Limited ability to assess cumulative and cross-sectoral regulatory impacts** affecting innovation capacity.
- **Persistent regulatory complexity and fragmentation**, which can undermine innovation even when individual measures are well designed.
- **Uneven capacity across policy areas and DGs to analyse innovation dynamics**, particularly beyond SME and R&D considerations.

**Lack of capacity-building and knowledge sharing** between DG RTD and other DGs in charge of applying the innovation principle.

### 3.4. Coherence

Another important element of the assessment of the innovation principle is its current coherence with wider EU policies, as they are shaping in the new legislature started at the end of 2024. Below, we tackle this issue by replying to two questions: whether the innovation principle is coherent with the new EU policies that have been adopted in the past years, and whether such policies have been forged by the implementation of the principle, thereby embedding pro-innovation features.

#### 3.4.1. To what extent is the innovation principle coherent with wider EU policy, such as the Omnibuses?

**The innovation principle is largely coherent with wider EU policy, but that coherence is implicit, partial and uneven, rather than fully institutionalised.** Recent initiatives such as the Omnibus simplification packages do not formally restate the innovation principle, yet they address many of the same underlying problems that the Principle was designed to flag—most notably regulatory burden, scale-up barriers and fragmentation. At the same time, they also expose the limits of the innovation principle as it is currently applied.

At a strategic level, the **innovation principle is consistent with the EU’s broader shift since 2020 towards competitiveness, productivity and scale-up as central policy objectives**. Political guidance from the Commission President, the focus on simplification, and the increasing attention to Europe’s innovation and scale-up gap all align with the Principle’s core idea that regulation should be designed so as not to unnecessarily hinder innovation. In this sense, the Omnibus packages can be seen as policy responses to issues that the innovation principle had already identified but struggled to operationalise.

The **Omnibus simplification initiatives are particularly coherent with the innovation principle in substance, though not in form**. By targeting regulatory complexity, administrative burden and “cliff effects” as firms grow, the Omnibuses directly address one of the main channels through which regulation can hinder innovation. Measures such as extending proportionality beyond SMEs to small mid-caps, streamlining reporting obligations, and reducing cumulative compliance costs align closely with the innovation principle’s concern for innovation over the firm life cycle. However, the fact that these issues are being tackled *ex post* through omnibus simplification suggests that the innovation principle has not been sufficiently effective upstream, at the *ex ante* impact assessment stage, in preventing such burdens from arising in the first place. This is even more evident since the Omnibus legislation applies predominantly to legislation that has been adopted during years in which guidance on the innovation principle was already available in the Better Regulation Toolbox (first as Tool 21, then as Tool #22).

At the same time, there is a risk of incoherence through duplication or substitution. If innovation challenges are increasingly addressed through horizontal simplification packages and dedicated innovation legislation, the innovation principle could become marginalised within the Better Regulation process, reduced to a rhetorical reference rather than a meaningful analytical constraint. Conversely, **if the innovation principle is strengthened and aligned with these initiatives—by explicitly incorporating scale-up dynamics, cumulative burden analysis and post-SME impacts—it could serve as the analytical backbone that anticipates problems later addressed by Omnibuses or sectoral fixes**. And it would also become a stronger pillar in a broadly competitiveness-oriented better regulation agenda, as an input to the broader competitiveness test now required for every relevant IA.

Overall, the innovation principle is directionally coherent but operationally weaker than newer policy instruments. **The Omnibuses confirm the validity of its underlying diagnosis**—namely that regulation can unintentionally hinder innovation through complexity, fragmentation and disproportionate burdens—but **they also implicitly acknowledge that the Principle, as currently applied, has not been sufficient on its own**. Future coherence will depend on whether the innovation principle evolves from a general exhortation into a more concrete, life-cycle-aware and cumulative-impact-sensitive tool that complements, rather than trails behind, the EU’s innovation and competitiveness agenda.

### **3.4.2. How helpful has the innovation principle been in forging innovation-friendly EU regulation? Which of its particular elements have been able to achieve this?**

Based on our analysis, it is possible to conclude that the innovation principle has been moderately helpful, but not transformative, in forging more innovation-friendly EU regulation. Its main contribution has been in embedding foresight (though the latter is subject to a dedicated tool in the toolbox) in the agenda-setting phase, and legitimising innovation as a regulatory concern, rather than systematically reshaping regulatory outcomes.

At its most basic level, the innovation principle has helped normalise the idea that regulation can affect innovation both positively and negatively. Before its introduction, innovation was often treated as an exogenous benefit of research policy rather than as something influenced by regulatory design. The Principle made it politically and analytically legitimate to ask whether regulatory choices might hinder experimentation, market entry or scaling. This has had a visible

effect on the language of impact assessments, which increasingly reference innovation, competitiveness and scale-up risks, especially in digital, data and emerging-technology files.

The innovation principle has also indirectly supported the emergence of innovation-friendly instruments, most notably **regulatory sandboxes and experimentation clauses**. While these tools stem from broader policy developments, the Principle has provided a conceptual rationale for allowing supervised experimentation within regulatory frameworks. This has been particularly visible in areas such as AI and digital finance, where regulatory sandboxes are framed as ways to reconcile innovation with risk management. Here, the Principle has helped bridge the gap between innovation policy and regulatory enforcement.

By contrast, some elements of the innovation principle have been far less effective. Its lack of clear operational criteria or indicators has limited its ability to discipline impact assessments. Innovation is often treated as an assumed downstream effect of legal certainty rather than as an outcome to be tested across options. As a result, the Principle has rarely driven decisive changes in preferred options, and the Regulatory Scrutiny Board has frequently criticised innovation claims as insufficiently evidenced. This shows that the Principle's exhortative nature weakens its practical influence.

Another limitation is that the innovation principle has struggled to address systemic, interactive and cumulative effects, such as regulatory complexity across policy domains or innovation barriers at the scale-up and post-SME stage. These issues have only recently gained policy traction through separate initiatives. This suggests that the Principle has been more effective at flagging potential innovation concerns than at preventing them *ex ante*.

Overall, the innovation principle has been most helpful as a framing and enabling device, rather than as a decisive regulatory filter. Its most effective elements have been those that could be embedded into existing Better Regulation practices: integration with competitiveness analysis, support for proportionality and flexibility, and justification for experimentation mechanisms. Its weakest elements are those requiring precision, measurement and lifecycle thinking. As a result, the Principle has contributed to making EU regulation more aware of innovation, but only selectively more innovation-friendly, depending on how far its tools are taken up and enforced in practice.

### **3.5. EU added value**

The assessment of the innovation principle also includes an evaluation of the added value of having such a principle specified at the EU level, rather than at national level only in the EU. To some extent, this question is self-explanatory, as the innovation principle refers to the EU policy cycle, and applies to legislation that is adopted based on the subsidiarity principle. That said, below we briefly compare the innovation principle with existing similar experiences at the national or regional level, and gauge the distance between the existing Commission guidance and available national experiences.

#### **3.5.1. To what extent has the innovation principle so far demonstrated the added value at European level if compared to similar national or regional initiatives?**

The OECD Regulatory Policy Outlook 2025 finds that “only about a third of OECD members report that their regulatory impact assessment (RIA) systems explicitly address innovation-related challenges, typically by updating RIA templates/guidance or by encouraging instruments like experimentation/regulatory sandboxes and more outcome-oriented approaches”<sup>125</sup>. Some

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<sup>125</sup> Figure 4.1 and p. 98, [https://www.oecd.org/en/publications/oecd-regulatory-policy-outlook-2025\\_56b60e39-en.html](https://www.oecd.org/en/publications/oecd-regulatory-policy-outlook-2025_56b60e39-en.html)

EU member states have introduced “Tool-22-like” instruments, and the best documented ones are Finland (explicit innovation IA guidance), Denmark (innovation/entrepreneurship check + oversight), and Germany (digital-ready test inside RIA), with the Netherlands showing a strong framework that can host innovation considerations even if not labelled as such. These tools are most clearly successful at institutionalising an innovation lens and improving regulatory design processes, while hard, outcome-level evidence (innovation rates, scale-up effects) is still limited and often acknowledged as difficult to attribute. That framing is close to what the EU’s Tool #22 (innovation principle) tries to do: force an ex-ante “innovation lens” (barriers to experimentation/scale-up, technology neutrality, standards, regulatory sandboxes, etc.).

Among the most notable existing experiences, the following can be highlighted.

- **Finland has an explicit “Innovation Impact Assessment” guidance for law drafters** (2022), which helps officials assess how draft legislation affects innovation, complementing its general impact-assessment guidelines. The guide is framed as a practical tool for drafting (i.e., an ex-ante innovation check very similar in purpose to Tool #22), and Finland’s government also describes it as building on pilot work. Evidence on “success” is still mostly about institutionalisation and usability (a concrete method and guidance now exist), rather than quantified innovation outcomes, but it is one of the clearest cases of a formal innovation test embedded in drafting practice.
- **In Denmark, the DBA has implemented an innovation and entrepreneurship check** as part of its regulatory impact assessment system, supported by strong central oversight. This check requires policymakers to consider how proposed measures affect business dynamics, market entry and innovation, and it is reinforced through quality control by a dedicated Better Regulation unit. Denmark’s approach is effective in procedural terms: it ensures early identification of innovation-relevant burdens and creates incentives for policymakers to address them. However, as with many similar tools, the impact on innovation outcomes is difficult to measure, and evaluations suggest that awareness of its concrete effects varies among stakeholders.
- **Germany’s approach focuses on ensuring that legislation is digital-ready** through the use of a systematic “digital check” embedded in regulatory impact assessments. This instrument requires lawmakers to consider whether rules can be implemented digitally and whether they support modern, efficient processes. Although it is more narrowly focused on digitalisation than on innovation in a broader sense, it plays an important role in enabling innovation by reducing administrative friction and improving the conditions for digital business models. Its effectiveness is strongest in terms of implementation quality and regulatory practicability, rather than in directly stimulating innovation activity.
- **The Netherlands has taken a more framework-based approach through its Policy Compass**, which replaces traditional impact assessment templates with a modular, proportionate system. While innovation is not assessed through a standalone test, the framework encourages early problem definition, proportional analysis and consideration of implementation issues. This creates space for innovation concerns to be addressed where relevant, particularly through an early implementation review that allows policymakers to learn from real-world effects shortly after rules enter into force. The main contribution of this approach lies in improving regulatory learning and adaptability rather than explicitly promoting innovation.

Overall, these national experiences show that tools comparable to Tool #22 are most effective when they are embedded in everyday drafting practices and supported by institutional oversight. Their success is clearest at the level of regulatory process quality—such as better anticipation of innovation-related risks and more proportionate design—rather than in demonstrable increases in innovation performance. This mirrors the EU experience with the innovation principle itself: it is easier to institutionalise an innovation lens in regulation than to attribute concrete innovation outcomes directly to regulatory tools.

Table 5 – Select tools similar to the innovation principle in the EU Member States

Country	Instrument	Closest equivalent to Tool #22	Evidence of effectiveness	Main limitations
<b>Finland</b>	Innovation-friendly regulation guidance (2022)	Explicit <b>innovation impact assessment</b> for draft laws; asks how regulation affects innovation, experimentation and scaling	Strong institutionalisation: dedicated guidance, developed after pilot use; widely cited as a best practice for embedding innovation thinking ex ante	Limited outcome evidence; effectiveness measured mainly in drafting quality, not innovation performance
<b>Denmark</b>	Innovation & Entrepreneurship Check + Better Regulation oversight	Mandatory <b>innovation/entrepreneurship screen</b> within RIA, backed by central quality control	High procedural effectiveness: strong compliance culture, central scrutiny, early flagging of innovation-relevant burdens	Innovation impacts remain hard to attribute; evaluations show mixed stakeholder awareness of concrete benefits
<b>Germany</b>	Digitalcheck (digital-ready legislation)	Systematic <b>ex-ante test for digital feasibility and innovation-enabling design</b>	Clear mainstreaming into drafting practice; support structures (training, guidance) added post-introduction	Focuses more on digitalisation and implementation than broader innovation or scale-up dynamics
<b>Netherlands</b>	Beleidskompas (Policy Compass) + Invoeringstoets	Modular, proportionate RIA framework that can <b>host innovation analysis</b> , plus early interim evaluation	Strong process innovation: earlier problem framing, proportionality, learning from implementation	Innovation not a standalone test; depends heavily on policy team priorities

Going one level deeper, some EU countries have successfully embedded foresight in their policy cycle, but such developments cannot replace the important role foresight plays at the EU level in the early phases of the cycle, i.e. agenda-setting.

Innovation deals were also mirrored by similar initiatives in some of the Member States. Their introduction was actually modelled around the **Dutch “Green Deals”**, which created a structured channel for companies, NGOs, universities and public authorities to identify concrete regulatory/administrative barriers and agree on actions to remove or work around them. They are widely used in the circular economy context and are explicitly described as helping innovators overcome non-financial barriers (e.g., permits, classification issues, procurement constraints), with ministries acting as problem-solvers and conveners. Evidence of their success

is mostly qualitative and process-based: Green Deals are repeatedly characterised as useful for unblocking barriers and enabling pilots and collaborations, and the key critique tends to be the lack of clear outcome indicators rather than lack of activity or relevance.

In **Spain** the national financial regulatory sandbox (Law 7/2020) involved multiple cohorts and documented supervisory learning. Spain's sandbox is one of the clearest EU examples of a structured, repeatable sandbox process with published cohort information. The Bank of Spain reports multiple calls, numbers of applications, and how many projects progressed into testing. An IMF country report noted that, across cohorts, authorities gained “significant learning” from the sandbox process—exactly the type of regulatory-learning outcome regulatory sandboxes are designed to produce (even if the link to innovation outputs remains indirect). Spain replicated its sandbox also in the field of AI, with limited success so far.

In **Portugal**, “technological Free Zones” (ZLT/TFZs) were introduced as cross-sector experimentation frameworks, an initiative that goes beyond sectoral sandboxes to enable real-environment testing of innovative products, services, processes and models across sectors. This is conceptually very close to the EU Innovation Deals’ “test-and-learn” logic, but with a more formal experimentation architecture. Evidence of “success” here is mainly institutional (a general framework exists and is described in EU-level analytical work as a general sandbox scheme), rather than quantified outcomes, but it stands out as a scalable model for experimentation beyond finance.

Finally, **Lithuania**'s central bank operates a fintech regulatory sandbox for live testing under supervisory guidance. In addition, Lithuania has been visible internationally for experimentation-oriented initiatives (e.g., blockchain-oriented testbed activity documented in innovation practice repositories), which illustrates an ecosystem approach: combine supervisory support with structured testing environments.

### **3.5.2. 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 or coherence?**

To date, many years after the introduction of the innovation principle, it is very difficult to answer this question. **There is no single, uncontested “gold-standard” example of the innovation principle being fully and rigorously applied in an impact assessment, ex post evaluation of piece of legislation.** This is not accidental: the innovation principle was conceived as a horizontal consideration rather than a binding test, and it was never equipped with precise criteria, indicators or thresholds that would allow it to operate as a decisive filter in the regulatory process. As a result, its influence has tended to be indirect and uneven, shaping the framing of problems, the justification of mitigation measures and the choice of regulatory design features, rather than determining outcomes in a clearly traceable way. In most EU impact assessments, innovation is discussed qualitatively, often under the headings of competitiveness or SME impacts, and is rarely used as a primary dimension for comparing policy options.

This structural feature of the innovation principle makes it difficult to identify a case where it can be said, unequivocally, that innovation considerations drove the regulatory outcome. **In practice, innovation impacts are usually treated defensively, as something regulation should not unduly harm, rather than proactively, as something regulation should actively enable.** This defensive orientation reinforces the tendency to rely on generic arguments about legal certainty, harmonisation or trust in markets, rather than on more granular analysis of experimentation, scaling and diffusion. The absence of systematic monitoring and evaluation indicators for innovation further weakens the ability to demonstrate that the principle has been applied successfully in any given case.

Within these constraints, **the impact assessment for the Artificial Intelligence Act nevertheless stands out as the most instructive and comparatively strong example of the**

**innovation principle influencing EU regulatory design.** In that assessment, innovation is not merely mentioned in passing but is woven into the core narrative of the initiative. The IA explicitly recognises that regulatory choices can affect investment incentives, market entry and the ability of firms to scale, particularly in a fast-moving technological field. It acknowledges risks that regulation could lead to offshoring, discourage smaller innovators or slow down the deployment of beneficial applications if compliance costs are disproportionate or legal requirements are overly rigid. These concerns are not confined to the background sections of the AI Act IA but are reflected in the comparison of policy options and in the architecture of the preferred option. The introduction of a risk-based approach, the differentiation between high-risk and non-high-risk systems, the reliance on harmonised standards, and the creation of regulatory sandboxes are all explicitly justified as ways to balance safety and fundamental-rights protection with innovation and competitiveness. The Regulatory Scrutiny Board's repeated focus on SME impacts, fixed compliance costs and proportionality further indicates that innovation-relevant issues were treated as central to the assessment rather than peripheral. In this sense, the AI Act IA comes closer than any other recent file to demonstrating how the innovation principle can shape regulatory design choices in a meaningful way.

Other recent impact assessments show partial and sector-specific manifestations of the innovation principle, but none reach the same level of integration. Files such as **Open Finance, the Data Act or the European Health Data Space** explicitly link regulatory intervention to innovation through data access, interoperability and reuse. In these cases, innovation is more clearly connected to the substance of the policy, and in some instances it is used as a criterion when comparing options. However, these initiatives tend to conceptualise innovation narrowly, as a spillover of infrastructure and data availability, and they remain reliant on assumed causal chains rather than on demonstrated effects. Innovation is again subordinate to other objectives, such as consumer protection, data governance or market fairness, and is not monitored independently.

Looking beyond impact assessments to legislative outcomes, **one of the most tangible legacy of the innovation principle lies in the increasing use of regulatory sandboxes and experimentation mechanisms in EU law.** These instruments reflect the principle's core intuition that regulation should allow for controlled experimentation and learning, rather than imposing rigid ex ante constraints on emerging technologies. Their inclusion in legislation such as the AI Act suggests that innovation-friendly concepts have migrated from abstract principles into concrete governance tools. Yet even here, the innovation principle operates more as a background justification than as an explicit doctrinal anchor, and the success of these instruments is measured mainly in terms of regulatory learning rather than innovation performance.

Taken together, these observations suggest that the innovation principle has been most effective as a framing and enabling device, rather than as a decisive analytical or legal instrument. It has contributed to making innovation a legitimate concern in regulatory debates, to embedding proportionality and flexibility into legislative design, and to justifying new governance tools such as regulatory sandboxes. What it has not yet achieved is a consistent, measurable and enforceable integration of innovation impacts into the core of EU regulatory decision-making. The absence of a single outstanding example is therefore less a failure of individual impact assessments than a reflection of the principle's deliberately soft and non-prescriptive nature.

## 4. Going forward: policy recommendations for unleashing the potential of the innovation principle in the EU policy cycle

There is no doubt that innovation will continue to play an important role in EU policy, as well as in the better regulation agenda. The key question is whether guidance on how to consider and promote innovation should be updated, consolidated with other guidance, or simply reformulated and placed in upstream parts of the policy cycle. The acceleration of the cycle and the increasing uncertainty faced by EU policymakers has already called for a significant redefinition of the role of ex ante impact assessments in general: in many cases, the European Commission has relied on broader- all-encompassing reports as the basis for a more agile series of downstream decisions. As stated in this report, this is certainly the case of foresight, with the JRC Strategic Foresight Reports becoming an important benchmark for Commission services in the problem definition and baseline assessment phase of the impact assessment. But also the Draghi report, as translated into broad agenda documents such as the Competitiveness Compass and the Clean Industrial Deal. These documents are clearly presented as setting the agenda, and include a timeline for subsequent legislative measures to be adopted. Once they are in place, the rationale for intervention and the need to qualitatively emphasise the importance of the measures for innovation and competitiveness becomes weaker. Rather, the role of impact assessments may slightly change as a result of this new way of setting priorities.

Moreover, the better regulation agenda should gradually be updated in its content and governance, to reflect the innovation being introduced by the evolution of general-purpose technologies such as Artificial Intelligence, especially in the form of trustworthy large language models. Given the size and continuous expansion of the Toolbox, as already suggested in Renda (2022), the next iteration of guidance for services should take the form of an interactive atlas, possibly supported by a conversational bot, acting on curated data only (through Retrieval-Augmented Generation, RAG), and overseen by a centralised service located in the European Commission or in the RSB.

Below, we distinguish three types of recommendations: a first list (section 5.1) includes the recommendations directly tackling the problems identified in this report; a second list (section 5.2) includes recommendations on how to reform guidance on innovation, SMEs and competitiveness by bringing it upstream, in the agenda-setting phase of the policy cycle; and a third list (section 5.3) contains the recommendations on how to fully embrace AI and interactive guidance to services on how to promote research and innovation, or avoid hindering it, when carrying out ex ante and ex post analysis of legislation. Yet, before we formulate new recommendations, we look at the conclusions of the earlier report by Renda and Simonelli (2019), to see if any of the problems identified in that report have been adequately addressed over the past years.

### 4.1. How relevant are the conclusions of the 2019 study today?

Renda and Simonelli (2019) found several problems preventing the innovation principle from producing its intended effects. Below, we list the problems identified already in 2019, and comment on their relevance today.

- *The lack of a clear legal basis.* This problem still persists, as no legal basis was introduced for the innovation principle since 2019.

- *The lack of a widely acknowledged definition.* If anything the principle is now more directly overlapping with other guidance in the toolbox, such as the competitiveness check introduced in 2023, the SME test, etc. A clear definition would lead to easier institutionalisation and mainstreaming of the principle in the jargon and practice of EU better regulation.
- *Insufficient awareness among services.* Services in charge of ex ante IA or ex post evaluation do not mention the principle, but somehow follow at least part of its overall guidance. This may depend on the fact that the principle “codified” existing instruments that were considered, in the mid-2010s, as innovation-friendly. Some of them, like various forms of co-regulation, were already deeply embedded in the EU *acquis*, and if anything saw a slight evolution of the past years. Other approaches that could have been included in the innovation principle, like RegTech, SupTech, code as law or third-party access to AI systems, have been rather placed in other tools in the Toolbox, such as Tool #69.
- *Lack of institutionalisation of support for implementation.* The support for the application of the innovation principle, to be provided by DG RTD, has not been entirely engineered into the workflow of the Commission.
- *Limited skills and expertise in appraisal of R&I impacts.* This problem persists. In almost all cases in which innovation impacts have been considered by the lead DGs, their assessment ended up being rather qualitative, and often not directly linked to the creation of an adequate ecosystem for research and innovation to flourish.
- *Lack of clarity on relation between the precautionary principle and the innovation principle.* While the European Commission seems to have more decisively moved in the direction of pro-innovation regulation in key areas where the EU wants to restore or anyway gain competitiveness, no public statement or official documents were released, which give guidance to services on how to strike a proper balance between the application of the precautionary principle and the need for innovation-friendly legislation.
- *Need to link the principle to experimental governance approaches.* The Commission has progressed on experimental approaches, mostly introducing regulatory sandboxes: however, the implementation of regulatory sandboxes at EU level has proven challenging and remains at a rather embryonic stage (Renda, Mifsud and Haegeman forthcoming).
- *Critical role of the timing of the application of the principle.* There seem to be good bases for proposing that the assessment of innovation occurs at an early stage, either at the agenda-setting phase of the policy cycle, or in the early stages of the ex ante impact assessment. Currently, innovation impacts are often treated as an afterthought, or taken for granted given that the legislation at hand has been proposed for competitiveness purposes. As a result, the innovation principle (of related approaches) seem to surface either too early, or too late in the policy cycle of the European Commission.
- *Need for a reflection on the correct application of 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. On this, there still seems to be a lack of guidance in the Better Regulation Toolbox, which remains a catalogue of tools, with limited guidance or early checkpoints as to which ones should give rise to *ad hoc* assessments in specific ex ante IAs or ex post evaluations.
- *Need for updating the approaches included in the Tool (e.g. RegTech, SupTech, “open API”).* This has actually occurred, although only partially and in a different tool of the toolbox (Tool #69). The creation of a different tool for these instruments risks being detrimental to the legitimacy of Tool #22 as devoted *i.a.* to innovation-friendly policy design.

- *Lack of implementation of the Tool especially when it comes to monitoring and evaluation indicators.* Here too, the problem persists. We found very little uptake of concrete R&I-related indicators in the monitoring and evaluation section of the impact assessments we reviewed. This is regrettable, as the European Commission is supposed to keep track of whether the assumed effects on innovation are materialising, and if not, why.
- *Lack of uptake of the innovation deals.* The “deals” have been gradually discontinued in the EU better regulation agenda. And while there were structural, design-related reasons for the innovation deals’ lack of uptake and concrete implementation, today the possibility for stakeholders to “challenge” existing regulation could become an ally of the European Commission’s attempt to reduce regulatory burdens, provided that the “deals” are adequately redesigned and any proposal by regulated entities is properly scrutinised. Renda (2016) already reviewed similar schemes adopted in the United States, mostly by the Environmental Protection Agency, and known mostly under the label of “negotiated rulemaking”.

## 4.2. Consolidation and improvement of innovation-related guidance in the Better Regulation Toolbox

How to ensure that the innovation principle can really deliver the results and impacts it was expected to produce? Below, we offer a number of recommendations that do not question the current positioning of the principle in the European Commission’s better regulation agenda.

- R1. Reinforce the innovation principle through capacity-building by a dedicated service in the Commission.** For it to properly work, the innovation principle should be translated into a number of concrete steps. In addition, a dedicated service in DG RTD or in the JRC should support services in the quantification of expected R&I impacts of the baseline and alternative policy options. The same service should also support lead DGs with ongoing training, as well as with support on how to properly embed R&I in monitoring and evaluation indicators; and should publish a yearly report on the topic, drawing *i.a.* from individual legislative files to draw conclusions on the evolution of the R&I ecosystem in the EU (if done by DG RTD, this could be added to the SRIP; if done by the JRC, perhaps to the strategic foresight report).
- R2. Bring foresight and horizon scanning more deeply into *ex ante* impact assessments.** The significant uptake of strategic foresight in 2020-2025 impact assessments is limited to references to the JRC strategic foresight report. This very often stops at the problem definition stage, and does not lead to a full incorporation of alternative futures in the analysis. In practice, (strategic) foresight and horizon scanning should inform the problem definition and, where appropriate, depart from a single baseline scenario (“projected future”) to include also “probable”, “plausible” and “possible” futures. On that basis, a preferred future could also be identified, leading to so-called back-casting, *i.e.* the identification of the policies, the contingency measures, as well as the innovation that would be needed to make the preferred future as likely as possible.
- R3. Clarify and review the scope of the innovation principle, updating it with new tools.** Guidance on innovation-friendly regulation should become a single policy document, and be updated regularly. Ideally, there should be no distinction between the techniques outlined in Tool #22 (Innovation Principle) and the ones included in Tool #69 (covering *i.a.* Regulatory Sandboxes). The combined list should be subject to interactive, more in-depth guidance and training, and the list should be extended to include all the data- and AI-enabled regulatory approaches that technological evolution has made possible over the past few years (see figure 5 above, and accompanying text). Furthermore, the current tool #22 should be updated to reflect cumulative impacts and scale-up problems.

- R4. Build a repository of international good practices, and explain the factors for the success of given regulatory approaches.** Guidance should be extensive and based on existing success stories. Simply mentioning regulatory sandboxes, for example, hides available evidence that these instruments tend to work only if the authority that puts them in place is highly reputed, well resourced, and highly competent. Some countries have abandoned the idea of introducing or implementing regulatory sandboxes, to rely on less structured policy dialogues aimed at increasing regulatory certainty for stakeholders.
- R5. Deepen the guidance given to Commission services.** As an example, the future Tool #22 could include third-party access to APIs, or algorithms; yet implementing these measures very often relies on deep competences existing in the administration, or among external stakeholders. Not surprisingly, the Open API approach in PSD2 and the “vetted researchers” provision in the DSA have proven very difficult to implement in practice, and easily prey of the informational asymmetry existing between the regulator (at a disadvantage) and the regulated entities. Explaining how to choose co-regulatory solutions without incurring problems such as the ones unveiled by the so-called “Volkswagen scandal” – which could represent itself in a much more dramatic form in pieces of legislation such as the AI Act – is essential for services to correctly appraise the alternative policy options. Likewise, explaining how algorithmic inspection could take place, and the risks associated with it, would be very important and perhaps more feasible now, that the European Commission can count on the Sevilla-based Centre for Algorithmic Transparency. These skills are at the moment largely concentrated in a few people inside the European Commission, if any, and very often even the RSB does not possess the knowledge needed to guide the services in choosing the most sophisticated regulatory options.
- R6. Give more focus and a clearer label to the tool, also to distinguish it from the competitiveness check.** On many occasions, innovation may be assessed as part of a broader competitiveness goal. This is largely the approach adopted by the Draghi report. However, R&I does not only have to serve the goal of making Europe more competitive; it could also aim at addressing societal challenges, or contribute to the equally (if not more) urgent objective of strengthening EU resilience and/or security. Clarifying the lack of full overlap between innovation and competitiveness is very important to continue arguing for a stand-alone tool dedicated to R&I. The fact that the European Commission is now looking into research security and dual use R&I “by default” in parts of the next budget exemplifies this shift rather clearly.
- R7. Support the innovation principle with a more data-driven analysis.** As shown by the Draghi report, and by research carried out inside DG RTD, economic complexity and data-driven analysis of R&I ecosystems can shed light on the factors and conditions that boost innovation in specific regions or territories. The analysis of prospective impacts of new policies on research and innovation would significantly benefit from the wider availability of economic complexity analysis for the whole of the EU, and for individual regions. This would enable also simulations and projections that are seldom possible in individual impact assessment, unless specific models are made available alongside research support (e.g. RHOMOLO, used in six out of the 219 IAs; or FIDELIO). Modelling the European economy through complexity analysis is something DG RTD has specialised in over the past few years, as demonstrated by the richness of the data contained in the Science, Research and Innovation Performance of the EU (SRIP) reports, but also in the recent contributions to the [R&I paper series](#), and in the Projects for Policy (P4P) series. The recent experience of the [IFRAG expert group](#) could be replicated to provide more direct assistance in the formulation of new approaches to policymaking.
- R8. Revamp and recast the “innovation deals” instrument.** As already explained, innovation deals were not successful when they were first introduced, and already Simonelli and Renda (2019) found several design flaws that hampered their effectiveness as instruments of pro-innovation regulatory reform. In the future, the European

Commission may decide to revive the instrument by creating new spaces for stakeholders and regulated entities to propose meaningful regulatory reform, challenging the existing text of a regulation. Reforms, if related to the main text of a regulation or directive, would of course still need to go through the ordinary legislative procedure; however, softer or more adaptive forms of regulatory design could create situation in which regulators accept to pilot reforms for a limited period of time. Policy dialogues, hubs, testbeds, or even the UK Regulators' [Pioneer Fund](#) could become useful benchmarks in this case.

- R9. Introduce better guidance to adaptive regulation.** [Adaptive regulation](#), or “planned adaptive regulation”, is an approach to policymaking that takes into account deep uncertainty and fast-changing regulatory subject matters. Pioneered in the United States, it counts important examples also in the practice of the European Medicines Agency, and in the [Dutch](#) experience. In the case of the European Commission, services may usefully receive guidance on how to take into account the possible evolution of the subject matter by incorporating in their alternative options flexible and adaptive elements, such as benchmarks and points of discontinuity/decision-making. Moreover, in cases of deep uncertainty, services may need guidance on whether and how to choose more “reversible” or “incremental” options, rather than options that appear preferable, but only if the projected future (baseline) or the best-case scenario materialise.
- R10. Include guidance on ex post evaluations.** The current Tool #22 contains very little guidance on how to conduct an ex post evaluation by considering R&I impacts under the lens of effectiveness, efficiency, relevance, coherence and EU added value. A structured list of questions and resources for the lead DGs could motivate them to perform more innovation-aware ex post evaluations. Furthermore, the learning effect for EU institutions and external stakeholders would be stronger if all ex post evaluations were made public, on a dedicated European Commission’s website.

### **4.3. Recommendations for a more radical reform of the innovation principle**

The full implementation of the innovation principle seems to have been gradually hampered also by the changes introduced, whether intentionally or out of necessity, in the *modus operandi* and the *ratio decidendi* of the European Commission. In particular, on the one hand the second von der Leyen Commission has expedited decision-making by often resorting to fast-track procedures; on the other hand, it also has extensively relied on foundational reports, such as the Draghi and Letta reports, to then distil a whole policy agenda which rests on a common background and rationale. In this respect, replicating the R&I analysis at every impact assessment may not be the optimal solution, also since R&I analysis requires an ecosystem approach, and thus an analysis of the cumulative and interactive impacts of whole sections of the *acquis*. From this perspective, past tools used by the European Commission in the better regulation agenda, such as fitness checks and cumulative cost assessments, now largely discontinued, could prove useful and perhaps more compatible with the new balance in the Commission, between “thinking fast and slow”. Below, we explore ways for DG RTD and the European Commission to depart from the current approach to the innovation principle, largely focused on the ex ante impact assessment instrument.

- R11. Replace the application of the innovation principle to individual ex ante impact assessment with comprehensive reports per policy domains or sectors.** A yearly addition to the SRIP, looking at the R&I ecosystem in general, and in different sectors, could become the basis for a more thorough, standardised application of the innovation principle. Lead DGs could be involved in these forms of analysis, which would then increase their sense of “ownership” when using its results to shape the agenda in their sectors of competence. Pre-existing analysis would also make it easier to quantify prospective impacts, and choose monitoring and evaluation indicators. DG RTD could

work with lead DGs to define scenarios for various sectors, and back-cast them to define a policy and investment agenda to make the preferred future as likely as possible. The motivation of legislation would then rest in the need to pursue the preferred future, preserving the needed flexibility and mitigating possible risks.

- R12. Reconsider fitness checks and cumulative cost assessments rather than applying the innovation principle for each individual legislative proposal.** Similarly to R11, in this case the European Commission would return to the use of studies and reports that were usefully launched a decade ago. Cumulative cost assessments took as a unit of analysis a given industry sector, and assessed the compliance costs generated by various relevant policy measures from different domains on the businesses operating in the sector at hand (for example, we at CEPS led studies on steel, aluminium, glass and ceramics). On the other hand, fitness checks focused on one policy domain, and aimed at evaluating the interactive and cumulative effects generated by all legislative measures in the domain at hand. These studies can unveil important avenues for regulatory improvements and simplification, with a stronger focus on competitiveness and innovation.
- R13. Transform the Better Regulation Toolbox into real-time, interactive, AI-assisted guidance for services.** Technological progress in AI, especially in conversational bots based on large language models, make it possible to train an AI system to assist lead DGs in drafting their legislation and impact assessments. LLMs can work with curated datasets (so-called RAG) to avoid hallucinations, and could usefully guide services in the selection of the methods and tools to use when approaching an impact assessment exercise. The RSB could, in this respect, provide useful human oversight, in the form of a human “on” the loop, overseeing the exchange between the services and the AI system and intervening whenever the interaction drifts away from the expected “orthodox” solutions. Recent pilots such as SITRA’s Eur-Lex GPT confirm the prospective viability of these solutions, provided that high quality data is used, alongside transparency and human oversight.

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# Annex 1 – Guidance on how to score European Commission impact assessment documents to track the implementation of the innovation principle

## Introduction: how to read impact assessments

Read through the impact assessment document. Typically you will find a general introductory part and a problem definition. Then, a description of stakeholder consultation, possible external studies, and an identification of the potential policy options. Sometimes the Commission breaks down the problem into sub-issues, and identified options for each of the sub-issues, so the IA becomes more complex.

After the options have been analysed, the Commission applies analysis, often in the form of a multi-criteria analysis leading to a comparative table, in which options are compared based on their impacts (economic, social, environmental, plus individual screens such as innovation and competitiveness, or human rights - see also the list used by the Regulatory Scrutiny Board in its annual reports).

The final part of the IA typically includes a section on monitoring and evaluation, which is important for the post-adoption phase, and for the evaluation of the relevance, effectiveness, coherence and EU added value of the legislation in question. This, in the absence of other specific provisions in the legislation happens five years after the entry into force of the rules.

In the study, we will have to look at the overall implementation of Tool #22, plus possibly some of the complementary tools in the Toolbox, but not all (some of them are too general, such as evidence-based policymaking, whereas others are directly relevant, such as the one on sandboxes).

I suggest that we do this in the following way. Below, I illustrate the main steps of our analysis. Once you have completed these steps for each Impact Assessment, you will need to fill a row of an excel table. I will give you a template.

### 1. Look for direct references to Tool #22

*Locate any reference to “Tool #22” or to the “innovation principle” in the Impact Assessment documents. Note also that in some cases the impact assessment consists of more than one PDF file, please read all of them.*

*Key questions:*

#### **1.1 Does the impact assessment refer to Tool #22?**

*Please note in a separate cell/column the page and section in which the reference is made*

#### **1.2 Does the impact assessment refer to the innovation principle?**

*Please note in a separate cell/column the page and section in which the reference is made*

#### **1.3 Is the subject matter relevant for the application of the innovation principle?**

*Please comment in a separate cell/column why the matter subject to the impact assessment could have been suitable for an application of Tool #22*

### 2. Look for cases in which the RSB mentioned Tool #22 in its opinion on the Impact Assessment

Locate any reference to Tool #22 in the RSB opinion(s) on the impact assessment. Note that most often the opinion is available as a separate document. I will upload all opinions for you to read.

### **2.1 Does the opinion of the RSB refer to Tool #22?**

Please note in a separate cell/column the page and section in which the reference is made

### **2.2 Does the opinion of the RSB refer to the innovation principle?**

Please note in a separate cell/column the page and section in which the reference is made

## **3. Identifying individual questions and issues related to Tool #22 that were explicitly tackled in the impact assessment (even if there is no specific mention of Tool #22)**

### **3.1 Foresight/horizon scanning**

Did any foresight or horizon scanning exercise contribute to the definition of the problem? This includes cases in which foresight or horizon scanning were carried out as part of the evaluation of the legislation to be reformed.

Did a foresight or horizon scanning exercise shape or inspire the description of the “baseline” option (also known as “do nothing” or “zero option”)?

Did the foresight/horizon scanning feed the definition and/or comparison of specific policy options in the impact assessment?

Were foresight or horizon scanning evoked when performing sensitivity analysis or anyway identifying possible contingency risks, *after* the preferred policy option was chosen?

### **3.2 Innovation principle in the impact assessment**

Did the Impact Assessment use the checklist provided at page 175 of the Better Regulation Toolbox?

Did the policy at hand potentially affect the research, testing or demonstration phase?

Did the policy measure at hand affect the application of innovative solutions or their commercialisation?

Did the measure potentially affect incentives to invest and/or scale-up in Europe?

Does the impact assessment contemplate experimentation clauses?

Does the impact assessment consider outcome-oriented legislation?

Does the impact assessment consider sunset clauses?

Does the impact assessment consider the possibility to leave it to applicants to test for alternatives (i.e. weigh potential alternatives and justify why their chosen solution is the optimal way to meet the policy goals underlying regulation?)

Does the impact assessment consider a top-runner approach (i.e. a provision that envisages the updating of a requirement to reflect higher performance levels that have become possible because of scientific or technological progress)?

Does the impact assessment consider a combination of the approaches mentioned above?

Does the impact assessment consider policy options that can be considered as particularly suited to promote innovation, even if they do not correspond to the ones mentioned in Section 4 of Tool #22? For example:

- Regulatory sandboxes
- Policy dialogues

- Regulatory experiments
- TechSprints, Hackathons
- Self-regulation
- Co-regulation
- Testbeds
- Innovation deals
- Government or third-party access to algorithms/AI systems
- API-based regulations (e.g. Open Banking)
- Law as Code
- SupTech (supervision through technology)

For each of the questions above, you must specify if the Commission considers these policy measures at the time of identifying alternative policy options, or after having chosen the preferred policy option. It would be also good to know if the option in question was retained as the preferred one, or not.

### 3.3 From options to impacts

*Even if an impact assessment does not run Tool #22, it may still want to assess the impact of alternative policy options on innovation, either directly or indirectly (e.g. competitiveness proofing, dynamic efficiency, diffusion of new solutions and other similar terms.*

Does the Commission impact assessment assess innovation impacts? If yes, what type?

Does the Commission impact assessment assess competitiveness impacts?

Does the Commission impact assessment assess impacts on SMEs, or run a “SME test”?

Does the Commission impact assessment assess any other impact related to innovation?

### 3.4 Monitoring and evaluation

*At the end of an impact assessment document, the European Commission typically lists indicators that will be used to monitor and evaluate the proposal over time.*

Does the Commission list any innovation-related monitor and evaluation indicator? *E.g. the creation of new startups; investment in R&D; etc.*

## Annex 2 – Methodological note

The analysis is based on a comprehensive coding of all IAs in the sample (IA1–IA219) and all RSB opinions (RSB1-RSB219), using a structured framework derived directly from the Commission’s own guidance in Tool #22 (see Annex 1 for our guidance document, which was later used to train different AI systems, overseen by a group of CEPS researchers, to carry out the full scoring of all 219 IAs).<sup>126</sup> Ex post evaluation documents are not covered by this analysis, also due to their partial unavailability on public websites.

The choice of using Artificial Intelligence to provide a systematic coding of the content of European Commission IAs was motivated by several factors, including the limited time available for the Study. The results of the analysis are subject to additional scrutiny by human researchers, but may not be taken as a fully accurate appraisal, due to the limitations in current

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<sup>126</sup> The AI models used are GPT 5.2, Gemini 3 (Pro and Flash), and Claude 4.2.

AI models in understanding the context of the analysis, and in particular the factors that entered the definition of the baseline, as well as the consideration of impacts. That said, the analysis that follows provides a broad-brushed overview of the uptake of several aspects of Tool #22 in European Commission IAs, as well as current trends in the operationalisation of the content of the Tool.

Each question in the guidance document (see Annex 1) was operationalised as a variable coded on a three-point scale, where 1 indicates clear and explicit evidence; 0.5 indicates partial, indirect, or ambiguous evidence; 0 indicates no evidence identified. This approach captures both explicit application and more implicit forms of consideration. Variables are grouped into six analytical dimensions corresponding to the structure of Tool #22 and the Better Regulation impact assessment process. The first dimension captures explicit references to the innovation principle and Tool #22. These variables assess formal visibility and signalling. The second dimension captures relevance for innovation, reflecting the guidance's emphasis on proportionality. The third dimension captures foresight and future-oriented analysis, including treatment of uncertainty. The fourth dimension captures innovation-friendly regulatory design, focusing on flexibility, experimentation, and adaptive governance. The fifth dimension captures innovation-related impacts, including both explicit innovation impacts and related proxy categories. The sixth dimension captures monitoring, evaluation, and learning, assessing whether innovation considerations are carried forward into ex post frameworks.

## Annex 3 – List of impact assessments

The analysis is based on a comprehensive coding of all IAs in the sample (IA1–IA219) and all RSB opinions (RSB1–RSB219), using a structured framework derived directly from the Commission’s own guidance in Tool #22 (see Annex 1 for our guidance document, which was later used

Year	IA_ID	Document full name	Reference	Date	Responsible service	Short name
2025	IA1	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT accompanying the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2019/2088 on sustainability-related disclosures in the financial services sector (SFDR), Regulation (EU) No 1286/2014 on key information documents for packaged retail and insurance-based investment products (PRIIPs) and repealing Commission Delegated Regulation (EU) 2022/1288	SWD(2025)838	20/11/2025	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA
2025	IA2	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document COMMISSION REGULATION laying down ecodesign requirements for external power supplies, wireless chargers, wireless charging pads, battery chargers for portable batteries of general use and USB Type-C cables, pursuant to Directive 2009/125/EC of the European Parliament and of the Council and repealing Commission Regulation (EU) 2019/1782	SWD(2025)288	13/10/2025	Directorate-General for Energy	ENER
2025	IA3	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT on the Single Market and Customs Programme Accompanying the document Proposal for a Regulation of the European Parliament and of the Council establishing the Single Market and Customs Programme for the period 2028-2034 and repealing Regulations (EU)2021/444, (EU)2021/690, (EU)2021/785, (EU)2021/847 and (EU) 2021/1077	SWD(2025)592	03/09/2025	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW

2025	IA4	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European fisheries and aquaculture statistics and repealing Regulations (EC) No 1921/2006, (EC) No 762/2008, (EC) No 216/2009, (EC) No 217/2009 and (EC) No 218/2009	SWD(2025)232	30/07/2025	Eurostat	EUROS TAT
2025	IA5	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC as regards the addition of substances and setting limit values in its Annexes I, III and IIIa	SWD(2025)192	18/07/2025	Directorate-General for Employment, Social Affairs and Inclusion	EMPL
2025	IA6	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing the European Fund for economic, social and territorial cohesion, agriculture and rural, maritime, prosperity and security for the period 2028-2034 and amending Regulation (EU) 2023/955 and Regulation (EU, Euratom) 2024/2509	SWD(2025)565	16/07/2025	Directorate-General for Regional and Urban Policy	REGIO
2025	IA7	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a COUNCIL DIRECTIVE on the structure and rates of excise duty applied to tobacco and tobacco related products (recast)	SWD(2025)560	16/07/2025	Directorate-General for Taxation and Customs Union	TAXUD
2025	IA8	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT on the European Competitiveness Fund Accompanying the documents Proposal for a Regulation of the European Parliament and of the Council on establishing the European Competitiveness Fund ('ECF'), including the specific programme for defence research and innovation activities, repealing Regulations (EU) 2021/522, (EU) 2021/694, , (EU) 2021/697, (EU) 2021/783, repealing provisions of Regulations (EU) 2021/696, (EU) 2023/588, and amending Regulation (EU) [EDIP] Proposal for a Regulation of the European Parliament and of the Council	SWD(2025)555	16/07/2025	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW

		establishing Horizon Europe, the Framework Programme for Research and Innovation, for the period 2028-2034 laying down its rules for participation and dissemination, and repealing Regulation (EU) 2021/695 Proposal for a Council Decision on establishing the Specific Programme implementing Horizon Europe - the Framework Programme for Research and Innovation for the period 2028-2034, laying down the rules for participation and dissemination under that Programme, and repealing Decision (EU) 2021/764				
2025	IA9	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a budget expenditure tracking and performance framework and other horizontal rules for the Union programmes and activities	SWD(2025)590	16/07/2025	Directorate-General for Budget	BUDG
2025	IA10	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing Global Europe	SWD(2025)552	16/07/2025	Directorate-General for International Partnerships	INTPA
2025	IA11	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a Regulation of the European Parliament and of the Council establishing the 'AgoraEU' programme for the period 2028-2034, and repealing Regulations (EU) 2021/692 and (EU) 2021/818 and Proposal for a Regulation of the European Parliament and of the Council establishing the Erasmus+ programme for the period 2028-2034, and repealing Regulations (EU) 2021/817 and (EU) 2021/888	SWD(2025)550	16/07/2025	Directorate-General for Communications Networks, Content and Technology	CNCT
2025	IA12	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on a framework of measures for the establishment of the Union Civil Protection Mechanism and for health preparedness and	SWD(2025)545	16/07/2025	Directorate-General for European Civil Protection and Humanitarian Aid	ECHO

		response repealing Decision 1313/2013 (Union Civil Protection Mechanism).			Operations (ECHO)	
2025	IA13	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on the safety, resilience and sustainability of space activities in the Union	SWD(2025)335	25/06/2025	Directorate-General for Defence Industry and Space	DEFIS
2025	IA14	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Review of the Securitisation Framework Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2017/2402 of the European Parliament and of the Council of 12 December 2017 laying down a general framework for securitisation and creating a specific framework for simple, transparent and standardised securitisation and Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) No 575/2013 on prudential requirements for credit institutions as regards requirements for securitisation exposures	SWD(2025)825	17/06/2025	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA
2025	IA15	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT on the revision of the Directives of the Roadworthiness package Accompanying the documents Proposal for a Directive of the European Parliament and of the Council amending Directive 2014/45/EU on periodic roadworthiness tests for motor vehicles and their trailers, and amending Directive 2014/47/EU on the technical roadside inspection of the roadworthiness of commercial vehicles circulating in the Union Proposal for a Directive of the European Parliament and of the Council on the registration documents for vehicles and vehicle registration data recorded in national vehicle registers, and repealing Council Directive 1999/37/EC	SWD(2025)96	24/04/2025	Directorate-General for Mobility and Transport	MOVE

2024	IA16	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document COMMISSION REGULATION (EU) .../... implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for fans driven by motors with an electric input power between 125 W and 500 kW, and repealing Commission Regulation No (EU) 327/2011	SWD(2024)155	03/07/2024	Directorate-General for Energy	ENER
2024	IA17	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document COMMISSION REGULATION (EU) .../... implementing Directive 2009/125/EC of the European Parliament and of the Council as regards ecodesign requirements for local space heaters and separate related controls and repealing Regulation (EU) 2015/1188	SWD(2024)62	18/04/2024	Directorate-General for Energy	ENER
2024	IA18	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a Directive of the European Parliament and of the Council on improving and enforcing working conditions of trainees and combating employment relationships disguised as traineeships and Proposal for a Council Recommendation on a reinforced Quality Framework for Traineeships and replacing the Council Recommendation of 10 March 2014 on a Quality Framework for Traineeships	SWD(2024)67	20/03/2024	Directorate-General for Employment, Social Affairs and Inclusion	EMPL
2024	IA19	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Part 1 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 Securing our future Europe's 2040 climate target and path to climate neutrality by 2050 building a sustainable, just and prosperous society	SWD(2024)63	06/02/2024	Directorate-General for Climate Action	CLIMA

2024	IA20	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND THE COUNCIL on combating child sexual abuse and sexual exploitation and child sexual abuse material, and replacing Council Framework Decision 2004/68/JHA (recast)	SWD(2024)33	06/02/2024	Directorate-General for Migration and Home Affairs	HOME
2024	IA21	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive 2005/44/EC on harmonised river information services (RIS) on inland waterways in the Community	SWD(2024)15	26/01/2024	Directorate-General for Mobility and Transport	MOVE
2024	IA22	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive 2009/38/EC as regards the establishment and functioning of European Works Councils and the effective enforcement of transnational information and consultation rights	SWD(2024)10	24/01/2024	Directorate-General for Employment, Social Affairs and Inclusion	EMPL
2023	IA23	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council establishing harmonised requirements in the internal market on transparency of interest representation carried out on behalf of third countries and amending Directive (EU) 2019/1937 and Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) No 1024/2012 and (EU) 2018/1724 as regards certain requirements laid down by Directive (EU) XXXX/XXXX	SWD(2023)663	12/12/2023	Directorate-General for Justice and Consumers	JUST
2023	IA24	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of animals during transport and related	SWD(2023)401	07/12/2023	Directorate-General for Health and Food Safety	SANTE

		operations, amending Council Regulation (EC) No 1255/97 and repealing Council Regulation (EC) No 1/2005				
2023	IA25	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a Council Directive amending Directive (EU) 2015/637 on the coordination and cooperation measures to facilitate consular protection for unrepresented citizens of the Union in third countries and Directive (EU) 2019/997 establishing an EU Emergency Travel Document	SWD(2023)941	06/12/2023	Directorate-General for Justice and Consumers	JUST
2023	IA26	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive (EU) 2015/2302 to make the protection of travellers more effective and to simplify and clarify certain aspects of the Directive	SWD(2023)906	29/11/2023	Directorate-General for Justice and Consumers	JUST
2023	IA27	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 261/2004, (EC) No 1107/2006, (EU) No 1177/2010, (EU) No 181/2011 and (EU) 2021/782 as regards enforcement of passenger rights in the Union Proposal for a Regulation of the European Parliament and of the Council on passenger rights in the context of multimodal journeys	SWD(2023)386	29/11/2023	Directorate-General for Mobility and Transport	MOVE
2023	IA28	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the proposal for a Regulation of the European Parliament and of the Council on a monitoring framework for resilient European forests	SWD(2023)373	22/11/2023	Directorate-General for Environment	ENV
2023	IA29	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and the Council establishing an EU Talent Pool	SWD(2023)717	15/11/2023	Directorate-General for Migration and Home Affairs	HOME

2023	IA30	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Council Directive 92/106/EEC as regards a support framework for intermodal transport of goods and Regulation (EU) 2020/1056 of the European Parliament and the Council as regards calculation of external costs savings and generation of aggregated data	SWD(2023)351	07/11/2023	Directorate-General for Mobility and Transport	MOVE
2023	IA31	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2013/11/EU on alternative dispute resolution for consumer disputes, as well as Directives (EU) 2015/2302, (EU) 2019/2161 and (EU) 2020/1828	SWD(2023)335	17/10/2023	Directorate-General for Justice and Consumers	JUST
2023	IA32	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Combatting microplastic pollution in the European Union Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on preventing plastic pellet losses to reduce microplastic pollution	SWD(2023)332	16/10/2023	Directorate-General for Environment	ENV
2023	IA33	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and the Council on combating late payments in commercial transactions	SWD(2023)314	12/09/2023	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW
2023	IA34	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a COUNCIL DIRECTIVE establishing a Head Office Tax system for micro, small and medium sized enterprises, and amending Directive 2011/16/EU	SWD(2023)302	12/09/2023	Directorate-General for Taxation and Customs Union	TAXUD

2023	IA35	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council establishing the European Disability Card and the European Parking Card for persons with disabilities	SWD(2023)290	06/09/2023	Directorate-General for Employment, Social Affairs and Inclusion	EMPL
2023	IA36	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council on European cross-border associations	SWD(2023)293	05/09/2023	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW
2023	IA37	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on European labour market statistics on businesses, repealing Council Regulation (EC) No 530/1999 and Regulations (EC) No 450/2003 and (EC) No 453/2008 of the European Parliament and of the Council	SWD(2023)265	28/07/2023	Eurostat	EUROSTAT
2023	IA38	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the safety of toys and repealing Directive 2009/48/EC	SWD(2023)269	28/07/2023	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW
2023	IA39	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT IMPACT ASSESSMENT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury as regards dental amalgam and other mercury-	SWD(2023)396	14/07/2023	Directorate-General for Environment	ENV

		added products subject to manufacturing, import and export restrictions				
2023	IA40	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on circularity requirements for vehicle design and on management of end-of-life vehicles, amending Regulations (EU) 2018/858 and 2019/1020 and repealing Directives 2000/53/EC and 2005/64/EC	SWD(2023)256	13/07/2023	Directorate-General for Environment	ENV
2023	IA41	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents COMMISSION REGULATION (EU) .../... of XXX implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for household tumble dryers, amending Commission Regulation (EU) 2023/826, and repealing Commission Regulation (EU) No 932/2012 and COMMISSION DELEGATED REGULATION (EU) .../... of XXX supplementing Regulation (EU) 2017/1369 of the European Parliament and of the Council with regard to energy labelling of household tumble dryers and repealing Commission Delegated Regulation (EU) No 392/2012	SWD(2023)252	13/07/2023	Directorate-General for Energy	ENER
2023	IA42	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2012/29/EU establishing minimum standards on the rights, support and protection of victims of crime, and replacing Council Framework Decision 2001/220/JHA	SWD(2023)246	12/07/2023	Directorate-General for Justice and Consumers	JUST
2023	IA43	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT [ ] Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Council Directive 96/53/EC laying down for certain road vehicles circulating within the Community the maximum authorised	SWD(2023)445	11/07/2023	Directorate-General for Mobility and Transport	MOVE

		dimensions in national and international traffic and the maximum authorised weights in international traffic				
2023	IA44	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND THE COUNCIL on the accounting of greenhouse gas emissions of transport services	SWD(2023)441	11/07/2023	Directorate-General for Mobility and Transport	MOVE
2023	IA45	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on the use of railway infrastructure capacity in the single European railway area, amending Directive 2012/34/EU and repealing Regulation (EU) No 913/2010	SWD(2023)443	11/07/2023	Directorate-General for Mobility and Transport	MOVE
2023	IA46	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 223/2009 on European statistics	SWD(2023)240	10/07/2023	Eurostat	EUROS TAT
2023	IA47	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the proposal for a Directive of the European Parliament and of the Council on Soil Monitoring and Resilience (Soil Monitoring Law)	SWD(2023)417	05/07/2023	Directorate-General for Environment	ENV
2023	IA48	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625	SWD(2023)412	05/07/2023	Directorate-General for Health and Food Safety	SANTE
2023	IA49	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of plant reproductive material in the	SWD(2023)414	05/07/2023	Directorate-General for Health and Food Safety	SANTE

		Union, amending Regulations (EU) 2016/2031, 2017/625 and 2018/848 of the European Parliament and of the Council, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90 (Regulation on plant reproductive material) and Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of forest reproductive material in the Union, amending Regulations (EU) 2016/2031 and 2017/625 of the European Parliament and of the Council, and repealing Council Directive 1999/105/EC (Regulation on forest reproductive material)				
2023	IA50	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Directive of the European Parliament and of the Council amending Directive 2008/98/EC on waste	SWD(2023)421	05/07/2023	Directorate-General for Environment	ENV
2023	IA51	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a Regulation of the European Parliament and of the Council on the establishment of the digital euro and Proposal for a Regulation of the European Parliament and of the Council on the provision of digital euro services by payment services providers incorporated in Member States whose currency is not the euro and amending Regulation (EU) 2021/1230 of the European Parliament and the Council and Proposal for a Regulation of the European Parliament and of the Council on the legal tender of euro banknotes and coins	SWD(2023)233	28/06/2023	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA
2023	IA52	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on a framework for Financial Data Access and amending Regulations (EU) No 1093/2010, (EU) No 1094/2010, (EU) No 1095/2010 and (EU) 2022/2554	SWD(2023)224	28/06/2023	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA

2023	IA53	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on payment services in the internal market and amending Regulation (EU) No 1093/2010 and Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on payment services and electronic money services in the Internal Market amending Directive 98/26/EC and repealing Directives 2015/2366/EU and 2009/110/EC	SWD(2023)231	28/06/2023	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA
2023	IA54	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT New EU system for the avoidance of double taxation and prevention of tax abuse in the field of withholding taxes (WHT) Accompanying the document Proposal for a Council Directive on Faster and Safer Relief of Excess Withholding Taxes	SWD(2023)216	19/06/2023	Directorate-General for Taxation and Customs Union	TAXUD
2023	IA55	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Commission Regulation laying down ecodesign requirements for smartphones, mobile phones other than smartphones, cordless phones and slate tablets pursuant to Directive 2009/125/EC of the European Parliament and of the Council and amending Commission Regulation (EU) 2023/826 and Commission Delegated Regulation supplementing Regulation (EU) 2017/1369 of the European Parliament and of the Council with regard to the energy labelling of smartphones and slate tablets	SWD(2023)101	16/06/2023	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW
2023	IA56	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on the transparency and integrity of Environmental, Social and Governance (ESG) rating activities	SWD(2023)204	13/06/2023	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA

2023	IA57	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive 2009/18/EC establishing the fundamental principles governing the investigation of accidents in the maritime transport sector	SWD(2023)145	01/06/2023	Directorate-General for Mobility and Transport	MOVE
2023	IA58	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents COMMUNICATION FROM THE COMMISSION Approval of the content of a draft for a Communication from the Commission – Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements COMMISSION REGULATION (EU) .../... of XXX on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of research and development agreements COMMISSION REGULATION (EU) .../... of XXX on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of specialisation agreements	SWD(2023)167	01/06/2023	Directorate-General for Competition	COMP
2023	IA59	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive 2009/16/EC on port State control	SWD(2023)148	01/06/2023	Directorate-General for Mobility and Transport	MOVE
2023	IA60	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive 2009/21/EC on compliance with flag State requirements	SWD(2023)165	01/06/2023	Directorate-General for Mobility and Transport	MOVE
2023	IA61	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive	SWD(2023)159	01/06/2023	Directorate-General for Mobility and Transport	MOVE

		2005/35/EC on ship-source pollution and on the introduction of penalties, including criminal penalties, for pollution offences				
2023	IA62	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a Regulation of the European Parliament and of the Council on jurisdiction, applicable law, recognition and enforcement of measures and cooperation in matters relating to the protection of adults and proposal for a Council decision authorising Member States to become or remain parties, in the interest of the European Union, to the Convention of 13 January 2000 on the International Protection of Adults	SWD(2023)155	31/05/2023	Directorate-General for Justice and Consumers	JUST
2023	IA63	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Rules on breaks and rest periods rules in occasional bus and coach transport Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 561/2006 as regards minimum requirements on minimum breaks and daily and weekly rest periods in the occasional passenger transport sector	SWD(2023)137	24/05/2023	Directorate-General for Mobility and Transport	MOVE
2023	IA64	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directives (EU) 2009/65/EC, 2009/138/EC, 2011/61/EU, 2014/65/EU and (EU) 2016/97 as regards the Union retail investor protection rules and Regulation of the European Parliament and of the Council amending Regulation (EU) No 1286/2014 as regards the modernisation of the key information document	SWD(2023)278	24/05/2023	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA
2023	IA65	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT [ ] Accompanying the document Proposal for a Regulation of the European Parliament and of the Council establishing the Union Customs Code and the European Union Customs Authority, and repealing Regulation (EU) No 952/2013	SWD(2023)140	17/05/2023	Directorate-General for Taxation and Customs Union	TAXUD

2023	IA66	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on detergents and surfactants, amending Regulation (EU) 2019/1020 and repealing Regulation (EC) No 648/2004	SWD(2023)114	28/04/2023	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW
2023	IA67	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast) and Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast) and Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013 and Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products	SWD(2023)118	27/04/2023	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW
2023	IA68	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006	SWD(2023)121	27/04/2023	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW
2023	IA69	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on standard essential patents and amending Regulation (EU) 2017/1001	SWD(2023)124	27/04/2023	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW

2023	IA70	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006	SWD(2023)192	26/04/2023	Directorate-General for Health and Food Safety	SANTE
2023	IA71	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Revision of EU marketing standards for agricultural products to ensure the uptake and supply of sustainable products Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Council Directives 2001/110/EC relating to honey, 2001/112/EC relating to fruit juices and certain similar products intended for human consumption, 2001/113/EC relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption, and 2001/114/EC relating to certain partly or wholly dehydrated preserved milk for human consumption	SWD(2023)97	21/04/2023	Directorate-General for Agriculture and Rural Development	AGRI
2023	IA72	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents COMMISSION IMPLEMENTING REGULATION (EU) /... implementing Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings and repealing Commission Regulation (EC) No 802/2004 COMMISSION NOTICE on a simplified treatment for certain concentrations under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings	SWD(2023)80	20/04/2023	Directorate-General for Competition	COMP

2023	IA73	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the Proposals for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND COUNCIL amending Directive 2014/59/EU as regards early intervention measures, conditions for resolution and financing of resolution action REGULATION OF THE EUROPEAN PARLIAMENT AND COUNCIL amending Regulation (EU) 806/2014 as regards early intervention measures, conditions for resolution and financing of resolution action DIRECTIVE OF THE EUROPEAN PARLIAMENT AND COUNCIL amending Directive 2014/49/EU as regards the scope of deposit protection, use of deposit guarantee schemes funds, cross-border cooperation, and transparency	SWD(2023)225	18/04/2023	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA
2023	IA74	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document COMMISSION REGULATION (EU) .../... laying down ecodesign requirements for off mode, standby mode, and networked standby energy consumption of electrical and electronic household and office equipment pursuant to Directive 2009/125/EC of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1275/2008 and Commission Regulation (EC) No 107/2009	SWD(2023)86	17/04/2023	Directorate-General for Energy	ENER
2023	IA75	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on the approval and market surveillance of non-road mobile machinery circulating on public roads and amending Regulation (EU) 2019/1020	SWD(2023)65	30/03/2023	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW
2023	IA76	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directives 2009/102/EC and (EU) 2017/1132	SWD(2023)178	29/03/2023	Directorate-General for Justice and Consumers	JUST

		as regards further expanding and upgrading the use of digital tools and processes in company law				
2023	IA77	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council on common rules promoting the repair of goods and amending Regulation (EU) 2017/2394, Directives (EU) 2019/771 and (EU) 2020/1828	SWD(2023)59	22/03/2023	Directorate-General for Justice and Consumers	JUST
2023	IA78	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council establishing a framework for ensuring a secure and sustainable supply of critical raw materials and amending Regulations (EU) 168/2013, (EU) 2018/858, 2018/1724 and (EU) 2019/1020	SWD(2023)161	16/03/2023	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW
2023	IA79	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on driving licences, amending Directive (EU) 2022/2561 of the European Parliament and of the Council, Regulation (EU) 2018/1724 of the European Parliament and of the Council and repealing Directive 2006/126/EC of the European Parliament and of the Council and Commission Regulation (EU) No 383/2012 and Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Union-wide effect of certain driving disqualifications	SWD(2023)128	01/03/2023	Directorate-General for Mobility and Transport	MOVE
2023	IA80	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive (EU) 2015/413 facilitating cross-border exchange of information on road-safety-related traffic offences	SWD(2023)126	01/03/2023	Directorate-General for Mobility and Transport	MOVE

2023	IA81	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2019/1009 as regards the digital labelling of EU fertilising products	SWD(2023)49	27/02/2023	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW
2023	IA82	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on measures to reduce the cost of deploying gigabit electronic communications networks and repealing Directive 2014/61/EU (Gigabit Infrastructure Act)	SWD(2023)46	23/02/2023	Directorate-General for Communications Networks, Content and Technology	CNCT
2023	IA83	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Part 1 Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2019/1242 as regards strengthening the CO <sub>2</sub> emission performance standards for new heavy-duty vehicles and integrating reporting obligations, and repealing Regulation (EU) 2018/956	SWD(2023)88	14/02/2023	Directorate-General for Climate Action	CLIMA
2023	IA84	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Council Directive 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council as regards the limit values for lead and its inorganic compounds and diisocyanates	SWD(2023)35	13/02/2023	Directorate-General for Employment, Social Affairs and Inclusion	EMPL
2023	IA85	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European statistics on population and housing, amending Regulation (EC) No 862/2007 and repealing Regulations (EC) No 763/2008 and (EU) No 1260/2013	SWD(2023)11	20/01/2023	Eurostat	EUROSTAT

2022	IA86	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Commission Implementing Regulation laying down a list of specific high-value datasets and the arrangements for their publication and re-use	SWD(2022)432	21/12/2022	Directorate-General for Communications Networks, Content and Technology	CNCT
2022	IA87	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures	SWD(2022)435	19/12/2022	Directorate-General for Environment	ENV
2022	IA88	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2011/36/EU on preventing and combating trafficking in human beings and protecting its victims	SWD(2022)425	19/12/2022	Directorate-General for Migration and Home Affairs	HOME
2022	IA89	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT accompanying the documents Communication from the Commission Commission Regulation Guidelines on State aid in the agriculture and forestry sectors and in rural areas and Commission Regulation declaring certain categories of aid in the agricultural and forestry sectors and in rural areas compatible with the internal market in application of Articles 107 and 108 of the Treaty on the Functioning of the European Union	SWD(2022)418	14/12/2022	Directorate-General for Competition	COMP
2022	IA90	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Communication from the Commission — Guidelines for the examination of State aid to the fishery and aquaculture sector Commission Regulation (EU) .../... of XXX declaring certain categories of aid to undertakings active in the production, processing and marketing of fishery and aquaculture products compatible with the internal market in application of Articles 107 and	SWD(2022)408	14/12/2022	Directorate-General for Competition	COMP

		108 of the Treaty on the Functioning of the European Union and Commission Regulation (EU) No 717/2014 of 27 June 2014 on the application of Articles 107 and 108 of the Treaty on the Functioning of the European Union to de minimis aid in the fishery and aquaculture sector				
2022	IA91	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council	SWD(2022)414	13/12/2022	Directorate-General for Health and Food Safety	SANTE
2022	IA92	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a Regulation of the European Parliament and of the Council on the collection and transfer of advance passenger information (API) for enhancing and facilitating external border controls, amending Regulation (EU) 2019/817 and Regulation (EU) 2018/1726, and repealing Council Directive 2004/82/EC Proposal for a Regulation of the European Parliament and of the Council on the collection and transfer of advance passenger information for the prevention, detection, investigation and prosecution of terrorist offences and serious crime, and amending Regulation (EU) 2019/818	SWD(2022)422	13/12/2022	Directorate-General for Migration and Home Affairs	HOME
2022	IA93	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a COUNCIL DIRECTIVE amending Directive 2006/112/EC as regards VAT rules for the digital age Proposal for a COUNCIL REGULATION amending Regulation (EU) No 904/2010 as regards the VAT administrative cooperation arrangements needed for the digital age Proposal for a COUNCIL IMPLEMENTING REGULATION amending Implementing Regulation (EU) No	SWD(2022)393	08/12/2022	Directorate-General for Taxation and Customs Union	TAXUD

		282/2011 as regards information requirements for certain VAT schemes				
2022	IA94	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Initiative to strengthen existing rules and expand the exchange of information framework in the field of taxation so as to include crypto-assets Accompanying the document Proposal for a Council Directive amending Directive 2011/16/EU on administrative cooperation in the field of taxation	SWD(2022)401	08/12/2022	Directorate-General for Taxation and Customs Union	TAXUD
2022	IA95	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Council Regulation on jurisdiction, applicable law, recognition of decisions and acceptance of authentic instruments in matters of parenthood and on the creation of a European Certificate of Parenthood	SWD(2022)391	07/12/2022	Directorate-General for Justice and Consumers	JUST
2022	IA96	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council harmonising certain aspects of insolvency law	SWD(2022)395	07/12/2022	Directorate-General for Justice and Consumers	JUST
2022	IA97	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) No 648/2012, (EU) No 575/2013 and (EU) 2017/1131 as regards measures to mitigate excessive exposures to third-country central counterparties and improve the efficiency of Union clearing markets and Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directives 2009/65/EU, 2013/36/EU and (EU) 2019/2034 as regards the treatment of concentration risk towards central counterparties and the counterparty risk on centrally cleared derivative transactions	SWD(2022)697	07/12/2022	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA

2022	IA98	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2014/65/EU to make public capital markets in the Union more attractive for companies and to facilitate access to capital for small and medium-sized enterprises and repealing Directive 2001/34/EC Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on multiple-vote share structures in companies that seek the admission to trading of their shares on an SME growth market Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/1129, (EU) No 596/2014 and (EU) No 600/2014 to make public capital markets in the Union more attractive for companies and to facilitate access to capital for small and medium-sized enterprises	SWD(2022)762	07/12/2022	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA
2022	IA99	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a Union certification framework for carbon removals	SWD(2022)377	30/11/2022	Directorate-General for Climate Action	CLIMA
2022	IA100	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and the Council on packaging and packaging waste, amending Regulation (EU) 2019/1020, and repealing Directive 94/62/EC	SWD(2022)384	30/11/2022	Directorate-General for Environment	ENV
2022	IA101	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents to the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending COUNCIL REGULATION (EC) No 6/2002 on Community designs and repealing Commission Regulation (EC) No 2246/2002 and the Proposal for a DIRECTIVE	SWD(2022)368	28/11/2022	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW

		OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the legal protection of designs (recast)				
2022	IA10 2	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act)	SWD(2022)721	18/11/2022	Directorate-General for Informatics	DIGIT
2022	IA10 3	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on type-approval of motor vehicles and of engines and of systems, components and separate technical units intended for such vehicles, with respect to their emissions and battery durability (Euro 7) and repealing Regulations (EC) No 715/2007 and (EC) No 595/2009	SWD(2022)359	10/11/2022	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW
2022	IA10 4	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on data collection and sharing relating to short-term accommodation rental services and amending Regulation (EU) 2018/1724	SWD(2022)350	07/11/2022	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW
2022	IA10 5	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and the Council on import, export and transit measures for firearms, their essential components and ammunition, implementing Article 10 of the United Nations' Protocol against the illicit manufacturing of and trafficking in firearms, their parts and components and ammunition, supplementing the United Nations Convention against Transnational Organised Crime (UN Firearms Protocol) (recast)	SWD(2022)298	27/10/2022	Directorate-General for Migration and Home Affairs	HOME

2022	IA106	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a Directive of the European Parliament and of the Council concerning urban wastewater treatment (recast)	SWD(2022)541	26/10/2022	Directorate-General for Environment	ENV
2022	IA107	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) No 260/2012 and (EU) No 2021/1230 as regards instant credit transfers in euro	SWD(2022)546	26/10/2022	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA
2022	IA108	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council on ambient air quality and cleaner air for Europe (recast)	SWD(2022)545	26/10/2022	Directorate-General for Environment	ENV
2022	IA109	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive 2000/60/EC establishing a framework for Community action in the field of water policy, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration and Directive 2008/105/EC on environmental quality standards in the field of water policy	SWD(2022)540	26/10/2022	Directorate-General for Environment	ENV
2022	IA110	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document COMMUNICATION FROM THE COMMISSION Guidelines on the application of EU competition law to collective agreements regarding the working conditions of solo self-employed persons	SWD(2022)321	29/09/2022	Directorate-General for Competition	COMP
2022	IA111	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for	SWD(2022)316	28/09/2022	Directorate-General for Internal Market, Industry,	GROW

		a Directive of the European Parliament and of the Council on liability for defective products			Entrepreneurship and SMEs	
2022	IA11 2	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT [ ] Accompanying the document [Mandatory element] Proposal for a Directive of the European Parliament and of the Council amending Directive 2009/148/EC on the protection of workers from the risks related to exposure to asbestos art work	SWD(202)311	28/09/2022	Directorate-General for Employment, Social Affairs and Inclusion	EMPL
2022	IA11 3	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence	SWD(202)319	28/09/2022	Directorate-General for Justice and Consumers	JUST
2022	IA11 4	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL for a Single Market Emergency Instrument REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 as regards emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency and DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2013/29/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU as regard emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency	SWD(202)289	19/09/2022	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW
2022	IA11 5	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council establishing a common framework for media services in the internal	SWD(202)286	16/09/2022	Directorate-General for Communications	CNCT

		market (European Media Freedom Act) and amending Directive 2010/13/EU			Networks, Content and Technology	
2022	IA116	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on horizontal cybersecurity requirements for products with digital elements and amending Regulation (EU) 2019/1020	SWD(2022)282	15/09/2022	Directorate-General for Communications Networks, Content and Technology	CNCT
2022	IA117	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC	SWD(2022)190	14/07/2022	Directorate-General for Health and Food Safety	SANTE
2022	IA118	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on the sustainable use of plant protection products and amending Regulation (EU) 2021/2115	SWD(2022)170	22/06/2022	Directorate-General for Health and Food Safety	SANTE
2022	IA119	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the proposal for a Regulation of the European Parliament and of the Council on nature restoration	SWD(2022)167	22/06/2022	Directorate-General for Environment	ENV
2022	IA120	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council on asset recovery and confiscation	SWD(2022)245	25/05/2022	Directorate-General for Migration and Home Affairs	HOME
2022	IA121	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a COUNCIL DIRECTIVE on laying down rules on a debt-equity bias reduction allowance and on limiting the deductibility of interest for corporate income tax purposes	SWD(2022)145	11/05/2022	Directorate-General for Taxation and Customs Union	TAXUD

2022	IA12 2	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2011/83/EU concerning financial services contracts concluded at a distance and repealing Directive 2002/65/EC	SWD(2022)141	11/05 /2022	Directorate-General for Justice and Consumers	JUST
2022	IA12 3	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down rules to prevent and combat child sexual abuse	SWD(2022)209	11/05 /2022	Directorate-General for Migration and Home Affairs	HOME
2022	IA12 4	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space	SWD(2022)131	03/05 /2022	Directorate-General for Health and Food Safety	SANTE
2022	IA12 5	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 767/2008, (EC) No 810/2009, and (EU) No 2017/2226 of the European Parliament and of the Council, Council Regulations (EC) No 1683/95, (EC) No 333/2002, (EC) No 693/2003 and (EC) No 694/2003 and Convention implementing the Schengen Agreement, as regards the digitalisation of the visa procedure	SWD(2022)658	27/04 /2022	Directorate-General for Migration and Home Affairs	HOME
2022	IA12 6	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council concerning the status of third-country nationals who are long-term residents (recast)	SWD(2022)651	27/04 /2022	Directorate-General for Migration and Home Affairs	HOME

2022	IA127	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council on a single application procedure for a single permit for third-country nationals to reside and work in the territory of a Member State and on a common set of rights for third-country workers legally residing in a Member State (recast)	SWD(2022)656	27/04/2022	Directorate-General for Migration and Home Affairs	HOME
2022	IA128	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT on geographical indication protection for craft and industrial products Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on geographical indication protection for craft and industrial products and amending Regulations (EU) 2017/1001 and (EU) 2019/1753 of the European Parliament and of the Council and Council Decision (EU) 2019/1754	SWD(2022)115	13/04/2022	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW
2022	IA129	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on substances that deplete the ozone layer and repealing Regulation (EC) No 1005/2009	SWD(2022)99	05/04/2022	Directorate-General for Climate Action	CLIMA
2022	IA130	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014	SWD(2022)96	05/04/2022	Directorate-General for Climate Action	CLIMA
2022	IA131	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) and Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste and	SWD(2022)111	05/04/2022	Directorate-General for Environment	ENV

		Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on reporting of environmental data from industrial installations and establishing an Industrial Emissions Portal				
2022	IA13 2	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on European Union geographical indications for wine, spirit drinks and agricultural products, and quality schemes for agricultural products, amending Regulations (EU) No 1308/2013, (EU) 2017/1001 and (EU) 2019/787 and repealing Regulation (EU) No 1151/2012	SWD(2022)135	31/03/2022	Directorate-General for Agriculture and Rural Development	AGRI
2022	IA13 3	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directives 2005/29/EC and 2011/83/EU as regards empowering consumers for the green transition through better protection against unfair practices and better information	SWD(2022)85	30/03/2022	Directorate-General for Justice and Consumers	JUST
2022	IA13 4	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC	SWD(2022)82	30/03/2022	Directorate-General for Environment	ENV
2022	IA13 5	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT [ ] Accompanying the document Proposal for a Regulation of the European Parliament and of the Council laying down harmonised conditions for the marketing of construction products, , amending Regulation (EU) 2019/1020 and repealing Regulation (EU) 305/2011	SWD(2022)88	30/03/2022	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW
2022	IA13 6	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE	SWD(2022)75	16/03/2022	Directorate-General for Financial Stability,	FISMA

		COUNCIL amending Regulation (EU) No 909/2014 as regards settlement discipline, cross-border provision of services, supervisory cooperation, provision of banking-type ancillary services and requirements for third-country central securities depositories			Financial Services and Capital Markets Union	
2022	IA137	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on combating violence against women and domestic violence	SWD(2022)62	08/03/2022	Directorate-General for Justice and Consumers	JUST
2022	IA138	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act)	SWD(2022)34	23/02/2022	Directorate-General for Communications Networks, Content and Technology	CNCT
2022	IA139	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on Corporate Sustainability Due Diligence and amending Directive (EU) 2019/1937	SWD(2022)42	23/02/2022	Directorate-General for Justice and Consumers	JUST
2022	IA140	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing the Union Secure Connectivity Programme for the period 2022-2027	SWD(2022)30	15/02/2022	Directorate-General for Defence Industry and Space	DEFIS
2022	IA141	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document COMMUNICATION FROM THE COMMISSION Guidelines on State aid for climate, environmental protection and energy 2022	SWD(2022)19	27/01/2022	Directorate-General for Competition	COMP
2022	IA142	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a	SWD(2022)8	12/01/2022	Directorate-General for	HOME

		Regulation of the European Parliament and of the Council on the European Union Drugs Agency			Migration and Home Affairs	
2021	IA143	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a COUNCIL DIRECTIVE laying down rules to prevent the misuse of shell entities for tax purposes and amending Directive 2011/16/EU	SWD(2021)578	22/12/2021	Directorate-General for Taxation and Customs Union	TAXUD
2021	IA144	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the Proposal for a Regulation of the European Parliament and of the Council on methane emissions reduction in the energy sector and amending Regulation (EU) 2019/942	SWD(2021)459	15/12/2021	Directorate-General for Energy	ENER
2021	IA145	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the Proposal for a Directive of the European Parliament and of the Council on common rules for the internal markets in renewable and natural gases and in hydrogen (recast) Proposal for a Regulation of the European Parliament and of the Council on the internal markets for renewable and natural gases and for hydrogen (recast)	SWD(2021)455	15/12/2021	Directorate-General for Energy	ENER
2021	IA146	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the Proposal for a Directive of the European Parliament and of the Council on the energy performance of buildings (recast)	SWD(2021)453	15/12/2021	Directorate-General for Energy	ENER
2021	IA147	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of the environment through criminal law and replacing Directive 2008/99/EC	SWD(2021)465	15/12/2021	Directorate-General for Justice and Consumers	JUST
2021	IA148	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE	SWD(2021)472	14/12/2021	Directorate-General for	MOVE

		COUNCIL on Union guidelines for the development of the trans-European transport network, amending Regulation (EU) 2021/1153 and Regulation (EU) No 913/2010 and repealing Regulation (EU) 1315/2013			Mobility and Transport	
2021	IA149	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive 2010/40/EU of the European Parliament and of the Council of 7 July 2010 on the framework for the deployment of Intelligent Transport Systems in the field of road transport and for interfaces with other modes of transport	SWD(2021)474	14/12/2021	Directorate-General for Mobility and Transport	MOVE
2021	IA150	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2016/399 on a Union Code on the rules governing the movement of persons across borders	SWD(2021)462	14/12/2021	Directorate-General for Migration and Home Affairs	HOME
2021	IA151	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Council Recommendation on individual learning accounts	SWD(2021)369	10/12/2021	Directorate-General for Employment, Social Affairs and Inclusion	EMPL
2021	IA152	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council to improve the working conditions in platform work in the European Union	SWD(2021)396	09/12/2021	Directorate-General for Employment, Social Affairs and Inclusion	EMPL
2021	IA153	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on information exchange between law enforcement authorities of	SWD(2021)374	08/12/2021	Directorate-General for Migration and Home Affairs	HOME

		Member States, repealing Council Framework Decision 2006/960/JHA				
2021	IA15 4	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on the protection of the Union and its Member States from economic coercion by third countries	SWD(2021)371	08/12/2021	Directorate-General for Trade	TRADE
2021	IA15 5	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on automated data exchange for police cooperation ("Prüm II"), amending Council Decisions 2008/615/JHA and 2008/616/JHA and Regulations (EU) 2018/1726, 2019/817 and 2019/818 of the European Parliament and of the Council	SWD(2021)378	08/12/2021	Directorate-General for Migration and Home Affairs	HOME
2021	IA15 6	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the digitalisation of judicial cooperation and access to justice in cross-border civil, commercial and criminal matters, and amending certain acts in the field of judicial cooperation and Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on amending Council Directive 2003/8/EC, Council Framework Decisions 2002/465/JHA, 2002/584/JHA, 2003/577/JHA, 2005/214/JHA, 2006/783/JHA, 2008/909/JHA, 2008/947/JHA, 2009/829/JHA and 2009/948/JHA, and Directive 2014/41/EU of the European Parliament and of the Council, as regards digitalisation of judicial cooperation	SWD(2021)392	01/12/2021	Directorate-General for Justice and Consumers	JUST
2021	IA15 7	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a Regulation of the European Parliament and of the Council establishing a European single access point providing centralised	SWD(2021)344	25/11/2021	Directorate-General for Financial Stability, Financial Services	FISMA

		access to publicly available information of relevance to financial services, capital markets and sustainability			and Capital Markets Union	
2021	IA158	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the Proposal for a Directive of the European Parliament and of the Council amending Directives 2011/61/EU and 2009/65/EC as regards delegation arrangements, liquidity risk management, supervisory reporting, provision of depositary and custody services and loan origination by alternative investment funds	SWD(2021)340	25/11/2021	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA
2021	IA159	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2015/760 as regards the scope of eligible assets and investments, the portfolio composition and diversification requirements, the borrowing of cash and other fund rules and as regards requirements pertaining to the authorisation, investment policies and operating conditions of European long-term investment funds	SWD(2021)342	25/11/2021	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA
2021	IA160	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the transparency and targeting of political advertising	SWD(2021)355	25/11/2021	Directorate-General for Justice and Consumers	JUST
2021	IA161	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 600/2014 as regards enhancing market data transparency, removing obstacles to the emergence of a consolidated tape, optimising the trading obligations and prohibiting receiving payments for forwarding client orders Proposal for a Directive of the European Parliament and of the Council amending Directive 2014/65/EU on markets in financial instruments	SWD(2021)346	25/11/2021	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA

2021	IA16 2	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a COUNCIL DIRECTIVE laying down detailed arrangements for the exercise of the right to vote and to stand as a candidate in municipal elections by Union citizens residing in a Member State of which they are not nationals (recast) Proposal for a COUNCIL DIRECTIVE laying down detailed arrangements for the exercise of the right to vote and stand as a candidate in elections to the European Parliament for Union citizens residing in a Member State of which they are not nationals (recast)	SWD(2021)357	25/11/2021	Directorate-General for Justice and Consumers	JUST
2021	IA16 3	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on the statute and funding of European political parties and European political foundations (recast)	SWD(2021)359	25/11/2021	Secretariat-General	SG
2021	IA16 4	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a regulation of the European Parliament and of the Council on shipments of waste and amending Regulations (EU) No 1257/2013 and (EU) No 2020/1056	SWD(2021)331	17/11/2021	Directorate-General for Environment	ENV
2021	IA16 5	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Commission Delegated Regulation supplementing Directive 2014/53/EU of the European Parliament and of the Council with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of that Directive	SWD(2021)302	29/10/2021	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW
2021	IA16 6	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Annexes IV and V to Regulation (EU) 2019/1021 of the	SWD(2021)300	28/10/2021	Directorate-General for Environment	ENV

		European Parliament and of the Council on persistent organic pollutants				
2021	IA167	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) No 575/2013 on prudential requirements for credit institutions as regards requirements for credit risk, credit valuation adjustment risk, operational risk, market risk and the output floor Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2013/36/EU as regards supervisory powers, sanctions, third-country branches, and environmental, social and governance risks, and amending Directive 2014/59/EU	SWD(2021)320	27/10/2021	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA
2021	IA168	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment	SWD(2021)245	23/09/2021	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs	GROW
2021	IA169	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on applying a generalised scheme of tariff preferences and repealing Regulation (EU) No 978/2012 of the European Parliament and of the Council	SWD(2021)266	22/09/2021	Directorate-General for Trade	TRADE
2021	IA170	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a Directive of the European Parliament and of the Council amending Directive 2009/138/EC as regards proportionality, quality of supervision, reporting, long-term guarantee measures, macro-prudential tools, sustainability risks, group and cross-border supervision and Proposal for a Directive of the European Parliament	SWD(2021)260	22/09/2021	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA

		and of the Council establishing a framework for the recovery and resolution of insurance and reinsurance undertakings and amending Directives 2002/47/EC, 2004/25/EC, 2009/138/EC, (EU) 2017/1132 and Regulations (EU) No 1094/2010 and (EU) No 648/2012				
2021	IA17 1	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the Anti-money laundering package: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the mechanisms to be put in place by the Member States for the prevention of the use of the financial system for the purposes of money laundering or terrorist financing and repealing Directive (EU)2015/849 Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing the European Authority for Countering Money Laundering and Financing of Terrorism, amending Regulations (EU) No 1093/2010, (EU) 1094/2010 and (EU) 1095/2010 Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on information accompanying transfers of funds and certain crypto-assets	SWD(2021)190	20/07/2021	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA
2021	IA17 2	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Council Decision on the accession by the European Union to the Convention on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters	SWD(2021)192	16/07/2021	Directorate-General for Justice and Consumers	JUST
2021	IA17 3	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a regulation of the European Parliament and of the Council establishing a carbon border adjustment mechanism	SWD(2021)643	14/07/2021	Directorate-General for Taxation and Customs Union	TAXUD

2021	IA17 4	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2003/87/EC establishing a system for greenhouse gas emission allowance trading within the Union, Decision (EU) 2015/1814 concerning the establishment and operation of a market stability reserve for the Union greenhouse gas emission trading scheme and Regulation (EU) 2015/757	SWD(2021)601	14/07/2021	Directorate-General for Climate Action	CLIMA
2021	IA17 5	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Part 1 Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2019/631 as regards strengthening the CO2 emission performance standards for new passenger cars and new light commercial vehicles in line with the Union's increased climate ambition	SWD(2021)613	14/07/2021	Directorate-General for Climate Action	CLIMA
2021	IA17 6	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the Proposal for a Regulation of the European Parliament and of the Council on the deployment of alternative fuels infrastructure, and repealing Directive 2014/94/EU of the European Parliament and of the Council	SWD(2021)631	14/07/2021	Directorate-General for Mobility and Transport	MOVE
2021	IA17 7	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the Proposal for a Directive of the European Parliament and the Council amending Directive (EU) 2018/2001 of the European Parliament and of the Council, Regulation (EU) 2018/1999 of the European Parliament and of the Council and Directive 98/70/EC of the European Parliament and of the Council as regards the promotion of energy from renewable sources, and repealing Council Directive (EU) 2015/652	SWD(2021)621	14/07/2021	Directorate-General for Energy	ENER
2021	IA17 8	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the Proposal for a	SWD(2021)623	14/07/2021	Directorate-General for Energy	ENER

		Directive of the European Parliament and of the Council on energy efficiency (recast)				
2021	IA179	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2018/842 on binding annual greenhouse gas emission reductions by Member States from 2021 to 2030 contributing to climate action to meet commitments under the Paris Agreement	SWD(2021)611	14/07/2021	Directorate-General for Climate Action	CLIMA
2021	IA180	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and the Council amending Regulations (EU) 2018/841 as regards the scope, simplifying the compliance rules, setting out the targets of the Member States for 2030 and committing to the collective achievement of climate neutrality by 2035 in the land use, forestry and agriculture sector, and (EU) 2018/1999 as regards improvement in monitoring, reporting, tracking of progress and review	SWD(2021)609	14/07/2021	Directorate-General for Climate Action	CLIMA
2021	IA181	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the Proposal for a Regulation of the European Parliament and of the Council on the use of renewable and low-carbon fuels in maritime transport	SWD(2021)635	14/07/2021	Directorate-General for Mobility and Transport	MOVE
2021	IA182	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the Proposal for a Regulation of the European Parliament and of the Council on ensuring a level playing field for sustainable air transport	SWD(2021)633	14/07/2021	Directorate-General for Mobility and Transport	MOVE
2021	IA183	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Council Directive restructuring the Union framework for the taxation of energy products and electricity (recast)	SWD(2021)641	14/07/2021	Directorate-General for Taxation and Customs Union	TAXUD

2021	IA18 4	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2003/87/EC as regards aviation's contribution to the Union's economy-wide emission reduction target and appropriately implementing a global market-based measure	SWD(2021)603	14/07/2021	Directorate-General for Climate Action	CLIMA
2021	IA18 5	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European green bonds	SWD(2021)181	06/07/2021	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA
2021	IA18 6	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council, and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council	SWD(2021)168	30/06/2021	Directorate-General for Justice and Consumers	JUST
2021	IA18 7	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on consumer credits	SWD(2021)170	30/06/2021	Directorate-General for Justice and Consumers	JUST
2021	IA18 8	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Commission Delegated Regulation (EU) .../... supplementing Regulation (EU) 2020/852 of the European Parliament and of the Council by establishing the technical screening criteria for determining the conditions under which an economic activity qualifies as contributing substantially to climate change mitigation or climate change adaptation and for determining whether that	SWD(2021)152	04/06/2021	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA

		economic activity causes no significant harm to any of the other environmental objectives.				
2021	IA189	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) n° 910/2014 as regards establishing a framework for a European Digital Identity	SWD(2021)124	03/06/2021	Directorate-General for Communications Networks, Content and Technology	CNCT
2021	IA190	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a Council Regulation on the establishment and operation of an evaluation and monitoring mechanism to verify the application of the Schengen acquis and repealing Regulation (EU) No 1053/2013	SWD(2021)119	02/06/2021	Directorate-General for Migration and Home Affairs	HOME
2021	IA191	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the Proposal for a Regulation of the European Parliament and of the Council on foreign subsidies distorting the internal market	SWD(2021)99	05/05/2021	Directorate-General for Competition	COMP
2021	IA192	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the Proposal for a Regulation of the European Parliament and of the Council LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS	SWD(2021)84	22/04/2021	Directorate-General for Communications Networks, Content and Technology	CNCT
2021	IA193	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive 2013/34/EU, Directive 2004/109/EC, Directive 2006/43/EC and Regulation (EU) No 537/2014, as regards corporate sustainability reporting	SWD(2021)150	22/04/2021	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA

2021	IA19 4	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL to strengthen the application of the principle of equal pay for equal work or work of equal value between men and women through pay transparency and enforcement mechanisms	SWD(2021)41	04/03 /2021	Directorate-General for Justice and Consumers	JUST
2021	IA19 5	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the Proposal for a Regulation of the European Parliament and of the Council on roaming on public mobile telecommunications networks within the Union (recast)	SWD(2021)28	25/02 /2021	Directorate-General for Communications Networks, Content and Technology	CNCT
2021	IA19 6	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Forging a climate-resilient Europe - The new EU Strategy on Adaptation to Climate Change	SWD(2021)25	25/02 /2021	Directorate-General for Climate Action	CLIMA
2021	IA19 7	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe EU-Africa Global Health Partnership	SWD(2021)37	23/02 /2021	Directorate-General for Research and Innovation	RTD
2021	IA19 8	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the participation of the Union in the European Partnership on Metrology jointly undertaken by several Member States	SWD(2021)35	23/02 /2021	Directorate-General for Research and Innovation	RTD

2021	IA199	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Council Regulation on jurisdiction, applicable law, recognition of decisions and acceptance of authentic instruments in matters of parenthood and on the creation of a European Certificate of Parenthood	SWD(2016)207	11/02/2021	Directorate-General for Justice and Consumers	JUST
2021	IA200	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on guidelines for trans-European energy infrastructure and repealing Regulation (EU) No 347/2013	SWD(2016)346	22/01/2021	Directorate-General for Energy	ENER
2020	IA201	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on measures for a high common level of cybersecurity across the Union, repealing Directive (EU) 2016/1148	SWD(2020)345	16/12/2020	Directorate-General for Communications Networks, Content and Technology	CNCT
2020	IA202	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on a Single Market For Digital Services (Digital Services Act) and amending Directive 2000/31/EC	SWD(2020)348	16/12/2020	Directorate-General for Communications Networks, Content and Technology	CNCT
2020	IA203	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document [Mandatory element] Digital Markets Act	SWD(2020)363	16/12/2020	Directorate-General for Communications Networks, Content and Technology	CNCT
2020	IA204	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a Directive of the European Parliament and of the Council on the resilience of critical entities	SWD(2020)358	16/12/2020	Directorate-General for Migration and Home Affairs	HOME

2020	IA20 5	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Regulation of the European Parliament and of the Council on batteries and waste batteries, amending Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC	SWD(2020)335	10/12/2020	Directorate-General for Environment	ENV
2020	IA20 6	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2016/794, as regards Europol's cooperation with private parties, the processing of personal data by Europol in support of criminal investigations, and Europol's role on research and innovation	SWD(2020)543	10/12/2020	Directorate-General for Migration and Home Affairs	HOME
2020	IA20 7	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on a computerised system for communication in cross-border civil and criminal proceedings (e-CODEX system), and amending Regulation (EU) 2018/1726	SWD(2020)541	03/12/2020	Directorate-General for Justice and Consumers	JUST
2020	IA20 8	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act)	SWD(2020)295	25/11/2020	Directorate-General for Communications Networks, Content and Technology	CNCT
2020	IA20 9	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council establishing the European Union Single Window Environment for Customs and amending Regulation (EU) No 952/2013	SWD(2020)238	29/10/2020	Directorate-General for Taxation and Customs Union	TAXUD

2020	IA210	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Commission Proposal on adequate minimum wages in the EU	SWD(2020)245	29/10/2020	Directorate-General for Employment, Social Affairs and Inclusion	EMPL
2020	IA211	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on digital operational resilience for the financial sector and amending Regulations (EC) No 1060/2009, (EU) No 648/2012, (EU) No 600/2014 and (EU) No 909/2014	SWD(2020)198	24/09/2020	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA
2020	IA212	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council on exemptions under Directive 2014/65/EU, on digital operational resilience for the Union financial sector and amending Directives EU/2013/36, Directive 2014/65/EU, Directive (EU) 2015/2366, Directive 2009/138/EC, Directive EU/2016/2341, Directive 2009/65/EC, Directive 2011/61/EC and Directive 2006/43/EC	SWD(2020)203	24/09/2020	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA
2020	IA213	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on DLT market infrastructures	SWD(2020)201	24/09/2020	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA
2020	IA214	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on Markets in Crypto-assets and amending Directive (EU) 2019/1937	SWD(2020)380	24/09/2020	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA

2020	IA21 5	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.	SWD(2020)183	22/09/2020	Directorate-General for Employment, Social Affairs and Inclusion	EMPL
2020	IA21 6	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document COMMUNICATION FROM THE COMMISSION on Guidelines on certain State aid measures in the context of the system for greenhouse gas emission allowance trading post 2021	SWD(2020)190	21/09/2020	Directorate-General for Competition	COMP
2020	IA21 7	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT 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 Stepping up Europe's 2030 climate ambition Investing in a climate-neutral future for the benefit of our people	SWD(2020)176	17/09/2020	Directorate-General for Climate Action	CLIMA
2020	IA21 8	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2016/1011 as regards the exemption of certain third country foreign exchange benchmarks and the designation of replacement benchmarks for certain benchmarks in cessation	SWD(2020)142	27/07/2020	Directorate-General for Financial Stability, Financial Services and Capital Markets Union	FISMA
2020	IA21 9	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Tax fraud and evasion – better cooperation between national tax authorities on exchanging information Accompanying the document Proposal for a Council Directive amending Directive 2011/16/EU on administrative cooperation in the field of taxation	SWD(2020)131	16/07/2020	Directorate-General for Taxation and Customs Union	TAXUD

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This study assesses the implementation of the EU's innovation principle — anchored in Tool #22 of the Better Regulation Toolbox — across 219 ex ante impact assessments (IAs) and nine case studies from 2020 to 2025. The overall finding is that innovation is frequently acknowledged as a policy objective but rarely subjected to rigorous analysis: only 18% of impact assessments explicitly assessed R&I impacts, down from 35% in 2017–2018. Regulatory sandboxes have become the most visible innovation-friendly instrument, while foresight and horizon scanning remain largely contextual rather than analytical. The competitiveness check and SME test have partially substituted for a dedicated innovation test, but without equivalent depth on innovation dynamics. The report concludes that Tool #22 is unevenly and informally applied, and recommends stronger guidance, mandatory innovation checks in high-impact IAs, and better integration with foresight methodologies.

### *Studies and reports*

