European Commission

FINAL REPORT

Innovative Practices in Legislation around Emerging Tech

EUROPEAN COMMISSION

European Innovation Council and SMEs Executive Agency (EISMEA)
Unit EISMEA.I.01.1 - EU Innovation Ecosystems (EIE)

E-mail: EISMEA-EU-ECOSYSTEMS@ec.europa.eu

European Commission
B-1049 Brussels

This report is written by:

4Front: Vesa Salminen, Fabian Landes, Kimmo Halme, Heidi Uitto, Jaime del Valle-Ortiz

EFIS Centre: Lyudmyla Tautiyeva, Alessandro Muscio, Alasdair Reid

Visionary Analytics: Jonas Antanavičius, Rebecca Davies, Clara Doyle, Ignas Bernotas

LEGAL NOTICE

PDF	ISBN 978-92-9412-040-3	Doi :10.2826/7136426	EA-01-25-014-EN-N

Luxembourg: Publications Office of the European Union, 2025

Table of Contents

Executive Summary

Background, objectives and implementation

The rapid pace of technological development poses challenges for regulators as the existing regulatory and legal frameworks may not be compatible with emerging technologies and innovations. The regulators are met with a dual challenge, as they need to avoid hampering the development and market uptake of new innovations and, at the same time, ensure that these innovations do not pose any unnecessary risks for safety, security or the environment, for example. For firms and innovators the challenge is two-fold: fitting the new solutions with the existing (and new) regulation and legislation takes time and needs significant investments, while lack of or unclear regulation may cause uncertainty.

Regulatory experimentation and other innovation-friendly regulation approaches are seen as potential solutions for helping both regulators and innovators to navigate these challenges. However, despite several recent initiatives to support regulatory learning and experimentation spaces such as regulatory sandboxes, testbeds and living labs, more information is needed on the role of regulatory experimentation in supporting the development and market uptake of emerging technologies.

The objective of the study is to provide evidence on how the EU regulatory environment affects innovation and the uptake of emerging technologies, particularly in the areas outlined on the Strategic Technologies in Europe Platform (STEP) Platform. The specific objectives include:

- Identifying regulatory bottlenecks for market uptake of emerging technologies;
- Identifying un- or underregulated areas that create excess uncertainty or regulatory risk for innovators, particularly EIC beneficiaries;
- Identify which emerging technologies supported by the EIC would most benefit from flexible regulation, and in which phase or aspect of R&I;
- Catalogue what flexible regulatory instruments and experimentation spaces (e.g., regulatory sandboxes, testbeds or living labs) are being used by European innovators and regulators in the emerging areas supported by the EIC and collate the evidence of their efficacy where available.

The study was conducted between January 2024 – November 2024. The primary tasks and data sources included:

- Literature review, covering both academic research articles as well as policy reports, to analyse previous findings regarding regulatory bottlenecks, unregulated areas as well as regulatory experimentation spaces.
- Quantitative analysis of EIC project data to identify and classify EIC projects according to their main technology fields.
- Survey of EIC beneficiaries to gather insights from EIC funded projects on how EU and/or national legislation/regulation is hampering the market uptake of emerging technologies, and to identify unregulated areas. In total, 260 valid responses were collected to the survey.
- Mapping of regulatory experimentation spaces to facilitate the selection of regulatory case studies and provide an overview of existing innovative regulatory practices in the EU. The mapping was performed based on desk research and available online documents and information.
- Two types of case studies: Technology-specific case studies (8 cases) focused on selected EIC projects around different emerging technologies, while the

experimentation-specific case studies (4 cases) focused on a specific regulatory experimentation space (regulatory sandbox, living lab or testbed). Each case study consisted of desk research focusing on the specific case as well as interviews with key informants.

- Stakeholder interviews (13) to provide insights about regulatory barriers for hampering innovation and the market uptake of emerging technologies as well as areas that still remain unregulated.
- Benchmarking of regulatory approaches to emerging technologies across the US, UK and EU and analysis of practices in regulatory experimentation across the three jurisdictions.
- Policy roundtable with selected experts and stakeholders to discuss draft final report

Conclusions

Regulation is an important bottleneck for the development and uptake of emerging technologies

The study findings show that regulation presents significant bottlenecks for EIC beneficiaries. Innovators working with emerging technologies often face complex and burdensome regulatory requirements that can be particularly challenging for small and medium-sized enterprises (SMEs) and startups operating with limited resources or in fast-evolving sectors. These bottlenecks can increase the time and cost required to bring new innovations to market, hindering the development of high-risk, high-reward technologies. Compliance demands can discourage investment and slow down the pace of innovation – or encourage companies to move to countries with more flexible regulatory environment. Examples of these impacts were reported by EIC beneficiaries both through the survey and in the case studies.

Moreover, the findings show that especially EU level regulation is presenting challenges for the EIC beneficiaries. Indeed, according to a survey for EIC beneficiaries, 44 % of respondents reported EU legislation/regulation as hampering market uptake of emerging technologies. Especially EIC beneficiaries working with biotechnologies (67 % of respondents) and deep and digital technologies (52 %) consider EU legislation / regulation as a bottleneck. In comparison, on average only 20 % considered the same for national regulation/legislation. This is likely to be explained by the fact that the EIC beneficiaries are typically working in international projects and aiming for international markets and are therefore more concerned with EU level regulations.

However, it should also be emphasised that many emerging technologies come with significant – often also unknown – risks (to consumer safety, data privacy, environment, etc), and therefore regulation is often in place for a good reason. Thus, when discussing regulatory barriers for emerging technologies, careful consideration should be applied to differentiate between regulations that are essential – despite the resulting regulatory burden – to safeguard against potential negative impacts, and regulations that are outdated and/or poorly adapted to the latest technological developments. Making this distinction would require an extensive case-by-case analysis beyond the scope of this study.

However, findings from survey and cases studies indicate that for the EIC beneficiaries, the regulatory bottlenecks are related to both certain specific regulations and provisions (particularly Medical Device Regulation (MDR), In Vitro Diagnostic Medical Devices regulation (IVDR), AI Act, Machinery Directive, CE Marking Directive were identified by the EIC beneficiaries), as well as to more general regulatory challenges such as:

- Overall compliance burden resulting from the amount of (new) regulatory demands and complexity. This can be especially difficult for startups and SMEs with limited resources.

- Fragmented regulation/implementation across EU member states making it difficult for companies to achieve broader adoption of their innovations.
- Implementation of the regulation (e.g. differing interpretations, short transition periods, etc.).
- Competitive disadvantage of new technologies compared to incumbent technologies / lack of market incentives for new solutions, including public sector procurement practices.
- Uncertainty of future regulations resulting in anxiety and delayed investment decisions.
- Lack of (EU level) regulation (see below).

Lack of regulation creating legal uncertainty

As highlighted above, the study findings support the conclusions that the *lack of regulation* can also create significant legal uncertainty for innovators, who are left without clear guidelines on compliance, safety, and market entry requirements. Findings suggest that the absence of established regulations can lead to delays in product development and market entry, as companies may need to navigate ambiguous legal landscapes or face the risk of future regulatory changes that could impact their business models. This gap between technological advancement and regulatory oversight can create an environment of uncertainty, where innovators are unsure about the long-term regulatory landscape, potentially deterring investment and slowing down innovation. The absence of regulation in certain emerging technology sectors (such as digital- or biotechnologies) can lead to consumer and market hesitancy. Without regulatory guidance, there may be concerns about the safety, efficacy, or ethical implications of new technologies, which can impact public trust and market adoption. This regulatory uncertainty can slow down the uptake of new technologies, as both consumers and businesses may be reluctant to engage with products or services that lack clear regulatory backing.

In fact, as indicated by the study findings, many EIC beneficiaries operate in areas where no specific regulatory frameworks exist at either the EU or national levels. When asked about the challenges created by legal uncertainty, 40 % of respondents agreed or completely agreed that legal uncertainty in relation to emerging technologies (due to the lack of legislation and/or regulation at the EU or national level) creates challenges to develop or market products or services related to emerging technologies. Examples of the impacts resulting from the lack of regulation were identified also in most of the case studies (see for example case studies on Kraftblock, Clean HME, IQM, E.T. PACK-F or CATCHER).

Experimentation spaces provide opportunities for regulatory learning but should be seen as part of broader policy mix

Regulation has a pivotal role in supporting the development and market uptake of emerging technologies. In some cases it can create bottlenecks for innovators, while in some cases it can act as a driver by creating direction and demand for new innovations. In both cases, it is essential to aim for flexible and anticipatory development of regulatory frameworks. Regulatory experimentation spaces such as regulatory sandboxes, testbeds and living labs can be useful tools for this purpose. Each of these examples have their specific characteristics as well as pros and cons for both innovations and regulators:

Regulatory sandboxes (as commonly defined) can provide a controlled environment where high-risk, high-reward innovations can be tested, refined, and brought closer to market. Sandboxes allow innovators to test products and services under regulatory supervision without being subject to the full scope of regulations. Sandboxes are likely to be most beneficial for technologies with higher technology readiness levels (TRLs) as they are already closer to market and hence more likely to face regulatory demands, which can

be addressed in the sandbox. Regulators can use sandboxes to assess the impact of potential regulatory changes or adaptations before implementing them across the board, which helps in fine-tuning regulations based on empirical evidence. Therefore, regulatory sandboxes could be especially useful for emerging technologies with ongoing or planned regulatory reforms. While regulatory learning is typically an integral part of regulatory sandboxes, it should be noted that concept of regulatory sandboxes is used very broadly which can cause some confusion (see the following conclusion). Also, there is currently very little evidence of the impact of sandboxes on future development of regulations, especially on EU level.

Testbeds can provide a platform for early-stage technologies to demonstrate their potential in a real-world setting, and help securing further investment or regulatory approval. Testbeds are most valuable in sectors requiring rigorous technical validation, such as telecommunications (e.g., 5G networks), smart cities, and IoT. They provide a controlled environment to assess the performance, safety, and interoperability of technologies. In areas where industry standards are critical, testbeds are useful for developing, testing, and validating standards, ensuring that new technologies are compatible with existing systems. However, testbeds are less useful in sectors, where technical validation is not required and/or feasible. For regulators, testbeds could offer an opportunity to anticipate technology trends and get information for technical regulations and standards. However, as indicated by the previous literature and study findings, it seems that the role of regulators is typically very limited and there is a need to further develop regulatory learning mechanisms in testbed contexts.

Living labs offer an environment where technologies can be tested with actual users under controlled but realistic conditions. This can be especially beneficial for technologies that require user interaction and collection of feedback and data, which can be used to validate or refine the technology and ensure it meets market needs – such as smart city solutions, autonomous vehicles, and urban development. Living labs, especially if combined with public procurement, can also be particularly useful for innovators developing solutions for the public sector. For regulators, living labs could provide opportunities to anticipate and understand the socio-technical aspects and impacts of emerging technologies. Yet, similarly to testbeds, while public authorities (especially cities and regional authorities) are often key stakeholders in living labs, it seems that regulatory learning is not systematically integrated with living labs.

While the different experimentation spaces can be useful tools for enhancing the development and market uptake of emerging technologies, it should be highlighted that they are only one part of the toolbox, and should always be combined with a broader policy mix. There needs to be a clear pathway from these experimental environments to full-scale deployment. This includes support for scaling, such as access to funding, mentorship, and regulatory guidance. In addition to these tools, a broader innovation ecosystem that includes policy support, investment in research and development, and strong intellectual property protection is crucial. Experimentation spaces could be used as hubs or platforms to facilitate this broader systemic change. However, regulators should be aware of not using regulatory experimentation in cases, where the regulatory needs and options are already well-known, and there is actually no need for regulatory learning trough experimentation.

Especially for technologies that require significant capital investment or infrastructure, such as large-scale industrial innovations, the resources available for experimentations might be insufficient. Also, innovators working with emerging technologies often operate across multiple regulatory domains, such as digital health tools (which combine medical, data privacy, and AI regulations), and face complex and overlapping regulatory requirements. Addressing these systemic challenges through experimentation spaces can be tricky.

Furthermore, based on the findings of the study, only few EIC beneficiaries have utilised the different experimentation spaces. Interviews with EIC programme managers also

revealed a low awareness of regulatory experimentation spaces. This suggests that there is a lack of knowledge and awareness of these spaces, and/or the experimentation spaces available are not fully relevant to or do not meet the needs of the EIC beneficiaries.

European landscape of experimentation spaces is very heterogeneous – more evidence of impacts is needed

The mapping of regulatory experimentation spaces revealed a diverse landscape of regulatory experimentation spaces. Living labs are the most prevalent, reflecting their well-established role in Europe. They typically focus on real-world, market-ready technologies across various sectors, including digital and clean technologies (e.g. smart city solutions). Regulatory sandboxes, although fewer in number, demonstrate considerable variety, particularly in the deep and digital technologies space.

While the diversity of the landscape can be considered as an advantage, the lack of shared definitions and criteria, especially in regulatory sandboxes, can also be a disadvantage, leading to inconsistency in how these initiatives are applied and understood. This can create confusion for stakeholders and hinder broader adoption or scalability. For example, it should be noted that many regulatory sandboxes identified as part of this study do not include any regulatory derogations, but rather operate as 'advisory hubs' or 'help-desks' supporting companies' compliance with existing regulations, as well as providing a platform for dialogue between innovators and regulators. This does not mean that the initiatives are not useful or relevant – on the contrary, in many cases setting up these types of initiatives can actually be more feasible given the complexity in designing regulatory sandboxes with exemptions and experimentation clauses.

Overall, there is very limited evidence base on the impact of regulatory experimentation on innovation. This could be explained by the short life span as well as the relative novelty of these approaches. In addition, national schemes of regulatory experimentation are quite varied, making it difficult to draw general conclusions on their effectiveness. There is, therefore, a need for a more consistent and robust approach to evaluation and data collection to ensure the effectiveness of these tools in fostering innovation.

Policy Recommendations

Develop and adopt a broad range anticipatory regulation approaches

While experimentation spaces are useful tools for advancing the market uptake of emerging technologies, they should be part of a broader policy mix that ensures clear pathways to full-scale deployment through funding, mentorship, and regulatory support.

EISMEA and the European Commission should therefore seek to continue the efforts to develop and disseminate a broad range of innovative and anticipatory practices and approaches, including but not limiting to regulatory experimentation spaces.

In practice this would mean to:

1. Proactively **anticipate future regulatory needs and assess regulatory challenges** to keep pace with technological advancements. This could include targeted in-depth technology-specific regulatory reviews (such as the recent European Commission study on virtual worlds), for example as part or in parallel to the EIC Tech reports.
2. Establish **sector-specific guidelines** especially in areas where formal regulations have not yet been developed, to provide interim clarity and reduce uncertainty for innovators. These can serve as a foundation for future regulatory frameworks. Regulatory experimentation can be designed to provide further insights and lessons for developing these frameworks.

3. Foster and support the **dialogues between regulators across different sectors and DGs, industry stakeholders, and innovators** to ensure that regulations remain relevant and are informed by the latest technological developments and market needs. This could be facilitated through experimentation spaces but also with less institutionalised approaches such as the Innovation Deals, workshops, advisory panels, and collaborative research initiatives.
4. Ensure and strengthen the **capacities and knowledge of regulators regarding emerging technologies and innovative legislation practices**, for example through dedicated trainings and networks, and continuing the implementation of the Better Regulation Toolbox. This should also include the ethical, environmental, and societal impacts of emerging technologies.

It should be noted that these recommendations are in line with the recent and ongoing actions by the European Commission and EISMEA (such as the Innovation Deals, development of innovative-friendly regulation guidelines, etc.).

Support the development of regulatory experimentation landscape

As part of the broader policy mix, EISMEA and the European Commission should seek to strengthen the efforts to support the development of regulatory experimentation landscape across EU and Member States.

In practice this would mean to:

5. **Raise awareness** of regulatory experimentation spaces particularly among EIC beneficiaries and EIC programme managers, to increase the uptake of and participation in regulatory experimentation spaces. This could include for example the development of sector-specific guidedance documents and fact sheets ("to which door to knock"), in collaboration with relevant innovation intermediaries for each sector.
6. **Establish frameworks for cross-border regulatory sandboxes** that allow companies to test solutions under consistent regulatory conditions in multiple EU countries, especially for technologies with international applicability (e.g. AI and IoT).
7. **Set up an EU-level platform / network for collecting and sharing guidelines and best practices** for defining, designing, implementing and evaluating regulatory experimentation spaces. These guidelines could cover aspects such as eligibility criteria, data-sharing protocols, ethics, and consumer protection standards, as well criteria for monitoring and evaluation the effectiveness of different approaches to ensure the quality and comparability.
8. Develop and disseminate practices to **integrate regulatory learning more systematically to living labs and testbeds.** Consider integrating policy-testing into regulatory experimenation tools to accelerate regulatory learning and enable regulatory change necessary to accompany the deployment of new technologies.
9. Integrating experimentation spaces with other innovation support programmes (such as EIC funding programmes), as well as with programmes supporting innovative public procurement practices (e.g. Cities Mission) to engage EIC beneficiriares with potential public sector reference clients.
10. Organising **workshops and forums** that bring together regulators, innovators, and stakeholders to discuss outcomes and best practices.

1. Introduction

1.1. Background and objectives

Towards innovative practices in legislation around emerging technologies

The rapid pace of technological development poses challenges for regulators as the existing regulatory and legal frameworks may not be compatible with emerging technologies and innovations. The regulators are met with a dual challenge, as they need to avoid hampering the development and market uptake of new innovations and, at the same time, ensure that these innovations do not pose any unnecessary risks for safety, security or the environment, for example. For firms and innovators the challenge is also two-fold: fitting the new solutions with the existing (and new) regulation and legislation takes time and needs significant investments, while the lack of regulation may cause uncertainty. Regulatory experimentation and other innovation-friendly regulation approaches are seen as potential solutions for helping both regulators and innovators to navigate these challenges.[1]

The impact of regulation on innovation and the development of innovation friendly regulation has been an important topic in European policy debates in recent years. While the Green Paper on Innovation[2] identified regulation as a core issue for innovation policy as early as 1996, innovation friendly regulation came the forefront of discussion in the 2010s. In 2016 the European Commission (EC) launched a first Staff Working Document (SWD) on the Innovation Principle and subsequently introduced the innovation principle to the Better Regulation Guidelines in 2021. The innovation principle promotes the consideration of innovation and technological advancements when formulating regulations and policies. This principle emphasises a balanced approach that fosters innovation while still achieving regulatory objectives, promoting economic growth and competitiveness within the EU.[3] The Better Regulation Guidelines and the associated Better Regulation Toolbox includes tools for adaptive regulation instruments, such as experimentation clauses and regulatory sandboxes.[4] In 2020, the Council called on the EC to delineate the legal framework for sandboxes and gather evidence on the efficacy of the tools.[5] Similarly the OECD Council has recommended ”agile regulatory governance to harness innovation.[6]

The New European Innovation Agenda (NEIA), adopted in 2022, outlines five flagships, which include ‘Enabling innovation through experimentation spaces and public procurement’ (No. 2) and ‘Improving policy making tools’, which build on previous initiatives, such as the Innovation Principle and Better Regulation Guidelines, to enable policy makers across Europe to address structural and regulatory issues related to innovation.

In 2023 a Commission SWD on regulatory learning was published, providing guidance to innovators and regulators on regulatory sandboxes, testbeds, and living labs (LLs).[7] More

---

[1] See for example : Kert, K., Vebrova, M. & Schade, S. (2022) Regulatory learning in experimentation spaces. Joint Research Centre, European Commission; European Commission (2023) Regulatory learning in the EU. Guidance on regulatory sandboxes, testbeds, and living labs in the EU, with a focus section on energy. Commission Staff Working Document, SWD(2023) 277/2.

[2] European Commission (1996) Green Paper on innovation. Document drawn up on the basis of COM(95) 688 final, Bulletin of the European Union Supplement 5/95, 1996.

[3] European Commission (2021). Commission Staff Working Document on Better Regulation Guidelines.

[4] European Commission (2021).

[5] General Secretariat of the Council (2020). Council Conclusions on Regulatory sandboxes and experimentation clauses as tools for an innovation-friendly, future-proof and resilient regulatory framework that masters disruptive challenges in the digital age, 12683/1/20 REV 1

[6] OECD (2021). Recommendation of the Council for Agile Regulatory Governance to Harness Innovation, OECD/LEGAL/0464

[7] European Commission (2023)

recently, the Artificial Intelligence (AI) Act, passed by the European Parliament in March 2024, urges Member States to create at least one AI regulatory sandbox and plans to set up shared standards for consistent application of the sandboxes across the EU with suitable governance and supervision structures.[8] Yet, as concluded in the SWD, available evidence on the effectiveness of the proposed regulation tools for spurring innovation is relatively sparse and mixed.[9] Hence, more information is needed to understand the role of regulatory experimentation in supporting the development and market uptake of emerging technologies.

Key objectives of the study

The objective of the study is to provide evidence on how the EU regulatory environment affects innovation and the uptake of emerging technologies, particularly in the areas outlined on the Strategic Technologies in Europe Platform (STEP) Platform. The study's scope covers the EU and Horizon Europe associated countries (HEAC) but policy insights are also gleaned from several 'competitors countries'.

The specific objectives include:

- Identifying regulatory bottlenecks for market uptake of emerging technologies;
- Identifying un- or underregulated areas that create excess uncertainty or regulatory risk for innovators, particularly EIC beneficiaries;
- Identify which emerging technologies supported by the EIC would most benefit from flexible regulation, and in which phase or aspect of R&I;
- Catalogue what flexible regulatory instruments and experimentation spaces (e.g. regulatory sandboxes, testbeds or LLs) are being used by European innovators and regulators in the emerging areas supported by the EIC and collate the evidence of their efficacy where available.

The findings for the detailed study questions are presented in the conclusion section 0.

Box 1: The EIC instruments covered by this study

One of the study objectives is to identify which emerging technologies *supported by the EIC* would most benefit from flexible regulation. As set out in the terms of references, projects supported by the EIC Pathfinder are the focus of this study. However, links to other instruments (the EIC Accelerator and the EIC Transition) are explored in the analysis to the extent possible given data availability. The following section sets out a very brief introduction of the key EIC instruments that are the focus of this study.

The EIC Pathfinder provides funding for advanced research to develop scientific basis to underpin breakthrough technologies. EIC Pathfinder projects are built on new, cutting-edge directions in science and technology to disrupt markets or to create new opportunities by realising innovative technological solutions grounded in high-risk/high-gain research and development. There are two EIC Pathfinder instruments:

- 'EIC Pathfinder Open', supports projects in any field of science, technology or application without predefined thematic priorities. The aim of the funding is to realise

[8] Official Journal of the European Union (2024) Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act).

[9] European Commission (2023).

an ambitious vision for radically new technology, with potential to create new markets and/or to address global challenges;

- 'EIC Pathfinder Challenges' supports coherent portfolios of projects within predefined thematic areas with the aim to achieve specific objectives for each Challenge. The 'Challenges' identified will target specific technologies and innovations of strategic interest for the Union.

The **EIC Accelerator** supports companies (principally SMEs, startups, spin-offs and in exceptional cases small mid-caps) to scale up high impact innovations with the potential to create new markets or disrupt existing ones. The EIC Accelerator provides a unique combination of funding and Business Acceleration Services. The EIC Accelerator focuses on innovations building on scientific discovery or technological breakthroughs ('deep tech') where significant funding is needed over a long timeframe before returns can be generated ('patient capital'). Similarly, to EIC Pathfinder, there are two instruments under EIC Accelerator:

- EIC Accelerator Open, which has no predefined thematic priorities and is open to proposals in any field of technology or application;
- EIC Accelerator Challenge in predefined areas of emerging and strategic technologies.

Subsequently, the **EIC Transition** funding is available for innovation activities that supports both the maturation and validation of novel technology from the lab to the relevant application environments (by making use of prototyping, formulation, models, user testing or other validation tests) as well as explorations and development of a sustainable business case and business model towards commercialisation into high potential markets.

1.2. Key concepts and definitions

Emerging technologies

There is no clear or broadly agreed definition on emerging technologies. The World Economic Forum (WEF) conceptualises emerging technologies based on novelty (in incipient development, not widely used), applicability (elements of generic technology, wide applicability in industry and society), depth (likely to have wide impact in next 3-5 years), power (disruptive impact in established industries and society).[10] Others, such as Gartner, rank emerging technologies according to mass i.e. composite of market momentum, investment and expected impact, and range i.e. expected time to market launch.[11] Rotolo et al. draw together a wealth of academic discussion on the different aspects of defining emerging technologies and arrive to a definition according to which an emerging technology needs to satisfy five requirements: (i) radical novelty (new to the inventor and the market/society) (ii) relatively fast growth, (iii) coherence (persistent traceable trail from R&D towards markets), (iv) prominent impact, and (v) uncertainty and ambiguity.[12]

Depending on the source, the range of examples goes from generically naming areas such as AI, clean technologies, nanotechnologies and biotechnologies to more specific technologies or applications such as bio-based platform chemicals, digital twins, edge AI, etc. In the EIC report on Emerging Technologies and Breakthrough Innovations, those emerging technologies are highlighted that are important due to "their ground-breaking

[10] WEF (2023) Top 10 Emerging Technologies for 2023: Flagship Report.

[11] Gartner (2023) The Gartner 2023 Emerging Technologies and Trends Impact Radar.

[12] Rotolo, D., Hicks, D., Martin, B.R. What is an emerging technology?, Research Policy, Vol. 44, Is. 10, pp. 1827-1843.

nature due to their high societal and market impact". EIC funding can be directed to research, development or innovation up to piloting and demonstration (equivalent to technology readiness levels (TRLs) between 1-7 depending on the instrument).[13]

In 2023, the European Commission published a proposal for the STEP Platform to address the challenges faced by the EU industry. The objective of STEP is three-fold: 1) Providing flexibility in existing instruments for critical technology development, 2) reinforcing the strength of existing instruments for critical technology advancement, and 3) creating synergies among existing instruments to accelerate the adoption of critical technologies and enhance Europe's competitiveness in these areas. The regulation adds funding particularly to the EIC, Innovation Fund, and European Defence Fund (EDF).[14]

As set out in the Terms of Reference, in the context of this study, the term *emerging technologies* refer to EIC-supported technologies, particularly in the areas highlighted in the proposal for the STEP regulation. The main technology areas and their respective technologies are defined in the table below.

Table 1. Definition of technology areas in line with the STEP regulation

Technology area	Technologies
Deep and digital technologies	Microelectronics, high-performance computing, quantum computing, cloud computing, edge computing, artificial intelligence, cybersecurity, robotics, 5G and advanced connectivity, and virtual realities.
Clean technologies	Renewable energy; electricity and heat storage; heat pumps; electricity grid; renewable fuels of non-biological origin; sustainable alternative fuels; electrolysers and fuel cells; carbon capture, utilisation and storage; energy efficiency; hydrogen; smart energy solutions; technologies vital to sustainability, such as water purification and desalination; advanced materials, such as nanomaterials, composites of future clean construction materials; technologies for the sustainable extraction and processing of critical raw materials.
Biotechnologies	Biomolecules and its applications, pharmaceuticals, medical technologies and crop biotechnology, and biomanufacturing.

Experimentation spaces and regulatory learning

The focus of the study is on the three often used experimentation spaces, namely regulatory sandboxes, testbeds and LLs. In line with Kert et al (2022), these are all tools, which "enable experimentation with innovative solutions in a (near) real-world environment, typically involving multiple stakeholders, including users". Experimentation spaces can be used to facilitate regulatory learning across the different stakeholders, and help "striking a balance between supporting the development of innovations and mitigating any related risks on the market, the public, and the environment".[15] Besides the common characteristic of regulatory learning, there are many differences between these three different approaches, described in more detail below.

[13] EIC (2022). Identification of Emerging Technologies and Breakthrough Innovations, EIC Working Paper 1/2022.

[14] Official Journal of the European Union (2024b) Regulation of the Parliament and the Council, establishing the Strategic Technologies for Europe Platform ('STEP') and amending Directive 2003/87/EC, Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241, COM(2023) 335 final.

[15] Kert et al. (2022).

Regulatory learning, meanwhile, is used here in line with Kert et al to refer to "the collection and use of any evidence or knowledge that is relevant to current or future regulatory policy". Regulatory learning can be either top-down (initiated by a regulatory authority) or bottom-up (emerging from innovation activity).[16] Regulatory learning and experiments can also be seen as part of a broader discussion regarding innovation friendly regulation as well as anticipatory regulation. While the former is closely linked to the European Commission's work on better regulation, the latter has been used to cover different forward-looking approaches to regulation. These include *advisory regulation* to help new innovations adhere to existing regulations, *adaptive regulation* to adapt existing regulatory framework to support innovations, and *anticipatory regulation* to develop regulation and standards around the emerging field iteratively.[17]

It should be noted that while the focus of the study is on the three above-mentioned instruments (regulatory sandboxes, LLs and testbeds), there are also other approaches regulators can use to support innovators of emerging technologies. These include, for example, advisory services and helpdesks, innovation deals, streamlining of approvals or setting regulatory challenges (e.g. challenge competitions).[18] These approaches are not in the focus of the study, but are considered as part of the broader framework in assessing how different approaches work for certain emerging technologies.

The following figure illustrates the different interfaces between of regulation, innovation and experimentation, and the alignment of the key concepts in this study.

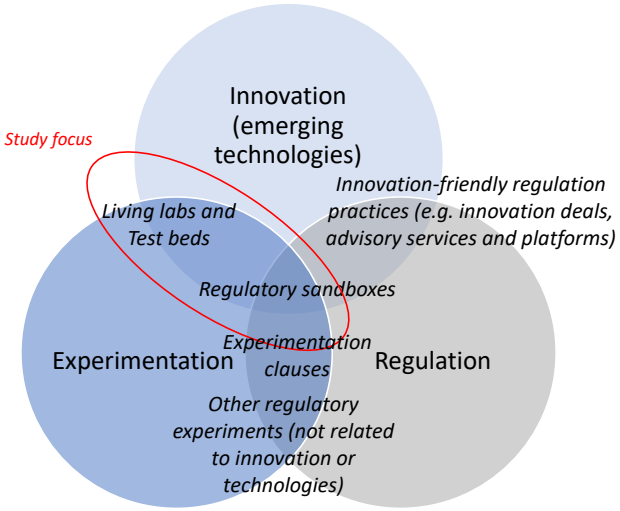

Figure 1. Illustration of key concepts of the study. Adapted from: Salminen et al (2022)[19]

Regulatory sandboxes

Regulatory sandboxes are, in line with Kert et al (2022), controlled environments where startups and businesses can experiment with new products, services, or business models while enjoying access to regulatory expertise and (in some cases) certain regulatory exemptions or relaxed requirements. Their purpose is also to test regulations in market conditions. These sandboxes are typically managed by regulatory authorities and allow innovators to test their ideas in a limited and monitored setting. Regulatory sandboxes aim

[16] Ibid.

[17] Armstrong, H., Gorst, C., Rae, J. (2019) Renewing regulation. 'Anticipatory regulation' in an age of disruption. Nesta.

[18] See e.g. Armstrong, H. et al (2020) Regulator approaches to facilitate, support and enable innovation. Final report. BEIS Research Paper Series Number 2020/003.; European Commission (2023).

[19] Adapted from. Salminen, V. et al (2022) Practices of innovation-friendly regulation in growth sectors (Innovaatiomyönteisen sääntelyn käytännöt kasvualoilla). Ministry of Economic Affairs and Employment of Finland, 2022:1. Full report available only in Finnish.

to strike a balance between encouraging innovation and protecting consumers and the broader market. They are mainly targeted for higher TRL levels (7-9) for limited timeframe. As they are usually operated by regulators themselves (through temporary changes in legal frameworks), the regulatory learning process is rather top down, but may include elements of bottom-up learning. Regulatory sandboxes may provide evidence by testing modifications of regulation, interpretation and application of regulations and assessing market and consumer risks.[20] In some cases, the authorities can also provide sandbox participants guidance for example on how the legal framework and requirements should be applied. Regulatory sandboxes can be set up either *bottom-up*, initiated by identified regulatory barriers by innovators, or *top-down*, when the regulator identifies legislative provisions for testing and calls for applications by interested organisations. In some cases, sandboxes can be used to test innovations in unregulated areas.[21]

Council Conclusions on Regulatory sandboxes and experimentation clauses perceives regulatory sandboxes as *"concrete frameworks which, by providing a structured context for experimentation, enable where appropriate in a real-world environment the testing of innovative technologies, products, services or approaches – at the moment especially in the context of digitalisation – for a limited time and in a limited part of a sector or area under regulatory supervision ensuring that appropriate safeguards are in place."*[22] While regulatory sandboxes are increasingly used across a variety of sectors[23], they have been most used in the fintech[24] and energy[25] sectors.

The concept of regulatory sandboxes is closely related to regulatory pilot projects. These are typically policy-driven projects, where the regulator defines a specific area of experimentation. These projects can have certain common elements with regulatory sandboxes, but typically lack the general legislative framework for regulatory sandboxes. Pilot regulation, on the other hand, can be understood as a temporary regulatory framework but without some of the elements of regulatory sandboxes such as the selection procedure. Both regulatory pilot projects and pilot regulation are tools that have been mainly used in the energy sector (e.g. ARERA in Italy).[26]

Derogations and experimentation clauses

One key question regarding regulatory sandboxes is, whether a derogation from existing legislation is needed. According to the Staff Working Document (2023), a derogation is not a necessary element of regulatory sandboxes, but the involvement of competent authorities is needed in order to "*make a link with existing or future legislation and thus to follow up (if appropriate) the regulatory learning generated by the sandbox*". In some cases, however, a derogation from existing legislation may be needed (or preferred). In these situations, a specific experimentation clause is typically required to enable the authorities to exercise the necessary degree of regulatory flexibility.[27]

According to the definition adopted in the Research and Innovation tool (22), "*an experimentation clause enables the authorities (…) to exercise a degree of flexibility in*

[20] Kert et al (2022)

[21] European Commission (2023).

[22] Council of the European Union (2020) Council Conclusions on Regulatory sandboxes and experimentation clauses as tools for an innovation-friendly, future-proof and resilient regulatory framework that masters disruptive challenges in the digital age.

[23] Attrey, A., Lesher, M. and Lomax, C., 'The role of sandboxes in promoting flexibility and innovation in the digital age', Going Digital Toolkit Policy Note 2, 2020.

[24] See e.g. ESMA (2018) FinTech: Regulatory sandboxes and innovation hubs.

[25] See e.g. European Commission (2023).

[26] European Commission (2023).

[27] European Commission (2023).

relation to innovation technologies, products, or approaches, even if they do not conform to all existing legal requirements".[28] The Council Conclusions on Regulatory sandboxes and experimentation clauses defines experimentation clauses as "*legal provisions which enable the authorities tasked with implementing and enforcing the legislation to exercise on a case-by-case basis a degree of flexibility in relation to testing innovative technologies, products, services or approaches."* The Conclusions also emphasise that *"experimentation clauses are often the legal basis for regulatory sandboxes and are already used in EU legislation and in many Member States' legal frameworks*".[29]

Testbeds

Testbeds are experiments that can be used "to develop, test and upscale a product or service in a dedicated environment". The focus of the experiment is mostly technical, and concerns technology requirements and performance (including user needs and consumer protection features). In many cases, the testbeds also provide an access to a dedicated research and technology infrastructures, as well as other forms of support and advise.[30] In practice, testbeds provide physical or digital environments for testing and experimenting with emerging technologies, such as IoT (Internet of Things), smart cities, or healthcare solutions. They are hence more targeted to lower TRL levels than regulatory sandboxes (4 and above). They often involve collaboration between public and private sectors, research institutions, and local communities. Testbeds include end-users as test users. The regulators' role in a testbed may be for instance to provide regulatory flexibility through experimentations clauses or special permits. The regulatory learning comes through both top down and bottom-up mechanisms, and they can be used to test technology requirements, technical regulations and standards and well as to assess user needs and protection. [31]

Living labs

LLs are, according to Kert et al (2022), open innovation ecosystems that involve end-users and stakeholders in the innovation process. They offer a real-life context for testing, co-creating, prototyping and upscaling new products and services. LLs can be urban districts, regions, or communities where innovations are tested and refined in collaboration with the people who will eventually use them. As a difference to sandboxes and testbeds, LLs are less controlled in their nature and not limited in their timeframe. Instead, LLs create a real-life testing environment for technologies, which can provide valuable feedback and inputs from end-users, which is important especially for the uptake of technologies. They are suitable for all TRL levels. LLs often utilise the quadrable helix model, which entails multistakeholder collaboration, ie., university-industry-government-public-environment interactions. The ownership of a LL may be by any of the stakeholders. Regulators are rarely systematically involved in living lab activities but may have a role as a stakeholder. The LLs owned by government stakeholder may however entail stronger role with regulators. In general, experiences of all types of LL may provide useful evidence for policy learning for instance via end-user feedback, which can be used to anticipate needs for regulation. [32] LLs may have different approaches to emerging technologies. They are rarely designed for a specific technology, but rather to solve broader complex challenges. As such, emerging technologies often have a role in a LL.

---

[28] European Commission: Better Regulation Toolbox, Tool 22. Research and Innovation.

[29] Council of the European Union (2020).

[30] European Commission (2023).

[31] Ibid.

[32] Ibid.

According to the definition of the European Network of Living Labs (ENoLL), "*Living Labs (LLs) are open innovation ecosystems in real-life environments using iterative feedback processes throughout a lifecycle approach of an innovation to create sustainable impact. They focus on co-creation, rapid prototyping & testing and scaling-up innovations & businesses, providing (different types of) joint-value to the involved stakeholders. In this context, living labs operate as intermediaries/orchestrators among citizens, research organisations, companies and government agencies/levels*." While there some common characteristics between LLs, they have also many different forms and a wide variety of implementations.[33]

The different characteristics regarding the role of regulators and mechanisms for regulatory learning are summarised in the following table (based on Kert et al 2022).

Table 2. Summary of key characteristics for regulatory sandboxes, living labs and testbeds.

Adapted from Kert et al (2022).

Key Characteristics	Regulatory sandboxes	Living labs	Testbeds
Primary focus	Regulation	Socio-technical	Technology
Context / environment	Controlled, typically regional / local	Uncontrolled; physical or virtual	Controlled; physical or virtual
Timeframe	Strictly limited	Varied	Limited
TRL	7-9	1-9	4 and above
Access rules	Competitive, based on eligibility criteria	Project dependent	Competitive
Role of regulators	Leading and systematic role in providing regulatory flexibility/ exemptions, setting up and supervising the experiments.	Ad hoc roles as project stakeholders (rarely systematically involved)	Varied roles in the governance and regulatory support.
Primary value proposition for participants	Enhanced legal certainty and access to regulatory and compliance support (potential increase in investor/customer confidence).	Access to collective knowledge and users/public feedback as part of R&I process; co-creation and prototyping.	Access to research or technology infrastructure for development and testing.
Primary mechanism and benefits for regulatory learning	Testing the (techno-legal) modification, interpretation and/or application of a regulation; assessing potential risks for consumers and markets.	Exploring (socio-technical) requirements and effects of innovation on users/society; assessing uptake of new solutions; anticipating future regulatory needs.	Testing and guiding technology (e.g. technical regulations and standards); assess user needs and consumer protection.

[33] ENoLL (n/a) What are Living Labs. https://enoll.org/about-us/what-are-living-labs/

1.3. Implementation of the study

The study, conducted between January 2024 – November 2024, consisted of five main tasks: 1) Desk research, 2) Data collection, 3) Data analysis, 4) Policy recommendations, and 5) Conclusions. Figure 2 provides an overview of the study process and tasks, described in more detail below.

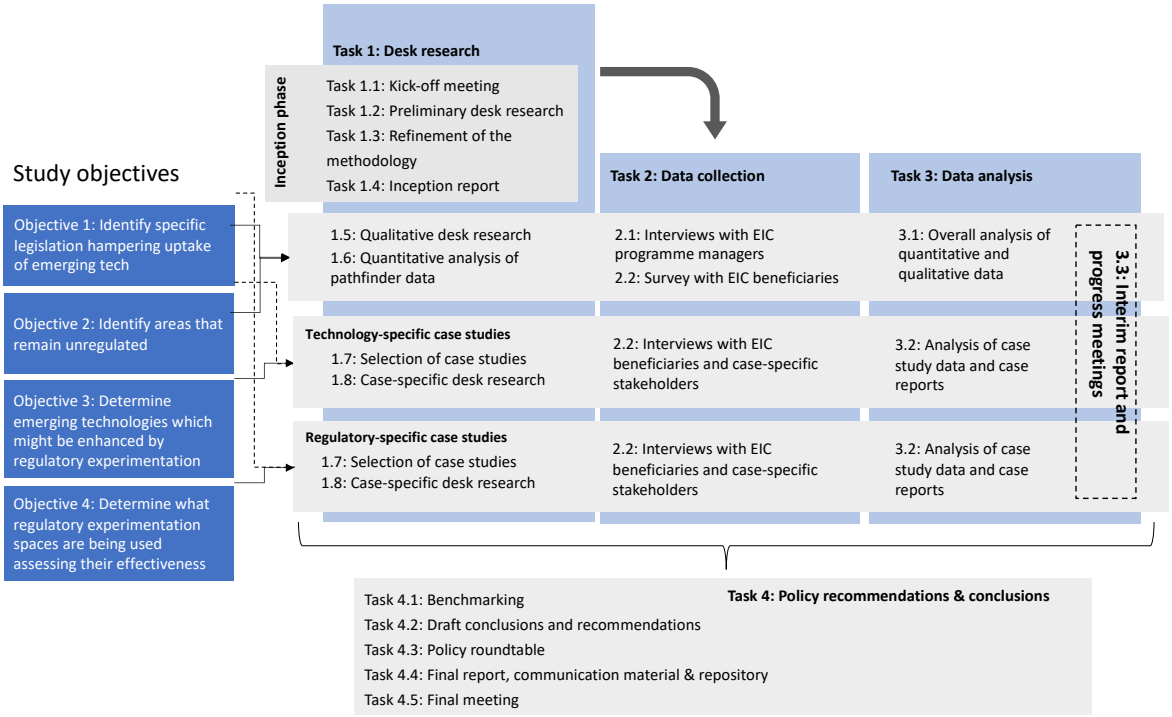

Figure 2. Overview of study process and tasks.

Desk research and literature review

The literature review was based on a search conducted on Scopus (www.scopus.com) based on relevant keywords in the field 'Article Title, Abstract, Keywords' following a multiple iterations approach. We conducted two iterations based on two sets of keywords. The first iteration included the keywords – (*innovation*) *AND* (*regulation OR legislation*). The second iteration included extended keywords related to specific technologies, presented in Table 3. The search was limited to journal articles published in English in the last 10 years (2014-2023) (in accordance with the emergence of the mission topic in the literature). The search was extended to all journal disciplines excluding those less likely to be related to R&I policy. Adopting these criteria, 22 articles on deep technologies, 250 articles on clean technologies (top 5%), and 128 articles on biotechnologies were obtained.

Table 3. Keywords for literature review.

Type	Keywords on Scopus and Overton.io	Records
Core keywords	('innovation') AND ('regulation' OR 'legislation')	9 867
Extended keywords	'deep technologies' OR '…' 'clean technologies' 'biotechnologies' OR 'pharmaceuticals' OR 'medical innovation'	22 records 250 (top 5%) 128 (76 selected)

Policy keywords	better regulation; regulatory experimentation; regulatory sandboxes; testbeds; living labs; EIC (Pathfinder); scale-ups; market uptake	60 records ca. (no specific technology)

A second search for policy reports was conducted on Overton (www.overton.io) based on the same keywords. The search generated 2 199 records followed by the removing of duplicates which resulted in 1 065 articles. After the second search for key technology fields based on the keywords, we selected 147 records in terms of relevance that were further analysed.

A commercial AI tool (www.elicit.com) was then used to support the team in the analysis of the papers and government reports. This taxonomy was primarily used to run semantic searches to extract data from PDFs. These searches included keywords related to specific policy measures. For example, we used it to select those papers that mentioned the words 'sandbox' and determine if there was evidence of any impact. We investigated study methodologies (e.g. econometrics, literature review, etc.), main findings, and looked for indications concerning the study questions and objectives. Finally, we then searched again Scopus and Overton.io to look for papers that mentioned keywords such as "better regulation" "regulatory experimentation", "regulatory sandboxes", "testbeds", "living labs", "EIC (Pathfinder)", "scale-ups", "market uptake", as mentioned in the TOR. In this case, 68 papers on Scopus were found.

The findings of the literature review are presented in report section 2.1.1 and 2.2.1. In respect of ethical standards, no AI tool was used in writing the literature review presented in the following section.

Quantitative analysis of EIC pathfinder data

The main objective of the quantitative analysis of EIC Pathfinder data is to classify the EIC Pathfinder projects according to their main technology fields (see definition of emerging technologies in 1.2). In addition, the analysis includes projects from other programmes (i.e. Accelerator, FTI, and Transition) that were identified as potential follow-up projects to Pathfinder projects based on participating entities, project timelines, and thematic alignment.

The thematic focus of the project and the relevant emerging technologies the project develops/ commercializes has been collected using natural language processing tools. Given the structure of the available data, natural language processing tools were considered as a more superior and accurate method than data mining, as data mining would need some already classified data to use it to classify the missing data. Natural language processing (NLP) tools are computational techniques and algorithms designed to enable computers to capture the structure and patterns of a language and interpret it.

An NLP tool (ChatGPT) was used to classify the EIC projects based on the emerging technology the project develops/ commercialises. The classification was implemented in the following steps: 1) Feeding the ChatGPT algorithm with the emerging technology descriptions from STEP Regulation as well the data on project name and description from the EIC data hub, 2) asking the algorithm to classify projects, based on their descriptions, to emerging technology categories, 3) manually cross-checking a sample of results to ensure that the classification works properly, 4) refining the task for ChatGPT and performing the classification again. The analysis findings are presented in 2.1.2 and more details about the analysis in Appendix 1.

Survey for EIC beneficiaries

The aim of the survey with EIC beneficiaries was to gather insights from coordinators and partners of EIC funded projects on how EU and/or national legislation/regulation is

hampering the market uptake of emerging technologies. Furthermore, this survey aimed to identify unregulated areas that cause challenges in the development or marketing of products or services and to collect data on beneficiaries' experiences with experimentation spaces. The survey was launched on March 13, 2024, via the online survey tool AlchemerTM and remained open for responses until April 10th, 2024. Contact details of EIC beneficiaries were provided by EISMEA and the survey was distributed to a total of 5 083 contacts, following the removal of invalid email addresses. In total, there were 260 valid responses to the survey. A detailed summary of the respondents profiles as well as survey questionnaire is provided in Appendix 2.

Mapping of regulatory experimentation spaces (see Appendix 3)

To facilitate the selection of regulatory case studies and provide an overview of existing innovative regulatory practices in the EU, a mapping of regulatory experiments was conducted as part of the study. The mapping was performed based on desk research and available online documents and information. In the inception phase, based on a preliminary mapping of experiments, the following dimensions/characteristics were defined.

Table 4. Type of information collected for mapping of regulatory experimentation spaces

Basic information	Detailed information (if available)
• Name of the experiment • Short description • Type of experiment (regulatory sandbox, living lab, testbed, other) • Country / geographical scope (EU, national, regional/city level) • Technology sector (deep and digital technologies, clean technologies, biotechnologies, other) • Name and type of responsible organisation	• TRL focus (if available / relevant) • Timeframe / year of establishment (if available / relevant) • Legal / regulatory context (e.g. experimentation clause) • Funding sources (if available / relevant) • Type and number of participants (if available / relevant) • Evidence / examples of efficacy and regulatory learning, e.g. contributions to past/current/future regulations (if available)

The actual mapping was conducted in two steps. In the first step, a long list of initiatives covering the basic information (when available) was developed based on scanning of previous reports, catalogues and targeted web searches. In total of 257 examples were identified across all technology areas and Member States. It should be noted that the mapping is not exhaustive and does not include all potential examples. In the second step, a more detailed analysis of selected 50 experiments was conducted to analyse the detailed information of the experimentation spaces. The analysis was based on a more extensive search and analysis of publicly available information. The findings of the 34mapping are presented in section 2.2.3.

Case studies (see Appendices 4 & 5)

The study included two types of case studies: Technology-specific case studies (8 cases) focus on selected EIC projects around different emerging technologies, while the experimentation-specific case studies (4 cases) focus on a specific experiment (regulatory sandbox, living lab or testbed) supporting regulatory decision-making and learning. Each

case study consisted of desk research focusing on the specific case as well as interviews with key informants (2-5 interviews per case).

The technology-specific cases studies (EIC projects) were selected from the analysed EIC Pathfinder/Accelerator data, taking also into account the feedback from interviews with EIC Programme managers and survey inputs. The final proposal for the selection of cases was discussed and agreed in a progress meeting with study steering group. In selecting the technology-specific case studies (8 cases), the following selection criteria were prioritised:

- Geographic scope of the project
- Technology area (deep & digital technologies, clean technologies, biotechnologies)
- Type of EIC support and technology readiness (Pathfinder, Accelerator)
- Availability of information and evidence regulatory challenges, EIC Programme Manager recommendations

The experimentation-specific cases were selected based on the qualitative desk research and mapping of experiments. In selecting the four experimentation-specific case studies, the following criteria were prioritised:

- Type of experiment (regulatory sandbox, testbed / LL), priotitising experiments with stronger links to regulatory learning
- Geographic scope (EU / national level, different countries represented)
- Technology focus (deep & digital technologies, clean technologies, biotechnologies)
- Availability of information (access tp evaluation and study reports and interviewees)

Stakeholder interviews

In addition to case-specific interviews (see above), 13 interviews with stakeholders were conducted. The interviews included EIC programme managers (9 interviews) and 4 interviews with associations and the Innovation Friendly Regulation Advisory Group (IFRAG) members. The interviews provided insights about regulatory barriers for hampering innovation and the market uptake of emerging technologies as well as areas that still remain unregulated. They were also used to provide examples of innovative legislation potential opportunities related to them.

Benchmarking

The benchmarking provides an overview of regulatory approaches to emerging technologies across the US, UK and EU and analysis of practices in regulatory experimentation across the three jurisdictions. The choice of the US and the UK for benchmarking draws on i) the commonalities in governance structures, i.e. federal/state in the US, central government/devolved nations in the UK and EU/Member states in the EU; ii) evidence from the desk research suggesting companies in emerging tech often choose the US and/or the UK over the EU, iii) the prominence of the three countries in technology development and facing rising competition from China. China was not included in this comparison due to the significant differences in regulatory frameworks and governance system with the ones in the EU, US or the UK (e.g. strong role of the state-owned enterprises and centralised/top-down approach to running regulatory experimentation spaces, more permissive with data access and usage in experimentation spaces).

The analysis contains benchmarking against several criteria such as regulatory approach, government involvement, scale, risk appetite, sector focus, cross-border-collaboration. It is complemented with more nuanced analysis based on the case studies in fintech, cleantech and biotech with insights for the EU.

Policy recommendations and policy roundtable

An online policy roundtable was organised on 18th November 2024 to present and validate the preliminary conclusions and recommendations of the study. The event consisted of presentation of study findings, conclusions and draft recommendations, two case study presentations from EIC participants, Q&A session, and moderated panel discussion. Besides the study team, the participants included representatives from DG RTD, EISMEA, as well as selected stakeholder experts and EIC beneficiaries (in total of 29 experts). Discussion and feedback from the policy roundtable were taken into account in finalising the conclusions and recommendations of the study.

2. Study findings

This chapter presents the findings of the study. The first part discusses the findings regarding regulatory bottlenecks and unregulated areas in emerging tech, while the second section focuses on the findings regarging regulatory experimentation spaces and how they can be used to improve the development and market uptake of emerging technologies.

2.1. Regulatory bottlenecks and unregulated areas in emerging tech

This section covers the key study findings regarding the legislation hampering the market uptake of emerging technologies as well as identified unregulated areas creating legal uncertainty (study questions 1 and 2). Additional details are provided in Appendices. The section first presents results of the literature review, and in section 2.1.2 results from the analysis of EIC project data, the online survey with EIC beneficiaries and the stakeholder interviews. Each section has specific sub-sections on the three main technology areas.

2.1.1. Findings from the literature review

Relationship between competition and regulation

The relationship between competition and regulation is ambiguous, as shown by the academic and policy literature. Thus, a part of the literature states that that more regulation leads to less competition, while a body of literature also agrees that regulation plays crucial role in enabling competition[35]. There is a general agreement that regulation has negative effects on competition when it increases barriers to entry for firms**.** Increased costs to enter the market are associated with higher prices for consumers, lower quality of products and services, and less choice, as firms are not able to invest and innovate and are discouraged from competing[36]. In other words, regulation is a means to **ensure a level playing field in the market** to drive productivity and economic growth. For instance, the EU's SME Strategy and the Small Business Act for Europe aims to ensure that SMEs do not bear the burden of the regulation disproportionately, especially given the fact that they represent 99.8% of all entreprises in business sector (excluding financial sector) and contribute 64.4% of employment and 51.8% of value added in the EU-27[37].

Furthermore, regulation allows to ensure that other policy goals in addition to economic growth are achieved. These goals are mostly concerned with consumer protection, health and safety, environment protection, etc[38].Given the complex relationship between competition and regulation, it is the question of **design and implementation of regulations** that comes to the forefront. For example, in the context of the rapid development of the digital markets, the regulation is regarded as means to address the increasing concentration

[35] UK Competition and Markets Authority. (2020). Regulation and Competition: A Review of the Evidence. Available at : https://assets.publishing.service.gov.uk/media/5e184a9940f0b65dbfbc1c4b/Regulation_and_Competition_report_-_web_version.pdf

[36] Swedish Agency for Economic and Regional Growth. (2017). *Regulation and Competition: A literature review.* Stockholm. Available at : https://tillvaxtverket.se/download/18.6855bfcf184896002ff9fa/1668765678928/Regulation%20and%20Competition.pdf

[37] European Commission. (2023). *SME Perfomance Review 2022/2023.* Luxembourg. Available at : https://single-market-economy.ec.europa.eu/document/download/b7d8f71f-4784-4537-8ecf-7f4b53d5fe24_en?filename=Annual%20Report%20on%20European%20SMEs%202023_FINAL.pdf

[38] UK Competition and Markets Authority. (2020). Regulation and Competition: A Review of the Evidence. Available at : https://assets.publishing.service.gov.uk/media/5e184a9940f0b65dbfbc1c4b/Regulation_and_Competition_report_-_web_version.pdf

in digital markets and the resulting decline in competitive pressures with negative effects for firms' performance and consumer safety and security (e.g. privacy, cybersecurity)[39]. In other words, in sectors like Big-tech, e-commerce, digital platforms, regulation serves to maintain fair competition and ensure consumer protection[40] with discussions around the need to provide for ex-ante measures to address the structural entry barriers and evolving digital market structures[41].

From the business sector perspective, regulation is often perceived as a major barrier for innovation and growth due to **costs and compliance burdens** it entails. For example, the study by the World Economic Forum on delivering on the European Green Deal demonstrated that the reality for the market participants is that the firms usually face legal complexities, red tape and high costs associated with administration and compliance[42]. In addition, the PwC 2022 EU Green Deal Survey of the European companies showed that less than half of the organisations are prepared for the EU Green Deal implementation with lack of awareness and of organisational skills to maximise the benefits of such transition being the largest challenges[43].

Nevertheless, the regulation is also regarded by the business sector as an important tool at governments disposal to **promote market entry and innovation** with positive effects for the long-term competitiveness of firms. For instance, the study of the effects of environmental regulation on competitiveness of European manufacturing sector found evidence of a positive impact of environmental regulation on the output of innovation activity[44]. At the same time, if the regulation is absent or not clear, it has negative effects on firms' performance, such as in the case of climate-related investments by European firms that are hampered by uncertainty about regulation and taxation (i.e. 43% of firms surveyed by the European Investment Bank in 2020 consider this a major obstacle)[45].

Finally, regulation is part of the toolbox governments dispose to promote their countries' international competitiveness with influence on trade and the state's position in the global economy. For instance, different approaches taken by the EU and the UK and US towards AI regulation have a direct impact on AI-technology contribution to economic competitiveness of those jurisdictions, with some concerns as to the EU AI Act having a negative impact on the market uptake of AI-enabled technologies due to the regulations' horizontal, risk-based approach entailing high non-compliance costs (see 2.2.5 on benchmarking). The approach to regulation, its governance framework (e.g., centralised/decentralised structures), risk appetite and flexibility, make a difference for international competition, especially vis-à-vis China, a crucial competitor of the EU, but also the UK and US.

Use of emerging technologies in support of the public sector

---

[39] Nicoletti, G. C. (2023). *Competition, regulation and growth in a digitized world : Dealing with emerging competition issues in digital markets.* Paris: Éditions OCDE. Available at : https://doi.org/10.1787/1b143a37-en.

[40] See https://www.apec.org/docs/default-source/publications/2022/3/competition-law-and-regulation-in-digital-markets/222_cplg_competition-law-and-regulation-in-digital-markets.pdf?sfvrsn=6b8748de_2

[41] Nicoletti, G. C. (2023). *Competition, regulation and growth in a digitized world : Dealing with emerging competition issues in digital markets.* Paris: Éditions OCDE. Available at : https://doi.org/10.1787/1b143a37-en.

[42] World Economic Forum. (2024). *Delivering on the European Green Deal: A Private-Sector Perspective.* Insight Report. Available at : https://www3.weforum.org/docs/WEF_Delivering_on_the_European_Green_Deal_2024.pdf

[43] PwC. (2022). *Are Europe's businesses ready for the EU Grean Deal? EU Green Deal Survey Report.*

[44] Yana Rubashkina, M. G. (2015). Environmental regulation and competitiveness: Empirical evidence on the Porter Hypothesis from European manufacturing sectors. *Energy Policy, 83*. Available at : https://doi.org/10.1016/j.enpol.2015.02.014.

[45] EIB. (2021). *European Firms and Climate Change 2020/2021: Evidence from the EIB Investment Survey.* Récupéré sur https://www.eib.org/attachments/publications/eibis_2020_report_on_climate_change_en.pdf

Public procurement accounts for over 14% of the EU's GDP, representing a significant opportunity to drive innovation and the development and scaling of emerging technologies. However, its potential remains largely underutilised. Ensuring that public sector procurement drives the demand for innovative technologies or services is a powerful tool to support development and scaling of emerging technologies. The case of public sector authorities tendering for a good, service or technology that does not exist yet or procuring an existing best-in-class goods, services, or technologies that are new to the market, is defined as innovation-enhancing public procurement[46]. According to the European Commission, **innovation procurement** involves:

1. Developing new solutions through R&D procurement.
2. Procuring innovations not yet available or existing in the market.
3. Procuring existing but not widely available innovative solutions.

Public buyers can use innovation procurement to:

- Shape and create markets.
- Promote adoption of innovative solutions.
- Improve public service quality.
- Support market access for SMEs.
- Boost smart investments.

For instance, the public sector can play a role of an “early adopter” of the new technologies leading the way for further adoption of the innovations by the market and generating the “multilier effects” for the economy as a whole. Furthermore, in case the public sector procures new technologies that do not exist at the time of a call to solve a specific challenges, it directly invests in R&D through a pre-commercial public procurement mechanism. For example, the Government of Norway developped the first in the EU carbon capture, transport and storage facility through a set of two pre-commercial public procurements that served evidence-gathering and technology testing purposes before the large public investement of 2.1 bn NOK in the CCU facility in 2020[47].

While new innovation procurement and usage of emerging technologies in the public sector present opportunities, they must align with administrative law, ethics, and human rights principles. In adopting emerging technologies, the public sector must ensure clear user benefits, proportionality of risks and benefits, and compliance with legal and ethical standards. The complexity of public sector ecosystems necessitates careful, context-sensitive technological integration.

In July 2024, the Innovation Friendly Regulation Advisory Group (IFRAG) published a report in response to the Commission Communication on a New European Innovation Agenda from 2022[48], in which they analyse the use of emerging technologies in support of the public sector to improve, optimise and innovate its operations and service provision. The report especially focuses on digital technologies and virtual worlds.[49]

---

[46] UNECE (2021) ‘Building Back Better: Innovation-enhancing Procurement for Sustainable Development’. Available at: https://unece.org/sites/default/files/2021-05/ECE_CECI_2021_5_2103936E.pdf.

[47] *Creating the world’s first and largest full-scale carbon capture, transport and storage facility | Shaping Europe’s digital future* (2021). Available at: https://digital-strategy.ec.europa.eu/en/news/creating-worlds-first-and-largest-full-scale-carbon-capture-transport-and-storage-facility .

[48] European Commission (2022) : Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions : a New European Innovation Agenda. COM/2022/332 final

[49] European Commission (2024): Directorate-General for Research and Innovation, *Emerging digital technologies in the public sector – The case of virtual worlds*, Publications Office of the European Union

The authors of the IFRAG report foresee a new wave of virtual world instances aimed at solving sector-specific challenges (e.g. in healthcare, education and other relevant sectors). Urban services (such as the CitiVERSE) and mobility.They argue that these sector-specific applications of virtual worlds are citizen-oriented services where the public sector might play a particularly strong role, for example through the use of innovative public procurement approaches. They highlight that while existing legislation (e.g. the AI Act, the Digital Services Act and the Digital Markets Act) might be sufficient to address issues raised by virtual worlds in the short and medium term, but as the technology matures, virtual world-specific amendments will have to be introduced to cover elements typical of virtual environments in the long term.

Impact of regulation on innovation

Recent European industrial policy has emphasised competition as a major policy instrument, and regulation was established predominantly as the enabler of competition. Starting in the early 2000s regulators followed the ladder-of-investment approach[50], which was based on the principle that regulated competition would lead to innovative investments by competitors of incumbent market players. Since then, several policy shifts have emphasised the role innovation in regulation[51]. Thus, the presumed causality links from regulation to competition and from competition to innovation has been replaced, or at least supplemented, by a direct causal link from regulation to innovation. Regulatory framework conditions have been identified as important factors influencing the innovation activities of companies, industries and whole economies[52]. While governments have often little capacity to increase public spending in R&D to promote innovation in key sectors due to public budgets restrictions, policies to improve the framework conditions relevant for innovation are becoming more important.

The effect of competition on innovation has been one key concern of innovation studies, since Schumpeter[53], further developed by Arrow[54] in his taxonomy of market structures and incentives for innovation activity, and later by Shapiro[55].Taken together with the express policy emphasis on innovation, there seems to be an ambiguous relationship between regulation and innovation. Currently, most economists support the **inverted "U" position on the relationship** between the extent of competition and innovation[56]. Accordingly, some competition is viewed as best for innovation, but even patenting activity, whose impact on innovation has long been debated, can be affected by antitrust regulation[57].

Many recent technologies have shaped new sectors and are viewed as particularly innovative. For example, there has been breath-taking progress in ICT technologies or biotech, and the rate of innovation has accelerated so much to generate a so-called 'patent-explosion'. Many innovations spur innovations throughout the economy, generating well-

---

[50] Vogelsang, Ingo, 2017. "The role of competition and regulation in stimulating innovation – Telecommunications," Telecommunications Policy, Elsevier, vol. 41(9), pages 802-812.

[51] Blind, Knut & Thumm, Nikolaus. (2004). Interrelation between patenting and standardisation strategies: Empirical evidence and policy implications. Research Policy. 33. 1583-1598. 10.1016/j.respol.2004.08.007.

[52] Blind, Knut, (2012), The influence of regulations on innovation: A quantitative assessment for OECD countries, *Research Policy*, 41, issue 2, p. 391-400, https://EconPapers.repec.org/RePEc:eee:respol:v:41:y:2012:i:2:p:391-400.

[53] Schumpeter, J.A. (1942) Capitalism, Socialism and Democracy. Vol. 36, Harper & Row, New York.

[54] Arrow, K.J. (1962) Economics Welfare and the Allocation of Resources for Invention. In: The Rate and Direction on Incentive Activity: Economic and Social Factors, National Bureau of Economic Research, Princeton University Press, Princeton.

[55] Shapiro, (2012). Competition and innovation: Did Arrow Hit the Bull's Eyes? In: The Rate and Direction of inventive Activity Revisited. pp. 361- 404. http://www.nber.org/chapters/c12360 .

[56] Aghion, Philippe et al., Competition and Innovation: An Inverted-U Relationship, *The Quarterly Journal of Economics*, Volume 120, Issue 2, May 2005, Pages 701–728, https://doi.org/10.1093/qje/120.2.701

[57] Kwon, S. and Marco, A.C. (2021), Can antitrust law enforcement spur innovation? Antitrust regulation of patent consolidation and its impact on follow-on innovations, *Research Policy*, 50(9), p. 104295. Available at: https://doi.org/10.1016/j.respol.2021.104295.

documented **spillovers into other sectors**. This justifies the design and implementation of specific innovation-enhancing policies in several fields and sectors. In fact, while the empirical evidence generally shows that more regulation would lead to less innovation in a few sectors such as TLCs[58], some authors find that the incremental effect of regulation on innovation turns positive in already highly regulated countries. Therefore, in the empirical literature, the impacts of regulation have been assessed as rather **ambivalent** for innovation[59]. Different types of regulations generate various impacts and even a single type of regulation can influence innovation in various ways depending on how the regulation is implemented.

Overall, the relationship between legislation and innovation can be considered as **heterogenous** depending on the sectors concerned. A 2016 survey of companies in the EU revealed that regulation was mostly perceived as a **driver for the economy**[6061]. This is particular the case of environmental protection regulation, standardisation, sectoral policies, and it is rather the conflicting requirements of different regulations that presented an obstacle to innovation[62]. In addition, the estimated positive net impact from regulation on investments in innovation corresponds to approximately 1.8% per year, or an additional EUR 3-6 billion of innovation investments annually[63]. However, the product safety regulation, environmental protection regulation, and labelling are perceived as a **barrier** for the manufacturing of food products, chemicals, pharmaceuticals, metals, health, and construction sectors[64].

Finally, the robust **assessment of regulatory impacts on innovation** are lacking as this process is fraught with challenges related to data availability and confidentiality concerns, variety in methods used to assess the impacts, and the difficulty to quantify the effects of innovation ex ante. To address these issues, the options for regulators include adopting a more theory-driven approach to Regulatory Impact Assessment (RIA) on innovation, alignment of methodologies and quantitative data used to carry out the assessment, as well as ensuring exchange on impact assessment for policymaking at the EU and national level. Ensuring that regulation is effectively responding to the fast development of innovative technologies, that are agile and future-proof, the regulatory authorities are increasingly turning to **experimentation tools**, such as sandboxes and testbeds[65].

Overview of regulatory barriers for SMEs in Europe – findings from EU-level surveys

[58] Grajek, M. and Röller, L.-H. (2012), Regulation and investment in network industries: evidence from European telecoms, Journal of Law and Economics, 55(1), pp. 189–216. Available at: https://econpapers.repec.org/article/ucpjlawec/doi_3a10.1086_2f661196.htm.

[59] Blind, Knut, (2012), The influence of regulations on innovation: A quantitative assessment for OECD countries, *Research Policy*, 41, issue 2, p. 391-400, https://EconPapers.repec.org/RePEc:eee:respol:v:41:y:2012:i:2:p:391-400.

[60] Gangale, F., Mengolini, A.M., Covrig, L., Chondrogiannis, S., Shortall, R., 2023. Making energy regulation fit for purpose. State of play of regulatory experimentation in the EU [WWW Document]. JRC Publications Repository. https://doi.org/10.2760/32253 .

[61] Malanowski, N., Steinbach, J., Nisser, A., Beesch, S., Von, P.S., Van, D.V.E., Kretz, D., 2022. Techno-Economic study on the potential of European Industrial Companies regarding Europe's Green Deal [WWW Document]. JRC Publications Repository. https://doi.org/10.2760/037744 .

[62] European Commission. DG RI, Technopolis Group., Fraunhofer ISI., 4Front., 2022. Study on the costs and benefits of innovation-sensitive legislation. Publications Office, LU.

[63] Directorate-General for Research and Innovation (European Commission), Roman, L., Venjakob, M., Adisorn, T., Enzing, C., Ravet, J., Dates, M., Seibt, C., Peter, V., 2017. Assessing the impacts of EU regulatory barriers on innovation: final report. Publications Office of the European Union.

[64] European Commission. DG RI, Technopolis Group., Fraunhofer ISI., 4Front., 2022. Study on the costs and benefits of innovation-sensitive legislation. Publications Office, LU.

[65] Ibid.

The European Investment Bank's (EIB) Investment Survey 2024[66] highlights several regulatory challenges faced by SMEs in the EU:

- A net balance of EU firms express concerns about the political and regulatory climate, with more anticipating deterioration than improvement over the next 12 months.
- Business regulations are identified as a significant obstacle to investment by EU firms, more so than by their US counterparts.
- SMEs are particularly affected by regulatory complexities, which can hinder their investment activities and growth prospects.
- Regulatory barriers vary significantly across EU countries, with firms in Southern and Eastern Europe more likely to report regulations as a major constraint compared to those in Northern and Western Europe.
- EU firms report a higher share of staff employed specifically to meet regulatory requirements compared to US firms, indicating a greater administrative burden in the EU regulatory environment.
- The report suggests that simplifying regulations and enhancing the single market could alleviate these barriers, fostering a more conducive environment for SME investment.

According to the European Central Bank's Survey on the Access to Finance of Enterprises (SAFE) for the third quarter of 2024[67]:

- Firms indicated that regulatory complexities contribute to difficulties in accessing external financing, with SMEs particularly affected due to their limited resources to navigate such challenges.
- The impact of regulatory barriers varies across EU countries, with firms in certain regions reporting more significant challenges in accessing finance due to local regulatory environments.
- Regulatory hurdles are cited as factors contributing to weak investment activity among firms, with expectations of continued low investment.

Regulatory bottlenecks and unregulated areas in deep and digital technologies

Many initiatives can promote innovation activity and the diffusion of innovations in the deep tech sector. For example, in the **IT industry**, the GDPR can promote innovation diffusion by incentivizing dominant firms to keep anti-competitive behaviour in check, shifting control of personal data to consumers, and aligning incentives for better adherence to data protection standards, ultimately fostering consumer trust, competition, and innovation in the digital economy[68]. At the same time, some evidence suggests that stringent data privacy regulations, such as GDPR, have shown negative effect on investment in new and

[66] EIB (2024) EIB Investment Survey 2024 - European Union overview. EIB, 23 Oct 2024. https://www.eib.org/en/publications/20240238-econ-eibis-2024-eu

[67] European Central Bank (2024) Survey on the Access to Finance of Enterprises in the euro area. Third quarter of 2024.

[68] Niebel, C., 2021. The impact of the general data protection regulation on innovation and the global political economy. Computer Law and Security Review 40. https://doi.org/10.1016/j.clsr.2020.105523.

innovative firms with disproportionate effect on smaller companies, leading to decrease in venture capital in these companies and hence the loss of potential new jobs[69].

Legislation and regulation are a decisive factor for the diffusion of technologies, but they can also be a real obstacle, as in the case of **e-mobility** in Germany. In this case, due to the lack of a long-term strategy for the energy transition, the investment risks of the automobile industry have not been reduced and the lack of adequate incentives has, among other things, prevented the implementation of standardized vehicle interfaces and communication infrastructures. The diffusion of e-vehicles has become difficult[70], further increasing people's reluctance to adopt them. In fact, legislation thus becomes an obstacle when excessive fragmentation and low standardisation increase the costs of access to different technologies and different access costs foster socio-economic inequality and the digital divide[71].

In the area of **IoT**, some authors have stressed how regulation is premature. Should legislation intervene, the risk of regulatory errors, would be very high to the point where, especially in the US, a polycentric regulatory system[72] based on self-regulation has been envisaged, but even in this case the result has been an undemocratic legal pluralism and a legal fragmentation that is difficult to manage[73].

Supporting this, other authors have pointed out how legislation and regulation can be an obstacle to the diffusion of **quantum technology**, as they need to be updated to adapt to the needs of a highly uncertain and rapidly changing industry. New policies can facilitate a more favourable environment for innovation and commercialisation of these technologies. This can be done by changing R&D policies by creating a more appropriate environment for them. This implies reconsidering how R&D resources are allocated, with a particular focus on knowledge production strategies in new industrialised countries[74].

In the case of **cybersecurity**, regulation can be an obstacle if it takes a fragmented approach focused only on the security obligations of individual organisations without defining end-to-end security standards that include all actors involved in technical solutions and services. This approach can leave vulnerabilities uncovered at the points of intersection between the various providers and partners. Another possible flawed approach that constitutes a real obstacle is regulatory inflexibility: laws and regulations often fail to keep pace with rapidly evolving technologies and threats to cyber security. Regulations that are

[69] Huddleston, J., 2021. The Price of Privacy: The Impact of Strict Data Regulations on Innovation and More. URL https://www.americanactionforum.org/insight/the-price-of-privacy-the-impact-of-strict-data-regulations-on-innovation-and-more/ .

[70] Wolf, S., Korzynietz, R., 2019. Innovation needs for the integration of electric vehicles into the energy system. World Electric Vehicle Journal 10. https://doi.org/10.3390/wevj10040076.

[71] Tsakalidis, A., Gkoumas, K., Pekár, F., 2020. Digital transformation supporting transport decarbonisation: Technological developments in EU-funded research and innovation. Sustainability (Switzerland) 12. https://doi.org/10.3390/su12093762.

[72] The polycentric regulatory system describes a structure where multiple centres or levels of authority—such as federal, state, and local governments—have the power to create and enforce rules. In the context of the U.S., this means that various jurisdictions and agencies can establish regulations independently or in coordination, leading to a system where rules can overlap or differ significantly depending on the state or locality. "The theory of polycentric regulation is distinct from other regulatory theories. In particular, it contrasts with state-centric approaches to Internet governance and cybersecurity that have been pursued by a number of nations. Indeed, polycentric regulation focuses on multi-stakeholder governance and embraces self-regulation. A system of polycentric (cyber) governance would enable stakeholders most familiar with the issue to devise appropriate rules which could then be codified" (Weber and Studer, 2016: 727-8).

[73] Weber, R.H., Studer, E., 2016. Cybersecurity in the Internet of Things: Legal aspects. Computer Law and Security Review 32, 715–728. https://doi.org/10.1016/j.clsr.2016.07.002.

[74] Kang, I., Choung, J.Y., Kang, D. in, Park, I., 2021. Divergence of knowledge production strategies for emerging technologies between late industrialized countries: Focusing on quantum technology. ETRI Journal 43, 246–259. https://doi.org/10.4218/etrij.2019-0501.

out of date or too specific can limit the adoption of new technologies or more effective security methods[75].

In the case of **UAS** (drones, etc.), the legislative implications of their use on the one hand deal with the safety of their use, but on the other hand with issues such as privacy and the protection of personal data and the environment. Moreover, dealing with safety in flight or on the ground to prevent collisions with other aircraft or with people and strategic structures makes such regulations very complex and often not centred on the specific type of operation[76].

The **Reg Tech** sector, a branch of fintech, represents the set of core technologies for regulatory compliance and risk monitoring. Reg Tech is particularly relevant for financial institutions, which must navigate and comply with a complex framework of regulations and laws governing anti-money laundering and financial transaction monitoring. The diffusion of Reg Tech innovations can attribute an important competitive advantage, that can however be hampered by legislation that imposes exorbitant compliance costs, limiting the ability of companies to invest in R&D[77].Uncertainty about the development of a technology such as **5G** generates direct, indirect, and systemic effects of regulations and policies that generate conflicting positive and negative effects on investment and innovation due to still large information gaps[78]. Moreover, it may be the case that while emerging technologies such as 5G offer revolutionary potential, existing regulations and the limitations of technological standards may represent significant obstacles to their full realisation and deployment, especially when they do not keep pace with technological innovation or are not flexible enough to adapt to new scenarios and requirements[79] .

Finally, the literature on the impact of regulation and legislation on the diffusion of deep tech innovations is largely focusing on **AI**, and it shows more than ever the difficulties of traditional regulations in keeping up with rapidly evolving emerging technologies. It highlights the 'pacing problem', i.e. the tendency for regulations to become obsolete shortly after their introduction, due to slow and rigid legislative and bureaucratic processes and rapid technological progress. For instance, the General Data Protection Regulation (GDPR) introduced in 2018 faced the pacing problem as it was unable to address the rapid development of AI and Big Data, complemented by progress in data transfer models (i.e. distributed data computing), and the development of metaverse. The AI Act and the Data Act were developed to address these gaps but as the technological advancements outpace regulatory response, they too will face the pacing problem, which highlights the need for a more adaptive and flexible regulatory framework. It is suggested that regulators should broaden their approach to include more agile and reflective institutions. Soft law emerges as an effective solution, overcoming the limitations of traditional regulation and better adapting to innovation, involving a variety of stakeholders and being able to have an international reach[80].

In the case of AI technology regulation, the approach taken by the EU through its AI Act is horizontal and risk-based. It is horizontal as it puts similar regulatory standards for AI

---

[75] Wallis, T., Dorey, P., 2023. Implementing Partnerships in Energy Supply Chain Cybersecurity Resilience. Energies (Basel) 16. https://doi.org/10.3390/en16041868 .

[76] Kasprzyk, P., 2022. The Basic Premises of EU Regulations Regarding the Safety of Unmanned Aircraft in the Context of their Development Process. Journal of Intelligent and Robotic Systems: Theory and Applications 106. https://doi.org/10.1007/s10846-022-01733-x .

[77] Grassi, L., Lanfranchi, D., 2022. RegTech in public and private sectors: the nexus between data, technology and regulation. Journal of Industrial and Business Economics 49, 441–479. https://doi.org/10.1007/s40812-022-00226-0 .

[78] Bauer, J.M., Bohlin, E., 2022. Regulation and innovation in 5G markets. Telecomm Policy 46. https://doi.org/10.1016/j.telpol.2021.102260.

[79] Festag, A., 2015. Standards for vehicular communication—from IEEE 802.11p to 5G. Elektrotechnik und Informationstechnik 132, 409–416. https://doi.org/10.1007/s00502-015-0343-0 .

[80] Wallach, W., Marchant, G., 2019. Toward the agile and comprehensive international governance of AI and robotics. Proceedings of the IEEE 107, 505–508. https://doi.org/10.1109/JPROC.2019.2899422.

development, deployment and governance across all sectors[81], and it is risk-based as the law categorises risks associated with the AI applications with higher risks regulated through more stringent requirements[82].The law received criticism because of these exact characteristics and the heavy non-compliance costs it emposes with potential to slow down the development and deployment of the AI technologies in the EU[83], in contrast to the UK and the US, for example. These different approaches draw on regulatory culture differences, as discussed in more detail in 2.2.5. In the UK, the Government has opted for a more flexible, sector and principles-based approach to AI regulation with no specific AI regulation envisaged, while in the US, the Executive Order on AI (30 October 2023) outlines eight broad principles for AI development with the technology regulated largely through specific provisions as part of comprehensive privacy laws (e.g. the California Privacy Rights Act), separate laws (e.g. to enter into force in Colorado, Connecticut and Montana) or through specific company obligations regarding use of AI in certain contexts (such as employment)[84].

Regulatory bottlenecks and unregulated areas in clean technologies

There is general agreement in the literature that legislation, or market regulation in general, does not hamper innovation diffusion. On the contrary, it can drive innovation in clean energy technologies, playing a crucial role in **influencing eco-innovation and driving environmental improvements**. Legislation or regulation can motivate stakeholders' compliance with standards and foster external knowledge flows and cooperation, potentially facilitating the diffusion of innovations[85].

In the literature on European countries, few papers highlight some negative effects of legislation/regulation. From the business perspective, according to some authors[86], the complexity of new legislation or regulation may pose challenges and inhibit certain beneficial choices during business project implementation and addressing intellectual property issues. However, experienced participants may navigate these rules more effectively, potentially increasing the odds of project success. In this respect according to Madaleno et al.[87] policy makers should consider **firm size** as a crucial factor in the relationship between eco-innovations and firm performance. The analysis of eco-innovations adoption by the EU firms showed that such adoption had a negative effect on performance of all firms (i.e. turnover and employment) but with a more prononced negative effect for small firms facing the demand for environmental benefits by the end consumer. The negative effect on performance might be explained by the increased costs associated with eco-innovation actions, hence, calling for additional state support to small firms to offset

[81] Palmer, N., 2024 , New study: UK should avoid EU-style AI regulation, but its current regulatory framework falls short, Available at: https://www.brunel.ac.uk/news-and-events/news/articles/New-study-UK-should-avoid-EU-style-AI-regulation-but-its-current-regulatory-framework-falls-short#:~:text=%E2%80%9CThe%20UK%20is%20set%20to,sectors%2C%E2%80%9D%20explained%20Dr%20Gikay.

[82] *Diverging regulatory approaches for AI* (no date) *KPMG*. Available at: https://kpmg.com/xx/en/our-insights/regulatory-insights/diverging-regulatory-approaches-for-ai.html .

[83] See Benizri, I. *et al.* (2023) 'A comparative perspective on AI regulation', *Default*. Available at: https://www.lawfaremedia.org/article/a-comparative-perspective-on-ai-regulation .

[84] Ibid.

[85] Saunila, M., Ukko, J., Rantala, T., 2018. Sustainability as a driver of green innovation investment and exploitation. J Clean Prod 179, 631–641. https://doi.org/10.1016/j.jclepro.2017.11.211 .

[86] Kostopoulos, K.C., Spanos, Y., Soderquist, K.E., Prastacos, G., Vonortas, N.S., 2019. Market-, Firm-, and Project-Level Effects on the Innovation Impact of Collaborative R&D Projects. Journal of the Knowledge Economy 10, 1384–1403. https://doi.org/10.1007/s13132-015-0342-8.

[87] Madaleno, M., Robaina, M., Ferreira Dias, M., Meireles, M., 2020. Dimension effects in the relationship between eco-innovation and firm performance: A European comparison, in: Energy Reports. Elsevier Ltd, pp. 631–637. https://doi.org/10.1016/j.egyr.2019.09.038 .

the costs of introducing the eco-innovation, and indirectly, to support the complliance with environment-related regulations..

The case of **renewable energy sources** is exemplar. In the case of the UK, certain authors[88] find that legislation or regulation may hamper innovation if government investments in infrastructure are not sufficient. In this case, the regulation exacerbates the costs businesses carry in terms of connection charges and overall lack of government investment in the electricity infrastructure, which together can hinder the uptake of new technologies. Additionally, changes in banking regulations affecting long-term debt financing for renewable projects may also pose challenges for innovation diffusion. Legislation or regulation can also hamper the diffusion of innovations in the biorefinery sector due to factors such as high production costs, lack of sustainability proof, concerns about competition with food resources, and the need for adherence to regulatory criteria for water quality[89]. There is no general financial support for investments or financial support for chemical and material products from biorefineries. Innovative biorefinery products face a substantial barrier due to the statutory requirement to register novel chemical substances. The registration process takes a lot of time and money.

Legislation or regulation can hamper innovation diffusion by confronting vested interests, determining the timing and pace of phase-out, relying on multiple benefit rationales, considering various factors for policy effectiveness, and potentially requiring prohibitions on technology use to meet emissions targets. In this respect, some authors highlight that policy mixes are important in easing transitions from old to new technology regimes[9091]. An effective **policy mix for technology phase-out** requires the appropriate combination of supply-side and demand-side interventions, and also, supporting the phasing-in of a replacement technology as well as disincentivising the use of the technology to be phased-out. Policies can facilitate demand-pull or technology-push conditions of environmental innovation depending on how they are designed[92]. For example, in the case of transport in the UK, the national government introduced financial and non-financial incentives for low emission vehicles before introducing the phase-out dates of combustion engines. The same has happened for home boilers and the case of EV recharging systems[93]. These issues are also highlighted in the case of biofuel intermodal transport[94]. The authors point out that policies that prioritise CO2 emissions reduction and incentivise lower-emission transport could support the adoption of intermodal biofuel transport, especially at the local level. On a higher, industry-level, policies impact the competitiveness of the industry, for example by taxing non-renewable energy. Finally, at the highest, national level, political decisions also impact the general competitiveness of transport modes via instruments such as road taxes, fuel taxes, infrastructure fees, etc. Supporting this, with reference to the biofuel technology

---

[88] Raybould, B., Cheung, W.M., Connor, C., Butcher, R., 2020. An investigation into UK government policy and legislation to renewable energy and greenhouse gas reduction commitments. Clean Technol Environ Policy 22, 371–387. https://doi.org/10.1007/s10098-019-01786-x .

[89] Peña-García, A., Nguyen, T.P.L., 2018. A global perspective for sustainable highway tunnel lighting regulations: Greater road safety with a lower environmental impact. Int J Environ Res Public Health 15. https://doi.org/10.3390/ijerph15122658 ..

[90] Kerr, N., Winskel, M., 2022. Have we been here before? Reviewing evidence of energy technology phase-out to inform home heating transitions. Energy Res Soc Sci. https://doi.org/10.1016/j.erss.2022.102640.

[91] Hojnik, J., Ruzzier, M., Manolova, T.S., 2018. Internationalization and economic performance: The mediating role of eco-innovation. J Clean Prod 171, 1312–1323. https://doi.org/10.1016/j.jclepro.2017.10.111

[92] Makkonen, T., Inkinen, T., 2018. Sectoral and technological systems of environmental innovation: The case of marine scrubber systems. J Clean Prod 200, 110–121. https://doi.org/10.1016/j.jclepro.2018.07.163 .

[93] Bakker, S., 2014. Actor rationales in sustainability transitions - Interests and expectations regarding electric vehicle recharging, in: Environmental Innovation and Societal Transitions. Elsevier B.V., pp. 60–74. https://doi.org/10.1016/j.eist.2014.08.002 .

[94] Flodén, J., Williamsson, J., 2016. Business models for sustainable biofuel transport: The potential for intermodal transport. J Clean Prod 113, 426–437. https://doi.org/10.1016/j.jclepro.2015.11.076.

in aviation[95], stress that in the case of Eastern Europe, legislation or regulation may hamper innovation due to limited public awareness and understanding, influenced by historical public distrust in national governments.

When it comes to cleantech, evidence from a firm-level dataset of global scope suggests that stricter regulations lead to increased innovation by suppliers at different levels of the **automotive value chain** showing that targeting downstream firms with policy instruments can effectively promote innovation uptake[96]. The experience from Germany on energy-efficiency in housing sector showed that environmental regulation significantly impacted the adoption of **energy-efficiency technology** in a low-quality market segment with regulatory intensity playing a crucial role[97]. Overall, the **European Green Deal is seen as enabler for clean technologies** even if it is reported to having had a negative impact on conventional sectors, through EU ETS which rises the price of CO2[98]. Elsewhere, evidence suggests that the regulatory landscape for autonomous vehicles (AVs) is currently focused on the requirements needed for testing, the US and China being leaders in attracting AV companies to test their technologies (e.g. the U.S. Department of Transportation's AV TEST Initiative includes 22 states, in China, at least 21 cities have released relevant regulations)[99]. In the EU, the regulations such as the RED II directive and the European Climate Law are reported to induce growth within the mobility sector, including investments in innovation[100].

Regulatory bottlenecks and unregulated areas in biotechnologies

In the European healthcare industry, in the broad sense, the role of legislation or regulation is dual as it depends on which field is implemented (e.g. pharmaceuticals, biotechnology or personalised medicine), if there are any differences among countries harmonisation, and which is the level of evaluation of therapies (advanced or no). To support this, the literature claims that legislation or regulation can **both enable and restrict** scientific innovation and product development, with tensions and potential non-alignment between market gatekeeping and health-care adoption gatekeeping[101].

In particular, when the focus is on **partnership with pharmaceutical firms, post-marketing commitments, closer cooperation and regenerative medicine**, legislation and regulation do not hamper the diffusion of innovations but rather support it, promoting the development and approval of new products[102], such as orphan medicines. A new initiative, the Advance therapy medicinal products (ATMP) Regulation, has been established in Europe to ensure the safety, efficacy, quality of medicinal products and quality data certification procedures while promoting research, innovation, and

[95] Filimonau, V., Mika, M., Pawlusiński, R., 2016. Public attitudes to biofuel use in aviation: Evidence from an emerging tourist market. J Clean Prod 172, 3102–3110. https://doi.org/10.1016/j.jclepro.2017.11.101 .

[96] Srinivasan, S., 2017. Driven up the wall? Role of environmental regulation in innovation along the automotive global value chain. CIES Research Paper series, CIES Research Paper series.

[97] El-Shagi, M., Michelsen, C., Rosenschon, S., 2014. Regulation, Innovation and Technology Diffusion: Evidence from Building Energy Efficiency Standards in Germany. https://doi.org/10.2139/ssrn.2432978 .

[98] Malanowski, N., Steinbach, J., Nisser, A., Beesch, S., Von, P.S., Van, D.V.E., Kretz, D., 2022. Techno-Economic study on the potential of European Industrial Companies regarding Europe's Green Deal [WWW Document]. JRC Publications Repository. https://doi.org/10.2760/037744 .

[99] Lewis, J.A., Lostri, E., Cheng, C., 2021. AI Strategies and Autonomous Vehicles Development.

[100] Malanowski, N., Steinbach, J., Nisser, A., Beesch, S., Von, P.S., Van, D.V.E., Kretz, D., 2022. Techno-Economic study on the potential of European Industrial Companies regarding Europe's Green Deal [WWW Document]. JRC Publications Repository. https://doi.org/10.2760/037744 .

[101] Faulkner, A., 2019. Special Treatment? Flexibilities in the Politics of Regenerative Medicine's Gatekeeping Regimes in the UK. Sci Cult (Lond) 28, 149–173. https://doi.org/10.1080/09505431.2017.1300641 .

[102] Hauray, B., 2017. From Regulatory Knowledge to Regulatory Decisions: The European Evaluation of Medicines. Minerva 55, 187–208. https://doi.org/10.1007/s11024-017-9323-2 .

collaboration[103]. It fosters the development of **gene therapy medicinal products (GTMPs)** and is considered powerful tool for early-phase GTMP developers. However, “some investigators find it onerous, suggesting potential challenges in the diffusion of innovations. The establishment of a 'mock appraisal' by the RMEG further indicates the need to assess and potentially adapt existing regulatory methodologies to better accommodate regenerative medicine”[104]. When it comes to the development of the AI-based telemedicine, establishing clear guidelines and regulations would help fostering the technology adoption while adressing the safety concerns it raises[105].

On the other hand, legislation or regulation may hamper innovation diffusion in many different cases of the EU healthcare industry. The first exceptional case stands out in the field of **human tissue engineered products (TEPs)**. The reasons can be due to regulatory divergences caused by a national variation in how these technologies are regulated, lack of clarity in evidence requirements, and differing opinions on the need for new legislation[106]. The consequences of this are lengthy approval procedures and high development costs, potential impairment of free movement of products, and inconsistencies in the regulatory framework[107]. However, recently, these challenges can be tackled by some new strategies, such as the creation of a forum for developers to engage with regulators as a way to anticipate and overcome obstacles to innovation diffusion[108].

Another limit in the biotechnological field is that legislation and regulation, if not adapted to the scientific state of the art, can hamper the diffusion of innovations leading to potential innovation standstills and challenges in international governance and coordination[109]. Particularly, in the realm of intellectual property, they can pose challenge to the diffusion of innovations in **synthetic biology**. SynBio researchers advocating for open access to knowledge may face pressures to protect intellectual property rights, highlighting the need for flexibility in IP strategies[110].

The third and last case regards the field of **advanced therapies and personalised medicine**. Although there are initiatives in place to encourage innovation and address unmet medical needs, according to the authors[111], there are challenges related to evaluating therapies and some barriers related to health technology assessment, the use of treatments under "hospital exemption", and the need for harmonisation and clarity in regulations.

Successful collaborations are imposing increased responsibilities and obligations between researchers and the industry (stakeholders) for approvals, potentially hampering the diffusion of innovations by making regulatory compliance more burdensome and dictating the adoption of certain interventions. This is, for instance, the case of the new EU Medical Device Regulation (MDR). The MDR's focus on clinical data for CE marking of high-risk

---

[103] Pita, R., Ehmann, F., Papaluca, M., 2016. Nanomedicines in the EU—Regulatory Overview. AAPS Journal 18, 1576–1582. https://doi.org/10.1208/s12248-016-9967-1 .

[104] Gardner, J., Webster, A., 2016. The social management of biomedical novelty: Facilitating translation in regenerative medicine. Soc Sci Med 156, 90–97. https://doi.org/10.1016/j.socscimed.2016.03.025 .

[105] Sharma, (2023). Technology and Society. Available at .

[106] Kent, J., Faulkner, A., Geesink, I., FitzPatrick, D., 2006. Towards governance of human tissue engineered technologies in Europe: Framing the case for a new regulatory regime. Technology Forecast Soc Change 73, 41–60. https://doi.org/10.1016/j.techfore.2005.06.006 .

[107] Brévignon-Dodin, L., Livesey, F., 2006. Regulation of tissue-engineered products in the European Union: where are we heading? Regenerative Med 1, 709–714. https://doi.org/10.2217/17460751.1.5.709 .

[108] Brévignon-Dodin, L., 2010. Regulatory enablers and regulatory challenges for the development of tissue-engineered products in the EU, in: Bio-Medical Materials and Engineering. pp. 121–126. https://doi.org/10.3233/BME-2010-0623 .

[109] Mampuys, R., Brom, F., 2018. Emerging crossover technologies: How to organize a biotechnology that becomes mainstream? Environ Syst Decis 38, 163–169. https://doi.org/10.1007/s10669-017-9666-1 .

[110] Douglas, C.M.W., Stemerding, D., 2014. Challenges for the European governance of synthetic biology for human health. Life Sci Soc Policy 10. https://doi.org/10.1186/s40504-014-0006-7.

[111] Corbett, M.S., Webster, A., Hawkins, R., Woolacott, N., 2017. Innovative regenerative medicines in the EU: A better future in evidence? BMC Med 15. https://doi.org/10.1186/s12916-017-0818-4 .

devices like biomaterial-based implants may also add complexity to the translation process. However, academic institutions are adapting by forming collaborative partnerships with industry and utilising dedicated teams for commercialisation assessments[112].

In biotech, some evidence suggests that regulation can significantly hamper innovation. This is, for instance, the case of Regulation (EC) No 1107/2009 on the placing of **plant protection products** on the market, which was noted to have had a negative impact on innovation and development of alternatives and new plant protection products (PPPs), discouraging investment in R&D due to escalating costs, and contributing to a decline in the competitive edge of European agriculture (European Parliament, 2018). With innovation in pharmaceuticals requiring significant investments, some studies show the importance of the regulation ensuring strong IPR, in particular regulatory data protection (RDP) for the availability of innovative medicines[113]. When it comes to **nanomedicines,** the "nanosimilars", i.e. products claiming to be similar to an innovator product, appear to be an unregulated area in the EU with the need for the nanocharacterisation and toxicological testing laboratory in Europe similar to the US to support the identification and development of new standards by the regulators[114]. The innovation in **microbiome editing** technologies seems to be hindered due to lack of clear regulatory criteria and standards on classification of microbiome-based products as drugs and therapies, foods or wellness products; lack of requirements for evidence robustness to determine safety and efficacy of microbiome-based products; and issues around regulation of data ownership, access, sharing and use[115]. Hence, the absence of well-designed regulation in the area of microbiome editing is hindering the uptake of technologies and innovation in the field. Finally, certain views from the US pertain that innovation that could be stirred through transatlantic cooperation in biotech is significantly hindered by the existing stringent regulation in the EU, in the area of the GMO, for instance[116].

2.1.2. Overview of legislative and regulatory barriers for EIC beneficiaries

This section provides the evidence collected through the analysis of EIC pathfinder and accelerator project databases, a survey with EIC beneficiaries and stakeholder interviews on regulatory barriers for EIC beneficiaries. The project data of 832 EIC Pathfinder (and potential follow-up) projects was analysed to consider the distribution of emerging technology categories, project calls, project budgets, and time frame of projects.

Box 2: Analysis of EIC project data

The quantitative analysis of EIC projects revealed that deep and digital technologies are the most represented category of emerging technologies (474 of 832 projects or 57%),

[112] Letourneur, D., Joyce, K., Chauvierre, C., Bayon, Y., Pandit, A., 2021. Enabling MedTech Translation in Academia: Redefining Value Proposition with Updated Regulations. Adv Healthc Mater 10. https://doi.org/10.1002/adhm.202001237 .

[113] Copenhagen Economics, 2023. Regulatory data protection – How adopting regulatory data protection can increase medicine availability, innovation, and investment.

[114] Bremer, S., Halamoda, K.B., Borgos, S.E., 2017. Identification of regulatory needs for nanomedicines: 1st EU-NCL survey with the "Nanomedicine" working group of the international pharmaceutical regulators [WWW Document]. JRC Publications Repository. https://doi.org/10.2788/585950.

[115] Cabling, M., Marciniak-Nuqui, Z., Marjanovic, S., 2022. Microbiome-Based Health and Wellness Innovation: Reflecting on Regulatory Challenges and Needs. URL https://www.rand.org/pubs/commentary/2022/07/microbiome-based-health-and-wellness-innovation-reflecting.html.

[116] Copenhagen Economics, 2023. Regulatory data protection – How adopting regulatory data protection can increase medicine availability, innovation, and investment.

which is closely followed by biotechnology (425 or 51%). The clean technologies category, however, was assigned to the fewest projects (220 or 26%).

Due to the potential for projects to be linked to several emerging technologies, the analysis allowed assigning more than one category of emerging technology to projects. This revealed that most projects (556 or 67%) were connected to one emerging technology; a third (265 or 32%) were connected to two categories and only 1% (11 projects) were connected to all three types of technology. The most common pair of technologies is deep and digital technologies and biotechnology (147 of 265 or 55%), followed by deep and digital technologies and clean technologies (70 or 26%), and clean technologies and biotechnology (48 or 18%).

Looking at the project budget (see Figure 16 in Appendix 1), projects related to clean technologies request a larger EU contribution on average (EUR 2 993 803), which is closely followed by biotechnology projects (EUR 2 965 479). As more costly projects, this could contribute to the lower number of projects found in clean technology across the data set. Conversely, although deep and digital technologies were identified in the largest share of projects, on average such projects request slightly less EU contribution (EUR 2 855 923).

In terms of project duration (see Figure 19 in Appendix 1), on average, biotechnology projects lasted the longest (1357 days), while clean technologies and deep and digital technologies projects were the shortest (1299 and 1282 days respectively).See Appendix 1 for methodological specifications and referred figures from the EIC project data analysis.

As part of the online survey of EIC beneficiaries, respondents were asked to select whether EU or national legislation or regulation hampered the market uptake of emerging technology. In total, 44% (or 77 of 174) selected EU legislation/regulation as hampering market update of emerging technology, compared to 20% (35 of 174) who selected national legislation/regulation (see Figure 3). However, 49% of respondents (85 of 174) selected that no legislation/regulation hampered the market uptake of emerging technologies.[117]

Importantly, these results could also reflect that across project stages, the focus of EIC beneficiaries is on research and development, prototyping, or market entry, making regulatory concerns less prominent. Especially the case studies but also the literature review revealed that regulatory barriers are impact most the market uptake and commercialisation. Hence early stage innovation projects are less impacted by regulation.

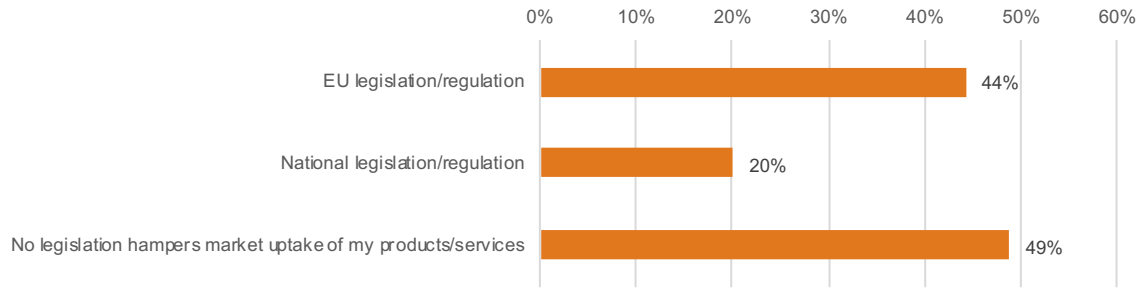

Figure 3. Q5: Which of the following types of legislation and/or regulation hampers the market uptake of emerging technology? Select all that apply. Note: N=174; more than one response option (legislation/regulation) could be selected. Source: Authors' own elaboration, based on survey data, 2024.

[117] The answer category "I do not know/ I cannot answer" was excluded from the analysis presented to determine which legislation/regulation, if any, was perceived to hamper the market uptake of technology among respondents who had insight. With the inclusion of "I do not know/ I cannot answer" the breakdown of responses is as follows: EU legislation/regulation – 36% or 77 of 215, National legislation/regulation – 16% or 35 of 215, No legislation/regulation – 40% or 85 of 215, I do not know/cannot answer – 19% or 41 or 215.

When considering the responses across the three main technology groups, there is variance across the sample. Figure 4 illustrates that 38 of 57 (or 67%) of respondents working with biotechnology and 34 of 66 (or 52%) of those in deep and digital technology indicated that EU legislation/regulation hampers the market uptake of technology, compared to 16 of 55 (or 29%) of those who selected clean technology. In fact, those respondents who selected clean technologies mostly selected that no legislation/regulation hampers the market uptake of emerging technology (33 of 55 or 60%), compared to those in biotechnology, of which only 16 of 57 (or 26%) selected no legislation/regulation.[118] This is in line with the findings of the literature review. While the literature acknowledges that legislation can drive innovation in clean technologies, evidence is less focused on regulatory barriers compared to biotechnologies and deep and digital technologies.

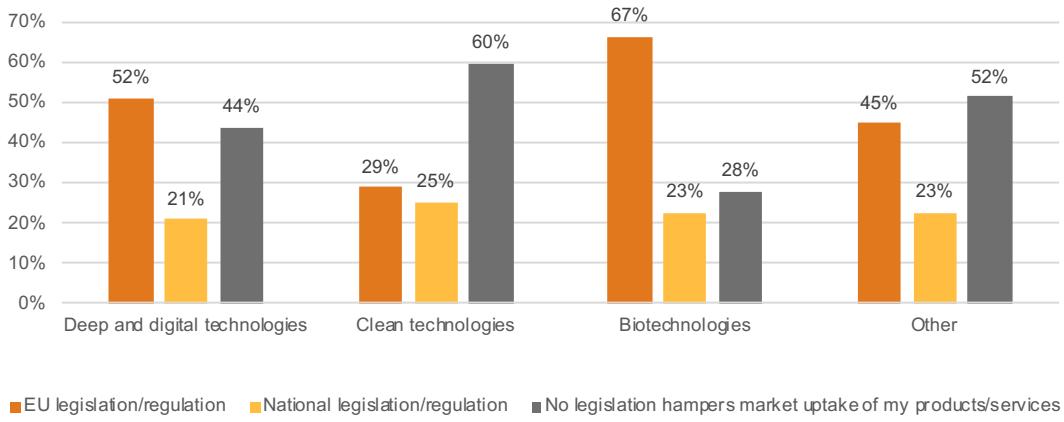

Figure 4. Q5: Which of the following types of legislation and/or regulation hampers the market uptake of emerging technology? Select all that apply. (By technology type). N=174; N Deep technologies = 66, N Clean technologies =55, N Biotechnologies = 37, N Other = 31. More than one response option (technology and legislation) could be selected. Source: Authors' own elaboration, based on survey data, 2024.

Respondents also specified particular legislation or regulation in their responses. At the EU level, the most common responses included the Medical Device Regulation (MDR) (21 respondents) and the In Vitro Diagnostic Medical Devices regulation (IVDR) (7). This corresponds with the data presented in Figure 4 which demonstrates that those working in biotechnology perceived EU legislation to be more hampering of market uptake compared to respondents working in other technology areas. Commonly cited aspects of product/service's development and/or market uptake being hampered by the MDR and IVDR included challenges complying with onerous requirements (e.g. clinical trials and other testing), and complicated, lengthy, and costly processes, including certification, which challenge and delay market access. Some respondents elaborated that these challenges can lead to ventures failing or moving to other markets, such as the US, or that they legislation favours large organisations as smaller companies are unable to afford the time and expense. This was echoed by another respondent who expressed that, generally, EU market penetration for small innovative companies is impeded by unfavourable competition regulation which favours large and established companies who operate in dominant positions.

Other responses also highlighted the AI Act (5) and in particular the need to consider the relationship between data security and privacy with the development and market uptake of

[118] The answer category "I do not know/ I cannot answer" was excluded from the analysis presented to determine which legislation/regulation, if any, was perceived to hamper the market uptake of technology among respondents who had insight.

new technology, which, according to some respondents lacks comprehension of the data risks associated with advanced technological development or can be restrictive and hinder development and innovation. Other specified legislation/regulation mentioned in the EIC survey as hampering the market uptake of technology included the Machinery Directive (2) with challenges in the scaling and adoption of collaborative robots and unmanned vehicles, as well as the CE Marking Directive (2), citing expensive certification processes and barriers to market access. In addition, the Novel Food regulation (1), EU Food Contact Materials regulation (1), the European Food Safety Authority (1) and the EU Packaging and Packaging Waste Regulation (1) were mentioned, with reference to barriers of growth due to restrictions in the adoption of new raw materials in the industry as well as for new materials for sustainable food packaging which were felt to be tailored to established materials. Lack of conformity or support of innovative products to current legislation/regulation was echoed with mention of the Measuring Instruments Directive (1) and the Water Framework Directive (1), making certification and market access challenging. These anecdotal responses suggest that, for some respondents, innovative products risk market exclusion due to legislative or regulatory bias towards conventional technologies and materials.

More generally, respondents referenced EU legislation/regulation in different areas such as privacy and security (including data protection, cybersecurity, and copyright), health and safety (including medical and product safety and road safety) and environment and sustainability (including waste, water, chemicals and renewable energy).

At national level, respondents highlighted particular aspects which were hindering to the development of or market uptake of technology. These included costly and complex regulatory processes (such as classification, certification and registration of products), environmental regulations which can incentivise (or not) the uptake of products, the need for fair competition regulations, cross-border recognition, and inflexible or lack of specific legislation/regulation.

Similar to EIC beneficiaries responding to the online survey, the EIC programme managers expressed a number of regulatory bottlenecks during the interviews in various technology fields. Regulatory heterogeneity was mentioned as one challenge by two EIC programme managers. As an example, varying import and export rules for renewable hydrogen in EU Member States were mentioned as a challenge to transport Hydrogen across EU Member States. Further, one interviewee highlighted the highly complex and detailed technical requirement as a barrier in the context of Carbon Capture and Storage technologies, for example it was mentioned to be very complex to upscale technologies that can produce synthetic fuels from industrial emissions, as such technologies have to adhere to regulations related to both industrial emissions and renewable energies.

Three EIC programme managers mentioned lack of market incentives for developing new and cleaner technologies as a regulatory challenge. As clean technologies often require a significant investment and they may be initially more expensive compared to conventional technologies, there is little economic incentive to invest in such technologies. The lack of regulatory means that create clear and lasting financial incentives to invest more in climate-friendly technologies (e.g. through the CO2-emsission trading system) was mentioned as a regulatory barrier. The position of EU-based manufacturers especially in the area of semi-conductors, chip-technologies and quantum computing is difficult compared to other international actors in the field, due to sanctions with non-EU countries or dominance of non-EU actors in international standardization committees.

Further, programme managers in areas of food and medical technologies pointed towards the exceptionally high security and safety standards for new technologies. While acknowledging the importance of having high safety standards in testing and developing new technologies in these fields, it was mentioned that faster and more approval processes would avoid that technology developers are leaving Europe in order to test and develop their products. Regulations on testing and approving new medical equipment are designed to target large manufacturers that have knowledge and capacities to run clinical trials within

all 27 Member States, however start-ups and scale-ups in this eara struggle to meet the regulatory requirements for implementing such trials.

To conclude, some stakeholders provided additional anecdotal insight into perceived legislative or regulatory challenges. Some responses indicated that there is a trade-off between the production of regulations and market competitiveness, a general advantage to already established solutions which align with current regulation, and that EU legislation/regulation can slow or hinder the innovation process. Others perceived that a lack of regulation poses more of a challenge than existing regulation does.

Key takeaways

- 44% (77 of 174) of respondents find that EU legislation/regulation is hampering the market uptake of emerging technologies, with several respondents specifically mentioning the MDR (21), IVDR (7) and AI Act (5). Only 20% (35 of 174) of respondents find that national legislation/regulation is hampering the market uptake of emerging technologies.
- Those in the area of biotechnology were more likely to find EU legislation hampering (34 of 66 or 52%). In particular, the Medical Device Regulation and the In Vitro Diagnostic Medical Devices regulation were viewed by respondents as impacting market entry due to costly, lengthy and complex clinical trial and certification requirements. Challenges especially for startups and SMEs with the MDR were also voiced by interviewed programme managers. Challenges occurred when setting up clinical trials due to vast and fragmented testing and certification requirements for early-stage technologies.
- Key areas of legislation/regulation highlighted by respondents as hampering included privacy and security, health and safety and environment and sustainability. Perceived challenges related to complex, lengthy and costly processes (at both EU and national level). Fragmented regulatory frameworks across the 27 EU Member States were highlighted by EIC programme managers and during case studies as a regulatory challenge for scaling up new technologies across the single market.

2.1.3. Specific regulatory challenges for emerging technology areas

Deep and digital technologies

This section presents the main findings from the survey concerning deep and digital technologies. Almost half (40% or 103 of 259) of survey respondents selected that their latest project was in the area of deep and digital technologies (see Figure 21 in Appendix 2). Only responses from these respondents are analysed in this section.

Legislation and/or regulation were considered a barrier to the market uptake by slightly more than half of respondents (see Figure 4). Many respondents (29 of 66 or 44%) felt that no legislation hampered market uptake of their emerging technologies. For the remaining respondents, EU legislation seems to hamper the market uptake more than national legislation. Over half (34 of 66 or 52%) of respondents indicated that EU legislation/regulation hampers the market update of their technology while 21% (or 14 of

66) selected that national legislation/regulation hampers the market uptake of emerging technologies[119].

While discussing concrete EU legislation that hampers the market uptake, several respondents referenced the Artificial Intelligence (AI) Act.[120] Respondents elaborated on specific challenges related to the regulations' lack of comprehension of data risks associated with technological development (such as data security and privacy) or restrictiveness which hinders the development of innovation. Some respondents noted that risk assessments of technologies do not consider the breadth of potential risks from different technologies and their applications, instead applying a blanket approach which targets the most high-risk technologies, making it challenging for lower-risk technologies to comply with stringent regulations. As well as the AI Act, this was also referenced in relation to aspects of data collection and privacy protection within the GDPR. Moreover, for developers, the perceived uncertainty as to what is allowable under complex and uncertain regulation also impedes innovation. If legislation/regulation was more tailored to different technology risk levels, it could ease the burden of compliance in this area.

When asked to highlight aspects of their product or services which were being hampered by legislation/regulation, respondents identified issues related to costly and timely risk assessment of new technologies which delays approval and market entry and compliance procedures, for example, safety and technical standards compliance with the MDD and MDR and a lack of clarity or uncertainty of the legality of products, making compliance more challenging and hindering market entry. Moreover, the ability to gather public data (due to GDPR or copyright restrictions), barriers to EU market entry, competition law which favours very large companies, and lack of enforcement of EU regulations at national level were referenced as additional challenges in development and marketing.

At a national level, aspects of development or market uptake mostly impacted by regulation/legislation included delays in development and marketing due to, for example, permitting, certification and licensing procedures or restrictions.

On the other hand, almost half of respondents (35 of 81 or 43%) agreed or completely agreed that legal uncertainty in relation to emerging technologies created challenges to develop or market their products or services (see Figure 6). Of those that (completely) agreed, two-thirds of respondents indicated that EU legislation is a barrier to market uptake of technology and just under a quarter of respondents selected that no legislation or regulation was a barrier to their technology (see Figure 7 Appendix 2), suggesting that despite existing legislation in place, there are regulatory gaps which cause uncertainty in the developing and marketing of deep and digital technologies. Survey respondents noted a lack of accommodation for new technologies within existing legislation, which is tailored to existing solutions and possibilities. According to some respondents, these gaps exist when legislation lags, causing uncertainty for developers, investors and consumers. Another respondent noted that the viability of small businesses is put at risk when they have to wait for legislation to catch up to their emerging technology, another suggesting more proactive legislation as a means to address such gaps and increase EU competitiveness. Information from the case studies showed that regulatory gaps create risks and unertainties, and result in lengthy approval process for novel technologies.

Some challenges due to the lack of legislation/regulation at the EU or national level highlighted by respondents included a lack of clarity in definitions and guidelines, outdated phrasing which is not reflective of advancing technology, and uncertainty generated from draft regulation and press releases, all of which were viewed to create mistrust or uncertainty for customers or investors. Also referenced by several respondents were cross-

[119] The answer category "I do not know/ I cannot answer" was excluded from the analysis presented to determine which legislation/regulation, if any, was perceived to hamper the market uptake of technology among respondents who had insight.

[120] European Commission (2021b) Proposal for a Regulation of the European Parliament and of the Concil Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) and Amending Certain Union Legislative Acts.

border challenges, such as the uncertainty created by exportation rules, data management regulation, and investment restrictions across borders, which impact delivery to customers and market possibilities.

Biotechnologies

This section presents the main findings from the survey concerning biotechnologies. A third (30% or 85 of 259) of survey respondents selected that their latest project was in the area of biotechnologies (see Figure 21 in Appendix 2). Only responses from these respondents are analysed in this section.

Two-thirds of respondents selected that EU legislation/regulation hampers the market uptake of technology (see Figure 4).[121] Those working in biotechnology perceived EU legislation to be more hampering to market uptake compared to respondents working in other technology areas.

At the EU level, those working with biotechnology most commonly referenced the Medical Device Regulation (MDR)[122] and the In Vitro Diagnostic Medical Devices Regulation (IVDR)[123] as examples of legislation/regulation hampering the market uptake of their technology. Commonly cited aspects of product/service development and/or market uptake being hampered by the MDR and IVDR included challenges complying with demanding requirements (e.g. clinical trials and other testing), and complicated, lengthy, and costly processes.

While national legislation or regulations were not as commonly perceived as creating barriers to the development or market uptake of biotechnologies (16 of 57 or 26%), some specific examples included restrictions on the adoption of new raw materials (insect protein) which limited industrial growth or the limitation of Brexit in cross-border commercialisation of products.

In terms of unregulated areas, almost half (31 of 74 or 42%) agreed or completely agreed that legal uncertainty in relation to emerging technologies created challenges to developing or marketing their products or services (see Figure 6). Of those that (completely) agreed, four-fifths of respondents indicated that EU legislation is a barrier to market uptake of technology and only 11% of respondents selected that no legislation or regulation was a barrier to their technology (see Figure 7). This could indicate that despite existing legislation in place, there are regulatory gaps which cause uncertainty in the development and marketing of biotechnologies. One interviewed EIC programme manager highlighted, that the complex nature of some of the biotechnologies such as biomarkers make it difficult to design clinical trials with the current criteria.

The aspects of development and market uptake affected by lack of, or under-regulation referenced by respondents were mostly related to delays and the increased cost of product development. Other responses included both too many standards and a lack of standards, constant adjustments and delays in regulation, and challenges with EU-wide ratification leading to market entry barriers.

Clean technologies

[121] The answer category "I do not know/ I cannot answer" was excluded from the analysis presented to determine which legislation/regulation, if any, was perceived to hamper the market uptake of technology among respondents who had insight.

[122] Official Journal of the European Union (2017) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

[123] Official Journal of the European Union (2017) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

This section presents the main findings from the survey concerning clean technologies. Almost a third (31% or 80 of 259) of survey respondents selected that their latest project was in the area of clean technologies (see Figure 21 in Appendix 2). Only responses from these respondents are analysed in this section.

Legislation or regulation was not considered to be a barrier to the market update of technology for almost two-thirds of participants (see Figure 4).[124] Despite this, the remaining responses suggest that both national and EU legislation or regulation are to some extent hampering market uptake of clean technologies. Almost a third of respondents (16 of 55 or 29%) indicated that EU legislation/regulation does hamper market uptake and a quarter (14 of 55 or 25%) find that national legislation/regulation does.

Respondents highlighted that timely, costly, and sometimes unclear procedures impact the development, testing, commercialisation, and market access of emerging technology. Specific EU legislation/regulation mentioned by respondents which create challenges to the development and market uptake of clean technology included those related to EU climate, waste, water, chemical and CO2 emissions regulations, as well as the electrification of vehicles, and cross-border transport of animal by-products.

Moreover, respondents pointed to national level legislative and regulatory challenges such as erratic politics related to green policies which lead to insecurity for investors and the need for certification or lack of recognition of international certification (which increases costs for customers).

In terms of unregulated areas, for respondents working in clean technologies, 29 of 68 (or 43%) agreed or completely agreed that legal uncertainty in relation to emerging technologies created challenges to developing or marketing their products or services (see Figure 6). Of those that (completely) agreed, over two-fifths indicated that no legislation or regulation is a barrier to market uptake of technology (see Figure 7 Appendix 2), which could indicate that there is a need for additional legislation or regulation within the clean technology sector. Moreover, those who perceived legal uncertainty due to lack of regulation perceived that national legislation or regulation was more hampering than EU legislation, which may point to regulatory gaps at the EU level which cause uncertainty in the development and marketing of clean technologies.

Challenges related to under- or un-regulation highlighted in the survey included slow permit processes, restrictions which limit sales, and customer and investor mistrust due to regulatory uncertainty.

2.1.4. Challenges related to legal uncertainty in emerging technologies

When asked about the challenges created by legal uncertainty, 40% (or 85 of 215) of respondents agreed or completely agreed that legal uncertainty in relation to emerging technologies (due to the lack of legislation and/or regulation at the EU or national level) creates challenges to develop or market your products/services (see Figure 5). The distribution across technology groups evenly reflected this response (see Figure 6). Comparatively, 23% (or 48 of 215) disagreed or completely disagreed with this sentiment, and this was most commonly reflected in respondents working in the area of deep and digital technologies (21 of 81 or 26% selected disagree or completely disagree). Importantly, a quarter of respondents (25% or 53 of 215) neither agreed or disagreed that legal uncertainty created challenges in the development or market uptake of technologies.

[124] The answer category “I do not know/ I cannot answer” was excluded from the analysis presented to determine which legislation/regulation, if any, was perceived to hamper the market uptake of technology among respondents who had insight.

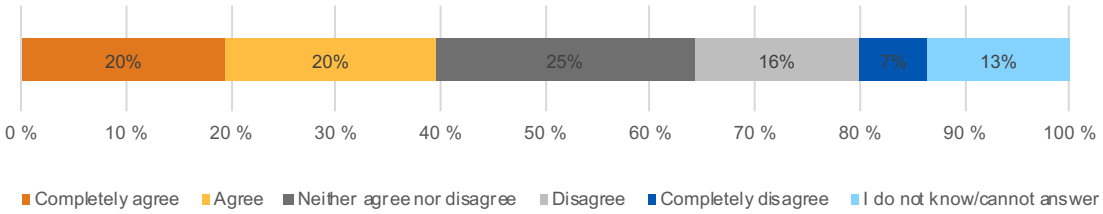

Figure 5. Q6: To what extent do you agree that the legal uncertainty in relation to emerging technologies (due to the lack of legislation and/or regulation at the EU or national level) creates challenges to develop or market your products/services?

N=215. Source: Authors' own elaboration, based on survey data, 2024.

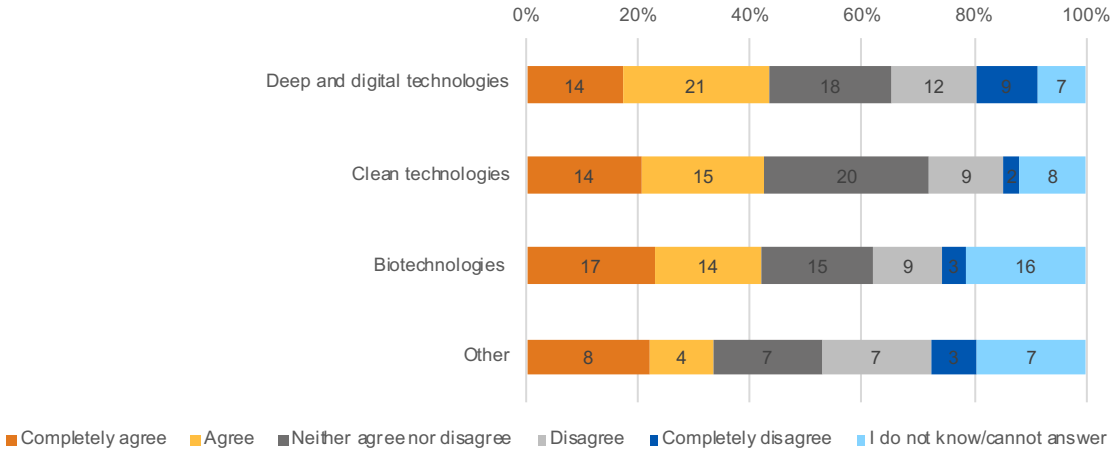

Figure 6. Q6: To what extent do you agree that the legal uncertainty in relation to emerging technologies (due to the lack of legislation and/or regulation at the EU or national level) creates challenges to develop or market your products/services? (By technology).

N=215, N Deep technologies = 81, N Clean technologies =68, N Biotechnologies = 74, N Other = 36. More than one response option (technology) could be selected. Source: Authors' own elaboration, based on survey data, 2024.

Figure 7 illustrates the responses of those that completely agreed and agreed to what type of legislation or regulation they perceive to be a barrier to the market uptake of their technology (Q5). Those in deep and digital technologies (20 of 30 or 67%) and biotechnologies (21 of 27 or 78%) were most likely to select that EU legislation or regulation was hampering the market uptake of emerging technologies. National legislation was selected by the majority of the clean technology group which to be the most hampering to market uptake (11 of 25 or 44%). Similarly, no legislation was perceived to be a barrier to market uptake for clean technologies (11 of 25 or 44%), while deep and digital and bio technologies were less likely to select these options.

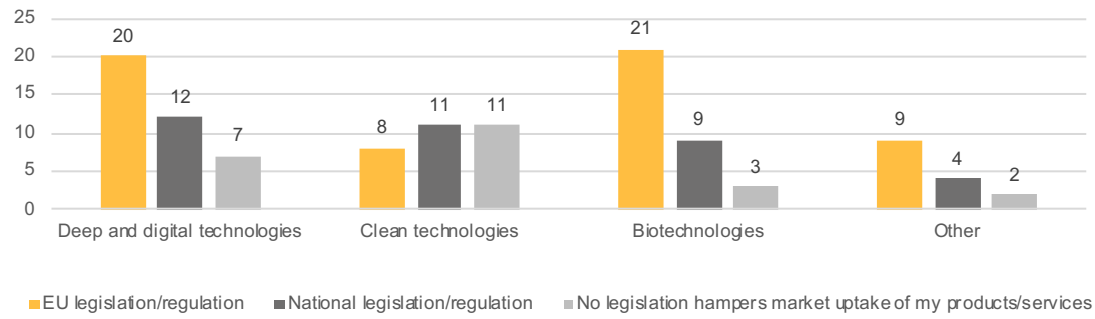

Figure 7. Responses to Q5 (Which of the following types of legislation and/or regulation hampers the market uptake of emerging technology?) of those that completely agreed and agreed that the legal uncertainty in relation to emerging

technologies (due to the lack of legislation and/or regulation at the EU or national level) creates challenges to develop or market products/services (Q6). (By technology group)

Note: N=85, N Deep technologies = 30, N Clean technologies = 25, N Biotechnologies = 27, N Other = 11. More than one response option (technology and legislation/regulation) could be selected. Source: Authors' own elaboration, based on survey data, 2024.

The respondents of the survey also highlighted several aspects of product/service development and/or market uptake which are affected by the lack of legislation/regulation at the EU or national level. Table 5 presents a compilation of responses related to these aspects in more detail. Most commonly, respondents noted a lack of clarity in various aspects such as permitting process, legality and standards as an issue impacting product development or market uptake, as well as barriers to market entry (including delays, delivery, and issues in exporting products), and finally, aspects related to reduced product uptake and loss of customer base. Some specific challenges were identified by some respondents across technology areas. For biotechnology, this included emphasis on delays and adjustments of MDR and IVDR, as previously discussed. For clean technologies, the need for legislative stimulation for solutions for pollution and climate change was mentioned. Finally, for deep and digital technologies unclear legislation/regulation was mentioned by several respondents, including unclear regulations between the EU and other countries, data transfer and use across countries, and a lack of clarity, for example of GDPR alignment with new technology and language of legislation, whereby legislation is phrased in terms of existing technology, making it challenging to understand the applicability and use of new technologies.

The findings were mirrored by two interviewees from EIC programme managers in the field of medical technologies. They highlighted that for many potential applications, no or unclear regulation exists making it risky for technology developers to invest in technological development. Here, ongoing dialogues between developers and regulators initiated by the EIC have been proven to provide a useful platform for exchange of information between industry and regulators. Interviewed EIC programme managers familiar with the field of quantum computing indicated the EU or its Member States have no regulatory framework in place for quantum computing at the moment, as there are no commercial product applications available yet. However, one interviewee identified a potential risk in the future, if no preparations for regulatory frameworks are made, that potential barriers could arise in the area of quantum computing once commercial product applications become available.

Table 5. Aspects of product/service's development and/or market uptake being affected by the lack of legislation/regulation at the EU or national level.

Aspects being hampered	Survey responses*[125]
Product development	• Innovation, development, and production of technologies. • Compliance and approval processes such as a lack of clarity on the legality of products, certification, standards, and risk assessment. • Delays the process of product development. • Lack of access to data for product development. • Increase cost of product.
Market uptake	• Mistrust among customers and investors due to lack of certainty. • Barriers and delays to market entry. • Reduced product uptake and adoption and loss of customers. • Hampers sales and commercial success.

[125] (*) Does not represent verbatim responses - presents a compilation of responses which have been thematically sorted based on descriptions provided by respondents.

Investment and financial concerns	• High cost of development is stifling SME and startup success. • Hinders investment, including investor confidence and cross-border investment.
Competition	• Creates competitive disadvantage and reduced global competitiveness. • Hampers exports.
Other comments	• Challenges include regulatory lag, lack of foresight, frequent regulatory changes or too many regulations. • Existing regulation fails to accommodate new and advancing technologies.

Key takeaways

- Legal uncertainty was perceived to create challenges in the development or market uptake of technologies for most respondents (40% or 85 of 215), but a quarter did not agree or disagree with this sentiment. Challenges related to legal uncertainty included product development, market uptake, investment and financial concerns, and competitiveness.
- EIC programme managers highlighted regulatory heterogeneity among EU Member States, lack of market incentives for more climate friendly technologies and very high safety and security standards as the main regulatory bottlenecks for emerging technologies

2.1.5. Synthesis of EIC project cases

In all eight case studies of EIC projects, EIC beneficiaries highlighted challenges that arise due to either unclear regulations or a lack of legislation that govern their specific technologies. Underregulation arose in different ways and had various consequences for EIC beneficiaries:

- In two case studies, lack of clear regulation for specific novel technologies meant that the technologies were governed by regulation that is designed for other similar types of technologies. This made complying with the regulatory frameworks challenging, as it was not tailored to the specific technology that was developed by the EIC beneficiaires.
- In one case of clean technologies, it is unclear which of the existing regulations would apply to the novel technologies. As a result, the technology is expected to have to comply with multiple regulations. In this case, under regulation may lead to overregulation, as there is no clarity on which regulation should apply.
- In at least three case studies, issues around uncertainty due to lack of regulation was brought up. This led to increased risks for EIC beneficiaries for the further development and deployment of their technologies that are not clearly regulated for placing on the market.

Almost all EIC beneficiaries highlighted the issue of different regulatory standards or frameworks in different EU Member States. Cross-border projects cause high regulatory burden to EIC beneficiaries, as they have to comply with multiple national regulatory frameworks. In at least three cases, this required EIC projects to subcontract national actors to ensure compliance with national regulatory frameworks, driving up costs for pilot or demonstration projects. Furthermore, EIC beneficiaries stressed that existing regulation might provide incentives for exisiting technologies, which makes new emerging technologies less competitive compared to existing technologies. This was brought up by EIC beneficiaries in the areas of clean technologies, biotechnologies and space

technologies. In the case of digital technologies, exisiting trade sanctions made it difficult to cooperate internationally and makes European technology developers less competitives in the international market.

Overall, commercialisation and market uptake during the R&I process were most impacted by over- or underregulation according the EIC beneficiaries interviewed for the case studies. During the R&I process, the EIC beneficiaries covered by the case studies did not report challenges during testing or development of new technologies due to regulatory barriers. In general, regulatory burden led to higher compliance costs with regulations and longer project durations. This is due to the complexity of regulatory frameworks, as EIC beneficiaries had to invest in understanding regulatory frameworks and assessing which regulations would apply to their novel technologies. In general, this was reported to limit the market potential of the new technologies. Testing and development of technologies was reported to be less impacted by over- or under regulation by EIC beneficiaries

2.2. Regulatory experimentation spaces and regulatory learning

This section describes the key study findings regarding regulatory experimentation spaces and their potential benefits for the development and market uptake of emerging technologies based on literature and previous studies as well as survey and interviews and case studies of experimentation spaces. The final subsection presents findings of benchmarking the regulatory approaches for emerging technologies in the EU, US, and UK.

2.2.1. Evidence from literature and previous studies

Overall, the literature review of academic literature provided very **little empirical evidence** concerning the use of specific regulatory experimentation tools. The policy literature, on the other hand, offers some insight into the use of regulatory tools, i.e. sandboxes, testbeds and LLs, lessons learnt, limitations and opportunities of regulatory innovation practice, but has **very limited evidence base** on their impact on innovation[126][127][128][129]. This is largely due to the **gap in evaluation of impact** of the regulatory tools on innovative technologies which could be explained by the short life span and divergent modalities for publication of data on the outcomes by the regulators[130], as well as the relative novelty of these approaches[131]. In addition, national schemes of regulatory experimentation are quite varied, making it difficult to draw general conclusions on their effectiveness[132]. The literature stipulates the adoption of a more consistent and robust approach to evaluation, data collection and publication, to make sure granular and comparable data is available to produce insights on the effectiveness of the regulatory tools[133]. To address the data gap in the EU context, the

[126] Bijkerk, W., 2021. Regulatory Sandboxes, Innovation Hubs, and Other Regulatory Innovation Tools in Latin America and the Caribbean. Inter-American Development Bank.

[127] Gangale, F., Mengolini, A.M., Covrig, L., Chondrogiannis, S., Shortall, R., 2023. Making energy regulation fit for purpose. State of play of regulatory experimentation in the EU [WWW Document]. JRC Publications Repository. https://doi.org/10.2760/32253 .

[128] Parenti, R., 2020. Regulatory Sandboxes and Innovation Hubs. European Union.

[129] UK BEIS, 2020. Regulator approaches to facilitate, support and enable innovation (Research Paper Series), 2020/003. UK Department for Business, Energy and Industrial Strategy.

[130] Parenti, R., 2020. Regulatory Sandboxes and Innovation Hubs. European Union.

[131] UK BEIS, 2020. Regulator approaches to facilitate, support and enable innovation (Research Paper Series), 2020/003. UK Department for Business, Energy and Industrial Strategy.

[132] Ibid.

[133] Ibid.

literature suggests establishing a set of common principles on **statistics and key indicators** to ensure data comparability[134].

Regulatory sandboxes

The few assessments there are on the effectiveness of the sandboxes, namely by FCA on sandbox within the "Innovate" programme (fintech) and "Innovation Link" by Ofgem (energy), use project **output data** complemented with **surveys/interviews with beneficiaries**. However, the methodology used for these assessments does not include the comparison with the counterfactual and performance of a rigorous econometric analysis, making the establishment of a causal link between the regulation and the innovative technology uptake impossible. For instance, there is evidence of positive impact of FCA's sandbox on provision of greater regulatory certainty for technology development by firms, but the report notes that causal link between the sandbox operation and improved firm performance cannot be established[135]. Ofgem's sandbox appears to have helped the companies to better understand their own innovation and how it can work within the market, gain confidence in making the next steps, and increase attractiveness of their innovative products to investors[136]. However, as the results are based on beneficiary survey, the risk of the self-reporting bias is high, especially in absence of counterfactual, undermining the robustness of the results.

More generally and in the same line of findings, some evidence on the use of live-testing environments suggests that they have a positive impact on innovation when it comes to "increasing investment and investor trust in new products, services or business models; and helping participating companies bring their innovations to market (or acquire a license) quicker"[137]. In addition, analysis of policy practices showed that sandboxes have had **three major impacts on innovation**, namely i) contributing to removing structural barriers to innovation process; ii) promoting knowledge sharing and cooperation between the actors, leading to establishment of communities of practice of LLs; iii) raising awareness on green objectives and enhancing their political buy-in[138]. A set of case studies of sandboxes across different sectors and geographies have led to identification of **policy lessons** to be applied to future regulatory innovation tools (e.g. for Latin America, testbeds may be more feasible than sandboxes, the multisectoral nature of some innovation requires coordinated action by actors and regulators, etc.)[139].

The cases of use of sandboxes, testbeds and LLs for specific technologies provide additional sectoral insights into the effects of regulatory innovation tools on new technology uptake. In the particular case of **fintech**, which is the first sector that has seen the sandbox applied, there is concern of the negative effect of sandboxes leads to a "race-to-the-bottom" style competition across different jurisdictions within the EU, distorting the level playing field, consumer protection, and leading to market fragmentation across the EU impeding the scaling-up on fintech across the EU[140].

---

[134] Ibid.

[135] FCA, 2019. The Impact and Effectiveness of Innovate. Available at https://www.fca.org.uk/publications/research/impact-and-effectiveness-innovate .

[136] CEPA, 2021. Evaluation of the Innovation Link: Ofgem. Available at https://www.ofgem.gov.uk/sites/default/files/docs/2021/05/cepareport_ofgem_evaluationofinnovationlink_final.pdf

[137] UK BEIS, 2020. Regulator approaches to facilitate, support and enable innovation (Research Paper Series), 2020/003. UK Department for Business, Energy and Industrial Strategy.

[138] Rosemberg, C., Potau, X., Leistner, S., Dijkstal, F., Vinnik, A., Tiriduzzi, C., Dave, A., Blind, K., 2020. Regulatory Sandboxes and Innovation Testbeds: A Look at International Experience in Latin America and the Caribbean. IDB Publications. https://doi.org/10.18235/0002526 .

[139] Ibid.

[140] Parenti, R., 2020. Regulatory Sandboxes and Innovation Hubs. European Union.

The surge of AI has posed a challenge for regulation of **AI-powered technologies**, with Governments looking to ensure innovation-friendly regulation of AI while ensuring public safety and security, transparency, traceability and non-discriminatory sue of AI-systems[141][142]. The **AI Act** adopted by the European Parliament in March 2024 stipulates the use of regulatory sandboxes to "facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service". The Act also encourages Member States to set up at least one AI regulatory sandbox and envisages establishing common rules for uniform implementation of the sandboxes across the EU with appropriate governance and supervision frameworks. In the UK, the initiatives on AI regulation include considering setting up a multi-regulator AI sandbox which would allow to experiment with new products and services under enhanced regulatory supervision without the risk of fines or liability[143]. Hence, sandboxes are perceived as an effective means to promote innovation in AI while ensuring safety, security, transparency, and non-discriminatory nature of the upcoming AI-technologies[144][145].

Overall, regulatory sandboxes have been recognised as important tools in creation of an innovation-friendly, future-proof, and resilient regulatory frameworks for **digital technologies**, offering flexibility for testing innovative technologies and enabling regulators to gain better regulatory knowledge based on real-world evidence (Council Conclusions on Regulatory Sandboxes and Experimentation Clauses as tools for an innovation-friendly, future-proof and resilient regulatory framework that masters disruptive challenges in the digital age 2020/C 447/01, 2020). Currently unregulated areas in digital technologies include medical devices based on AI[146]. Academic references to the use of sandboxes, focus on AI[147], data sharing governance[148] and the pursuit of the innovation economy in the digital technology sector[149].

The technologies supported by regulatory experimentation in Pošćić and Martinović[150]are innovative AI systems, with a focus on data protection, compliance costs for SMEs supplying high-risk AI systems, and the need for carefully calibrated conditions for sandbox operation. In their case, the sandbox worked to some extent, but its full impact on encouraging innovation and enhancing competitiveness for SMEs is still unclear. The transparency and user-friendliness of the sandbox procedure will be crucial in determining its success in enhancing legal certainty and alleviating concerns for firms.

Some authors[151] examine the outcomes of 72 approved sandbox projects in the area of **energy**, identifying areas of innovation and regulatory learning, and evaluating the

---

[141] European Artificial Intelligence Act, 2024. Available at https://commission.europa.eu/news/ai-act-enters-force-2024-08-01_en

[142] UK Government, 2022. Establishing a pro-innovation approach to regulating AI [WWW Document]. GOV.UK. URL https://www.gov.uk/government/publications/establishing-a-pro-innovation-approach-to-regulating-ai/establishing-a-pro-innovation-approach-to-regulating-ai-policy-statement .

[143] UK HM Treasury, 2023. Pro-innovation Regulation of Technologies Review: Digital Technologies.

[144] Ibid.

[145] European Parliament, 2022. Artificial intelligence act and regulatory sandboxes.

[146] UK HM Treasury, 2023. Pro-innovation Regulation of Technologies Review: Digital Technologies.

[147] Pošćić, A., Martinović, A., 2022. REGULATORY SANDBOXES UNDER THE DRAFT EU ARTIFICIAL INTELLIGENCE ACT: AN OPPORTUNITY FOR SMES? InterEULawEast 9, 71–118. https://doi.org/10.22598/iele.2022.9.2.3

[148] Graef, I., Prüfer, J., 2021. Governance of data sharing: A law & economics proposal. Res Policy 50. https://doi.org/10.1016/j.respol.2021.104330 .

[149] Rose, E., 2023. Pursuing the Innovation Economy: Implications for Startup Labour. Industrial Law Journal 52, 839–865. https://doi.org/10.1093/indlaw/dwad002 .

[150] Pošćić, A., Martinović, A., 2022. REGULATORY SANDBOXES UNDER THE DRAFT EU ARTIFICIAL INTELLIGENCE ACT: AN OPPORTUNITY FOR SMES? InterEULawEast 9, 71–118. https://doi.org/10.22598/iele.2022.9.2.3

[151] Beckstedde, E., Correa Ramírez, M., Cossent, R., Vanschoenwinkel, J., Meeus, L., 2023. Regulatory sandboxes: Do they speed up innovation in energy? Energy Policy 180. https://doi.org/10.1016/j.enpol.2023.113656 .

interaction between the design of the legal framework for regulatory sandboxes and their potential to bring innovation in northern European countries. The Netherlands, for instance, decided to close their programme and this has two policy implications: "First, the outcomes of existing sandbox projects validate the idea of using regulatory sandboxes to promote innovation under the REPowerEU Plan and indicate important areas for future regulatory learning. More specifically, the projects on synthetic methane injection in the gas network illustrate that sandboxes can **promote the diversification of the gas sector**. The projects on flexible connections to the electricity network show that regulatory derogations can **accelerate the rollout of renewables**. Second, to promote innovation and regulatory learning, it is important to make the regulatory scope of the sandboxes as open as possible while keeping it tangible for project applicants. Best practices in the analysed regulatory frameworks can be resumed as follows: i) including multiple regulatory entities in the administration process and having an open approach towards regulatory derogations, ii) providing regulatory advice to sandbox applicants, iii) administrators continuously evaluating and updating the sandbox program"[152].

Another author[153] investigated the institutional arrangements post the financial crisis, obstacles to cross-border regulatory cooperation between the EU and the US, and the challenges and theoretical implications of the financial regulatory reform. In this case, the sandbox did not work as intended due to concerns about distributive consequences, legislative barriers, and weak government networks. The policy recommendations include addressing concerns about distributional consequences, navigating legislative obstacles, strengthening and completing government networks, and considering alternative approaches like including financial regulation in trade deals for more effective global regulatory reform in the OTC derivatives market.

Addressing to some extent the negative effects of regulation could be done through regulatory sandboxes, testbeds and LLs. Among the key benefits for regulators of the use of sandboxes and other regulatory innovation tools is the **improved knowledge and expertise** around the needs of innovators, better **understanding of the types of innovations** emerging and their potential impacts for the formulation of the long-term policies; **increasing business trust** and facilitate a more open and transparent relationship with many businesses; fostering more innovation in the market[154]. A global survey of regulators also revealed that regulatory agencies have mostly positive perception of the impact of sandboxes, in particular when it comes to improving their understanding of key technologies and building stronger relationships with the business sector[155]. Innovative companies see quicker entry to market, reduced regulatory uncertainty, legitimacy and investor confidence as main benefits of sandboxes.

The literature also points to several **limitations** of the use of such tools, for example, cost implications (as such initiatives are resource-intensive with costs of launching of the sandboxes often underestimated by the regulators); concerns around testing representation (issue of managing the risks associated with unforeseen or unintended consequences); issues of disrupting competition or providing the firm with position advantage[156]; as well as consumer safety concerns related to technology testing (risk should be identified and managed through the set-up of consumer safeguards required as part of the eligibility

[152] Ibid.

[153] Knaack, P., 2015. Innovation and deadlock in global financial governance: transatlantic coordination failure in OTC derivatives regulation. Rev Int Polit Econ 22, 1217–1248. https://doi.org/10.1080/09692290.2015.1099555 .

[154] UK BEIS, 2020. Regulator approaches to facilitate, support and enable innovation (Research Paper Series), 2020/003. UK Department for Business, Energy and Industrial Strategy.

[155] World Bank, CCAF, 2019. Regulating Alternative Finance: Results from a Global Regulator Survey.

[156] UK BEIS, 2020. Regulator approaches to facilitate, support and enable innovation (Research Paper Series), 2020/003. UK Department for Business, Energy and Industrial Strategy.

criteria or as a mandatory requirement for the companies willing to take part in the test plan)[157].

In the context of the EU, the recent study of implementation of sandboxes in the **energy sector** emphasised the role the EU could play to support regulatory experimentation at the Member States level. In fact, the study showed the importance of providing regulatory authorities with the necessary powers to engage in regulatory experimentation, but also providing the opportunity to set-up consultancy/feedback services to support innovators[158]. The obstacles faced by the regulators in the EU include: the absence of a legal basis for the regulatory authority to conduct the experimentation initiatives and to derogate from the general regulatory framework (e.g. in some Member states an enabling legal provision is necessary to derogate from the general regulatory framework, while others have such provisions in place, e.g. Italy and Portugal energy regulators)[159]; the lack of resources and/or competences of national regulatory authorities (NRAs) for the management and monitoring of experimentation initiatives; difficulty in defining suitable indicators and rigorous methodology; and need for timely and scrupulous planning for effective changes in regulation[160].

Testbeds

Recent literature highlighted how testbeds and LLs as instruments for experimental innovation governance operating under real-world conditions[161].

In the case of testbeds, experimental research is directly linked to regulation. Tests for sustainable development in every research area are implemented as a bridge to understand both the gaps in regulation and to have adequate environments to carry out the appropriate experimental tests. In 2020, the European Council recognised the importance of improving regulation as a key factor for inclusive and sustainable growth. An inadequate regulatory framework, in fact, could be an obstacle to the development of research in all relevant fields[162]. Regarding the energy sector, for example, each country has used a regulatory model for experimentation based on different approaches. If we make a comparison between Netherlands, Great Britain and Italy: for Italy and Great Britain, the experiments are the main responsibility of the regulator; while for the Netherlands the important role of the Ministry and the Dutch Enterprising Agency appear to be more a supporting than a functional one[163]. Testbeds and related concepts such as LLs or real-world laboratories – have emerged as a prominent approach to structure and stimulate innovation by testing new sociotechnical arrangements. The testing could be considered as controlled experimental spaces that facilitate a kind of performance or hypothesis testing under presumably realistic conditions. Unlike simple technological tests of individual devices, their

---

[157] Gangale, F., Mengolini, A.M., Covrig, L., Chondrogiannis, S., Shortall, R., 2023. Making energy regulation fit for purpose. State of play of regulatory experimentation in the EU [WWW Document]. JRC Publications Repository. https://doi.org/10.2760/32253 .

[158] Ibid.

[159] This could also be potentially explained by the overall risk-aversion culture in the EU and the risks associated with experimentation in energy sector, such as the risk of disruption of competition and causing harm to the consumers.

[160] Ibid.

[161] Engels, F., Wentland, A., Pfotenhauer, S.M., 2019a. Testing future societies? Developing a framework for test beds and living labs as instruments of innovation governance. Res Policy 48. https://doi.org/10.1016/j.respol.2019.103826 .

[162] Bovera, F., Lo Schiavo, L., 2022. From energy communities to sector coupling:a taxonomy for regulatory experimentation in the age of the European Green Deal. Energy Policy 171. https://doi.org/10.1016/j.enpol.2022.113299 .

[163] Schittekatte, T., Meeus, L., Jamasb, T., Llorca, M., 2021. Regulatory experimentation in energy: Three pioneer countries and lessons for the green transition. Energy Policy 156. https://doi.org/10.1016/j.enpol.2021.112382 .

envisioned benefits and fully embraced new ways of living under the assumption that certain systemic changes have already happened, and that society has adjusted accordingly[164].

Living labs

Some 25 articles address LLs research. LLs are experimental activities carried out through a systematic co-creation approach to innovation and research processes. These models are characterised as open innovations. The range of activities in the field of innovations has led both public and private companies to consider a greater commitment to use these as development opportunities. The development of work team opportunities depends as always on overcoming obstacles[165].

In Europe, unlike other countries such as South Korea or the United States, where LLs are used to increase the development of new technologies, those activities are concentrated on real-life related fields such as safety, residence, traffic, environment or welfare and so on. While Europe has not yet been able to fully appreciate the potential of LLs, in Korea their use has led to surprise results in the development and diffusion of technologies on the market[166]. Some authors[167] analyse how LLs can address specific demographic needs and develop suitable solutions, especially in cases requiring user-behaviour transformation or business-model innovation. LLs are described as local entities that play a crucial role in stakeholder participation for implementing systemic innovations. The authors examine the case of Mobility-as-a-Service (MaaS), on-demand mobility services, and public-private partnerships.

The policy recommendations based on the study suggest finding a balance in regulation to allow for innovation while serving the public interest, emphasising the importance of public transport as the backbone of integrated mobility solutions, promoting broad stakeholder participation in transportation system development, encouraging collaboration to connect regional mobility systems, and considering the influence of legislation and path dependence in development activities. Collaboration is, in fact, vital for the living lab and challenges in collaboration processes might stagnate or even terminate the developments in the living lab[168]. In this respect, the authors argue that the collaboration process would significantly benefit from the implementation of a reflective layer, where through an iterative and incremental approach in each stage of collaboration, co-creation principles are employed to support, facilitate, maintain, and evaluate the alignment within a heterogeneous group of stakeholders.

Other authors[169] investigate how urban LLs accelerate the transition towards more sustainable and climate-resilient cities, highlighting the pivotal role of municipalities and how their collaborative function can range from merely participating as a silent partner to using collaboration as a policy instrument to actively promote change. The distinction between

---

[164] Engels, F., Wentland, A., Pfotenhauer, S.M., 2019b. Testing future societies? Developing a framework for test beds and living labs as instruments of innovation governance. Res Policy 48. https://doi.org/10.1016/j.respol.2019.103826 .

[165] Kratzer, J., Meissner, D., Roud, V., 2017. Open innovation and company culture: Internal openness makes the difference. Technol Forecast Soc Change 119, 128–138. https://doi.org/10.1016/j.techfore.2017.03.022 .

[166] Shvetsova, O.A., Lee, S.K., 2021. Living labs in university-industry cooperation as a part of innovation ecosystem: Case study of South Korea. Sustainability (Switzerland) 13. https://doi.org/10.3390/su13115793 .

[167] Surakka, T., Härri, F., Haahtela, T., Horila, A., Michl, T., 2018. Regulation and governance supporting systemic MaaS innovations. Research in Transportation Business and Management 27, 56–66. https://doi.org/10.1016/j.rtbm.2018.12.001 .

[168] Kalinauskaite, I., Brankaert, R., Lu, Y., Bekker, T., Brombacher, A., Vos, S., 2021. Facing societal challenges in living labs: Towards a conceptual framework to facilitate transdisciplinary collaborations. Sustainability (Switzerland) 13, 1–14. https://doi.org/10.3390/su13020614 .

[169] Kronsell, A., Mukhtar-Landgren, D., 2018. Experimental governance: the role of municipalities in urban living labs. European Planning Studies 26, 988–1007. https://doi.org/10.1080/09654313.2018.1435631 .

participating in a collaboration as a partner, and actually promoting or enabling collaboration is not always easy to make, also because that role can vary over time.

The concept of LLs is found in many fields and instead of the common meaning, in health care has been proposed as a framework to connect governmental, public-sector organisations, industry, higher education institutions, community-based organisations, and clinicians. The aim is to create an environment of creativity that encourages a collaborative approach in the developmental process of a product, service, or system. The idea of LLs facilitates the collaboration of knowledge sharing and research design which delivers a user-centred open innovation system. The key concept of this innovative field is the idea that a safe space is created to facilitate knowledge exchange, co-ideation, and testing between different stakeholder groups in real-life settings[170].

2.2.2. EIC beneficiaries' experiences with experimentation spaces

The majority of respondents (72% or 154 of 215) indicated they did not have experience working with specific conditions as part of experimentation spaces (such as regulatory sandboxes, LLs or testbeds to support highly innovative projects) (see Figure 8). A further 14% (or 30 of 215) did not know or could not answer. Only 14% of respondents (or 31 of 215) selected that they had experience working with experimentation spaces.

Across technology area, a fairly even distribution of responses can be seen in

Figure 9, with the clean technology group being slightly more likely to have experience with experimentation spaces (12 of 28 or 18%) than the biotechnology (8 of 74 or 11%) and deep and digital technology groups (10 of 81 or 12%).

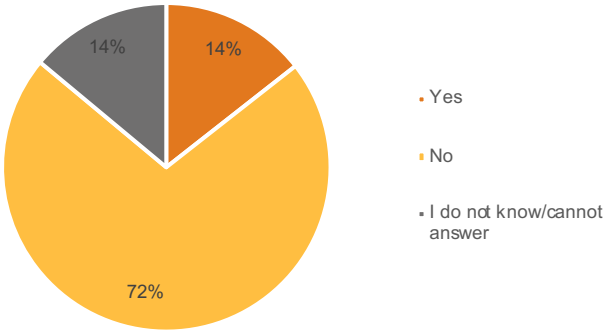

Figure 8. Q7: Have you experienced working with specific conditions as part of experimentation spaces (such as regulatory sandboxes, living labs or testbeds to support highly innovative projects)? N=215. Source: Authors' own elaboration, based on survey data, 2024.

[170] Byrne, T., Murray, N., McDonnell-Naughton, M., Rowan, N.J., 2023. Perceived factors informing the pre-acceptability of digital health innovation by aging respiratory patients: a case study from the Republic of Ireland. Front Public Health 11. https://doi.org/10.3389/fpubh.2023.1203937 .

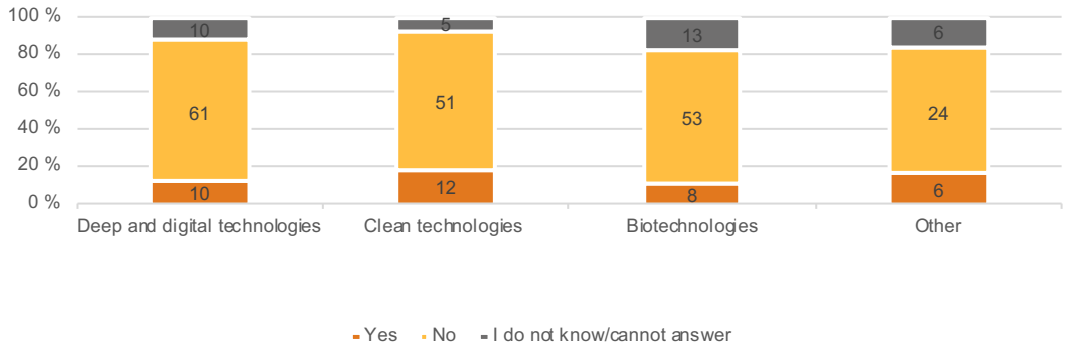

Figure 9. Q7: Have you experienced working with specific conditions as part of experimentation spaces (such as regulatory sandboxes, living labs or testbeds to support highly innovative projects)? (By technology). N=215, N Deep technologies = 81, N Clean technologies =68, N Biotechnologies = 74, N Other = 36. More than one response option (technology) could be selected. Source: Authors' own elaboration, based on survey data, 2024.

The most common type of experimentation space used by respondents was testbeds (14 of 31 or 45%), followed by regulatory sandboxes (10 of 31 or 32%) and then LLs (9 of 31 or 29%) (see Figure 10). A similar distribution can be seen across technology groups (see Figure 11), however it is not possible to extrapolate further given the small number or respondents within each group.

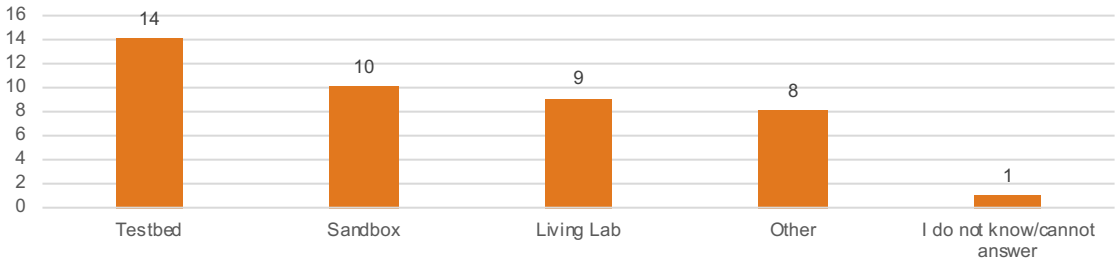

Figure 10. Q7.1: Please specify which experimentation space(s) you were involved in. Select all that apply. N= 31; More than one response option (experimentation space) could be selected. Source: Authors' own elaboration, based on survey data, 2024.

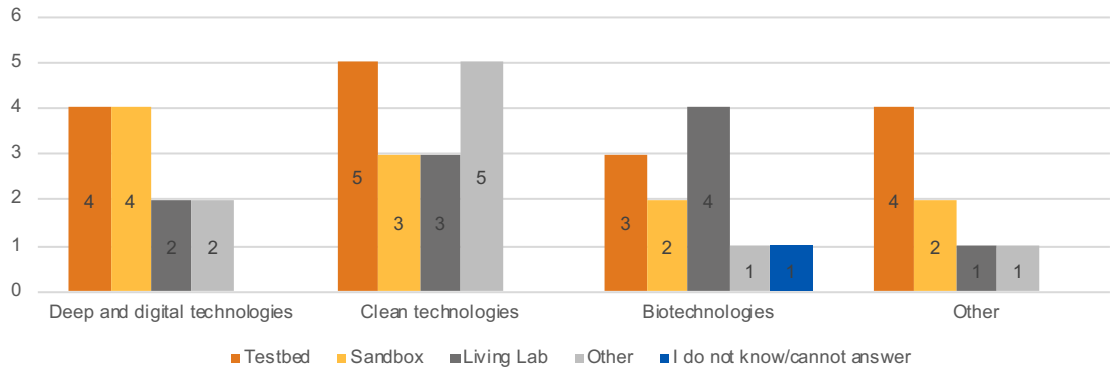

Figure 11. Q7.1: Please specify which experimentation space(s) you were involved in. Select all that apply. (By technology). N= 31, N Deep technologies = 10, N Clean technologies = 12, N Biotechnologies = 8, N Other = 6; More than one response option (technology and experimentation space) could be selected. Source: Authors' own elaboration, based on survey data, 2024.

Of those respondents with experience with experimentation spaces, they most commonly expressed that experimentation spaces increased investor/customer confidence and supported access to collective knowledge and users/public feedback as part of the R&I process (17 of 31 or 55% respectively) (see Figure 12). These aspects were perceived to provide access to guidance and opportunities for networking and support the validation of

technologies to customers or investors. Access to research or technology infrastructure was also highlighted by respondents (12 of 31 or 39%) as a supportive outcome of working within experimentation spaces. Enhanced legal certainty was not commonly viewed as a way in which experimentation space supported or helped work, with 7 of 31 (or 23%) selecting this option. Further elaborations provided by respondents on their selection are highlighted in Table 6.

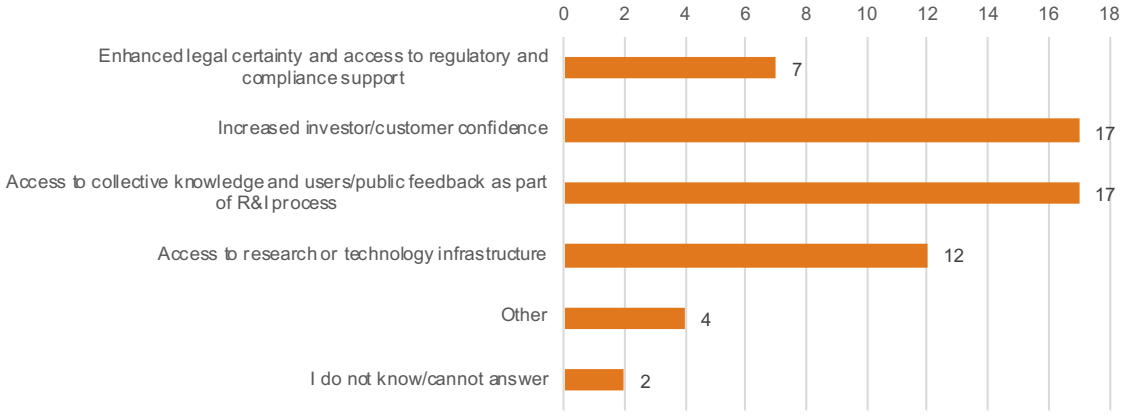

Figure 12. Q8: In what way did the experimentation space support/help your work? Select all that apply. N= 31; More than one response option (support type) could be selected. Source: Authors' own elaboration, based on survey data, 2024.

Table 6. Ways in which experimentation space supported/helped respondents' work

Aspects of support	Survey responses*[171]
Enhanced legal certainty and access to regulatory and compliance support	• Provide access to guidance • Increased confidence in compliance with regulation • Networking with experts • Supported needs to innovate • Access to platforms for registration and compliance
Increased investor/customer confidence	• Piloting helped to convince customers that technology works in real circumstances • Validating technologies • Demonstrate the suitability of products
Access to collective knowledge and users/public feedback as part of R&I process	• User-feedback for the evolution and refinement of product • Possibility of teaching experiences in the field with researchers • Opportunity to learn from clients' needs and improve solutions
Access to research or technology infrastructure	• Enables access to limited infrastructure support for SMEs • Access to facilities, labs, external spaces etc.
Other	• Supports the development of business model • Improved access to historical data

Moreover, when asked which aspects of highly innovative emerging technology development experimentation spaces could help to support, respondents provided a variety of answers, including:

[171] (*) Does not represent verbatim responses - presents a compilation of responses which have been sorted based on descriptions provided by respondents.

- Demonstration of technology and prototyping (including by increasing trustworthiness and reliability)
- Piloting and testing (including pilot studies, testing, evaluation of scalability, data collection and analysis)
- Engagement and collaboration (including networking, support and collaboration with industry, customers, end-users, and companies)
- Investment and market opportunities (including improving business models, time to market, investment opportunities, fair market access, and visibility)
- Skills development and training
- Risk aversion and insurance
- Company, SME, and start up support
- Faster development, manufacturing, market cycle and adoption of technology

Some respondents noted that having testbeds which provide a broader range of tools would better enable validation and demonstration of technology, for example than compared to generalised labs which do not meet specific equipment needs. It was also noted that test beds could improve visibility of new technologies. Other specific responses from the survey suggested that regulatory sandboxes could ease the pathway from lab to market, in this example, for clean technology.

Notably, EIC programme managers had very little experience with regulatory experimentation spaces in their project portfolios. None of the interviewed programme managers could name an example of such experimentation cases, which included EIC beneficiaries. However, most programme managers had a positive view on the opportunity of regulatory experimentation to be used in future EIC projects. Only in areas of bio- and health tech, EIC programme managers noted that it might be difficult to provide for regulatory derogations, as this could risk lowering safety and security standards for instance in clinical trials.

Key takeaways

- Most respondents (72% or 154 of 215) did not have previous experience working with experimentation spaces, such as regulatory sandboxes, LLs or testbeds). Only 14% (or 31 of 215) indicated they had this experience, most commonly with testbeds.
- Experimentation spaces were perceived to increase investor and customer confidence and provide access to collective knowledge and user feedback. They were also seen to provide opportunities for demonstration, piloting, engagement, and support a faster product cycle.
- The findings suggest that there is untapped potential in using the regulatory experimentation and different experimentation spaces to support the development and market uptake of emerging technologies among EIC beneficiaries' and other innovators.

2.2.3. Landscape of experimentation spaces and regulatory experiments in EU

One of the objectives of the study was to ascertain what regulatory experimentation spaces (e.g. regulatory sandboxes, testbeds or LLs) are being used by European innovators and

regulators in the emerging technology areas. This section provides a synthesis of the key findings.

Overview of experimentation spaces in EU

For the mapping of innovative regulatory experimentation spaces, a scanning was conducted based on previous reports and documents[172]. This scanning delivered 256 results, covering both EU and national level initiatives. These initiatives were classified according to the categories that are the focus of this study, namely regulatory sandboxes, LLs and testbeds. Also, an additional category was introduced to include relevant legislative or regulatory frameworks and/or regulations which provide the basis for regulatory experimentation but are not, as such, regulatory sandboxes (e.g. AI Act). These were included only if they were listed in existing reports, and were not systematically scanned across EU or Member States.

Moreover, each initiative was also categorized based on the type of emerging technology area that they concentrate on (biotechnologies, clean technologies, deep and digital technologies), as well as 'generic' category for spaces dealing with multiple technology areas, and an 'other' category for those dealing with not relevant areas. Additionally, the geographical scope of each regulatory space was considered, noting the country or countries involved.

It should be noted that the scanning is not an exhausting mapping of all experimentation spaces across EU, but rather a comprehensive sample of different initiatives.

Table 7. Total number of scanned regulatory spaces by type and technology area.

	Living lab	Regulatory sandbox	Testbed	Regulatory framework	Total
Biotechnologies	20	0	6	2	**28**
Clean Technologies	15	18	4	5	**42**
Deep and Digital Technologies	4	26	27	7	**64**
Generic	55	1	5	1	**62**
Other	53	3	2	2	**60**
Total	**147**	**48**	**44**	**17**	**256**

The analysis revealed that LLs were the most common type of regulatory experimentation space, with a total of 147 results. This number is most likely explained by the fact that LLs have been a popular initiative in Europe already for the last two decades, with some of the scanned projects going back to the beginning of the century (e.g. the Food&HealthLL from the University of Valencia, founded in 2003). Also, unlike for regulatory sandboxes and testbeds, there exists a comprehensive catalogue of these practices, regularly updated by ENoLL, which facilitates their identification and analysis.

[172] For example: European Commission (2023) ; Joint Research Centre (2023). Making energy regulation fit for purpose. State of play of regulatory experimentation in Europe ; ENoLL (2023), 2023 member catalogue. Available at : https://enoll.org/wp-content/uploads/2023/09/enoll-catalogue-2023_final.pdf

Of these 147 LLs, over one third (55) were classified as generic, as they did not focus on only one technology area but instead offered a real-life context for testing, co-creating, prototyping and upscaling multiple kinds of products and services. Among the technological areas, the most common category in the scanned LLs was biotechnologies (20 results), with a high number of those related to healthcare, nutrition, physical wellbeing, autonomy of senior people, and also agroecology and sustainable farming. Clean technologies followed with 15 results, and deep and digital technologies with 4 results. Regarding the technologies, it should be noted that most LLs seem to focus on technologies and innovations which are close to market. This is expected and in line with previous research (see 1.2) as LLs focus on testing solutions in real-life contexts, which is not possible for emerging technologies with low TRLs.

Regulatory Sandboxes, with 48 results, were the next most prevalent type of regulatory experimentation space. However, it should be noted that this includes all kinds of initiatives labelled as regulatory sandboxes, regardless of whether they include regulatory exemptions or not. This finding supports the fact that there is no broadly shared definition for regulatory sandboxes and the landscape of regulatory sandboxes is currently very heterogenous.

On the contrary, in the case of LLs, none of the sandboxes dealt with biotechnologies. As explained by several interviewees, this is because creating a controlled environment to test regulation related to experimental pharmaceuticals, medical technologies, and biomanufacturing processes is difficult and could entail serious risks.

Instead, the most common technological area among the scanned sandboxes was deep and digital technologies with 26 results. Most of these were design to allow startups, businesses and research institutions to experiment with new products and services while enjoying certain regulatory exemptions, while some others permitted regulatory agencies to test their regulations in market conditions and to improve legal certainty for investors. The most common specific technologies of these spaces were artificial intelligence, blockchain solutions, fintech, 5G networks, and nanotechnology. Furthermore, 18 regulatory sandboxes focused on clean technologies, with the majority of them providing a controlled environment where new renewable energies, smart electricity grids, energy storage solutions, or recycling and wate management technologies could be tested and refined without the constraints of full regulatory compliance.

Testbeds accounted for 44 of the scanned experimentation spaces. They served as specific physical or digital environments where new technologies can be tested and experimented with under controlled conditions, so that they can be validated before they are scaled up or fully implemented. As it occurred with the mapped regulatory sandboxes, the majority of the testbeds (27 of them) were focused on deep and digital technologies and sought to develop, test or validate services and products related to smart mobility and e-drive systems, nanotechnology-based medical devices, or AI for urban planning. Besides these, 6 testbeds focused on biotechnologies, especially on the testing of medical devices, and 4 more concentrated on clean technologies.

The remaining 17 results were classified as legislative/regulatory frameworks, which represented the efforts of regulatory bodies and policymakers to adapt or create legal frameworks that accommodate emerging technologies and support technological advancements. Of these, 7 results were related to deep and digital technologies, like the European Commission proposals for a Regulation on Artificial Intelligence and for an Interoperable Europe Act; 5 to Clean Technologies, like the European Commission's Recommendation on speeding up permit-granting procedures for renewable energy projects and facilitating Power Purchase Agreements; and 2 to biotechnologies, like the European Commission's proposal for a Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency. It should be noted that all of these examples were included in the mapping as they were listed in previous reports on regulatory sandboxes, and no specific mapping was conducted to identify these frameworks.

In terms of technological focus, the scanning showed that deep and digital technologies were the most common, with 64 regulatory spaces. This reflects a significant emphasis on digital transformation and advanced technologies within the EU, aligning with broader strategic goals to lead in the digital economy. Clean technologies were the next major focus, with 42 regulatory spaces, highlighting the EU's commitment to sustainability and green innovation. Biotechnologies, although less prevalent with 28 regulatory spaces, represent a growing area of interest and regulatory activity. The remaining regulatory spaces were classified under generic or other categories, indicating a diverse range of applications and innovations being explored.

Geographically, the scanned regulatory spaces were led by organizations distributed across 37 countries, plus the EU and the Nordic Countries as a whole. The vast majority of the spaces were coordinated by organizations from EU member States, which were scanned manually. Notable concentrations were found in Southern Europe, especially in Spain (30), France (26), and Italy (20). This can be explained by the high numbers of LLs established in these countries, with 23 found in Spain, 19 in France, and 17 in Italy. Additionally, several experimentation spaces were led by organizations from countries associated to Horizon Europe, such as Bosnia and Herzegovina (1), Canada (4), Great Britain (11), Montenegro (1), Norway (3), Serbia (2), and Turkey (3). Figure 13 below shows a map with the distribution of these spaces.

Detailed analysis of selected sample

A sample of 50 regulatory spaces was selected from the total 256 results, in order to provide a more detailed overview of experimentation spaces in Europe (see list in Appendix 3). The selection process for this sample aimed to be representative of and to reflect the overall distribution found in the complete dataset, ensuring proportionality in terms of types of regulatory spaces, technological focus, and geographical distribution of the leading organizations. The analysis was conducted by examining the available online information of each initiative (including websites, previous case studies, reports, etc). The findings of the analysis are presented in the following Table.

Table 8. Selected sample of experimentation spaces

	Living lab	Regulatory sandbox	Testbed	Total
Biotechnologies	8	0	5	**13**
Clean Technologies	7	6	0	**13**
Deep and Digital Technologies	1	10	9	**20**
Generic	4	0	0	**4**
Total	**20**	**16**	**14**	**50**

The selected sample includes 20 LLs, 16 regulatory sandboxes, and 14 testbeds. The technological focus within the sample also follows the trend observed in the full dataset, with a predominance of regulatory spaces focused on deep and digital technologies (20), followed by clean technologies (13) and biotechnologies (13). Likewise, the sample is as geographically balanced as possible, and includes regulatory experimentation spaces from 25 of the 37 countries represented in the full dataset. Although the information was not available for all of these 50 selected experimentation spaces, the majority of them did not target participants from markets outside of the EU, and had either a national (e.g. the Torino City Living Lab) or EU-level scope (e.g. the EU Testing and Experimentation Facilities).

The establishments of the selected initiatives spans from 2003 (University of Valencia Food & Health Living Lab) to 2024 (Danish Data Protection Authority regulatory sandbox for artificial intelligence), with a peak in new initiatives in 2019, when 9 of them were founded. Most selected spaces, especially regulatory sandboxes and testbeds, were planned with a specific timeline and a predetermined completion date (e.g. the Austrian Intelligent Open Test Bed for Materials Tribological Characterisation Services, active between 2019 and 2023). However, other spaces, especially LLs, remain active many years after they were set up (e.g. the Hungarian ÖMKi On-farm Living Lab, launched in 2012). Lastly, their target groups range from public administrations and governmental bodies to private organizations (including large multinationals and SMEs) and research institutions, and the technology sectors covered include (inter alia) AI, blockchain, fintech, energy, medical devices, agroecology, and food systems.

- **Living labs:** In the sample, LLs are the most established regulatory spaces, with some set up as early as in 2003, and with 12 of the total 20 launched before 2018. However, they remain largely active. The most common types of responsible organizations are universities (like the Swiss École Polytechnique Fédérale de Lausanne or the University of Limerick) and consortia of research institutions, indicating a strong academic and research orientation. Other labs are operated by municipality administrations (City of Copenhagen or City of Torino). Their target groups include both public and private stakeholders, often incorporating multinationals and foreign companies. This approach seeks a public-private collaboration that leverages academic expertise to foster innovation in emerging technologies. Technology sectors in LLs are broad, with 8 selected projects covering biotechnologies (e.g. healthcare, ecological farming), 7 covering clean technologies (e.g. energy efficiency, water management), 1 covering deep and digital technologies (aviation), and 4 covering other technologies.
- **Regulatory sandboxes:** The oldest regulatory sandbox in the sample was launched in 2010 (ARERA Regulatory experiments to promote innovation in the power system in Italy) and the most recent one (Croatia energy sector regulatory sandbox) was still under preparation at the time of writing this report. Of the total 16 selected sandbox projects, 9 of them were established after 2020. The majority of the projects (10 of them) focus on deep and digital technologies and are designed to help develop, test and validate AI technologies, decentralised finance projects and blockchain solutions, among others. The remaining 6 sanboxes focus on clean technologies and, like the Austrian Regulatory sandbox in the electricity sector, they deal mainly with energy-related technologies, smart energy grids, and storage. Regarding their types of responsible organizations, almost all of them are public bodies, either national regulatory agencies, such as the Danish Data Protection Authority and the Hellenic Competition Comission, or EU institutions like the European Commission. Lastly, they commonly target private sector participants like multinational companies and startups, but also research institutions. For instance, the French AI and Personal Data Sandbox and the European Blockchain Regulatory Sandbox both involve private companies and target AI and blockchain innovators, respectively.
- **Testbeds:** All but one of the 14 selected testbeds (the EU Interoperability Testbed from 2017) were established during or after 2019, which shows a surge in demand for spaces where new technologies can be tested at scale. The technology sectors that these testbeds focus on are closely aligned with industrial applications, with 9 of them designed to advance deep and digital technologies (e.g. the Estonian Digital Testbed Framework, or the Austrian Intelligent Open Testbed for Materials Tribological Characterisation Services), and 5 related to biotechnologies (e.g. the British NHS Innovation Testbed). Target groups for these testbeds are highly diverse, ranging from public administrations to European industries, like the automotive, space, energy, healtcare, food production or farming. For example, the

EU-wide Testing and Experimentation Facility (TEF) for manufacturing seeks to support the European manufacturing sector and invites manufacturers from different fields to engage in innovation related to AI, robotics, smart and autonomous systems.

2.2.4. Synthesis of case studies on experimentation spaces

As part of the study, four case studies of experimentation spaces (three cases of regulatory sandboxes and one testbed) was conducted. Generally, the four experimentation spaces that have been studied have all met or are on track of meeting their objectives. All interviewees highlighted the importance of such experimentation spaces to design and test novel technologies in real-life environment, integrating them with other technologies, and exploring the human-technology interaction within the innovation process.

The selected cases demonstrate different mechanisms for regulatory learning. One of the cases (SINTEG) can be considered as an example of "adaptive regulation" (see definitions in section 1.2), where regulatory framework has been adapted to support the uptake of innovations. Two cases (EBS and NDPA) are examples of "advisory regulation" approach, providing help for innovators to adhere to existing regulations and navigate the regulatory framework. One of the cases (i-Tribomat) is a relatively typical testbed. While its connection to regulatory learning is less evident, it can contribute to the development of standards for emerging (material) technologies and thus provide an example "anticipatory regulation" approach.

Also, the institutional set-ups of these examples were very diverse, reflecting the diverse landscape of different experimentation spaces. However, two principal types of institutional set-ups can be identified. SINTEG and NDPA are examples of "top-down" setting, where public authorities set up funding calls that include experimentation within a certain regulatory framework, as well as other support activities such as advisory services, networking opportunities or participatory research. EBS and i-Tribomat, in turn, are examples of more network-based set-ups, that focus on fostering dialogues between innovation actors and regulators or other stakeholders. In only one of the four case studies, (SINTEG) clear deviations or derogations of the common regulatory practices were included in the regulatory experimentation space. In two other sandbox cases (EBS, NDPA), there was a close collaboration between regulators and innovators, but no regulatory exemptions have been granted for participants of the regulatory experimentation space. These findings are in line with findings of the mapping exercise, indicating that the institutional set-ups and regulatory frameworks of regulatory sandboxes are very diverse, and "orthodox" sandboxes with regulatory derogations are still rare.

The EBS is a good example of addressing the uncertainty associated with new technologies and serves and the attempt to build trust and enhance understanding between the regulatory authorities and innovators. While not being formally a sandbox (e.g. no regulatory exemptions are provided for the participants, the work being mostly focused on dialogue between regulatory authorities and innovators), EBS has proven useful for the development of blockchain technologies in the EU (see Annex 6 for more details).

An important aspect of experimentation spaces that came up as part of the case studies is the role of the regulatory experimentation spaces as platforms for dialogue, building shared understanding and trust in a safe space. For instance, interviewees highlighted the importance of providing meaningful spaces to foster dialogues between regulators and innovators (SINTEG, EBS, NDPA). This is specifically important for achieving regulatory learning and knowledge exchange between technology developers and regulatory authorities with contributions to "anticipatory regulations".

In one case study, it was highlighted that the lack of technical knowledge within public authorities was one of the main barriers for developing innovative regulatory frameworks that are relevant for novel technologies. However, regulatory learnings and technical knowledge alone are not sufficient to achieve lasting impact on the regulatory environment.

In one case study, interviewees expressed that regulatory learnings that have been achieved throughout the dialogue in the implementation phase have not been followed up by concrete policy actions following the closure of the experimentation space.

In most case studies that focused on EIC funded projects, EIC beneficiaries expressed that regulatory experimentation spaces could help to test new technologies in a safe and real-life environment. In many cases, EIC beneficiaries also highlighted the opportunity of co-creation of regulatory specifications together with regulatory authorities as an important aspect of regulatory experiments, pointing at the high potential for regulatory learning and enhancing public authorities' understanding of novel technologies through regulatory experimentation spaces.

Overall, the findings from case studies further support the conclusion that while the selected case examples have been well documented and analysed, there is a lack of a general evidence of the broader impacts of experimentation spaces for the companies / innovators as well as for regulatory learning.

2.2.5. Benchmarking of regulatory approaches in the EU, UK and US

This section provides a succinct benchmark of the regulatory approaches to emerging technologies in the US, UK compared to the EU followed by an analysis of regulatory experimentation practices.

The benchmarking is based on i) the commonalities in governance structures, i.e. federal/state in the US, central government/devolved nations in the UK and EU institutions/Member states in the EU; ii) evidence from the desk research suggesting companies in emerging tech often choose the US and/or the UK over the EU, iii) the prominence of the three countries in technology development in the context of growing competition from China.

The "innovation first, regulation later" approach in the US and the UK versus the pre-emptive consumer-protection focused regulatory approach in the EU

The regulatory approach taken by the EU to emerging technologies differs from the those in the US and the UK in that it tends to be more precautionary in nature, more focused on consumer protection and ethical standards, hence perceived by some observers as more restrictive. The US approach could be considered as the opposite to the EU[173] due to its rather flexible, market-driven and less risk-averse nature. When it comes to the UK, the regulatory approach is less flexible compared to the US and closer to the EU in that it is focused on consumer protection. However, the UK adopts an incremental approach to regulating innovations (i.e. more of "wait and see" mentality – see the AI regulation example below). The analysis of the regulatory approaches across the three jurisdictions can be summarised across key areas and is presented in the table below.

Table 9. Comparative analysis of US, UK and EU regulatory approaches to innovation

Area	US	UK	EU
Regulatory approach	Decentralised and market-driven	Centralised and pro-active (regulatory oversight and consumer protection)	Standardised across Member States, drawing on the EU regulation and

[173] Even if this has been changing over the last years under the influence of trade relations with the EU, e.g. GDPR-inspired laws were adopted at the state level. See details : https://www.lawfaremedia.org/article/a-comparative-perspective-on-ai-regulation

			the national-level implementation
Government involvement	Private/third sector-driven, with federal and state support (except for health, defence, space sectors where the federal support plays a key role); strong regulatory fragmentation (federal/state level)	Strong government funding and coordination	Strong funding and coordination at EU level through Horizon Europe and similar framework programmes (however, coordination issues exist due to regulatory fragmentation)
Scale	Large-scale with regional variations and given federal/state level fragmentation (size of the market, current capabilities, high concentration of tech companies of global standing)	Medium scale with international collaboration (esp. post-Brexit)	Large-scale given the potential of the single market for cross-border collaboration with focus on scalability and interoperability)
Risk appetite	High risk tolerance, focus on innovation uptake (faster innovation cycle)	Moderate risk-aversion with focus on consumer protection with incremental and sectoral response to emerging technologies	Strong focus on consumer protection, ethical standards and regulatory compliance across all Member States; pre-emptive or anticipatory approach to regulating new technologies
Sandboxes characteristics	Few federal sandboxes, more state-level initiatives (due to fragmented regulatory landscape), including "sandbox-like" testing environments but with fewer formalised processes	Sector-specific sandboxes, particularly strong in fintech, AI, formalised as fully-fledges sandboxes and centrally coordinated	Sectoral sandboxes with focus on AI, fintech, and blockchain operating under strict regulatory environment and more conservative in nature
Sector focus	AI, autonomous vehicles, biotech, and space tech.	Fintech, AI, 5G, health-tech	AI, blockchain, digital sovereignty, green-tech.
Cross-border collaboration	Some cross-border collaboration, but more regionally specialized (e.g. North American partnerships)	High collaboration with the EU and international partners post-Brexit	High cross-border collaboration within the EU, focus on scalability and interoperability across the single market

Source: Author`s analysis based on desk research.

AI regulation is at the top of the agenda in many countries since the emergence of generative AI models (e.g. ChatGPT) with different approaches taken in the US, the UK and the EU. For instance, the EU took a horizontal and risk-based approach to AI regulation in its AI Act (adopted in May 2024), considered quite restrictive by some business stakeholders[174], whereas the US and the UK have a more flexible and principles-based approach (see Appendix 6 for more details) regarded as less risk-averse. These approaches are reflective of regulatory cultures described above.

If comparing the EU approach to regulatory innovation versus the US one, it is worth noting that in the US, the regulators at federal level use guidance, no-action letters (i.e. letters stating that no enforcement action against a specific entity will be taken under certain conditions) and pilot programmes (i.e. to test specific regulatory arrangements for a limited

[174] For instance, the survey by the Allied for Startups showed that 50% of startups surveyed are concerned that the AI Act will slow down AI innovation in Europe. Source : https://alliedforstartups.org/2023/01/26/summary-exploring-the-impact-of-the-ai-act-on-startups-in-europe-survey/.

period of time under certain conditions) rather than formal sandbox regulations to enable innovative firms to test their product and services. This approach could be explained by the fragmented regulatory system with federal and state jurisdictions overlap and duplication of functions, often complemented by the gap in legislation to allow for better coordination and cooperation between these jurisdictions.

In the U.S., the few examples of federal regulatory sandboxes are in the field of **fintech**[175]. This could be explained by the fintech sector modular and digital nature (easier to isolate for testing without impact on broader systems), dynamic regulatory landscape in financial services (tend to be more flexible and adaptable than in cleantech or biotech which are known to be very rigid due to health, safety and environment risks), fintech`s key role in driving economic growth in the U.S., and the rapid pace of innovations in fintech.

However, given the high level of regulatory fragmentation in the financial sector, operating a sandbox at the federal level is very challenging without amendments to legislation that would allow closer coordination between the federal and state regulators. Currently, no existing U.S. agency has the authority to impose a uniform state-federal sandbox framework and there is a lack of coordination between agencies in federal and state levels[176] (see Appendix 6 for more details). To address regulatory fragmentation, the US has been resorting more to 'soft instruments' (e.g. no-action letters) enabling innovation and experimentation rather than fully-fledged regulatory sandboxes at federal or state level.

In the UK, the approach to regulatory innovation has been similar to the US in its flexibility even if more focused on consumer protection and safety. In the case of fintech, the UK was a pioneer in introducing a dedicated sandbox in 2016. In 2023, the UK has announced taking the next step in regulatory experimentation in fintech building on the previous experience. Its new legislation, i.e. the Financial Services and Markets Act, not only delegates to HM Treasury the power to introduce financial markets infrastructure (FMI) sandboxes to facilitate the testing of new technologies, but also delegates the power to HM Treasury to disapply or modify certain legislation and regulations based on the results of the FMI sandboxes. This was considered as an important step towards ensuring the regulation is more agile in the face of the technological development in financial sector. The power to alter the regulation permanently based on the FMI results is a totally new element which is expected to generate more certainty for innovators and foster fintech innovations. In the EU, similar reflexion on the opportunities to be seized in emerging technologies in financial sector took form of a Distributed Ledger Technologies (DLT) Pilot Regime[177]. However, the DLT is set to run until 2026 based on the current legislation with ambiguity around its continuation beyond 2026 proving to have negative effect on applications to DLT by innovators[178]. The important element of ensuring certainty around the potential deployment of the new technology is better achieved in the UK case than in the EU case.

Depending on the sector, the variety of regulatory mechanisms to promote innovation could differ so as to better address the specificities of the sector. In the case of **energy** sector, in the UK, the Office of Gas and Electricity Markets (Ofgem) is running a Energy Regulation Sandbox (ERS) since 2020. In addition to a time-limited trial with the application of regulatory derogations, the ERS has other tools to facilitate the entry of new technologies and services into the market, namely a guidance, letters of comfort (agreeing and specifying

[175] This fact is also highlighted by Sherkow, Jacob S., Regulatory Sandboxes and the Public Health (February 1, 2022). University of Illinois Law Review, vol. 2022, pp. 357-410, Available at SSRN: https://ssrn.com/abstract=3792217.

[176] Review, T.R. (2021) *A sandbox for the u. S. Financial system | the regulatory review*. Available at: https://www.theregreview.org/2021/08/19/rossi-martins-sandbox-for-us-financial-system/ .

[177] ESMA (no date) *DLT Pilot Regime*. Available at: https://www.esma.europa.eu/esmas-activities/digital-finance-and-innovation/dlt-pilot-regime.

[178] ESMA (2024) 'Letter to the EU institutions on the DLT Pilot Regime Implementation '. ESMA. Available at: https://www.esma.europa.eu/sites/default/files/2024-04/ESMA75-117376770-460_DLT_Pilot_Regime_-_Letter_to_EU_Institutions.pdf.

what a compliant behaviour is for the period of the trial), and letters of confirmation (not an endorsement) to support the launch into the market. The evaluation of the sandbox activity has proved its relative success and usefulness for the participants and the regulator.

However, a new direction in regulatory experimentation in the UK has been taken with the recent launch of the Future Regulation Sandbox (FRS), which will not only allow the innovators to test their ideas in a live energy environment, but also allow regulators to test and trial changes to the energy rulebook in a controlled environment before introducing them to the regulatory framework. Such a combination of a product and policy-testing environment in one regulatory tool, FRS, is expected to inform the decisions on repealing or amending current regulation which is considered as 'outdated' by the majority of market stakeholders, and introducing new rules or guidance[179], to make regulations more fit for the rapid technology change and address the 'pacing problem'.

Hence, both the FMI and the FRS are the examples of a government attempting to address the pacing problem and thus ensure that regulation is able to keep up with the rapid technological advancements with benefits for the economy and society as a whole.

Implications for the EU:

- The current innovative approaches to fintech and energytech regulation in the UK highlighted the importance of adapting the legislation to capture the benefits of latest technological developments in the respective markets. The amendments in the legislation allowed for permanent changes to be made based on the results of the regulatory experimentation spaces in order to create the much-needed certainty for innovators and support the emerging technologies uptake. Thus, HM Treasury was empowered to amend, repeal, and revoke existing legislation to accommodate new technologies[180] in the case of DSS. In the EU, for instance, the DLT Pilot Regime does not guarantee permanent changes to the EU financial services legislation, or at least this has not been specified in the legislation in a clear way, and it creates uncertainty for the companies who hesitate to apply to the scheme. In addition, the UK regulatory authorities are moving towards a model of regulatory experimentation space that allows to test the introduction of new regulations and to do policy-testing within the sandbox, so as enable a more agile regulatory environment for new technologies (e.g. the case of FRS).
- In the US, given significant regulatory fragmentation (between the federal and state levels), the approach to regulatory experimentation is based on "soft tools" that are nor formally a regulatory sandbox. For instance, the no-action letters are being used to allow for some experimentation in fintech, energy-tech. In the UK, a similar approach in energy-tech can be observed. Here, letters of comfort and letters of confirmation serve to a means to support the product testing in the market. The EU could consider to which extent this "soft" approach could be used to catalyse emerging technologies in specific fields.

Testbeds as widely used tool for new technology testing and uptake across sectors: experiences from the US and the UK

Testbeds have become a relatively 'universal' means to test new technologies without regulatory derogations applied, with the aim of fostering innovation across industries to address pressing socio-economic challenges. The wealth of experiences in testbeds

[179] Ofgem (2023) 'Proposal to introduce the Future Regulation Sandbox'. Available at: https://www.ofgem.gov.uk/sites/default/files/2023-10/Proposal%20to%20introduce%20the%20Future%20Regulation%20Sandbox%20CfI%20final.pdf.

[180] Ryan Nabil, *How Regulatory Sandbox Programs Can Promote Technological Innovation and Consumer Welfare. Insights from Federal and State Experience*. Competitive Enterprise Institute, Aug 17, 2022. Available at https://cei.org/wp-content/uploads/2022/08/Ryan_Nabil_-_Regulatory_Sandboxes-3.pdf

implementation across different counties provides substantial grounds for learning, exchange of knowledge and practices, but also perspectives on the means for implementation. Testbeds across the US, the UK and the EU have several common observable characteristics, such as:

- multi-stakeholder/ partner structure (involvement of academia, private sector and public institutions);
- focus on solution to real-life challenges and supporting wider policy objectives across energy, industry, climate, etc.;
- cross-sectoral nature (e.g. smart city testbeds including solutions across mobility, energy, health, etc.);
- local rooting, i.e. implemented at the level of a city or a region, often providing place-based solutions to challenges;
- important role of state funding and support.

At the same time, there are several differences in testbed implementation practices across the three jurisdictions that are noticeable across the following areas:

- private sector involvement (relatively higher in the US as the companies are invited to co-develop the experimentation spaces, and comparatively lower in the EU and the UK where companies are engaged but in a more structured way)
- technological specialisation (the US is more focused on autonomous vehicles with a declared global leadership goal; the EU focuses on cleantech to meet Green Deal objectives, the UK has a historical strength in fintech and focuses on health-tech).

In the US, the approach to testbeds is decentralised with testbeds initiated both at the federal and state levels. The testbeds receive public funding, but private sector plays crucial role in provision of testing environment for innovators drawing on the more market-driven approach to innovation policy and building on existing pool of large tech companies in the US investing in innovation (e.g. Amazon, Google, Microsoft). At federal level, the testbeds often support US global leadership goals across areas such as AI, autonomous vehicles, space exploration. For example, the Federal Aviation Administration (FAA) oversees testbeds for drone technology, NASA runs testbeds for space technologies and the National Institute of Standards and Technology (NIST) runs a testbed on cybersecurity[181]. Cities are major players in enacting testbeds to find solutions to pressing socio-economic challenges. Thus, the New York City Smart City Testbed is focused on innovation for urban services delivery and efficiency, bridging digital divide, and enhancing social impact in communities. The City of Columbus, Ohio, launched a Smart Columbus Operating System (SCOS) in partnerships with private companies, research institutions, and the U.S. Department of Transportation to test new technologies in autonomous vehicles, intelligent transportation systems, and mobility-as-a-service solutions, in a real-world urban environment. Another example is the Virginia Smart Community Testbed which is a multi-partner testbed focused on potential solutions in four broad areas: public safety, data security and training, economic development and tourism, and use of 5G technology and broadband.

In the UK, the approach to testbeds is more centralised with the government playing a key role in fostering testing environments, notably through funding initiatives such as Innovate UK. The National Health Service (NHS) has been a prominent actor in testbed implementation running several testbeds, including, for example, the AI Lab[182] that aims to accelerate the safe adoption of artificial intelligence in health and care. The testbeds bring

[181] *NIST promotes testbed to address threats targeting ML systems* (2022) *Nextgov.com*. Available at: https://www.nextgov.com/cybersecurity/2022/07/nist-promotes-testbed-address-threats-targeting-ml-systems/374221/ .

[182] *The NHS AI Lab* (no date) *NHS Transformation Directorate*. Available at: https://transform.england.nhs.uk/ai-lab/ .

together innovation, industry and the NHS to tackle some of the biggest challenges facing the healthcare system, such as diabetes, mental health, long-term conditions treatment, etc[183]. For instance, the Lancashire and Cumbria Innovation Alliance (LCIA) testbed gathers industry (Philips), SMEs, social enterprises with the aim to develop solutions for the frail elderly population with dementia in the Lancashire and Cumbria geography to ensure that they remain well outside of hospital and avoid unnecessary admissions[184].

The EU's approach to testbeds is relatively standardised and builds on the EU regulatory frameworks with some variations at the Member State level. The Open Innovation Testbeds launched by the EU are an example of an attempt to shape innovation landscape and facilitate the testing and uptake of new and emerging technologies across the EU. The multi-partner and multi-country approach contributes to exchange of practices and cross-country collaboration fostering collaboration rather than competition across the EU Member States and ensuring the scalability of technologies in the single market. The testbeds in the EU are also closely aligned with and directly contribute to achieving the strategic goals set in energy, climate, innovation and other policies and are funded through large-scale public funding programmes such as Horizon Europe or Digital Europe.

Implications for the EU:

- US testbeds are driven by the private sector which invests in these testing environments more than in the EU and the UK. Given public budgets constraints across the EU Member States and at the EU level, there is merit in considering means for enhancing the engagement of the private sector in driving the testing of emerging technologies.

[183] NHS (no date) *NHS Test Beds programme*. Available at: https://www.england.nhs.uk/aac/what-we-do/how-can-the-aac-help-me/test-beds/nhs-test-beds-programme/ .

[184] NHS (no date) *Lancashire and Cumbria Innovation Alliance (LCIA)*. Available at: https://www.england.nhs.uk/aac/what-we-do/how-can-the-aac-help-me/test-beds/lancashire-and-cumbria-innovation-alliance-lcia/.

3. Conclusions and recommendations

3.1. **Conclusions**

Regulation is an important bottleneck for the development and uptake of emerging technologies

The study findings show that regulation presents significant bottlenecks for EIC beneficiaries. Innovators working with emerging technologies often face complex and burdensome regulatory requirements that can be particularly challenging for small and medium-sized enterprises (SMEs) and startups operating with limited resources or in fast-evolving sectors. These bottlenecks can increase the time and cost required to bring new innovations to market, hindering the development of high-risk, high-reward technologies. Compliance demands can discourage investment and slow down the pace of innovation – or encourage companies to move to countries with more flexible regulatory environment. Examples of these impacts were reported by EIC beneficiaries both through the survey and in the case studies.

Moreover, the findings show that especially EU level regulation is presenting challenges for the EIC beneficiaries. Indeed, according to a survey for EIC beneficiaries, 44 % of respondents reported EU legislation/regulation as hampering market uptake of emerging technologies. Especially EIC beneficiaries working with biotechnologies (67 % of respondents) and deep and digital technologies (52 %) consider EU legislation / regulation as a bottleneck. In comparison, on average only 20 % considered the same for national regulation/legislation. This is likely to be explained by the fact that the EIC beneficiaries are typically working in international projects and aiming for international markets and are therefore more concerned with EU level regulations.

However, it should also be emphasised that many emerging technologies come with significant – often also unknown – risks (to consumer safety, data privacy, environment, etc), and therefore regulation is often in place for a good reason. Thus, when discussing regulatory barriers for emerging technologies, careful consideration should be applied to differentiate between regulations that are essential – despite the resulting regulatory burden – to safeguard against potential negative impacts, and regulations that are outdated and/or poorly adapted to the latest technological developments. Making this distinction would require an extensive case-by-case analysis beyond the scope of this study.

However, findings from survey and cases studies indicate that for the EIC beneficiaries, the regulatory bottlenecks are related to both certain specific regulations and provisions (particularly Medical Device Regulation (MDR), In Vitro Diagnostic Medical Devices regulation (IVDR), AI Act, Machinery Directive, CE Marking Directive were identified by the EIC beneficiaries), as well as to more general regulatory challenges such as:

- Overall compliance burden resulting from the amount of (new) regulatory demands and complexity. This can be especially difficult for startups and SMEs with limited resources.
- Fragmented regulation/implementation across EU member states making it difficult for companies to achieve broader adoption of their innovations.
- Implementation of the regulation (e.g. differing interpretations, short transition periods, etc.).
- Competitive disadvantage of new technologies compared to incumbent technologies / lack of market incentives for new solutions, including public sector procurement practices.

- Uncertainty of future regulations resulting in anxiety and delayed investment decisions.
- Lack of (EU level) regulation (see below).

The table below summarises regulatory challenges that were identified during the study from consultation activities with EIC beneficiaries and stakeholders. They are differentiated by the stage of development of innovations, as different regulatory challenges occurred in early stage innovations compared to later stage innovations.

Table 10. Summary of regulatory challenges.

Stage of development	Regulatory challenges	Unregulation or under-regulation
Development, testing and piloting	- Existing regulations make testing and development of new technologies **long and cost-intensive, which discourages investments** (e.g. data privacy rules or requirements within clinical trials for medical equipment).	- Uncertainty in current regulation and future regulatory developments, and lack of regulatory direction **discourages investments for developing new innovations**, particularly in areas with long development-cycles (e.g. biotech).
Scaling and market adoption	- Compliance burden **favours incumbent operators** and large companies compared to start-ups and SMEs. - Regulation that is not tailored to novel technologies make it unclear whether or not it might apply to novel technologies and **may favour incumbent solutions**. - Public procurement practices may **favour incumbent technologies**	- Fragmentation of regulatory framework across EU Member States **makes scaling slow and cost-intensive**, affecting especially innovations aiming for international scaling. - Lack of regulation or market incentives may create a **competitive disadvantage for the uptake of new technologies** compared to existing technologies.

Lack of regulation creating legal uncertainty

As highlighted above, the study findings support the conclusions that the *lack of regulation* can also create significant legal uncertainty for innovators, who are left without clear guidelines on compliance, safety, and market entry requirements. Findings suggest that the absence of established regulations can lead to delays in product development and market entry, as companies may need to navigate ambiguous legal landscapes or face the risk of future regulatory changes that could impact their business models. This gap between technological advancement and regulatory oversight can create an environment of uncertainty, where innovators are unsure about the long-term regulatory landscape, potentially deterring investment and slowing down innovation. The absence of regulation in certain emerging technology sectors (such as digital- or biotechnologies) can lead to consumer and market hesitancy. Without regulatory guidance, there may be concerns about the safety, efficacy, or ethical implications of new technologies, which can impact public trust and market adoption. This regulatory uncertainty can slow down the uptake of new technologies, as both consumers and businesses may be reluctant to engage with products or services that lack clear regulatory backing.

In fact, as indicated by the study findings, many EIC beneficiaries operate in areas where no specific regulatory frameworks exist at either the EU or national levels. When asked about the challenges created by legal uncertainty, 40 % of respondents agreed or completely agreed that legal uncertainty in relation to emerging technologies (due to the lack of legislation and/or regulation at the EU or national level) creates challenges to develop or market products or services related to emerging technologies. Examples of the impacts resulting from the lack of regulation were identified also in most of the case studies (see for example case studies on Kraftblock, Clean HME, IQM, E.T. PACK-F or CATCHER).

Experimentation spaces provide opportunities for regulatory learning but should be seen as part of broader policy mix

Regulation has a pivotal role in supporting the development and market uptake of emerging technologies. In some cases it can create bottlenecks for innovators, while in some cases it can act as a driver by creating direction and demand for new innovations. In both cases, it is essential to aim for flexible and anticipatory development of regulatory frameworks. Regulatory experimentation spaces such as regulatory sandboxes, testbeds and living labs can be useful tools for this purpose. Each of these examples have their specific characteristics as well as pros and cons for both innovations and regulators:

Regulatory sandboxes (as commonly defined) can provide a controlled environment where high-risk, high-reward innovations can be tested, refined, and brought closer to market. Sandboxes allow innovators to test products and services under regulatory supervision without being subject to the full scope of regulations. Sandboxes are likely to be most beneficial for technologies with higher technology readiness levels (TRLs) as they are already closer to market and hence more likely to face regulatory demands, which can be addressed in the sandbox. Regulators can use sandboxes to assess the impact of potential regulatory changes or adaptations before implementing them across the board, which helps in fine-tuning regulations based on empirical evidence. Therefore, regulatory sandboxes could be especially useful for emerging technologies with ongoing or planned regulatory reforms. While regulatory learning is typically an integral part of regulatory sandboxes, it should be noted that concept of regulatory sandboxes is used very broadly which can cause some confusion (see the following conclusion). Also, there is currently very little evidence of the impact of sandboxes on future development of regulations, especially on EU level.

Testbeds can provide a platform for early-stage technologies to demonstrate their potential in a real-world setting, and help securing further investment or regulatory approval. Testbeds are most valuable in sectors requiring rigorous technical validation, such as telecommunications (e.g., 5G networks), smart cities, and IoT. They provide a controlled environment to assess the performance, safety, and interoperability of technologies. In areas where industry standards are critical, testbeds are useful for developing, testing, and validating standards, ensuring that new technologies are compatible with existing systems. However, testbeds are less useful in sectors, where technical validation is not required and/or feasible. For regulators, testbeds could offer an opportunity to anticipate technology trends and get information for technical regulations and standards. However, as indicated by the previous literature and study findings, it seems that the role of regulators is typically very limited and there is a need to further develop regulatory learning mechanisms in testbed contexts.

Living labs offer an environment where technologies can be tested with actual users under controlled but realistic conditions. This can be especially beneficial for technologies that require user interaction and collection of feedback and data, which can be used to validate or refine the technology and ensure it meets market needs – such as smart city solutions, autonomous vehicles, and urban development. Living labs, especially if combined with public procurement, can also be particularly useful for innovators developing solutions for the public sector. For regulators, living labs could provide opportunities to anticipate and understand the socio-technical aspects and impacts of emerging technologies. Yet, similar to testbeds, while public authorities (especially cities and regional authorities) are often key stakeholders in living labs, it seems that regulatory learning is not systematically integrated with living labs.

While the different experimentation spaces can be useful tools for enhancing the development and market uptake of emerging technologies, it should be highlighted that they are only one part of the toolbox, and should always be combined with a broader policy mix. There needs to be a clear pathway from these experimental environments to full-scale deployment. This includes support for scaling, such as access to funding, mentorship, and

regulatory guidance. In addition to these tools, a broader innovation ecosystem that includes policy support, investment in research and development, and strong intellectual property protection is crucial. Experimentation spaces could be used as hubs or platforms to facilitate this broader systemic change. However, regulators should be aware of not using regulatory experimentation in cases, where the regulatory needs and options are already well-known, and there is actually no need for regulatory learning trough experimentation.

Especially for technologies that require significant capital investment or infrastructure, such as large-scale industrial innovations, the resources available for experimentations might be insufficient. Also, innovators working with emerging technologies often operate across multiple regulatory domains, such as digital health tools (which combine medical, data privacy, and AI regulations), and face complex and overlapping regulatory requirements. Addressing these systemic challenges through experimentation spaces can be tricky.

Furthermore, based on the findings of the study, only few EIC beneficiaries have utilised the different experimentation spaces. Interviews with EIC programme managers also revealed a low awareness of regulatory experimentation spaces. This suggests that there is a lack of knowledge and awareness of these spaces, and/or the experimentation spaces available are not fully relevant to or do not meet the needs of the EIC beneficiaries.

Building on the findings from the case studies, mapping of experimentation spaces, as well as from previous literature, Table 11 provides a summary of identified benefits and potential limitations of the different experimentation spaces.

Table 11. Summary of benefits and limitations of experimentation spaces.

	Primary benefits for innovators	Primary benefits for regulators	Limitations for regulatory learning
Regulatory sandboxes	- Access regulatory expertise - Increase regulatory certainty	- Developing / adjusting regulations around emerging tech (e.g. as part of regulatory reforms)	- Need for regulatory framework / exemption clauses can cause challenges - Feedback loop for addressing the identified regulatory challenges
Testbeds	- Testing and technical validation of new technologies	- Anticipating tech trends - Feedback for technical regulations and standards	- Role of regulators typically limited, regulatory learning not systematically integrated - Less useful for non-technical innovations
Living labs	- User interaction, collection of feedback and data - Market validation	- Anticipate and understand the socio-technical aspects of emerging tech - Links to public procurement	- Regulatory learning not systematically integrated into Living Labs

European landscape of experimentation spaces is very heterogeneous – more evidence of impacts is needed

The mapping of regulatory experimentation spaces revealed a diverse landscape of regulatory experimentation spaces. Living labs are the most prevalent, reflecting their well-established role in Europe. They typically focus on real-world, market-ready technologies across various sectors, including digital and clean technologies (e.g. smart city solutions). Regulatory sandboxes, although fewer in number, demonstrate considerable variety, particularly in the deep and digital technologies space.

While the diversity of the landscape can be considered as an advantage, the lack of shared definitions and criteria, especially in regulatory sandboxes, can also be a disadvantage, leading to inconsistency in how these initiatives are applied and understood. This can create confusion for stakeholders and hinder broader adoption or scalability. For example, it should

be noted that many regulatory sandboxes identified as part of this study do not include any regulatory derogations, but rather operate as 'advisory hubs' or 'help-desks' supporting companies' compliance with existing regulations, as well as providing a platform for dialogue between innovators and regulators. This does not mean that the initiatives are not useful or relevant – on the contrary, in many cases setting up these types of initiatives can actually be more feasible given the complexity in designing regulatory sandboxes with exemptions and experimentation clauses.

Overall, there is very limited evidence base on the impact of regulatory experimentation on innovation. This could be explained by the short life span as well as the relative novelty of these approaches. In addition, national schemes of regulatory experimentation are quite varied, making it difficult to draw general conclusions on their effectiveness. There is, therefore, a need for a more consistent and robust approach to evaluation and data collection to ensure the effectiveness of these tools in fostering innovation.

3.2. Policy Recommendations

Develop and adopt a broad range anticipatory regulation approaches

While experimentation spaces are useful tools for advancing the market uptake of emerging technologies, they should be part of a broader policy mix that ensures clear pathways to full-scale deployment through funding, mentorship, and regulatory support.

EISMEA and the European Commission should therefore seek to continue the efforts to develop and disseminate a broad range of innovative and anticipatory practices and approaches, including but not limiting to regulatory experimentation spaces.

In practice this would mean to:

11. Proactively **anticipate future regulatory needs and assess regulatory challenges** to keep pace with technological advancements. This could include targeted in-depth technology-specific regulatory reviews (such as the recent European Commission study on virtual worlds), for example as part or in parallel to the EIC Tech reports.

12. Establish **sector-specific guidelines** especially in areas where formal regulations have not yet been developed, to provide interim clarity and reduce uncertainty for innovators. These can serve as a foundation for future regulatory frameworks. Regulatory experimentation can be designed to provide further insights and lessons for developing these frameworks.

13. Foster and support the **dialogues between regulators across different sectors and DGs, industry stakeholders, and innovators** to ensure that regulations remain relevant and are informed by the latest technological developments and market needs. This could be facilitated through experimentation spaces but also with less institutionalised approaches such as the Innovation Deals, workshops, advisory panels, and collaborative research initiatives.

14. Ensure and strengthen the **capacities and knowledge of regulators regarding emerging technologies and innovative legislation practices**, for example through dedicated trainings and networks, and continuing the implementation of the Better Regulation Toolbox. This should also include the ethical, environmental, and societal impacts of emerging technologies.

It should be noted that these recommendations are in line with the recent and ongoing actions by the European Commission and EISMEA (such as the Innovation Deals, development of innovative-friendly regulation guidelines, etc.). Figure 13 illustrates the different options for regulators for enhancing the development and market uptake of emerging technologies.

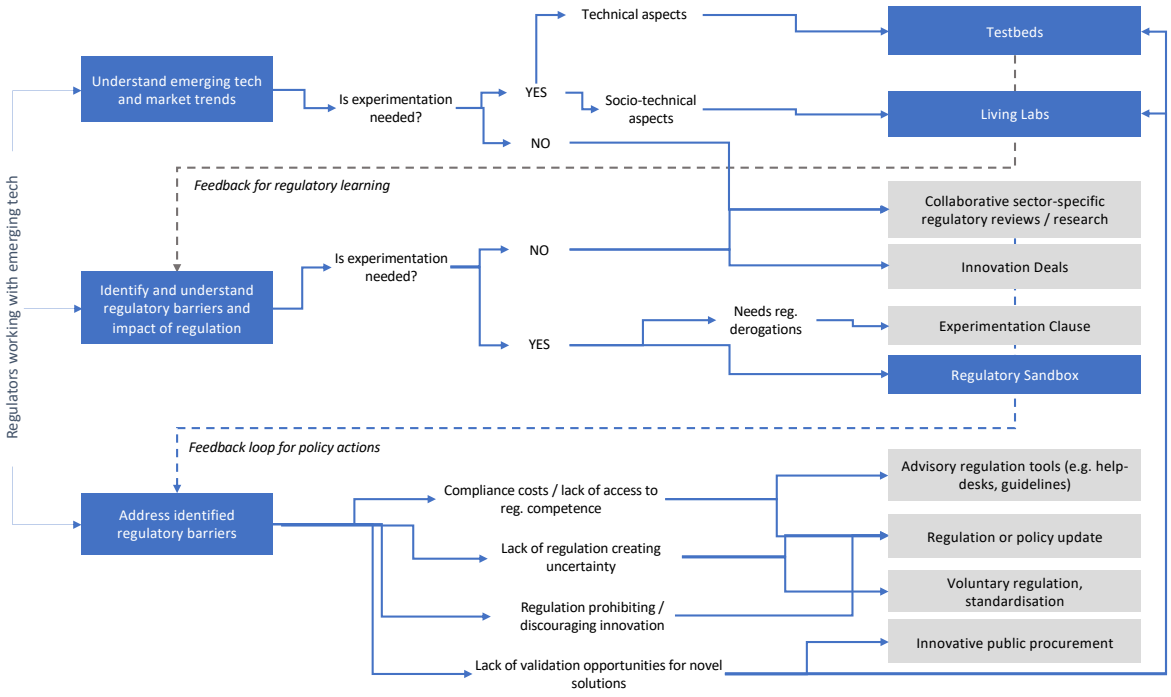

Figure 13. Decision guide for regulators to assess options for enhancing the development and market uptake of emerging technologies. Parts of the figure adapted from Jenik, I. & Staff, D. (2020).

Support the development of regulatory experimentation landscape

As part of the broader policy mix, EISMEA and the European Commission should seek to strengthen the efforts to support the development of regulatory experimentation landscape across EU and Member States.

In practice this would mean to:

15. **Raise awareness** of regulatory experimentation spaces particularly among EIC beneficiaries and EIC programme managers, to increase the uptake of and participation in regulatory experimentation spaces. This could include for example the development of sector-specific guidedance documents and fact sheets ("to which door to knock"), in collaboration with relevant innovation intermediaries for each sector.

16. **Establish frameworks for cross-border regulatory sandboxes** that allow companies to test solutions under consistent regulatory conditions in multiple EU countries, especially for technologies with international applicability (e.g. AI and IoT).

17. **Set up an EU-level platform / network for collecting and sharing guidelines and best practices** for defining, designing, implementing and evaluating regulatory experimentation spaces. These guidelines could cover aspects such as eligibility criteria, data-sharing protocols, ethics, and consumer protection standards, as well criteria for monitoring and evaluation the effectiveness of different approaches to ensure the quality and comparability.

18. Develop and disseminate practices to **integrate regulatory learning more systematically to living labs and testbeds.** Consider integrating policy-testing into regulatory experimenation tools to accelerate regulatory learning and enable regulatory change necessary to accompany the deployment of new technologies.

19. Integrating experimentation spaces with other innovation support programmes (such as EIC funding programmes), as well as with programmes supporting innovative public procurement practices (e.g. Cities Mission) to engage EIC beneficiriares with potential public sector reference clients.

20. Organising **workshops and forums** that bring together regulators, innovators, and stakeholders to discuss outcomes and best practices.

4. References

References for Appendices provided in Appendix footnotes (not included in the list).

Aghion, Philippe et al., Competition and Innovation: an Inverted-U Relationship, *The Quarterly Journal of Economics*, Volume 120, Issue 2, May 2005, Pages 701–728, https://doi.org/10.1093/qje/120.2.701

Armstrong, H., Gorst, C., Rae, J. (2019) Renewing regulation. 'Anticipatory regulation' in an age of disruption. Nesta.

Armstrong, H. et al (2020) Regulator approaches to facilitate, support and enable innovation. Final report. BEIS Research Paper Series Number 2020/003.; European Commission (2023).

Arrow, K.J. (1962) Economics Welfare and the Allocation of Resources for Invention. In: The Rate and Direction on Incentive Activity: Economic and Social Factors, National Bureau of Economic Research, Princeton University Press, Princeton.

Attrey, A., Lesher, M. and Lomax, C., 'The role of sandboxes in promoting flexibility and innovation in the digital age', Going Digital Toolkit Policy Note 2, 2020.

Bakker, S., 2014. Actor rationales in sustainability transitions - Interests and expectations regarding electric vehicle recharging, in: Environmental Innovation and Societal Transitions. Elsevier B.V., pp. 60–74. https://doi.org/10.1016/j.eist.2014.08.002

Bauer, J.M., Bohlin, E., 2022. Regulation and innovation in 5G markets. Telecomm Policy 46. https://doi.org/10.1016/j.telpol.2021.102260

Beckstedde, E., Correa Ramírez, M., Cossent, R., Vanschoenwinkel, J., Meeus, L., 2023. Regulatory sandboxes: Do they speed up innovation in energy? Energy Policy 180. https://doi.org/10.1016/j.enpol.2023.113656

Bijkerk, W., 2021. Regulatory Sandboxes, Innovation Hubs, and Other Regulatory Innovation Tools in Latin America and the Caribbean. Inter-American Development Bank.

Blind, Knut & Thumm, Nikolaus. (2004). Interrelation between patenting and standardisation strategies: Empirical evidence and policy implications. Research Policy. 33. 1583-1598. 10.1016/j.respol.2004.08.007.

Blind, Knut, (2012), The influence of regulations on innovation: A quantitative assessment for OECD countries, *Research Policy*, 41, issue 2, p. 391-400, https://EconPapers.repec.org/RePEc:eee:respol:v:41:y:2012:i:2:p:391-400.

Bovera, F., Lo Schiavo, L., 2022. From energy communities to sector coupling:a taxonomy for regulatory experimentation in the age of the European Green Deal. Energy Policy 171. https://doi.org/10.1016/j.enpol.2022.113299

Bremer, S., Halamoda, K.B., Borgos, S.E., 2017. Identification of regulatory needs for nanomedicines: 1st EU-NCL survey with the "Nanomedicine" working group of the international pharmaceutical regulators [WWW Document]. JRC Publications Repository. https://doi.org/10.2788/585950

Brévignon-Dodin, L., 2010. Regulatory enablers and regulatory challenges for the development of tissue-engineered products in the EU, in: Bio-Medical Materials and Engineering. pp. 121–126. https://doi.org/10.3233/BME-2010-0623

Brévignon-Dodin, L., Livesey, F., 2006. Regulation of tissue-engineered products in the European Union: where are we heading? Regenerative Med 1, 709–714. https://doi.org/10.2217/17460751.1.5.709

Byrne, T., Murray, N., McDonnell-Naughton, M., Rowan, N.J., 2023. Perceived factors informing the pre-acceptability of digital health innovation by aging respiratory patients: a

case study from the Republic of Ireland. Front Public Health 11. https://doi.org/10.3389/fpubh.2023.1203937

Cabling, M., Marciniak-Nuqui, Z., Marjanovic, S., 2022. Microbiome-Based Health and Wellness Innovation: Reflecting on Regulatory Challenges and Needs. URL https://www.rand.org/pubs/commentary/2022/07/microbiome-based-health-and-wellness-innovation-reflecting.html (accessed 5.7.24).

CEPA, 2021. Evaluation of the Innovation Link: Ofgem.

Copenhagen Economics, 2023. Regulatory data protection – How adopting regulatory data protection can increase medicine availability, innovation, and investment.

Corbett, M.S., Webster, A., Hawkins, R., Woolacott, N., 2017. Innovative regenerative medicines in the EU: A better future in evidence? BMC Med 15. https://doi.org/10.1186/s12916-017-0818-4

Council of the European Union (2020) Council Conclusions on Regulatory sandboxes and experimentation clauses as tools for an innovation-friendly, future-proof and resilient regulatory framework that masters disruptive challenges in the digital age.

Council of the European Union (2018) Council Regulation establishing the European High Performance Computing Joint Undertaking.

Council of the European Union (2021) Council Regulation establishing the European High Performance Computing Joint Undertaking and repealing Regulation (EU) 2018/1488

Douglas, C.M.W., Stemerding, D., 2014. Challenges for the European governance of synthetic biology for human health. Life Sci Soc Policy 10. https://doi.org/10.1186/s40504-014-0006-7

EIB (2024) EIB Investment Survey 2024 - European Union overview. EIB, 23 Oct 2024. https://www.eib.org/en/publications/20240238-econ-eibis-2024-eu

EIC (2022). Identification of Emerging Technologies and Breakthrough Innovations, EIC Working Paper 1/2022.

El-Shagi, M., Michelsen, C., Rosenschon, S., 2014. Regulation, Innovation and Technology Diffusion: Evidence from Building Energy Efficiency Standards in Germany. https://doi.org/10.2139/ssrn.2432978

Engels, F., Wentland, A., Pfotenhauer, S.M., 2019a. Testing future societies? Developing a framework for test beds and living labs as instruments of innovation governance. Res Policy 48. https://doi.org/10.1016/j.respol.2019.103826

Engels, F., Wentland, A., Pfotenhauer, S.M., 2019b. Testing future societies? Developing a framework for test beds and living labs as instruments of innovation governance. Res Policy 48. https://doi.org/10.1016/j.respol.2019.103826

ENoLL (n/a) What are Living Labs. https://enoll.org/about-us/what-are-living-labs/ [accessed 19.11.2024]

ENoLL (2023), 2023 member catalogue. Available at: https://enoll.org/wp-content/uploads/2023/09/enoll-catalogue-2023_final.pdf

ESMA (2018) FinTech: Regulatory sandboxes and innovation hubs. https://www.esma.europa.eu/sites/default/files/library/jc_2018_74_joint_report_on_regulatory_sandboxes_and_innovation_hubs.pdf

European Central Bank (2024) Survey on the Access to Finance of Enterprises in the euro area. Third quarter of 2024.

European Commission: Better Regulation Toolbox, Tool 22. Research and Innovation.

European Commission. DG RI, Technopolis Group., Fraunhofer ISI., 4Front., 2022. Study on the costs and benefits of innovation-sensitive legislation. Publications Office, LU.

European Commission (1996) Green Paper on innovation. Document drawn up on the basis of COM(95) 688 final, Bulletin of the European Union Supplement 5/95, 1996.

European Commission (2021). Commission Staff Working Document on Better Regulation Guidelines.

European Commission (2021b) Proposal for a Regulation of the European Parliament and of the Concil Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) and Amending Certain Union Legislative Acts. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52021PC0206

European Commission (2023). Regulatory learning in the EU. Guidance on regulatory sandboxes, testbeds, and living labs in the EU, with a focus section on energy. Commission Staff Working Document, SWD(2023) 277/2.

European Commission (2023). Joint communication to the European Parliament, the European Council and the Council of "European Economic Security Strategy" JOIN(2023) 20 final.

European Commission. The European Quantum Communication Infrastructure (EuroQCI) Initiative. Accessed: 20.11.2024. https://digital-strategy.ec.europa.eu/en/policies/european-quantum-communication-infrastructure-euroqci

European Commission (2022) : Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions : a New European Innovation Agenda. COM/2022/332 final

European Commission (2024): Directorate-General for Research and Innovation, Emerging digital technologies in the public sector – The case of virtual worlds, Publications Office of the European Union

European Parliament, 2022. Artificial intelligence act and regulatory sandboxes.

European Parliament, 2018. The impact of Regulation (EC) No 1107/2009 on innovation and development of alternatives and new plant protection products (BRIEFING).

European Parlament and Council (2016). Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)

European Parlament and Council (2019). Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (Text with EEA relevance)

European Parlament and Council (2021). Regulation (EU) 2021/821 of the European Parliament and of the Council setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items.

European Parlament and Council (2021). Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items (recast)

European Parlament and Council (2022). Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive) (Text with EEA relevance)

European Parlament and Council (2023). Regulation (EU) 2023/588 of the European Parliament and of the Council of 15 March 2023 establishing the Union Secure Connectivity Programme for the period 2023-2027

European Parlament and Council (2023). Regulation of the European Parliament and of the Council establishing the Strategic Technologies for Europe Platform ('STEP') COM(2023) 335 final.

Faulkner, A., 2019. Special Treatment? Flexibilities in the Politics of Regenerative Medicine's Gatekeeping Regimes in the UK. Sci Cult (Lond) 28, 149–173. https://doi.org/10.1080/09505431.2017.1300641

Festag, A., 2015. Standards for vehicular communication—from IEEE 802.11p to 5G. Elektrotechnik und Informationstechnik 132, 409–416. https://doi.org/10.1007/s00502-015-0343-0

Filimonau, V., Mika, M., Pawlusiński, R., 2016. Public attitudes to biofuel use in aviation: Evidence from an emerging tourist market. J Clean Prod 172, 3102–3110. https://doi.org/10.1016/j.jclepro.2017.11.101

Flodén, J., Williamsson, J., 2016. Business models for sustainable biofuel transport: The potential for intermodal transport. J Clean Prod 113, 426–437. https://doi.org/10.1016/j.jclepro.2015.11.076

Gangale, F., Mengolini, A.M., Covrig, L., Chondrogiannis, S., Shortall, R., 2023. Making energy regulation fit for purpose. State of play of regulatory experimentation in the EU [WWW Document]. JRC Publications Repository. https://doi.org/10.2760/32253

Gardner, J., Webster, A., 2016. The social management of biomedical novelty: Facilitating translation in regenerative medicine. Soc Sci Med 156, 90–97. https://doi.org/10.1016/j.socscimed.2016.03.025

Gartner (2023) The Gartner 2023 Emerging Technologies and Trends Impact Radar.

General Secretariat of the Council (2020). Council Conclusions on Regulatory sandboxes and experimentation clauses as tools for an innovation-friendly, future-proof and resilient regulatory framework that masters disruptive challenges in the digital age, 12683/1/20 REV 1.

Giddings, V., 2022. Prospects for Transatlantic Cooperation in Biotech Policy—A U.S. Perspective. WITA. URL https://www.wita.org/blogs/transatlantic-cooperation-biotech/ (accessed 5.7.24).

Graef, I., Prüfer, J., 2021. Governance of data sharing: A law & economics proposal. Res Policy 50. https://doi.org/10.1016/j.respol.2021.104330

Grajek, M. and Röller, L.-H. (2012), Regulation and investment in network industries: evidence from European telecoms, Journal of Law and Economics, 55(1), pp. 189–216. Available at: https://econpapers.repec.org/article/ucpjlawec/doi_3a10.1086_2f661196.htm.

Grassi, L., Lanfranchi, D., 2022. RegTech in public and private sectors: the nexus between data, technology and regulation. Journal of Industrial and Business Economics 49, 441–479. https://doi.org/10.1007/s40812-022-00226-0

Hauray, B., 2017. From Regulatory Knowledge to Regulatory Decisions: The European Evaluation of Medicines. Minerva 55, 187–208. https://doi.org/10.1007/s11024-017-9323-3

Hojnik, J., Ruzzier, M., Manolova, T.S., 2018. Internationalization and economic performance: The mediating role of eco-innovation. J Clean Prod 171, 1312–1323. https://doi.org/10.1016/j.jclepro.2017.10.111

Huddleston, J., 2021. The Price of Privacy: The Impact of Strict Data Regulations on Innovation and More. URL https://www.americanactionforum.org/insight/the-price-of-privacy-the-impact-of-strict-data-regulations-on-innovation-and-more/ (accessed 5.7.24).

Jenik, I. & Staff, D. (2020) How to Build a Regulatory Sandbox? A Practical Guide for Policy Makers. CGAP, September 2020.

Joint Research Centre (2023). Making energy regulation fit for purpose. State of play of regulatory experimentation in Europe. https://publications.jrc.ec.europa.eu/repository/handle/JRC132259

Kalinauskaite, I., Brankaert, R., Lu, Y., Bekker, T., Brombacher, A., Vos, S., 2021. Facing societal challenges in living labs: Towards a conceptual framework to facilitate transdisciplinary collaborations. Sustainability (Switzerland) 13, 1–14. https://doi.org/10.3390/su13020614

Kang, I., Choung, J.Y., Kang, D. in, Park, I., 2021. Divergence of knowledge production strategies for emerging technologies between late industrialized countries: Focusing on quantum technology. ETRI Journal 43, 246–259. https://doi.org/10.4218/etrij.2019-0501

Kasprzyk, P., 2022. The Basic Premises of EU Regulations Regarding the Safety of Unmanned Aircraft in the Context of their Development Process. Journal of Intelligent and Robotic Systems: Theory and Applications 106. https://doi.org/10.1007/s10846-022-01733-x

Kent, J., Faulkner, A., Geesink, I., FitzPatrick, D., 2006. Towards governance of human tissue engineered technologies in Europe: Framing the case for a new regulatory regime. Technol Forecast Soc Change 73, 41–60. https://doi.org/10.1016/j.techfore.2005.06.006

Kerr, N., Winskel, M., 2022. Have we been here before? Reviewing evidence of energy technology phase-out to inform home heating transitions. Energy Res Soc Sci. https://doi.org/10.1016/j.erss.2022.102640

Kert, K., Vebrova, M. & Schade, S. (2022) Regulatory learning in experimentation spaces. Joint Research Centre, European Commission.

Knaack, P., 2015. Innovation and deadlock in global financial governance: transatlantic coordination failure in OTC derivatives regulation. Rev Int Polit Econ 22, 1217–1248. https://doi.org/10.1080/09692290.2015.1099555

Kostopoulos, K.C., Spanos, Y., Soderquist, K.E., Prastacos, G., Vonortas, N.S., 2019. Market-, Firm-, and Project-Level Effects on the Innovation Impact of Collaborative R&D Projects. Journal of the Knowledge Economy 10, 1384–1403. https://doi.org/10.1007/s13132-015-0342-8

Kratzer, J., Meissner, D., Roud, V., 2017. Open innovation and company culture: Internal openness makes the difference. Technol Forecast Soc Change 119, 128–138. https://doi.org/10.1016/j.techfore.2017.03.022

Kronsell, A., Mukhtar-Landgren, D., 2018. Experimental governance: the role of municipalities in urban living labs. European Planning Studies 26, 988–1007. https://doi.org/10.1080/09654313.2018.1435631

Kwon, S. and Marco, A.C. (2021), Can antitrust law enforcement spur innovation? Antitrust regulation of patent consolidation and its impact on follow-on innovations, *Research Policy*, 50(9), p. 104295. Available at: https://doi.org/10.1016/j.respol.2021.104295.

Lauber, K., Brooks, E., 2023. Why meta-regulation matters for public health: the case of the EU better regulation agenda. Global Health 19. https://doi.org/10.1186/s12992-023-00971-4

Letourneur, D., Joyce, K., Chauvierre, C., Bayon, Y., Pandit, A., 2021. Enabling MedTech Translation in Academia: Redefining Value Proposition with Updated Regulations. Adv Healthc Mater 10. https://doi.org/10.1002/adhm.202001237

Lewis, J.A., Lostri, E., Cheng, C., 2021. AI Strategies and Autonomous Vehicles Development.

Madaleno, M., Robaina, M., Ferreira Dias, M., Meireles, M., 2020. Dimension effects in the relationship between eco-innovation and firm performance: A European comparison, in: Energy Reports. Elsevier Ltd, pp. 631–637. https://doi.org/10.1016/j.egyr.2019.09.038

Makkonen, T., Inkinen, T., 2018. Sectoral and technological systems of environmental innovation: The case of marine scrubber systems. J Clean Prod 200, 110–121. https://doi.org/10.1016/j.jclepro.2018.07.163

Malanowski, N., Steinbach, J., Nisser, A., Beesch, S., Von, P.S., Van, D.V.E., Kretz, D., 2022. Techno-Economic study on the potential of European Industrial Companies regarding Europe's Green Deal [WWW Document]. JRC Publications Repository. https://doi.org/10.2760/037744

Mampuys, R., Brom, F., 2018. Emerging crossover technologies: How to organize a biotechnology that becomes mainstream? Environ Syst Decis 38, 163–169. https://doi.org/10.1007/s10669-017-9666-1

Niebel, C., 2021. The impact of the general data protection regulation on innovation and the global political economy. Computer Law and Security Review 40. https://doi.org/10.1016/j.clsr.2020.105523

OECD (2021). Recommendation of the Council for Agile Regulatory Governance to Harness Innovation. OECD/LEGAL/0464

Official Journal of the European Union (2017) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745

Official Journal of the European Union (2017) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. Available at: https://eur-lex.europa.eu/eli/reg/2017/746/oj

Official Journal of the European Union (2024) Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act).

Official Journal of the European Union (2024b) Regulation of the Parliament and the Council, establishing the Strategic Technologies for Europe Platform ('STEP') and amending Directive 2003/87/EC, Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241, COM(2023) 335 final.

Parenti, R., 2020. Regulatory Sandboxes and Innovation Hubs. European Union.

Payne-Gifford, S., Srinivasan, C.S., Dorward, P., 2021. Blunting EU Regulation 1107/2009: following a regulation into a system of agricultural innovation. Agric Human Values 38, 221–241. https://doi.org/10.1007/s10460-020-10183-w

Peña-García, A., Nguyen, T.P.L., 2018. A global perspective for sustainable highway tunnel lighting regulations: Greater road safety with a lower environmental impact. Int J Environ Res Public Health 15. https://doi.org/10.3390/ijerph15122658

Pita, R., Ehmann, F., Papaluca, M., 2016. Nanomedicines in the EU—Regulatory Overview. AAPS Journal 18, 1576–1582. https://doi.org/10.1208/s12248-016-9967-1

Pošćić, A., Martinović, A., 2022. REGULATORY SANDBOXES UNDER THE DRAFT EU ARTIFICIAL INTELLIGENCE ACT: AN OPPORTUNITY FOR SMES? InterEULawEast 9, 71–118. https://doi.org/10.22598/iele.2022.9.2.3

Raybould, B., Cheung, W.M., Connor, C., Butcher, R., 2020. An investigation into UK government policy and legislation to renewable energy and greenhouse gas reduction commitments. Clean Technol Environ Policy 22, 371–387. https://doi.org/10.1007/s10098-019-01786-x

Rose, E., 2023. Pursuing the Innovation Economy: Implications for Startup Labour. Industrial Law Journal 52, 839–865. https://doi.org/10.1093/indlaw/dwad002

Rosemberg, C., Potau, X., Leistner, S., Dijkstal, F., Vinnik, A., Tiriduzzi, C., Dave, A., Blind, K., 2020. Regulatory Sandboxes and Innovation Testbeds: A Look at International Experience in Latin America and the Caribbean. IDB Publications. https://doi.org/10.18235/0002526

Rotolo, D., Hicks, D., Martin, B.R. What is an emerging technology?, Research Policy, Vol. 44, Is. 10, pp. 1827-1843.

Salminen, V. et al (2022) Practices of innovation-friendly regulation in growth sectors (Innovaatiomyönteisen sääntelyn käytännöt kasvualoilla). Ministry of Economic Affairs and Employment of Finland, 2022:1. Full report available only in Finnish.

Saunila, M., Ukko, J., Rantala, T., 2018. Sustainability as a driver of green innovation investment and exploitation. J Clean Prod 179, 631–641. https://doi.org/10.1016/j.jclepro.2017.11.211

Schittekatte, T., Meeus, L., Jamasb, T., Llorca, M., 2021. Regulatory experimentation in energy: Three pioneer countries and lessons for the green transition. Energy Policy 156. https://doi.org/10.1016/j.enpol.2021.112382

Schumpeter, J.A. (1942) Capitalism, Socialism and Democracy. Vol. 36, Harper & Row, New York.

Shvetsova, O.A., Lee, S.K., 2021. Living labs in university-industry cooperation as a part of innovation ecosystem: Case study of south korea. Sustainability (Switzerland) 13. https://doi.org/10.3390/su13115793

Srinivasan, S., 2017. Driven up the wall? Role of environmental regulation in innovation along the automotive global value chain. CIES Research Paper series, CIES Research Paper series.

Surakka, T., Härri, F., Haahtela, T., Horila, A., Michl, T., 2018. Regulation and governance supporting systemic MaaS innovations. Research in Transportation Business and Management 27, 56–66. https://doi.org/10.1016/j.rtbm.2018.12.001

Tsakalidis, A., Gkoumas, K., Pekár, F., 2020. Digital transformation supporting transport decarbonisation: Technological developments in EU-funded research and innovation. Sustainability (Switzerland) 12. https://doi.org/10.3390/su12093762

UK BEIS, 2020. Regulator approaches to facilitate, support and enable innovation (Research Paper Series), 2020/003. UK Department for Business, Energy and Industrial Strategy.

UK Government, 2022. Establishing a pro-innovation approach to regulating AI [WWW Document]. GOV.UK. URL https://www.gov.uk/government/publications/establishing-a-pro-innovation-approach-to-regulating-ai/establishing-a-pro-innovation-approach-to-regulating-ai-policy-statement (accessed 5.7.24).

UK HM Treasury, 2023. Pro-innovation Regulation of Technologies Review: Digital Technologies.

United States Congress (2022). H.R.7535 - Quantum Computing Cybersecurity Preparedness Act. https://www.congress.gov/bill/117th-congress/house-bill/7535

Vogelsang, Ingo, 2017. "The role of competition and regulation in stimulating innovation – Telecommunications," Telecommunications Policy, Elsevier, vol. 41(9), pages 802-812.

VTT (2023). Finland launches a 20-qubit quantum computer – development towards more powerful quantum computers continues. Press release. https://www.vttresearch.com/en/news-and-ideas/finland-launches-20-qubit-quantum-computer-development-towards-more-powerful-quantum

Wallach, W., Marchant, G., 2019. Toward the agile and comprehensive international governance of AI and robotics. Proceedings of the IEEE 107, 505–508. https://doi.org/10.1109/JPROC.2019.2899422

Wallis, T., Dorey, P., 2023. Implementing Partnerships in Energy Supply Chain Cybersecurity Resilience. Energies (Basel) 16. https://doi.org/10.3390/en16041868

Weber, R.H., Studer, E., 2016. Cybersecurity in the Internet of Things: Legal aspects. Computer Law and Security Review 32, 715–728. https://doi.org/10.1016/j.clsr.2016.07.002

WEF (2023).Top 10 Emerging Technologies for 2023: Flagship Report.

Wolf, S., Korzynietz, R., 2019. Innovation needs for the integration of electric vehicles into the energy system. World Electric Vehicle Journal 10. https://doi.org/10.3390/wevj10040076

World Bank, CCAF, 2019. Regulating Alternative Finance: Results from a Global Regulator Survey.

Appendices

Appendix 1. Analysis of EIC project data

The quantitative analysis of EIC project data covered all 805 Pathfinder projects; in addition, 27 projects from other programmes (i.e. Accelerator, FTI, and Transition) were included as potential follow-ups to Pathfinder projects. This detection of potential follow-ups was executed manually by comparing projects' team composition, temporal sequence of projects, and projects' topics based on abstracts. The abstracts of 832 Pathfinder and potential follow-up projects were then analysed using the latest (as of April 2024) ChatGPT 4 Turbo API.

In this analysis, natural language processing (NLP) tool – ChatGPT – was chosen over traditional data mining methods due to the unstructured nature of the data. It is important to note that there are alternative NLP tools and libraries available, such as spaCy or BERT, which can be geared towards narrow scientific and technical texts. However, ChatGPT was selected as the most suitable for this project's requirements. The choice of the tool was based on its powerful contextual comprehension, extensive pre-training on a diverse and inclusive corpus – including scientific literature – and its tested robust performance in accurately classifying complex project descriptions with minimal customisation. Additionally, its performance in minimizing errors (such as "hallucinations") through iterative prompt testing, ensured accuracy for the broad scope of technologies in the analysed dataset.

Box 3 below presents the used prompt while interacting with ChatGPT, while Box 4 shows the used code for interaction with ChatGPT API and extracting the analysis results. To minimise the "hallucinations" of ChatGPT responses (incorrect/unwanted information), the prompt was tested numerous times and refined to the final prompt. This final prompt results in ChatGPT providing the type of emerging technology by comparing the definitions of emerging technologies with the project abstract. Moreover, considering the possibility of several emerging technologies being represented in the project, the prompt allowed assigning more than one category to the project. In addition, to inspect the validity of classification, we manually checked 15 randomly selected cases, which did not show classification error.

It is important to note, however, that although specific measures were taken to limit the chance of ChatGPT "hallucinations" (i.e. refining the used prompt, allowing for multiple classifications, manually checking a sample of the classification), it is still possible that some projects were connected to wrong emerging technologies. To increase classification accuracy, more detailed definitions of emerging technologies would be required (compared to the used definitions provided by STEP Regulation). In addition, although the latest ChatGPT 4 Turbo model was used to increase classification accuracy, future GPT versions could provide more accurate results.

Box 3: ChatGPT API prompt

Classify the research project based on its alignment with the three emerging technologies defined below. Provide just the category without any explanation. If necessary, more than one category separated by a semicolon can be assigned to the project. The abstract of the research project is as follows: [*INSERT PROJECT ABSTRACT*]

Deep and digital technologies: should include microelectronics, high-performance computing, quantum technologies (i.e. computing, communication and sensing technologies), cloud computing, edge computing, and artificial intelligence, cybersecurity

technologies, robotics, 5G and advanced connectivity and virtual realities, including actions related to deep and digital technologies for the development of defence and aerospace applications.

Clean technologies: should include, among others, renewable energy; electricity and heat storage; heat pumps; electricity grid; renewable fuels of non-biological origin; sustainable alternative fuels; electrolysers and fuel cells; carbon capture, utilisation and storage; energy efficiency; hydrogen and its related infrastructure; smart energy solutions; technologies vital to sustainability such as water purification and desalination; advanced materials such as nanomaterials, composites and future clean construction materials, and technologies for the sustainable extraction and processing of critical raw materials.

Biotechnology: should include technologies such as biomolecules and its applications, pharmaceuticals and medical technologies vital for health security, crop biotechnology, and industrial biotechnology, such as for waste disposal, and biomanufacturing.

Source: Visionary Analytics based on STEP Regulation.

Box 4: Python code for project classification using ChatGPT API

```
# Importing data manipulation libraries
import pandas as pd
import numpy as np
# Reading data and extracting project abstracts
df = pd.read_excel('/content/Projects.xlsx')
docs = df['Project Abstract'].dropna().unique()
# Importing OpenAI
from openai import OpenAI
client = OpenAI(api_key="INSERT YOUR KEY")
# Create empty lists to store abstracts and categories
abstracts = []
categories = []
# Loop through abstracts list
for i, abstract in enumerate(docs):
    prompt = f"Classify <…> The abstract of the research project is as follows: {abstract} <…>"
    response = client.chat.completions.create(
        model="gpt-4-turbo-2024-04-09",
        messages=[{"role": "user", "content": prompt}]
    )
    category = response.choices[0].message.content
    # Append abstract and category to lists
    abstracts.append(abstract)
    categories.append(category)
```

```
    print(f"Abstract {i + 1}: {category}")
# Create dataframe and export to Excel
data = {"Project Abstract": abstracts, "Category": categories}
df_result = pd.DataFrame(data)
df_result.to_excel("classification_results.xlsx", index=False)
```

Source: Visionary Analytics

The figures below present the data from quantitative EIC project analysis.

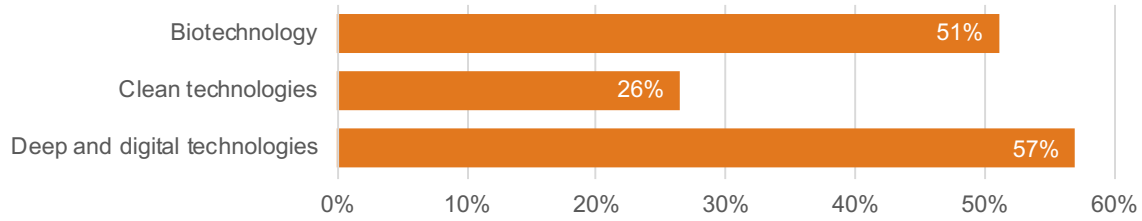

Figure 14: Project classification by emerging technologies. Source: Visionary Analytics. Note: N=832 (N Deep and digital technologies=474; N Clean technologies=220; N Biotechnology=425). More than one emerging technology could be assigned to a project.

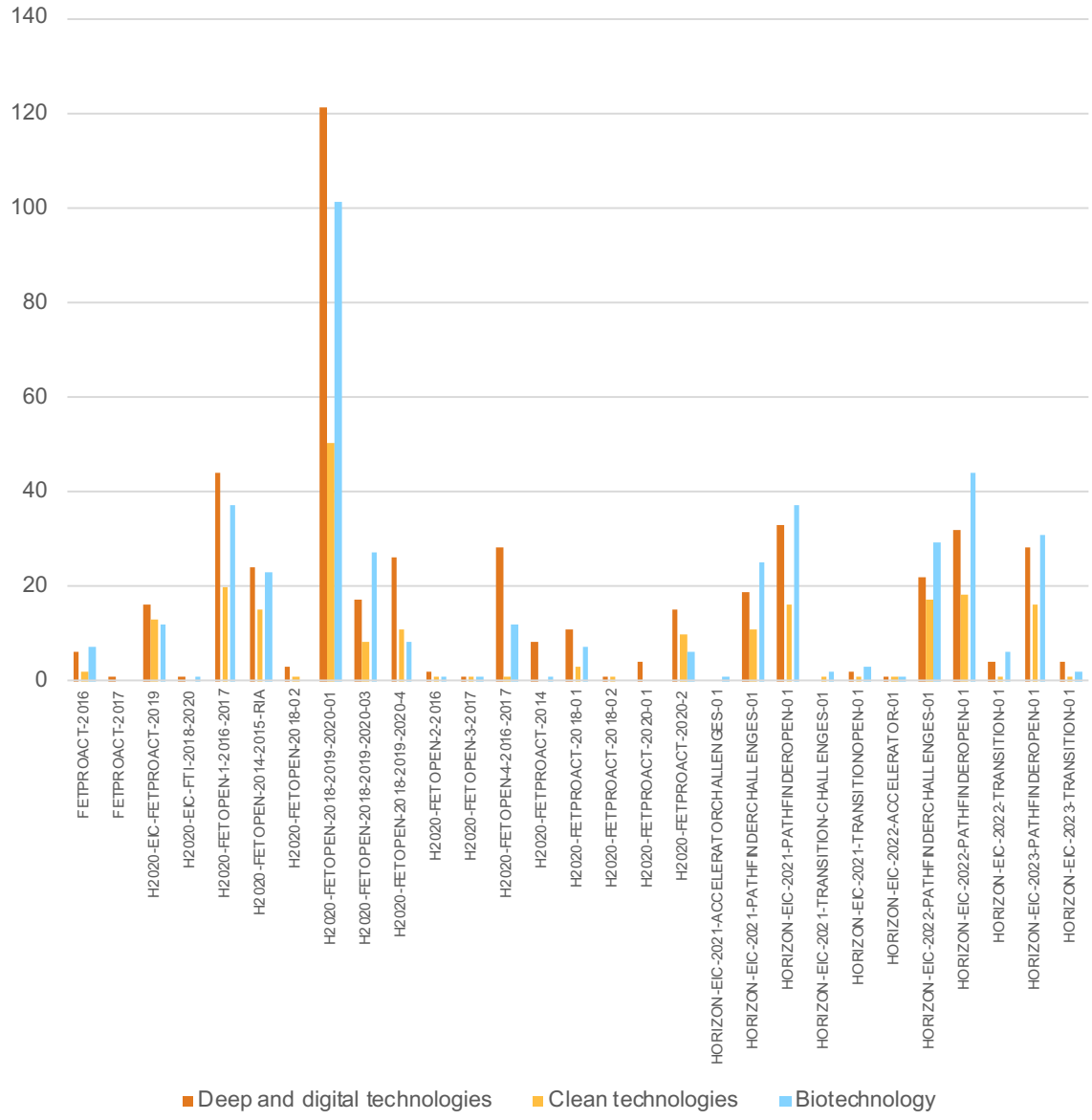

Figure 15: Count of categories across calls. Source: Visionary Analytics. Note: N=832; more than one emerging technology could be assigned to a project.

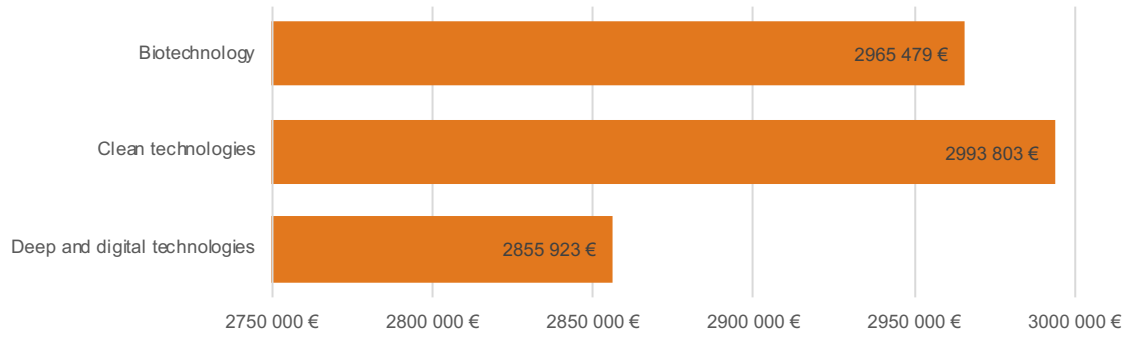

Figure 16: Average project requested EU contribution across different emerging technologies. Source: Visionary Analytics. Note: N=832; more than one emerging technology could be assigned to a project.

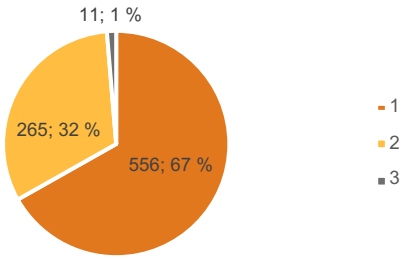

Figure 17: Number of assigned categories to projects. Source: Visionary Analytics. Note: N=832.

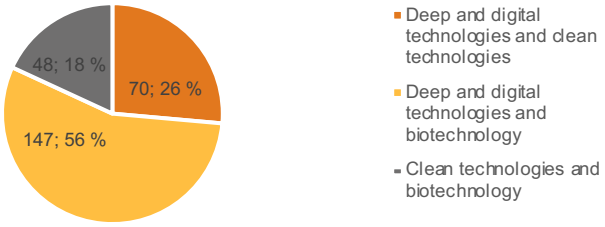

Figure 18: Number of emerging technology pairs. Source: Visionary Analytics. Note: N=265.

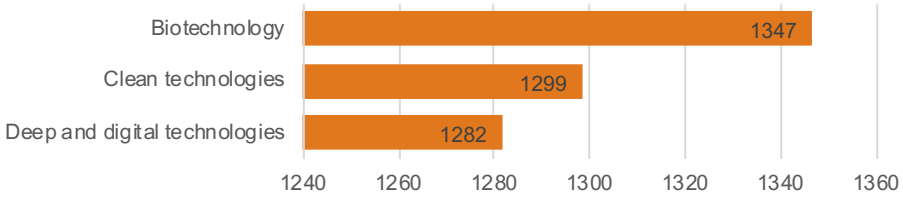

Figure 19: Average project duration in days across different emerging technologies. Source: Visionary Analytics. Note: N=832; more than one emerging technology could be assigned to a project.

Appendix 2. Survey for EIC beneficiaries

The aim of the survey with EIC beneficiaries was to gather insights from coordinators and partners of EIC funded projects on how EU and/or national legislation/regulation is hampering the market uptake of emerging technologies. Furthermore, this survey aimed to identify unregulated areas that cause challenges in the development or marketing of products or services and to collect data on beneficiaries' experiences with experimentation spaces.

The survey was launched on March 13, 2024, via the online survey tool Alchemer™ and remained open for responses until April 10th, 2024. Contact details of EIC beneficiaries were provided by EISMEA and the survey was distributed to a total of 5083 contacts, following the removal of invalid email addresses. In total, there were 260 valid responses to the survey. A detailed summary of the respondents profile is provided below.

Survey respondents

The majority of respondents to the survey indicated that they had participated in the Accelerator programme (70% or 182 of 259 respondents), followed by the Pathfinder programme (19% or 50 of 259) (See Figure 20). The remaining responses were evenly split between the Fast Track to Innovation (FTI) programme and the Transition programme (9% each or 24 and 23 of 259 respectively). A further 8% (or 20 of 259) indicated that they did not know or could not answer.

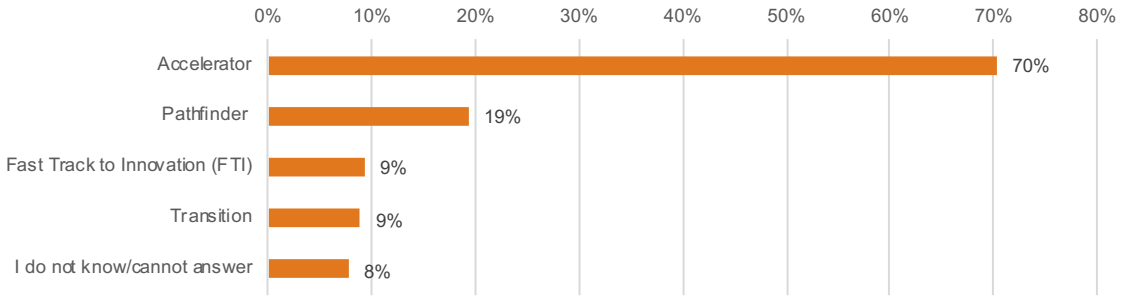

Figure 20. Q3: Please select the EIC programme(s) you have participated in. Select all that apply. N=259; more than one response option (EIC programme) could be selected. Source: Authors' own elaboration, based on survey data, 2024.

Regarding the technological area of respondents' most recent projects, 40% (or 103 of 259 respondents) indicated that their projects were related to deep and digital technologies (see Figure 21). The selection of biotechnologies and clean technologies was evenly split (33% or 85 of 259 and 31% or 80 or 259, respectively). The remaining 16% (or 42 of 259) of respondents selected "other". **Error! Reference source not found.** thematically presents the areas of technology identified by respondents when asked to specify their response, which mostly relate to areas of infrastructure, environment, health and medicine, and other advanced technologies.

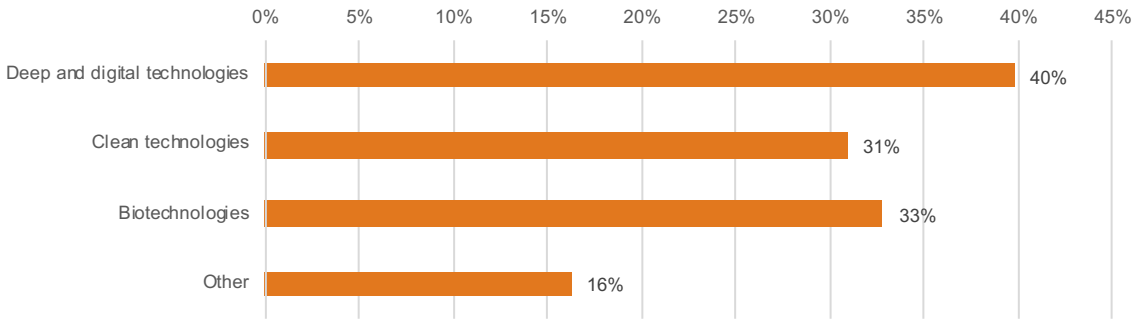

Figure 21. Q4: Please select the technological area(s) your latest projects focused on. Select all that apply. Note: N=259; more than one response option (technological area) could be selected. Source: Authors' own elaboration, based on survey data, 2024.

Table 12. 'Other' technological areas listed by respondents (Q4.1).

Area	Survey responses*[185]
Infrastructure	Road infrastructure digitalisation; telecom passive infrastructures; construction and manufacturing; advanced composite building materials; horizontal drilling technologies; space technologies (electric propulsion, re-entry); hyperloop; energy and electricity grid.
Environmental sustainability and solutions	Behaviour and cultural change in mobility; environmental intelligence; forestry; advanced clean packaging; biopolymers and bioplastics production from renewable feedstock; renewable/recycled raw materials and solutions.
Healthcare and Medical Technology	Medical devices; biomedical imaging and clinical imaging; medical it; single molecule nuclear; magnetic resonance microscopy; life science tools; applications mainly in the health sector; structural health monitoring.
Advanced technologies	THz (Terahertz) technology, LINAC (Linear Accelerator); IT; quantum technology; robotics; advanced optics and photonics sensors; advanced electron microscopy; DNA data storage; key enabling technologies (meta-technologies); sensor technology; data analysis; electronics; education technology.
Other	Security; service industry.

[185] (*) Does not represent verbatim responses - the main technology has been listed based on descriptions provided by respondents. Source: Authors' own elaboration based on survey data, 2024

Appendix 3. List of experimentation spaces and regulatory experiments

Name (* = selected for sample of 50 initiatives)	Scope	Type	Tech sector
Commission proposal for a regulation on artificial intelligence	EU	Legislative/regulatory framework	Deep & digital technologies
Commission Communication 'An SME Strategy for a sustainable and digital Europe'	EU	Legislative/regulatory framework	Deep & digital technologies
Commission proposal for an Interoperable Europe Act	EU	Legislative/regulatory framework	Deep & digital technologies
Commission Recommendation on speeding up permit-granting procedures for renewable energy projects and facilitating Power Purchase Agreements	EU	Legislative/regulatory framework	Clean technologies
Legislative proposal to amend the Renewable Energy Directive 2018/2001	EU	Legislative/regulatory framework	Clean technologies
Distributed Ledger Technology Pilot Regulation	EU	Legislative/regulatory framework	Deep & digital technologies
Proposal for Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency	EU	Legislative/regulatory framework	Biotechnologies
Net Zero Industry Act	EU	Legislative/regulatory framework	Clean technologies
Commission proposal for a regulation on European statistics	EU	Legislative/regulatory framework	Other (non relevant area)
AutomatFahrVerordnung - Regulation on automated vehicle functionalities	AT	Legislative/regulatory framework	Deep & digital technologies
Use of radio frequencies for experimental purposes	CZ	Legislative/regulatory framework	Deep & digital technologies
Self-driving vehicles licence	EE	Legislative/regulatory framework	Deep & digital technologies
Germany regulatory sandboxes strategy and general framework	DE	Legislative/regulatory framework	Generic
Federal Regulatory Sandbox Law	AT	Legislative/regulatory framework	Other (non relevant area)
Hungary regulatory sandbox scheme	HU	Legislative/regulatory framework	Clean technologies
Sweden energy pilot regulation	SE	Legislative/regulatory framework	Clean technologies
Commission proposal for the Pharmaceutical Regulation	EU	Legislative/regulatory framework	Biotechnologies
MOVE 21 - testing an integrated method towards greener transport systems	EU	Living lab	Clean technologies
UP 2030 - urban planning with a focus on climate change	EU	Living lab	Clean technologies
Limerick's Citizen Innovation Lab	IE	Living lab	Clean technologies

Kraków Living Lab	PL	Living lab	Generic
***Regulatory sandbox for artificial intelligence**	DK	Regulatory sandbox	Deep & digital technologies
***European Blockchain Regulatory Sandbox**	EU	Regulatory sandbox	Deep & digital technologies
***AI and personal data sandbox**	FR	Regulatory sandbox	Deep & digital technologies
Prolida	AT	Living lab	Biotechnologies
StadtLABOR	AT	Living lab	Clean technologies
Inagro Living Labs	BE	Living lab	Biotechnologies
IMEC Living Labs	BE	Living lab	Generic
Licalab - Living & Care Lab	BE	Living lab	Generic
Ghent Living Lab	BE	Living lab	Generic
Living Lab Animal Husbandry (LLAH)	BE	Living lab	Biotechnologies
Smart Retail City Lab	BE	Living lab	Other (non relevant area)
***5G Innovation Sandbox**	LT	Regulatory sandbox	Deep & digital technologies
ZorgLab Aalst	BE	Living lab	Other (non relevant area)
Prijedor Circle Hub	Bosnia	Living lab	Other (non relevant area)
***Testing and Experimentation Facility (TEF) for Manufacturing (AI-MATTERS)**	EU	Testbed	Deep & digital technologies
The Open Innovation Living Lab (LLio)	Canada	Living lab	Generic
Mandalab	Canada	Living lab	Other (non relevant area)
Rehabilitation Living Lab in the mall	Canada	Living lab	Other (non relevant area)
Pismo Hub	HR	Living lab	Generic
Rijeka iLivingLab	HR	Living lab	Other (non relevant area)
***Testing and Experimentation Facility (TEF) for Health AI and Robotics (TEF Health)**	EU	Testbed	Biotechnologies
Forum Virium Helsinki (FVH)	FI	Living lab	Generic
TAMK Living Lab	FI	Living lab	Generic

Lahti Living Lab	FI	Living lab	Generic
CODER Living Lab	FI	Living lab	Deep & digital technologies
Laurea Living Labs Network	FI	Living lab	Generic
Universcience Living Lab	FR	Living lab	Generic
Lorraine Smart Cities Living Lab	FR	Living lab	Generic
ICT Usage Lab	FR	Living lab	Generic
Brie Nov	FR	Living lab	Other (non relevant area)
E2L Earth Observation Living Labs	FR	Living lab	Other (non relevant area)
Gerontopole Nouvelle-Aquitaine	FR	Living lab	Generic
Living Lab Saint Victor	FR	Living lab	Generic
La Fabrique du Futur	FR	Living lab	Generic
Smart City Living Lab	FR	Living lab	Generic
Normandy Living Lab	FR	Living lab	Generic
***Testing and Experimentation Facility (TEF) for Agri-Food (Agrifood TEF)**	EU	Testbed	Biotechnologies
Aktan	FR	Living lab	Generic
Design Creative City Living Lab	FR	Living lab	Other (non relevant area)
ICM cLLAPS LivinLab@ PitieSalPetriere	FR	Living lab	Biotechnologies
Nantes City Lab	FR	Living lab	Generic
Pasteur Innovative Living Lab of Nice	FR	Living lab	Biotechnologies
UDD - Universite du Domicile	FR	Living lab	Biotechnologies
Healthy Ageing and Well-Being Living Lab	FR	Living lab	Generic
Ocean Living Lab	FR	Living lab	Other (non relevant area)
PRAXLABS	DE	Living lab	Generic
SmartFactoryOWL	DE	Living lab	Deep & digital technologies

K8 Institut fuer strategische Aesthetik gGmbH	DE	Living lab	Generic
Living Labs Incubator	DE	Living lab	Generic
Thessaloniki Smart Mobility Living Lab	EL	Living lab	Other (non relevant area)
***Testing and Experimentation Facilities (TEF) for Smart Cities and Communities (CITCOM.AI)**	EU	Testbed	Deep & digital technologies
Well-being Living Lab Nagykovacsi	HU	Living lab	Other (non relevant area)
***Spanish Regulatory Sandbox on Artificial Intelligence**	ES	Regulatory sandbox	Deep & digital technologies
***Sandbox of National Bank of Slovakia**	SK	Regulatory sandbox	Deep & digital technologies
Netwell CASALA	IE	Living lab	Other (non relevant area)
Atlantic Innovation Region	IE	Living lab	Generic
Dingle Peninsula	IE	Living lab	Generic
Torino City Lab	IT	Living lab	Generic
Green Schools Living Lab	IT	Living lab	Other (non relevant area)
***Sandbox for sustainable development and competition**	EL	Regulatory sandbox	Clean technologies
Textile & Clothing Living Lab (TECLA)	IT	Living lab	Other (non relevant area)
InnovAALab - Apulian Living Lab on Healthy, active & Assisted Living	IT	Living lab	Other (non relevant area)
Lunigiana Amica	IT	Living lab	Other (non relevant area)
Thriving Entrepeneurial and Creative Lab	IT	Living lab	Other (non relevant area)
City of the Future Living Lab	IT	Living lab	Generic
Santa Chiara Lab	IT	Living lab	Generic
UNIS&F Lab	IT	Living lab	Generic
Mediterranean Innovation Rural Living Lab	IT	Living lab	Other (non relevant area)
Apulian ICTLiving Lab	IT	Living lab	Other (non relevant area)
***Citizen Innovation Lab**	IE	Living lab	Generic
Lecco Innovation Living Lab	IT	Living lab	Other (non relevant area)

Puglia Smart Lab	IT	Living lab	Deep & digital technologies
TIE-LL Technology Innovation Ecosystem	IT	Living lab	Other (non relevant area)
ADP Zid Living Lab	ME	Living lab	Generic
***Digital testbed framework**	EE	Testbed	Deep & digital technologies
Blue Hotspot Dordrechtt (PPS The Water Route)	NL	Living lab	Clean technologies
Eindhoven Living Lab	NL	Living lab	Generic
Care Innovation Center West-Brabant	NL	Living lab	Biotechnologies
Urban Management - Fieldlabs	NL	Living lab	Other (non relevant area)
Wireless Trondheim Living Lab	NO	Living lab	Generic
PSNC Future Labs	PL	Living lab	Generic
Krakow Living Lab	PL	Living lab	Generic
***Fibi On-farm Living Labs**	CH	Living lab	Biotechnologies
UVT Digital & Green Living Lab	RO	Living lab	Generic
Transilvania Living Lab	RO	Living lab	Generic
Living Lab Tomsk Network	RU	Living lab	Generic
***Sandbox For Responsible Artificial Intelligence (Regulatory privacy sandbox)**	NO	Regulatory sandbox	Deep & digital technologies
BELgrade Urban Living LAB	RS	Living lab	Other (non relevant area)
Green Point - DIH AGRIFOOD based Living Lab	SI	Living lab	Generic
E-zavod Living Lab	SI	Living lab	Generic
Neurolab ADACEN Living Lab	ES	Living lab	Biotechnologies
Health Care Living Catalonia	ES	Living lab	Generic
Library Living Lab	ES	Living lab	Other (non relevant area)
Neapolis	ES	Living lab	Generic
UJI.>LAB	ES	Living lab	Generic

SSI Living Lab	ES	Living lab	Other (non relevant area)
Colaboratoris Catalunya	ES	Living lab	Other (non relevant area)
Fundacion Epica La Fura dels Baus	ES	Living lab	Other (non relevant area)
UAB Smart Campus Living Lab	ES	Living lab	Generic
Vuela Guadalinfo	ES	Living lab	Other (non relevant area)
OZEAN LIVING LAB	ES	Living lab	Other (non relevant area)
BIRD Living Lab	ES	Living lab	Other (non relevant area)
IoT Smart Santander Living Lab	ES	Living lab	Generic
***End-to-end digitalised production testbeds (KIC)**	EU	Testbed	Deep & digital technologies
***Sofia Lab**	BG	Living lab	Generic
Galician Network of Health Living Labs	ES	Living lab	Biotechnologies
LABe Digital Gastronomy Labs	ES	Living lab	Biotechnologies
MINDLab	ES	Living lab	Other (non relevant area)
Interiors Living Lab	ES	Living lab	Other (non relevant area)
Medialab UGR: Research Laboratory for Digital Culture and Society	ES	Living lab	Other (non relevant area)
Cotilab Cornella	ES	Living lab	Other (non relevant area)
La Marina Living Lab	ES	Living lab	Clean technologies
Living Lab Social in real environment	ES	Living lab	Other (non relevant area)
HSB Living Lab	SE	Living lab	Generic
OpenLab	SE	Living lab	Generic
Botnia Living Lab	SE	Living lab	Generic
Living Lab at Malarden University	SE	Living lab	Other (non relevant area)
Smaland Living Lab	SE	Living lab	Other (non relevant area)
The Swedish Living Lab on Vehicle and Transport ICT	SE	Living lab	Other (non relevant area)

Geneve Lab	CH	Living lab	Other (non relevant area)
Senior-Lab	CH	Living lab	Other (non relevant area)
Living Lab for Special Needs	CH	Living lab	Other (non relevant area)
Creative Living Laboratory	CH	Living lab	Other (non relevant area)
Lugano Living Lab	CH	Living lab	Other (non relevant area)
***MedTech Lab**	FR	Living lab	Biotechnologies
Ecopol living lab & ecovillages Romandie	CH	Living lab	Other (non relevant area)
NEST (Explore the future of buildings)	CH	Living lab	Other (non relevant area)
iHomeLab (iHL)	CH	Living lab	Clean technologies
Mobile Communications and Computer for Life Quality	CH	Living lab	Other (non relevant area)
Mobility Lab CH	CH	Living lab	Other (non relevant area)
***Austria: Regulatory sandbox in the electricity sector (Energy.Free.Room)**	AT	Regulatory sandbox	Clean technologies
***Central Bank of Hungary Regulatory Sandbox**	HU	Regulatory sandbox	Deep & digital technologies
Mezopotamya Living Lab	TR	Living lab	Generic
Basaksehir Living Lab	TR	Living lab	Generic
Bodrum Living Lab	TR	Living lab	Other (non relevant area)
The Innovative Dementia Transnational Living Lab	GB	Living lab	Biotechnologies
Social Informatics Lab, Newcastle Living Lab	GB	Living lab	Other (non relevant area)
Manchester Digital Innovation Living Lab	GB	Living lab	Other (non relevant area)
Lab4Living	GB	Living lab	Biotechnologies
Knowle West Media Centre, Bristol Living Lab	GB	Living lab	Other (non relevant area)
Northern Germany Living Lab (NRL)	DE	Living lab	Clean technologies
PoDIUM living labs	EU	Living lab	Other (non relevant area)
City Lab Coventry	GB	Living lab	Generic

***i-TRIBOMAT (Intelligent Open Test Bed for Materials Tribological Characterisation Services)**	AT	Testbed	Deep & digital technologies
EdTech sandbox	FR	Regulatory sandbox	Other (non relevant area)
***OASIS (Open Access Single entry point for scale-up of Innovative Smart lightweight composite materials and components)**	ES	Testbed	Deep & digital technologies
FMA Sandbox	AT	Regulatory sandbox	other (non relevant area)
The Danish Energy Agency's regulatory sandbox	DK	Regulatory sandbox	Clean technologies
Regulatory sandbox in the financial sector	DK	Regulatory sandbox	Deep & digital technologies
Sandbox for self-driving motor vehicles	DK	Regulatory sandbox	Deep & digital technologies
Regulatory sandbox for autonomous shipping and related technologies	DK	Regulatory sandbox	Deep & digital technologies
Multiple sandboxes (established by the Energy Regulatory Commission - CRE)	FR	Regulatory sandbox	Clean technologies
Multiple sandboxes (established by the Electronic Communications , Postal and Print Media Distribution Regulatory Authority - ARCEP)	FR	Regulatory sandbox	Deep & digital technologies
Multiple sandboxes (established by 'France Expérimentation ', a one-stop interministerial agency led by the interministerial delegate for public transformation - DITP)	FR	Regulatory sandbox	Generic
Multiple sandboxes (established by the Commission nationale de l'informatique et des libertés – CNIL)	FR	Regulatory sandbox	Deep & digital technologies
***SAFETY TESTING IN THE LIFE CYCLE OF NANOTECHNOLOGY-ENABLED MEDICAL TECHNOLOGIES FOR HEALTH (SAFE-N-MEDTECH)**	ES	Testbed	Deep & digital technologies
Regulatory sandbox of the Bank of Greece	EL	Regulatory sandbox	Deep & digital technologies
Financial and Capital Market Authority sandbox	LV	Regulatory sandbox	Deep & digital technologies
The regulatory sandbox of the Bank of Lithuania	LT	Regulatory sandbox	Deep & digital technologies
***MDOT**	DE	Testbed	Biotechnologies
Regulatory sandbox for energy innovations	LT	Regulatory sandbox	Clean technologies
MFSA FinTech Regulatory Sandbox	MT	Regulatory sandbox	Deep & digital technologies
***TBMED**	ES	Testbed	Biotechnologies
Financial Sector Regulatory Sandbox	ES	Regulatory sandbox	Deep & digital technologies
ICO Sandboxes	UK	Regulatory sandbox	Deep & digital technologies

***Torino City Living Lab**	IT	Living lab	Clean technologies
UK FCA Sandbox	UK	Regulatory sandbox	Deep & digital technologies
***Technological sandbox at the Bank of Lithuania LBChain**	LT	Regulatory sandbox	Deep & digital technologies
Sofia Regtech Sandbox	BG	Regulatory sandbox	Other (non relevant area)
***KNF Regulatory Sandbox**	PL	Regulatory sandbox	Deep & digital technologies
Experimental projects in the Dutch energy legislation	NL	Regulatory sandbox	Clean technologies
BRUGEL Regulatory sandbox	BE	Regulatory sandbox	Clean technologies
Flanders regulatory sandbox	BE	Regulatory sandbox	Clean technologies
Wallonia renewable energy community	BE	Regulatory sandbox	Clean technologies
***Interoperability Test bed**	EU	Testbed	Deep & digital technologies
Portugal regulatory sandboxes and pilot projects in energy sector	PT	Regulatory sandbox	Clean technologies
Spain regulatory sandboxes in the energy sector	ES	Regulatory sandbox	Clean technologies
Norway regulatory sandbox scheme on power systems	NO	Regulatory sandbox	Clean technologies
Innovation Sandbox	Canada	Regulatory sandbox	Clean technologies
***ENERGY & WATER - Greater Copehagen Living Lab**	DK	Living lab	Clean technologies
***SINTEG - Smart Energy Showcases – Digital Agenda for the Energy Transition**	DE	Regulatory sandbox	Clean technologies
Technology Assurance Sandbox (TAS)	MT	Regulatory sandbox	Deep & digital technologies
Sandbox Vlaanderen	BE	Regulatory sandbox	Deep & digital technologies
Bank of Cyprus Sandbox	CY	Regulatory sandbox	Deep & digital technologies
***Ofgem Innovation Link**	UK	Regulatory sandbox	Clean technologies
JenErgieReal Regulatory Sandbox	DE	Regulatory sandbox	Clean technologies
***Living Lab Agrifood Technology (LLAT)**	BE	Living lab	Biotechnologies
***PA4ALL - Precision Agriculture Living Lab**	RS	Living lab	Biotechnologies
Banca d'Italia Regulatory Sandbox	IT	Regulatory sandbox	Deep & digital technologies

***KLIOLab - Knowledge-based Lifecycle InnOvation Laboratory**	IT	Living lab	Deep & digital technologies
***Smart Living Lab**	CH	Living lab	Clean technologies
***Water Campus Leeuwarden**	NL	Living lab	Clean technologies
SHOW Project - automated vehicles for sustainable urban transport	EU	Testbed	Deep & digital technologies
ENSEMBLE – Enabling Safe Multi-Brand Platooning for Europe	EU	Testbed	Deep & digital technologies
Baden-Württemberg Autonomous Driving Test Bed	DE	Testbed	Deep & digital technologies
SAIFE - Safety testbeds through AI for Food production Environment	EU	Testbed	Deep & digital technologies
eMOTOR Virtual Testbed	IT	Testbed	Deep & digital technologies
Convert2Green	EU	Testbed	Clean technologies
Exploit4InnoMat	EU	Testbed	Clean technologies
Data space for media	EU	Testbed	Deep & digital technologies
***Energy Living Lab**	CH	Living lab	Clean technologies
***Omki on-farm living lab**	HU	Living lab	Biotechnologies
***Smart Rural Living Lab**	PT	Living lab	Generic
***ARERA Regulatory experiments to promote innovation in the power system in Italy**	IT	Regulatory sandbox	Clean technologies
***Smartcity Malaga Living Lab**	ES	Living lab	Clean technologies
Testing of drones, sensors, and other flight systems	DK	Testbed	Deep & digital technologies
***Food & Health Living Lab**	ES	Living lab	Biotechnologies
***User validation labs (ULabs)**	EU	Living lab	Biotechnologies
UK Catapult network	UK	Testbed	Generic
AI4EU AI on Demand	EU	Testbed	Deep & digital technologies
TNO Labs	NL	Testbed	Generic
Fraunhofer testbeds	DE	Testbed	Generic
AIT Cyber Range	AT	Testbed	Deep & digital technologies

ORS 5G Boadscast Testbed	AT	Testbed	Deep & digital technologies
***JRC Living Labs**	EU	Living lab	Generic
CityLab	BE	Testbed	Deep & digital technologies
Franco-German-Luxembourg digital testbed	EU	Testbed	Deep & digital technologies
5G Industry 4.0 test bed	DE	Testbed	Deep & digital technologies
Digital Motorway Test Bed	DE	Testbed	Deep & digital technologies
Nordic Test Beds (NoTeB)	Nordics	Testbed	Biotechnologies
HellasQCI test bed	EL	Testbed	Deep & digital technologies
National Sustainable Building Energy Test Bed (NSBET)	IE	Testbed	Clean technologies
Testbed Helsinki	FI	Testbed	Generic
Finnish Data Economy Testbed	FI	Testbed	Deep & digital technologies
Testbed for innovative products	LU	Testbed	Generic
Industry 4.0 Test Bed	SK	Testbed	Deep & digital technologies
FormPlanet	ES	Testbed	Other (non relevant area)
TEESMAT	FR	Testbed	Clean technologies
***Thessalinoki Action for Health & Wellbeing Living Lab**	EL	Living lab	Biotechnologies
LEE-BED	DK	Testbed	Deep & digital technologies
***SOLAR LIVING LAB (SOLL)**	IT	Living lab	Clean technologies
LightCoce	EL	Testbed	Other (non relevant area)
***Croatia energy sector regulatory sandbox**	HR	Regulatory sandbox	Clean technologies
***NHS Innovation Test Beds**	UK	Testbed	Biotechnologies
***5G Test Networks (5GTNF), Finland**	FI	Testbed	Deep & digital technologies

Appendix 4. Experimentation case studies

Case E1: Smart Energy Showcases – Digital Agenda for the Energy Transition (SINTEG)

Case in brief

The "Smart Energy Showcases – Digital Agenda for the Energy Transition" (SINTEG) programme was established within the framework of Germany's ambitious energy transition policy, commonly referred to as the "Energiewende." This policy aims to transition the country towards a sustainable energy system primarily powered by renewable energy sources, such as wind and solar. As Germany increased its reliance on these intermittent energy sources, it faced significant challenges in ensuring the stability and efficiency of its electricity grid. To address these challenges, the Federal Ministry for Economic Affairs and Energy (BMWi) launched the SINTEG programme. It was part of a broader initiative to digitize the German energy sector, improve energy efficiency, and integrate renewable energy sources on a large scale. The programme was launched in December 2016 and ran until the end of March 2021. The programme's strategic objective aligns with the triad of energy policy goals: economic efficiency (affordability), environmental compatibility, and supply security, as outlined in §1 of the Energy Industry Act (EnWG). The development of model solutions and blueprints for addressing the technical, economic, and regulatory challenges of the energy transition was considered by the BMWi to be a key goal and a distinctive feature of the program.

Background and context

The primary objective of SINTEG was to develop and demonstrate scalable and replicable solutions for a reliable, economical, and environmentally friendly energy supply. The programme focused on:

- **Integrating Renewable Energy:** Ensuring that high shares of renewable energy could be efficiently integrated into the energy grid.
- **Enhancing Grid Stability and Efficiency:** Developing technologies and processes for a flexible and secure energy system.
- **Promoting Digitalization:** Leveraging digital technologies to optimize energy generation, distribution, and consumption.

The SINTEG programme provided specific regulatory derogations to facilitate the testing and implementation of innovative technologies and solutions. These regulatory flexibilities were essential for allowing programme participants to explore new approaches without being constrained by existing regulatory frameworks. In addition, the programme included continued collaboration with researchers in order to monitor and synthesise the SINTEG programme results. The objective of the SINTEG results synthesis was to aggregate, contextualize, and evaluate the transferability of insights gained from the five showcases.

Objectives, governance and funding model

First and foremost, SINTEG was a funding programme with a competitive call procedure. The showcases were selected based on project proposals. The financial and geographic scope of the showcases was extensive, allowing the real-life testing of new business models and cooperation processes.

ISBN [number]

Publications Office
of the European Union

The objectives of the SINTEG programme focused on the following aspects:

- Develop and demonstrate scalable solutions for integrating high shares of renewable energy into the power grid to enhance grid stability and efficiency.
- Leverage digital technologies to modernize the energy sector, create regulatory sandboxes for experimentation, and develop blueprints for addressing technical, economic, and regulatory challenges.
- Ensure that the energy transition is economically efficient, maintains supply security, and significantly reduces greenhouse gas emissions, contributing to environmental sustainability.

In addition, the SINTEG-regulation (SINTEG Verordnung) provided a regulatory framework established to facilitate and support the implementation of SINTEG. It provided a legal basis for experimental projects within the energy sector, allowing for regulatory flexibility and fostering innovation which is the key factor distinguishing SINTEG from ordinary R&D funding programmes. SINTEG programme involved a high number of stakeholders, each with distinct roles:

- Federal Ministry for Economic Affairs and Energy (BMWi): Provided strategic direction, funding, and regulatory oversight, ensuring alignment with national energy goals.
- Project Coordination Teams: Managed regional showcase projects, coordinated activities, and ensured compliance and data collection.
- Companies and Industry Participants (beneficiaries): Developed and deployed new technologies, providing technical expertise and private co-financing.
- Research Institutions and Universities (beneficiaries): Conducted research, provided scientific insights, and facilitated knowledge transfer.
- Municipalities and Local Authorities: Supported local implementation, engaged communities, and integrated project outcomes into local energy systems.
- Grid Operators: Integrated new technologies into the grid, ensuring stability and compliance.

Operating model and practices

The funding programme funded 5 showcases with different regional and technology focuses. The total budget of SINTEG was EUR 168 million, and the total private co-financing amounted to EUR 163 million. Each of them included multiple individual projects and participants, resulting in 189 funded projects with an average project size of around EUR 1.7 million.[186] Their main information is indicated in the table below.

Table 13 Overview on the five showcases funded by SINTEG

Showcase	Region	Focus	Key Features	Budget
C/sells	Southern Germany (Baden-Württemberg, Bavaria, Hesse)	Development of a cell-based energy system for solar	Integration of over 10,000 smart meters, creation of autonomous energy cells.	EUR 40 million

[186] Evaluation, p. 23

		energy optimization.		
Designetz	North Rhine-Westphalia, Rhineland-Palatinate, Saarland	Modular solutions for integrating decentralized energy sources to supply industrial centers.	Involvement of more than 7,000 households and 140,000 meters, demonstrating decentralized energy usage.	EUR 25 million
enera	Lower Saxony	Enhancing grid stability and flexibility through advanced technologies and data integration.	Installation of 40,000 smart meters and sensors, development of a communication network.	EUR 27 million
NEW 4.0	Northern Germany (Schleswig-Holstein, Hamburg)	Demonstrating high renewable energy integration with a focus on wind energy.	Technologies to manage wind energy, increased regional consumption and export of renewable energy.	EUR 44 million
WindNODE	Northeastern Germany (Berlin, Brandenburg, Mecklenburg-Vorpommern, Saxony, Saxony-Anhalt, Thuringia)	Integration of renewable energy into a multi-sector energy system.	Development of an ICT platform, nine demonstrators for smart energy management across sectors.	EUR 33 million

The SINTEG programme allowed participants to receive compensations for economic disadvantages incurred due to the experimentation. This incentive was not initially planned but was introduced after the projects have been awarded and it became clear that the project implementation would otherwise have been financially risky due to regulatory disadvantage.[187] The compensations had to be applied for separately and external auditors were required in order to show additional costs that arose from the implementation of the projects. Project participants had to prove, that they did have financial disadvantages from participating in a SINTEG project. For example, in one project under c/cell, electricity-intensive industries developed a technical solution for a flexible production system to increase their productions in times when high amounts of renewable energy were available, and respectively lowered their production during peak demand times in order to balance the load on the electricity grids. This however resulted in higher electricity costs for them, due to the design of calculating electricity costs. These higher costs could be reimbursed afterwards under the framework of the SINTEG regulation.

The implementation of SINTEG was accompanied by continued dialogue between the project participants and regulatory authorities that helped to flag problems during the implementation of the showcases. The overall regulatory challenges that were included in SINTEG regulation were however fixed and could not be changed.

[187] Expert interview

Results and evidence of impact

During interviews with two participants from different projects funded by SINTEG, it was confirmed that the programme had impact on the development of new technologies and processes for developing more flexible electricity distribution frameworks. One interviewee highlighted, that the focus of many projects was more on the development of techno-economic processes and finding new business models for marketing renewable electricity in a flexible way, rather than on developing or testing new technologies.[188] In many cases, existing technologies or products were applied in a novel manner. Nevertheless, interviewed participants could name a number of technological advancements that were made thanks to the regulatory framework and funding from SINTEG, such as application of blockchain technologies in the electricity market, technologies for monitoring the power grid, technical specification for smart meter gateways and online platforms to manage IoT networks.[189]

Further, interviewees highlighted the novelty of the SINTEG regulation in the German regulatory framework, as it was the first time that regulatory experimentation clauses were introduced in the energy regulation. While interviewees noted that the legal procedure of introducing a specific regulation for one funding programme which had to be approved by the Parliament was very burdensome, it set precedent in the German legislative landscape for regulatory experimentation clauses. While no explicit connection could be made by interviewees, it was mentioned that the German government is planning to introduce a general regulatory experimentation law that could simplify this process in future use cases, and interviewees indicated that learnings from the SINTEG regulation could have accelerated the political process for such a regulatory experimentation law.

Despite these impacts, interviewees pointed to some learnings that could be drawn from the SINTEG lesson. The reimbursements of costs arising from the project participation (which is one of the main experimental elements of the SINTEG-regulation) was described as very bureaucratic by interviewees and resulted in very few companies applying for reimbursements. As cost were only reimbursed after expenses already had occurred, they also provided economic risks for interested companies, leading to the non-participation of some companies. One interviewee mentioned, that rather than reimbursing extra costs, additional funding as an incentive would have rewarded the participation in a new experiment and would have provided for much more participants, which could have increased the results of testing new processes and business models. From a legal perspective, the main problem that the regulatory experiment touched upon was the equality of economic operators, as only those who participated in SINTEG project did receive reimbursements. [190]

Further, core regulatory problems that SINTEG projects faced have not been resolved. Interviewees mentioned that flexibility as a service provided by electricity consumers is still not financially incentivized in the German electricity renumeration system, which was one of the core problems faced by SINTEG project participants. The final evaluation of SINTEG pointed towards the need to improve the regulatory framework to enhance the impacts of SINTEG projects.[191] However, learnings from SINTEG showcases have also inspired regulatory changes, such as the 2023 reform of the Energy Industry Act (EnWG), which is designed to

[188] Interview 1

[189] Interviews 1 and 2

[190] Interview 2

[191] Evaluation, p. 95

allow for more flexible energy consumption in times of high renewable energy production, to avoid shutting off renewable energy power plants during very sunny and/or windy days.[192]

Key takeaways

- The main impact of SINTEG projects was on developing new techno-economic processes and business models by integrating digital technologies in the electricity grid to develop more flexible and decentralised electricity markets for integrating renewable energy sources and electricity storage systems in the electricity mix in Germany. In many cases, already existing technologies were applied in a new context and with new processes. The programme went beyond testing and developing individual specific technologies, but focused on integrating various new and existing technological solutions in a real-life setting.
- SINTEG also helped to create platforms, dialogues and cooperation among important stakeholders of the electricity supply, such as electricity grid providers, energy producers, individual and industrial electricity consumers. The final evaluation of SINTEG showed, that two out of three participating companies acchieved new cooperations through their participation in SINTEG, which especially improved their ability to develop innovative products and solutions.
- SINTEG showed that R&D funding in combination with applied regulatory flexibility can be a successful approach to develop and test novel technologies in a real-life setting with an extensive scope. The availability of funding enabled the participation of a large and diverse set of actors that are needed to create a real-life testing environment for complex socio-technical systems in the electricity sector.
- The SINTEG regulation provided a novelty in the German legislative landscape in the energy sector by providing an experimentation clause. This paved the way for the ongoing discussion on a national and cross-sectoral regulatory experimentation law, which can simplify and encourage future regulatory experimentations in other areas.
- The bureaucratic design of the regulatory experimentation elements within the SINTEG regulation hindered the showcases to develop their full potentials and more flexible regulatory frameworks could have allowed higher participation

Case E2: Norwegian Data Protection Authority's Regulatory Sandbox (NDPA)

Case in Brief

The Norwegian Data Protection Authority's Regulatory Sandbox (NDPA) was established in autumn 2020. It aims to promote the development and implementation of innovative artificial intelligence (AI) solutions that are ethical and responsible from a data protection perspective. It does so by providing a platform where organizations can develop and test AI technologies within a controlled environment that ensures compliance with data protection laws.

The relevance of the sandbox as a case study relates to the current importance of the technological and policy landscape that it deals with. It addresses the crucial intersection of data privacy and AI, a topic of growing importance as AI technologies increasingly handles

[192] Bundesnetzagentur. (2023). Nutzen statt Abregeln: § 13k EnWG in Kraft getreten. Retrieved June 19, 2024, from https://www.bundesnetzagentur.de/DE/Fachthemen/ElektrizitaetundGas/Versorgungssicherheit/NSA/start.html

sensitive personal data. By fostering responsible AI development, the sandbox seeks to contribute to policy goals related to data privacy and innovation, providing valuable insights into how regulatory bodies can facilitate compliance while encouraging technological advancement.

Background and Context

The Norwegian Data Protection Authority's regulatory sandbox was established in the Fall of 2020 for an initial period of two years as part of the 'National Strategy for Artificial Intelligence' developed by the Erna Solberg Government.[193] This strategy emphasizes the need for Norway to become a leader in responsible AI development, focusing on ethical considerations, privacy protection, and the promotion of human-centric AI. This way, the sandbox was created in response to growing concerns about the impact of AI on data privacy and the need for a regulatory framework that could keep pace with technological advancements. It offers participants the opportunity to receive advice and guidance from an interdisciplinary team from the Data Protection Authority, to ensure that their service or product complies with relevant regulations and respects data privacy requirements.

In 2023, after 4 successful application rounds and more than 10 projects completed, it was decided that the initiative would become a permanent regulatory sandbox for data protection-friendly innovation and digitalization. This way, the sandbox's mandate ceased to be limited to solutions involving artificial intelligence and was expanded to also cover the provision of guidance on the development of innovative and data protection-friendly technological solutions.

The policy context for the sandbox is found in Norway's commitment to data protection as enshrined in the Personal Data Act,[194] which incorporates the EU General Data Protection Regulation (GDPR) into Norwegian Law. These pieces of legislation are designed to ensure that personal data is handled in a manner that respects individuals' privacy rights while allowing for the use of data in innovative ways. The sandbox provides a controlled environment where organizations can explore how to implement AI technologies in compliance with these existing regulations.

The regulatory context also includes the European Union's AI strategy, whose objective is to promote the development of trustworthy AI across Member States. Although Norway is not part of the EU, the sandbox seeks to align with the EU's goals by promoting AI that is ethical, respects fundamental rights, and complies with existing international legal frameworks. In turn, this alignment has the potential to ensure that solutions developed within the sandbox can be scaled and deployed across the European market, enhancing their potential impact and adoption.

Moreover, the sandbox is part of a broader effort by the Norwegian government to enhance the country's digital competitiveness started already years ago. This way, it complements other national initiatives aimed at fostering digital innovation, such as the 2016 Norwegian Digital Agenda[195] and the 2020 National AI Strategy.[196]

---

[193] Ministry of Local Government and Modernisation (2020), 'National Strategy for Artificial Intelligence', https://www.regjeringen.no/contentassets/1febbbb2c4fd4b7d92c67ddd353b6ae8/en-gb/pdfs/ki-strategi_en.pdf

[194] Ministry of Justice and Public Security (2018), 'Act on the Processing of Personal Data' (Personal Data Act), https://lovdata.no/dokument/NL/lov/2018-06-15-38

[195] Ministry of Digitalization and Public Governance (2016), 'Digital Agenda for Norway), https://www.regjeringen.no/en/dokumenter/digital-agenda-for-norway-in-brief/id2499897/?ch=8

[196] Ministry of Digitalization and Public Governance (2015), 'National Strategy for Artificial Intelligence', https://www.regjeringen.no/en/dokumenter/nasjonal-strategi-for-kunstig-intelligens/id2685594/?ch=6

Objectives, Governance, and Funding Model

Steering and Governance

The sandbox is governed by the Norwegian Data Protection Authority (NDPA), which oversees the selection and management of participating projects. A steering committee, comprised of representatives from said Authority, is responsible for ensuring that the sandbox operates in accordance with its objectives and regulatory framework. Moreover, an external reference group, including members from organizations like Innovation Norway and the Norwegian Computing Centre, provides additional oversight and guidance. The purpose of this governance structure is to ensure that the sandbox maintains a balance between regulatory oversight and support for innovation, fostering a collaborative environment where stakeholders can work together to address data protection challenges in AI development.

Funding Model

The sandbox is financed through a combination of public and private funding sources. The main part of the funding is provided by the Norwegian government, with contributions from various ministries including the Ministry of Local Government and Regional Development, the Ministry of Labour and Social Affairs, the Ministry of Health and Care Services, the Ministry of Education and Research, the Ministry of Trade, Industry and Fisheries, and the Ministry of Transport. This multi-ministerial funding approach reflects the interdisciplinary nature of the sandbox and underscores the government's commitment to fostering innovation in the AI sector.

Objectives

- Support innovation in AI: The sandbox's purpose is to serve as a platform for testing and developing innovative AI solutions in a safe, controlled environment.
- Promote ethical and responsible AI development: The sandbox aims to foster the creation of AI solutions that comply with data protection laws and ethical standards.
- Enhance regulatory understanding of participating organisations: It seeks to improve participants' knowledge of data protection regulations and how they apply to AI technologies.
- Improve the Data Protection Authority's knowledge of the practical applications of AI: This expertise will be used to strengthen the agency's advice, administrative processes, supervisory methods and recommendations to policymakers in matters involving AI and privacy.
- Identify potential regulatory risks and problems at an early stage: The initiative seeks to help policymakers to detect regulatory vacuums and sectors in need for their own industry standards.
- Disseminate knowledge and best practices: The sandbox aims to share insights and lessons learned from participating projects with the broader community, contributing to a deeper understanding of how to manage data protection issues in AI development.
- Build societal trust in AI technologies: Ultimately, society at large is expected to benefit from the creation and implementation of innovative AI-based solutions within a framework that emphasizes accountability and transparency and that considers the individual's fundamental rights.

Operating Model and Practices

Participants and Target Groups

The regulatory sandbox targets a wide spectrum of participants, including both public and private sector organizations, and ranging from small startups and SMEs to large enterprises and public institutions. The primary focus is on organizations that are developing or deploying AI technologies and are seeking to ensure that their solutions comply with data protection regulations. Between the establishment of the Sandbox in 2020 and mid-2023, four application rounds have been fully completed, with a total of 63 applications received. Of those, the highest number of applications (19) came from the healthcare sector, followed by the finance sector (11), and the welfare sector (7). Notable participants who participated and successfully completed their project include the Bergen Hospital Trust (BHT), the Akershus Hospital, Finterai, or the Norwegian Labour and Welfare Administration. Notably, the number of applications has decreased over time, going from 25 applications in its first application round, to 6 in the fourth one in the year 2023.

Table 14. Application rounds of Norwegian AI Regulatory Sandbox

Application round	Deadline	Applications	Applications from private sector	Applications from public sector	Accepted projects
1	15/01/2021	25	14	11	4
2	15/09/2021	21	15	6	4
3	25/03/2022	11	8	3	3
4	01/02/2023	6	4	2	2

Besides the actual participants, the sandbox also engages with academic institutions and research organizations, providing them with a platform to test their theoretical models and AI applications in a real-world regulatory environment. Likewise, policymakers and regulators who are interested in understanding how AI technologies can be developed and deployed get involved in the Sandbox. This collaboration aims to bridge the gap between technology development and regulatory compliance, fostering a mutual understanding of the challenges and opportunities associated with AI and data protection.

Roles of Different Stakeholders

- **Norwegian Data Protection Authority (NDPA):** The NDPA is responsible for examining and selecting the projects that will participate in the sandbox. To these participants, the NDPA provides regulatory oversight and guidance, ensuring that their projects comply with data protection laws. The NDPA project group, composed of lawyers, technologists, social scientists and communication consultants, draws up an individual plan for each participant, describing the need for guidance and how it be prepared and implemented. Generally, between 3 and 5 workshops are organized by the NDPA during a total project period of approximately 3 to 6 months. The NDPA is also responsible for the preparation of a final report for the project.
- **Participants:** Organizations developing or deploying AI technologies are the primary participants of the sandbox. These include both public and private sector organizations and range from small startups and SMEs to large enterprises and public institutions.

They are responsible for developing and testing their AI solutions within the sandbox, with the guidance of the NDPA. The kind of support that they receive from the NDPA includes receiving help with identifying data protection issues, getting feedback on relevant technical and legal solutions or data protection challenges, gaining access to an arena for knowledge transfer, and participating in networking opportunities with other relevant actors.

- **Industry stakeholders:** These include technology companies, industry associations, and venture capital firms. They provide financial support, resources, and expertise to the sandbox, helping to foster innovation and commercialization of AI solutions.
- **Academic and research institutions:** These institutions participate in the sandbox to test their research models and AI applications. They contribute to the knowledge base of the sandbox, providing valuable insights and advancing the state of AI research and development.

Key Processes and Services

The sandbox operates through a series of processes and services designed to support participants at every stage of their project development.

- **Application rounds for project selection:** The sandbox organizes periodic application rounds to select new participating projects. These rounds are open to organizations from various sectors, and projects are selected based on their potential impact, innovation, and compliance with data protection laws. An interviewee from the NDPA's management explained that, although for the moment participation in the sandbox remains application-based, the agency is considering transitioning in the future towards a model whereby organizations would be formally 'invited' to participate in the sandbox. Under this model, there would be no application rounds with strict deadlines, and invitations could be sent out whenever it is appropriate. This would be used to ensure that stakeholders deemed by the NDPA with a special potential to benefit from the sandbox participate in it.
- **Selection of participating projects:** The sandbox selection committee, formed by an internal, interdisciplinary group, conducts interviews with all applicants and assess their adequacy and potential to participate in the sandbox. An external reference group, comprised of members from Innovation Norway, the Norwegian Computing Centre, and the Equality and Anti-Discrimination Ombud, helps in assessing the public benefit of the applicants. The final selection of projects is made by the steering committee, made up by the NDPA's management.
- **Interdisciplinary team guidance:** Participants receive support from an interdisciplinary team of experts, including lawyers, technologists, and social scientists. This team provides tailored advice on data protection issues, helping participants address specific challenges related to their AI solutions.
- **Workshops and co-creative sessions:** The sandbox facilitates workshops and collaborative sessions where participants can share experiences, learn from each other, and co-create solutions to common challenges. These sessions promote knowledge sharing and foster a collaborative environment.
- **Final project reports and knowledge dissemination:** Upon completion of their projects, participants are required to submit final reports detailing their findings and experiences. The sandbox publishes these reports to disseminate knowledge and best practices to a broader audience, contributing to the global discourse on AI and data protection.

Collaboration Models and Best Practices

The sandbox emphasizes collaboration between various stakeholders, fostering a multidisciplinary approach to AI development. The NDPA strives to promote open communication and knowledge sharing, encouraging participants to work together to address data protection challenges. Collaborations are facilitated through regular meetings, workshops, and advisory sessions, with the intention of keeping all stakeholders engaged and informed throughout the project lifecycle.

The sandbox promotes best practices in AI development and data protection, encouraging participants to adopt principles of transparency, fairness, and data minimization. It emphasizes the importance of integrating privacy considerations into the design and development of AI solutions from the outset. Participants are encouraged to adopt a proactive approach to data protection, conducting regular privacy impact assessments and engaging with stakeholders to address potential risks. By fostering a culture of compliance and ethical responsibility, the sandbox seeks to helps to build trust in AI technologies and to promote their acceptance and use in society.

Results and Evidence of Impact

The impact of the sandbox can be seen in several key areas:

- **Enhanced regulatory understanding:** According to an interviewee from the NDPA's management, the sandbox has provided the agency with significant insights into the practical application of data protection regulations to AI technologies. Specifically, the sandbox has allowed the NDPA to learn more about the privacy safety considerations of using deep and digital technologies in products and services such as facial detection, identification and personal authentication using biometrics, generative language models, or machine-learning for AI solutions. This has been a valuable resource for the NDPA and has served in the production of guidance materials and policy recommendations. Notably, the interviewee also underscored how this thorough expertise of the functioning of AI technologies has helped the NDPA in inspections and case-handling.
- **Successful project outcomes**: In their final project reports, several sandbox participants express having gained valuable knowledge and experience in managing data protection issues in the development of their AI-related innovations. For instance, Finterai, a Norwegian fintech startup focused on developing machine-learning solutions to detect and prevent money laundering and the financing of terrorism, indicates having reached useful answers to different potential data privacy challenges.
- **Policy development and influence**: The insights and recommendations generated by the sandbox have served to identify regulatory vacuums and to inform the development of new policies and guidelines that promote responsible AI innovation. An example of this can be found in the final report conclusions of the sandbox project of the Norwegian Labour and Welfare Administration (NAV), which dealt with the use of machine learning to predict which patients on sick leave would require a medical follow-up after two months. It argued that for NAV to continue advancing said technology further, legislators would need to develop a supplementary legal basis that clarifies the extent to which personal information can be used for machine learning in the development of artificial intelligence and provides legal certainty.
- **Economic and social impact:** AI solutions that address key societal challenges have been selected to participate in the Sandbox. For example, some projects have focused on developing AI applications for healthcare, which have the potential to improve patient outcomes and enhance the efficiency of healthcare delivery.

Knowledge Dissemination

Due to the limited number of participants that can join the sandbox, sharing the project results, regulatory learning, best practices, and other insights is crucial. Therefore, at the start of their projects, participants must agree to the dissemination and use of their experiences and project outcomes by others. The goal is that not only the participants but also others can gain valuable knowledge on hot to manage data protection issues in developing their AI innovations.

To achieve this, the NDPA diffuse

the knowledge and best practices gained from the sandbox projects in multiple ways. Most importantly, the NDPA produces a series of publications that document the lessons learned from the projects and provide practical guidance on data protection and AI development, including an exit report for each completed project and a comprehensive external evaluation of the sandbox's performance.

However, the interviewed representative of the NDPA mentioned that the dissemination of these resources could be improved and emphasized that reaching as many stakeholders as possible is one of the priorities of the agency's priorities. Specifically, he noted that the NDPA is considering engaging with the higher education sector to share insights from the sandbox with the research and education communities. Additionally, he suggested that the NDPA could not just wait for applications but instead actively r

ach out to potential applicants to ensure a diverse range of applications for sandbox projects.

Key Takeaways

- **Enhanced regulatory understanding**: Since its establishment in 2020, the sandbox has intended to serve as a platform for testing and developing innovative AI solutions in a safe, controlled environment. Its objective was to provide the NDPA with a deeper understanding of the practical applications of AI, and to improve participants' knowledge of data protection regulations.
- **Significant project outcomes**: The sandbox has completed over 10 projects, aimed at helping participants to ensure that their AI-related service or product complies with relevant regulations and respects data privacy requirements. For example, Finterai, a fintech startup, was able to identify potential data privacy challenges related to their machine learning for anti-money laundering.
- **Policy development influence**: The sandbox has identified regulatory vacuums and needs for new policies. An example is the Norwegian Labour and Welfare Administration's project, which highlighted the need for legal clarification on the use of personal data in AI and could lead to potential legislative changes.
- **Challenges in participation and dissemination**: In its latest application rounds, the sandbox has seen a decline in application numbers. The NDPA acknowledges the need to improve the dissemination of knowledge and engage a broader range of stakeholders, especially in terms of potential project applicants, to ensure diverse and impactful participation.

Case E3: European Blockchain Sandbox (EBS)

Case in Brief

The European Blockchain Sandbox (EBS) for Distributed Leger Technologies (DLT) was launched in 2023 with the objective to provide a framework for regulators, supervising authorities and blockchain innovators to engage in regulatory dialogue, identify obstacles from a legal & regulatory perspective in a safe and confidential environment, and thus increase legal certainty for innovative decentralized technology solutions, including blockchain[197]. The sandbox includes a thorough selection of companies on the basis of transparent and non-discriminatory selection criteria and their matching with relevant national and EU regulatory authorities. The EBS allows companies to present their use cases and engage in a safe and constructive dialogue on the most relevant regulatory issues while regulators and authorities are provided the possibility to enhance their understanding of innovative DLT applications and the implications for their relevant areas of regulation. The use cases are selected based on their maturity, legal and regulatory relevance and their contribution to the EU wider policy priorities. The dialogues are held across industry sectors and EU/EEA geographic regions and are expected to identify and communicate best practices in the interest of the wider community[198].

The EBS is an initiative of the European Commission aiming at establishing "a pan-European framework for regulatory dialogues to increase legal certainty for innovative blockchain technology solutions"[199]. This regulatory experimentation tool is focused on digital technologies, i.e. blockchain and other DLT, which fall under "deep and digital technologies" of the STEP classification. Given the accelerated development of the blockchain technology over the last couple of years and the increasing number of regulatory and legislative instruments on digital technologies in the EU (e.g. MICAR, eIDAS, Data regulation and cyber security regulations), the sandbox makes an important contribution to facilitating the uptake of the blockchain technology solutions.

The project is financed by the Digital Europe Programme and is expected to run until 2026. The first year of the sandbox, i.e. 2023, registered a significant success fostering even greater interest among regulators and authorities as well as innovators, compared to the first year.

Background and context

The EBS was established as a result of a reflection within the European Commission on how to enhance the uptake and commercialization of innovative technologies developed by the EU innovators. It is part of the implementation of ambition for Europe's digital leadership in the Digital Decade through increasing legal certainty for innovators. In fact, in the context of the continuously evolving regulatory and legislative framework for digital technologies in Europe (i.e. the regulations are being amended and updated to reflect the fast-changing technology landscape), the legal certainty is enhanced through fostering an informal and safe dialogue between the innovators in blockchain technology and the regulatory and supervisory authorities. Such dialogue helps not only innovators to be compliant with regulations but also builds better understanding of blockchain technology developments among regulators in Europe.

Such dialogue hence plays multiple roles, such as 1) it allows to foster compliance of innovators with regulation in place; 2) explores means through which technology can make compliance and oversight more efficient, 3) raises awareness of the innovators on the benefits

[197] See more details at *European Blockchain Sandbox* (no date). Available at: https://ec.europa.eu/digital-building-blocks/sites/display/EBSI/Sandbox+Project .

[198] EBSI SANDBOXCollab (no date) *European blockchain sandbox Wiki*. Available at: https://ec.europa.eu/digital-building-blocks/sites/display/EBSISANDCOLLAB/European+Blockchain+Sandbox+Wiki .

[199] *European Blockchain Sandbox* (no date). Available at: https://ec.europa.eu/digital-building-blocks/sites/display/EBSI/Sandbox+Project .

the new EU regulations in the area could provide for them – an often-overlooked element of regulations on digital technology, and 4) contributes to regulatory learning in the cross-border and cross-sectoral context since the blockchain technologies are cross-sectoral by nature, enabling exchange of good practices and experiences between the regulators in the field.

The sandbox was also conceived to address the fragmentation in the perception of the blockchain technology across regulators in various EU countries (e.g. some perceiving it as "evil" due to strong association with the cryptocurrency, having little knowledge on the topic, and others having good knowledge of the technology and promoting its development), and to enhance the implementation of the relevant regulations at the level of the EU Member States through increased knowledge on cutting edge blockchain technologies.

Currently, the EU has a set of regulations and legislations which are relevant for the area of digital technologies. A series of them were in focus of the first year of EBS operation, drawing on the use cases selection. These include, for example:

- DLT- and crypto asset specific regulations (Regulation (EU) 2023/1114 of the European Parliament and of the Council of 31 May 2023 on markets in crypto-assets (MiCA Regulation); Regulation (EU) 2022/858 of the European Parliament and of the Council of 30 May 2022 on a pilot regime for market infrastructures based on distributed ledger technology (DLT-pilot Regulation); Regulation (EU) 2023/1113 on information accompanying transfers of funds and certain crypto-assets).
- Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries.
- Commission Implementing Regulation (EU) 2018/2066 on the monitoring and reporting of greenhouse gas emissions pursuant to Directive 2003/87/EC of the European Parliament and of the Council.
- Data protection (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data)
- Data governance (Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance).

Objectives, governance and funding model

The main objective of the EBS is to foster dialogue and cooperation between national and EU-level regulators and supervising authorities with innovative companies (including startups and scaleups), non-profit organisations and public bodies with at least a validated proof of concept. This dialogue aims at removing regulatory and legal uncertainties for use cases in blockchain and DLT[200]. Each year the EBS selects 20 innovators as use cases to take part in the dialogue.

Enhancing the legal certainty passes through the legal advice and regulatory guidance provided to the selected innovators in a safe and confidential environment, thus increasing their understanding of relevant rules and standards to comply with. The dialogue allows to identify regulatory challenges and solutions across industry sectors with blockchain and DLT applications which are represented by the 20 use cases. In parallel, the dialogue between innovators and regulators contributes to better knowledge of cutting edge blockchain technologies by the regulators. The EBS summarizes the experience and lessons learned in

[200] EBSI SANDBOXCollab (no date) *European blockchain sandbox Wiki*. Available at https://ec.europa.eu/digital-building-blocks/sites/display/EBSISANDCOLLAB/Frequently+Asked+Questions .

the sandbox through best practices reports raising the attention of regulators to issues with the law as it stands and benefitting wider blockchain community.

The EBS is governed by a consortium under the lead of the international law firm Bird & Bird with its consulting arm OXYGY supported by the blockchain experts of Warren Brandeis. In addition, the selection of the use cases following the application process managed by Warren Brandeis is overseen by a panel of independent academic experts from European universities. These include Professor Roman Beck (IT-University, Copenhagen), Professor Soulla Louca (University of Nicosia, Cyprus) and Professor Walter Blocher (Universities of Kassel and Vienna). This same panel of experts evaluates regulators participation in the sandbox for the award of the "most innovative regulator".

The EBS is funded by Digital Europe Programme (DIGITAL) and is to run over the period of 2023-2026. The EBS is expected to have three cohorts of innovators in 2023, 2024, and 2025. The first cohort successfully completed its participation[201], and the second cohort has been selected and takes part in the EBS in 2024 at the moment of writing.

Operating model and practices

The EBS does not include legal endorsement or regulatory approval of the use cases, and there are no derogations of applicable laws and regulations. The results of the EBS are made available through best practice reports that include the overview of lessons learnt and next steps while keeping business information confidential.

The target group from the innovators side include companies (including startups and scale-ups), non-profit organisations and public bodies with a validated proof of concept based in the EEA. Non-EEA companies/entities can take part as a consortium member led by an EEA-based entity. From the regulator side, the target group are regulators and supervisory authorities in relevant sectors from the EEA countries and on EU level.

The EBS publishes a call with the expression of interest allowing the innovators to apply to the EBS. The call opening is broadly promoted through an outreach and social media campaign across the EEA countries. The applications are assessed based on the selection criteria (in consultation with the European Commission) by the independent blockchain specialists from Warren Brandeis supervised by a panel of independent academic blockchain experts. The main criteria concern the maturity of the use case (TRL level 5 to 9), legal and regulatory relevance, and contribution to the EU's wider policy priorities, such as the Green Deal and Data Strategy.

The selected cases are then matched with regulatory authorities based on the legal/regulatory analysis of the use case and the regulatory focus area(s) as defined in consultation with the selected use case owner. The use case owner is also invited to voice their ideas on the most relevant regulators/authorities for their case. The identified regulatory/authorities are then approached by the Consortium. In some cases, the innovators provide one or more regulator support letters to their applications which allows then to invite these regulators to participate in the dialogues as the natural starting point for the matching process.

The call to regulators and authorities is made by the Consortium with the organisation of introductory meetings to explain the EBS objectives, answer follow-up questions and agree on the matching combinations. Once the matching process is completed, the dialogue phase starts. It follows the following protocol:

- One-hour technical blockchain session

[201] The best practices report was published in June 2024, Available at: European Blockchain Sandbox releases the complete Cohort 1 Best Practices Report - EBSI SANDBOXCollab - (europa.eu)

- Onboarding webinar of 15 minutes
- First use-case dialogue meeting (1.5 hours, online).
- Second use-case dialogue meeting (1.5 hours, online).
- Provide feedback by submitting a feedback form via EUSurvey (for both regulators and innovators).

For some of the use-cases an extra meeting is organized if appropriate. The objective of the programme is to have 1.5 regulator on average taking part in a dialogue with one use case. For the 2023 cohort, the average was 4 regulators per use case.

The last stage is the development of the "Best Practices Report" per each cohort to summarise the lessons learnt and describe the results[202], as well as the next steps (incl. enhancements to be introduced into the process based on the participants feedback).

After the dialogues for each cohort, the most innovative regulator participating in the sandbox will be awarded a non-monetary prize. The selection of the regulator is done by the panel of independent academic blockchain experts. In 2023, 5 regulators were awarded the prize (Spain, Italy, Germany, and Norway represented).

Results and evidence of impact

The first cohort (first year of operation) of the EBS in 2023 has registered significant success. In particular, the interest among the regulators and innovators to take part in the sandbox was higher than expected. For instance, the EBS received 90 applications for 20 spots in the sandbox from the innovators. Moreover, there are for instance several companies re-applying for the EBS with a different use case demonstrating usefulness of the EBS for the development of their ideas.

When it comes to regulators, well over 50 national and EU regulators and authorities across the EEA expressed their interest in participating in EBS with an average of 4 regulators per use case, more than twice as high as the set target of 1.5 for regulator participation. Almost all regulators manifested interest to take part in the second cohort.

The overall feedback of the first cohort was very positive, the innovators appreciating the legal/regulatory guidance and the possibility to have an open dialogue with regulators/authorities, while the regulators found the EBS useful in learning more about DLT use cases and having a cross-border dialogue with other national and EU regulators/authorities[203].

The Best Practices Report 2023 noted that the regulators appreciated the following aspects of the EBS: the relatively limited time commitment in view of capacity and workload; absence of the regulatory approval and derogation as elements of the EBS; high quality of use cases selected based on the non-discriminatory and transparent criteria and overseen by the panel of academic experts.

The Consortium believes that among the main success factors of the EBS is the quality of use cases participating (due to thorough selection) and of the competence of the team running the project. Among the main achievements is the excellent engagement of regulatory authorities (across sectors and geographical locations) taking part in the EBS in addition to their mandates and on a voluntary basis. Interestingly, the "Most Innovative Regulator" award adds value to the project. The winning regulatory authorities (from different EU regions and competent in a

[202] Ibid.

[203] Ibid.

broad range of regulatory areas) were publicly announced and various authorities have expressed to be keen to be awarded “most innovative regulator”.

Finally, the sandbox got a lot of positive media attention inside the EU but also outside the EU given the innovativeness of the approach adopted to reduce the legal uncertainty in blockchain and DLT.

Key takeaways

- In the case of complex technologies development requiring cooperation of multiple actors from various sectors (e.g. for blockchain/DLT applications, regulators in financial, data protection, intellectual property, consumer protection, healthcare/energy/ICT sectors are involved), the importance of fostering trust between firms and regulators to ensure regulatory certainty and regulatory learning cannot be underestimated. The EBS is an example of provision of such space for interaction between innovators and regulators. It contributes to 1) incentivising firms to innovate further, take on risks while having an increased understanding of the regulatory space and regulators’ approaches to this type of technology; 2) contributes to regulatory learning and strengthening of the capabilities of regulators to support the uptake of such innovations.
- Despite the absence of legal endorsement or regulatory approval of the use cases under EBS and no regulatory derogations provided under the sandbox, the dialogue that the EBS managed to stir seems to have contributed to enhancing the regulators’ understanding of the new technology and fostering trust between the innovators and regulators. This, in its turn, contributes to minimising the risk of the new technology being “too regulated” and not accessing the market relatively quickly.
- Replicating and adapting the model of the EBS to other complex emerging technologies could help reduce regulatory uncertainty and increase regulatory learning at the national and the EU level contributing to improved new technologies uptake and hence, the EU’s competitiveness. The success factors such as the thorough selection of use cases, independent (academic) expert panel for the evaluation of applications by innovators, competent and capable management organisation operating the sandbox, and reflecting on the experiences and lessons learnt in the “Best Practices” report (annually), should be taken into account in this regard.
- The EBS has managed to generate strong positive feedback by both firms and regulators participating, higher than expected levels of engagement (4 regulators per use case instead of 1,5) and interest (90 applications by firms for 20 spots in the programme). It has also contributed to better cross-border collaboration among the regulatory authorities dealing with the DLT development and has fostered significant relevant stakeholders buy-in for the second and third cohorts of the programme.

Case E4: Open Innovation Test Bed for Materials Tribological Characterisation Services (i-TRIBOMAT)

Case in brief

The i-TRIBOMAT is an Open Innovation Test Bed (OITB) for Materials Tribological Characterisation Services. The OITB project ran from 1 Jan 2019 until 31 March 2023 under

the Horizon2020 funding (grant agreement ID: 814494)[204] of the total amount of EUR 7.8 million (EUR 7.1 million as EU contribution). The objective of the project was to facilitate the integration of new materials into products through provision of extensive material characterization services enabling to predict durability of materials in use or novel materials for a wide field of industrial applications. Within the project, use cases included energy efficiency (transportation), renewable energy (wind turbine) and manufacturing (seals). The final outcome of the project was to ensure the establishment of a self-sustained European Single-Entry Point (SEP) offering intelligent tribological materials characterization services.

The project was coordinated by the AC2T research GmbH (Austria), gathering five leading research centres in tribology from Austria (AC2T research), Finland (VTT Technical Research Centre), Germany (Federal Institute for Materials Research and Testing (BAM)), Spain (Fundación Tekniker), and Sweden (Luleå University of Technology). They were joined by two beneficiaries specialised in software (Atos, Spain and Granta, UK) and three industrial partners, namely Toyota Europe (Belgium), Trygonal Iberia (Spain), and Moventas (Finland).

During the Horizon2020 funding, the project established shared infrastructure consisting of different equipment types, including more than 100 tribometers and characterisation equipment, and created an IT-platform and a catalogue of materials characterisation services, novel material database and validated services, as well as collaboration interface[205]. The project results are expected to lead to minimising costs for product design, accelerated development cycles, reduction by 20% of the time-to-market, enhanced materials lifetime and improved components efficiency[206]. The i-Tribomat had an ambition to become the world's first user-driven Open Innovation Test Bed dedicated solely to validating and upscaling new materials, which has turned out to be the case. As of May 2023, i-Tribomat operates as a private enterprise, i.e. i-TRIBOMAT: The European Tribology Centre (i-TRIBOMAT GmbH), representing a European Single-Entry Point for the Materials Tribological Characterisation Services.

Background and context

The i-TRIBOMAT is part of the large-scale initiative of Open Innovation Test Beds launched by the European Commission. The aim of this initiative is to accelerate the development and uptake of innovative advanced materials by European SMEs and industries to help meet EU`s long-term economic, technological and environmental objectives[207]. OITBs offer an opportunity for European innovators to test and validate new and essential technologies before they reach the market. In fact, by pulling together the knowledge, infrastructure and networks of different innovation ecosystem actors in the EU, OITBs address the challenges of high capital costs and complex regulation the tech industries face in the EU, thus helping to bring new innovations to the market faster.

The EU invested more than EUR 319 million to support access to OITBs which is essentially access to the physical facilities and services for the development, testing and upscaling of nanotechnology and advanced materials. The implementation of OITBs is expected to greatly contribute to green and digital transition of the EU and is focused on seven key technology domains: 1) lightweight nano-enabled multifunctional materials and components; 2) safety testing medical technologies; 3) nano-enabled surfaces and membranes; 4) bio-based nanomaterials and solutions; 5) functional materials for building envelopes; 6)

[204] See https://cordis.europa.eu/project/id/814494

[205] Ibid.

[206] Ibid.

[207] See https://cordis.europa.eu/article/id/436434-open-innovation-test-beds-to-accelerate-european-innovation

nanopharmaceuticals production; and 7) climate-neutral and circular materials technologies. In addition, there are two cross-cutting OITBs for material characterisation and modelling, one of which is i-TRIBOMAT[208]. The 2023 publication by the European Commission of CORDIS Results Pack on OITBs featured 10 case studies and 12 cases in the area of advanced composite materials manufacturing[209].

Operating model and practices

The project included 10 participants from 7 countries (as mentioned above), bringing the five leading European tribology research centres, i.e. AC2T research (Austria), VTT Technical Research Centre (Finland), Federal Institute for Materials Research and Testing (BAM) (Germany), Fundación Tekniker (Spain), and Luleå University of Technology (Sweden) join forces under the Singe-Entry Point for tribological characterization of materials services. This consisted in establishing a shared infrastructure and a database of the tribological equipment available, including protocols providing new mechanistic information on materials tribological performance, and developing (and further updating) a catalogue of tribological services with focus on transport, energy and manufacturing sectors.

As part of the project implementation, a database was established to store data generated during tribological materials characterisation, existing material data (material properties, sample history), and data generated before and after tribological materials characterisation (tribo-analytics)[210]. In addition, an IT-Platform was created to provide a web-interface to the end-users and perform the services provided by the to-be-single-entry-point i-TRIBOMAT. Finally, a collaboration interface was established to enable transfer of computational models (i.e. Model-based Lab-to-Field up-scaling tools for materials) and ensure collaboration between stakeholder and dissemination of results to customers (e.g. product design engineers and materials modellers).

An open call was organised in January 2022 to invite innovators to test the services provided by i-TRIBOMAT. External Advisory Board was set up and outreach to the ecosystem was conducted through various awareness raising events, communication channels of partners and dedicated workshops for applicants explaining the objectives of the Open Call. As the result of the call, 18 “Early Adopters” were selected out of 30 applicants who applied to test the services of the OITB. The call was concerned with SMEs and/or large industries based in the EU or H2020 associated countries that apply in given timeframe providing all the necessary information as requested by the application form. The i-TRIBOMAT Evaluation Committee, consisting of i-TRIBOMAT consortium members, was in charge of applications evaluation, having previously signed the non-disclosure agreement. The participation in the OITB for the 18 selected applicants was free of charge (i.e. covered by the H2020 funding) and took form of a collaboration agreement[211]. The services provision by i-TRIBOMAT following the Open Call was used to test the shared infrastructure and the database that were established in the prior phases of the project.

Results and evidence of impact

During the last months of the H2020 funding, the Single-Entry Point resulting from the project was registered as a company (i.e. i-TRIBOMAT: The European Tribology Centre, legally i-TRIBOMAT GmbH), thus meeting the objectives of the H2020 project. The company currently

[208] See https://cordis.europa.eu/article/id/436434-open-innovation-test-beds-to-accelerate-european-innovation

[209] Ibid.

[210] See http://www.i-tribomat.org/project.html#brochure

[211] See http://www.i-tribomat.org/opencall.html

comprises three shareholders, i.e. two out of five research centres initially involved in the project and an external one. The five research centres opted for becoming Service Providers requiring payment of the yearly fees to be "associated" with the European Tribology Centre and receive industry customers. The company shifted towards fee-based provision of services to industry which is the main source of revenues together with the associate membership fees. i-TRIBOMAT GmbH currently employs one person full-time and 3 persons half-time.

The i-TRIBOMAT positions itself as a one-stop shop for the tribological characterisation of advanced materials and a single European entry point for the tribological characterisation services. It offers on-demand services across several categories[212]:

- shared infrastructure for advance tribological material characterisation (i.e. user-specific benchmarking of new materials, evaluation of wear properties and lifetime; friction behaviour under real life conditions, material and surface analysis) providing more than 150 test-facilities and 20 analysis methods.
- data-driven services and insights (e.g. handling and storing test data sets; data base search and big data analysis, tailored report generation)
- customer interface with virtual work rooms, integrated lab-to-field upscaling of materials via simulation and modelling.

By performing the role of a one-stop-shop, the company provides fast time-to-market and cost-efficient material validation to its customers. The customers establish contract with i-TRIBOMAT and the company further matches the demands of its customers with capacities and resources of its partners, i.e. the five leading research centres in tribological material characterisation, drawing on the architecture of infrastructure and database established under the H2020 phase.

Among the key benefits of the OITB phase under the H2020 phase, it could be noted the importance of building strong cross-border linkages and collaborations despite partners/participants being competitors in the field. The excellent support from the project officer within the EC was also noted among the key success elements of i-TRIBOMAT.

Despite being operational and self-sustained currently, i-TRIBOMAT faces several challenges.

The company has difficulties in attracting new clients. The concept of the OITB is poorly understood by the industry which sees OITB as mere intermediaries. Hence, many customers prefer not to pass through the OITB making it necessary for i-TRIBOMAT GmbH to advertise the added-value they have.

From the companies who took part in the Open Call under the H2020 phase, only one company came back to procure services at i-TRIBOMAT at the later stage. The major reason for this might be the unwillingness of companies to pay for such services after getting them free of charge, and the lack of private sector awareness about the opportunities offered by the OITBs in general and the i-TRIBOMAT in particular.

Furthermore, under the H2020 call, the i-TRIBOMAT was supposed to also contribute to normalisation of standards in the area of tribological material characterisation. i-TRIBOMAT has recently launched the Tribology Challenge[213] to harmonize the practices in the field worldwide. However, this task, even though not obligatory, has been very difficult to execute given the substantial resources required to invest in such normalisation, low return (in terms of investments made, especially now that i-TRIBOMAT is operating as a profit-seeking a company) and no support provided in this regard by the European Commission. If some i-

[212] See http://www.i-tribomat.org/content/itribomat-brochure2020.pdf

[213] Tribology Challenge (https://i-tribomat.eu/tribology-challenge/).

TRIBOMAT`s activities had to be dropped to ensure its financial sustainability, standardization activities are likely to be the ones abandoned.

Finally, i-TRIBOMAT highlighted that a relevant follow-up on the OITB once the H2020 funding cycle is over could have been useful to contribute to the sustainability of the OITB (e.g. checking for the matching opportunities, exposing potential further funding options, etc.) and, if done systematically across all OITBs, enable the evaluation of impact of the OITBs on the emerging-tech ecosystem along with evidence-based analysis on improvement of the tool of the OITB going forward (at the European level).

Key takeaways

- OITBs are a powerful tool to build cross-border linkages in the field, promote cooperation (instead of competition) across leading centres of research in Europe, and enable testing of new technologies while connecting the research sector and industry more closely, fostering innovation. Since OITBs do not provide any regulatory derogations and do not directly involve regulators, their strength is ensuring knowledge exchange within multiple geographies in the EU and cross-discipline (at times) and providing space for experimentation that would otherwise not be available for innovators.
- The OITBs can, however, contribute to the normalisation of standards, as actions to promote such normalisation are foreseen by the open call. However, in practice, the OITBs rarey engage in normalisation activities due to associated costs. The role of OITBs in standardisation could be enhanced through dedictaed support from the EC, such as facilitating contact between successful and operational OITBs and EU-funded organizations working on standards, such as the National Metrology Institutes (NMIs), EURAMET, HSBooster, StandICT, Stand4EU, etc.
- OITBs seem to lack follow-up support from the EC once the funding is over which has a negative impact on their effecitveness in the long-term, as the OITBs are expected to become the Single-Entry Points in their respective field under the Horizon Europe call. The follow-up would allow to collect data and evidence of impact of the OITBs to further adapt the EC support for better OITB efficiency. It could also help avoid duplication and unnecessary competition between the OITBs. Currently, there is no catalogue of existing operational OITBs in the EU noting the company type, field, type of services provided, management organization, shareholders, partners involved, etc.
- OITBs are playing an important role in connecting industry to academia. However, there is a lack of awareness among the private sector in the EU on the nature, purpose and benefits of the OITBs. Certain relunctance to engage with OITBs, which was observed in the case of i-TRIBOMAT, is an obstacle for ensuring that the testbeds are achieving the goals they are intended to achieve, especially once their funding is over (i.e. funding under the Horizon Europe). An approach to “label” operational OITBs could help to faciliate the linkages between the OITBs and the industry and to ensure OITBs are powerful and widely used platforms to accelerate the testing and further uptake of technology in the EU.

Appendix 5. EIC project case studies

Table 15. Summary of EIC project case studies.

Case #	EIC project	EIC Programme	Tech area (Sector)	Project Start - End Date	Requested EU Contribution
1	B4Plastics	Accelerator	Biotechnology (Bio-polymers)	01/12/2020 – 30/11/2022	EUR 803 507
2	CleanHME	EXCELLENT SCIENCE - Future and Emerging Technologies (FET)	Clean technologies (Nuclear energy)	01/08/2020 – 31/01/2025	EUR 5 509 447
3	E.T. PACK-F	Transition	Deep and digital technologies (Space)	01/09/2022 – 28/02/2025	EUR 2 499 513
4	Prometheus	EIC SME instrument	Deep and digital technologies (Quantum technologies)	01/08/2020 – 31/10/2022	EUR 2 497 250
5	CATCHER	Transition	Clean technologies (Energy conversation)	01/04/2022 – 31/03/2026	EUR 2 996 550
6	BRIGHT	Accelerator	Biotechnology (non-invasive monitoring)	08/01/2022 – 04/30/2025	EUR 2 497 885
7	SUBRACABLE	Accelerator	Deep and Digital technologies (Superconductivity)	01/09/2023 – 31/08/2025	EUR 2 497 491
8	KRAFTBLOCK	Accelerator	Clean technologies (Energy storage)	01/03/2022 – 29/02/2024	EUR 1 788 062

Case P1: Bioplastics by B4Plastics

Case in brief

B4Plastics is a bio-polymer architecture company, designing and upscaling novel polymeric biomaterials to achieve a new balance in function and sustainability at affordable cost. B4Plastics is operating since summer 2018 and has acquired over 100 active partnerships from its EU/national and business R&D projects, creating forefront IP to new biopolymer families to substitute conventional multibillion markets of (mainly) polyamides, polyesters, polyurethanes, polyvinylchlorides, polyvinyl alcohols, polyolefins, polyethylene glycols. The company is IP intensive and has filed 10 patents over the last six years. The team is comprised of 25 people, 13 being from academic field. The company has survived the “valley of death” and is now in the scale up phase having reached ton-scaled production capacity. The company has recently had its first order of 20 tons of production of the trimming line made from bioplastic.

The company is tapping into the market of trimming line of EUR 400 million and a EUR 500 million market of brush/broom hairs with the innovative FORTAN® product (TRL 9, FortePlastics Platform). B4P's potential markets include tubing for underground drainage and energy infrastructure with the HUMICUR® product (TRL9, TriggerPlastics Platform) complemented by the new AI-supported biodegradability monitoring technique.

The firm's technology – biopolymers fall under the EGD agenda as it aims to help prevent 8 million of tons of plastic waste leaking into the ocean yearly. Designing biomaterials from local renewable resources, also significantly contributes to reducing GHG emissions and hence helping reach the climate neutrality goal. The market for biopolymers in the EU is largely untapped with the overwhelming presence of Asian commodity materials.

To move from an R&D company to a commercial supplier, B4Plastics applied for an EIC grant and obtained under the B4PNOW project a EUR 803 507 contribution for a total cost of EUR 1 147 867,50. The project ran from 1 December 2020 to 30 November 2022 and aimed at moving the technology from TRL 6 to 8. The objective was to launch two first proprietary polymer families (FortePlastics entering an EUR 42+ billion market and TriggerPlastics entering an EUR 300+ billion market). As the result of the EIC project, the B4P brought FORTAN® and HUMICUR® to TRL 9, both being non-persistent mostly bio-based materials offering an alternative to plastics for household and agro applications, such as trimmer lines, clips for tomato cultivation, and underground drainage tubing.

Background and context

The EU framework regulating packaging and plastic waste consists of the Directive 2008/98/EC as amended (the Waste Framework Directive) and Directive 94/62/EC as amended (the Packaging and Packaging Waste Directive). These regulations set out definitions of waste, waste, end-of-waste criteria; introduce the polluter-pays principle, the concept of extended producer responsibility ("EPR") and set the recovery and recycling targets to reduce packaging and packaging waste. In line with the New Circular Economy Action Plan (2020), the European Green Deal (2019) and the Plastics Strategy (2018), the European Commission developed and adopted the EU policy framework on the sourcing, labelling and use of bio-based plastics, and the use of biodegradable and compostable plastics[214] in 2022. However, the framework is not legally binding and there is no EU law currently in place to regulate biobased, biodegradable and compostable plastics in a comprehensive manner with only two laws tackling the issue to a very limited extent, i.e. Directive on single-use plastics (2019), and Directive on plastic bags (2015). Furthermore, there are no EU sustainability criteria that apply to biobased plastics and no standards for bio-based plastics have been set. However, there is a harmonised standard for industrially compostable packaging, and one for biodegradable soil mulch firms, used in agriculture with standards for marine biodegradation missing[215].

Key regulatory challenges of the project

The company highlighted the lack of incentives in the EU legislation on introduction of bioplastics, especially when it comes to bioplastics with new sustainability features for niche applications, as alternative to polymer plastics in industries where B4Plastics can place their products. This includes the telecom industry (i.e. underground tubing from glass fibre infrastructure), household chemicals (i.e. packaging), agro-appliances (i.e. trimming line

[214] *Biobased, biodegradable and compostable plastics - European Commission* (2024). Available at: https://environment.ec.europa.eu/topics/plastics/biobased-biodegradable-and-compostable-plastics_en (Accessed: 12 June 2024).

[215] Ibid.

coatings on seeds or fertilisers, tie-wraps and binders for crop growth), and cosmetics or services industry (i.e. brush and brooming plastic hairs on cosmetic brushes or on street sweepers). The main issue behind the lack of incentives is a financial one, according to the company, i.e. the conventional plastics are cheaper to buy and there are no tax reduction, compensation or subsidy mechanism in place to promote the shift to bioplastics in Europe. The related issue is the need for behavioural change among consumers and industry that could be influenced through policies and legislation sending clear messages on the means of reaching climate neutrality and EGD sectoral objectives, including when it comes to reduction of the use of plastics and transitioning to more biodegradable and compostable alternatives.

B4Plastics considers that sending a strong signal at the EU level to the market on the direction to be taken in shift to bioplastics with clear steps and a timeline would help tackling the problem. The company believes setting concrete and measurable targets on bioplastics use and introducing the mechanism to facilitate and incentivize the industry transition to these alternatives is a viable solution going forward. It was noted that the incentive scheme should be attractive enough to enact the change, i.e. covering half or 2/3 of the cost difference associated with switching to bioplastics by companies. In addition, the creation of a dedicated "reward scheme" for the "first-movers" or compliant companies and labelling products that are not biodegradable could help to set the process on the right track. When asked about the type of incentives to be most effective, the company noted that specific, or product-targeted incentives would bring more positive results rather than generic industry-wide incentives. This position is motivated by the nature and peculiarity of the product use in different industries, e.g. the plastics used for above-ground tubing does not have the same effect on nature as plastics used for under-ground tubing, as these plastic tubes are not excavated after the end of use and remain in soil for 15 or more years.

The company's recent experience with the lollipop sticks producer is a case in point highlighting the crucial role legislation plays in accelerating the bioplastics uptake in a specific sector or in a specific application. In fact, following the adoption of Single-Use Plastics Directive (2019/904) in Belgium on July 5th 2024, using plastic sticks for lollipops was totally banned starting from January 5th, 2025. Hence, the lollipop sticks producer reached out to B4Plastics to explore the solutions offered by company in this regard. Unlike in 2019, when only Belgian competing lollipop producer was in discussions and successful technical trials with B4Plastics on bioplastics alternative for its lollipop sticks and found the price too high, this time the producer prioritised putting the biobased plastics solution quickly into production due to time constraints related to the Directive's entering into force in a couple of months and accepting the higher costs for the bio-based alternative of its plastic sticks.

The other element important to enable the progress on the EU's climate-neutrality objective is the development of evidence base on the transformations of plastics in nature to ensure informed policy decisions in plastics regulation and incentivize durable change in consumer and industry behaviour. This knowledge has so far been quite rudimentary with few tools in place to enable foresight on plastics and other chemicals biodegradation and current certification schemes on biodegradability unfit to effectively address the issue. In this regard, B4Plastics has launched an Accelerated Biodegradability Monitoring Platform (ABMP) which fills the identified gap and allows to get the results on the biodegradability of a chemical or a polymer faster through accelerated test method, i.e. in one year instead of 10 years. The ABMP could be used as a testbed offering the opportunity for European companies to acquire data on their chemicals and plastics transformation in natural habitats. The ABMP is suitable for all chemicals and polymers offering situational biodegradability simulations (e.g. temperature, type of soil, bio microbial composition, etc.). The latest obtention of the mini authorization to gather big data by the company and the use of AI are important drivers behind the predictive power of the ABMP, the recent technology developments in AI offering an opportunity to improve the knowledge on biodegradability as a whole at the EU level.

Opportunities for regulatory experimentation and innovative legislation practices

The following conclusions on the regulatory and legislative framework development in bioplastics could be drawn based on the interview:

- There is currently no legislation in place in the EU to incentivise the shift to for specific applications in industry, even when technology is available at affordable prices. Besides that the market is dominated by the cheap and pollutant Asian plastics (with the exceptions of Directives on single-use plastics and plastic bags).
- There is an ample room for regulatory and legislative change to tackle the issue of plastics, namely:
    - Setting clear targets on bioplastics use in industry (policy);
    - Introduction of specific incentives for shifting to bioplastics in target applications with a proven European green solution that can secure affordability and scale up (e.g. compensation schemes, tax reduction, bonus points or reward mechanisms) targeting specific products to the extent possible;
    - Introduction of labelling of nondegradable products (to facilitate consumer behavioural change);
- Regulatory experimentation spaces and mechanisms should be used to develop evidence base on the fate of chemicals in nature (e.g. launching an Accelerated Biodegradability Monitoring Platform testbed) and promote behaviour change among consumers and industry. For example, European scale-ups in the areas covered by the Green Deal could be awarded to launch pilots of their products in target application fields under specific regulatory regime (derogatory) to gain feedback from the market and introduce improvements for a better technology uptake once it is on the market.

Key takeaways

- There is no EU law in place to regulate biobased, biodegradable and compostable plastics in a comprehensive manner with only two laws tackling the issue to a very limited extent (Directive on single-use plastics (2019), and Directive on plastic bags (2015) and the EU policy framework on the sourcing, labelling and use of bio-based plastics, and the use of biodegradable and compostable plastics[3] adopted in 2022 is not legally binding. There is merit in regulating the target applications of plastics that pollute today (e.g. typical applications that leave microplastics behind in nature, fauna and flora: trimmer lines, brush hairs, cosmetic ingredients, etc.) to promote biobased or “green” alternatives.
- The legislation and regulation in place do not comprehensively tackle the issue of incentives to transition to the biobased plastics alternatives for industry and households. This has a strong negative effect on innovators in the bioplastics sector which do not manage to deploy their technology for years (due to the lack of the demand), despite the high levels of technology readiness and investments made for the technology applications in different sectors.
- The lack of understanding of the life-cycle of the plastics in nature, i.e. concrete data on its degradation and the awareness related to the fate of accumulating microplastics in fauna and flora, and human bodies, hampers the development of a more binding legislation on the use of plastics and foster consumer behaviour change (as an important element of the demand for the bioplastics).
- Regulatory experimentation in the field of bioplastics could contribute to elaboration of regulation on bioplastics conducive to their uptake in the market in line with the European Green Deal objectives. In this regard, “greening” target applications of

plastics could take form of a testbed allowing EU scale-ups to test their product in the real market (with the support of a well-established firm in the dedicated target application field that has put its stamp of approval on the proposed innovation/ is the potential user of the proposed technology). The information gathered during the pilot would allow to better understand the obstacles for the market uptake of the new technology and introduce tailored regulations to foster technologies deployment.

Case P2: Clean energy from hydrogen-metal systems

Case in brief

Clean energy remains a central focus of the EU, in its effort to transition to a low-carbon society. This is partly because both the production and the use of energy account for more than 75% of the EU's greenhouse gas emissions.[216] Therefore, to reach its 2030 climate objectives and to achieve the long-term strategy of achieving carbon neutrality by 2050, the EU must work to decarbonise its energy system.[217]

Hydrogen-metal and plasma systems would facilitate this transition because they could provide a stable source of low-carbon energy. These systems are low-carbon because they use low-energy nuclear reactions (LENR), a type of nuclear reaction that occurs at moderate temperatures as opposed to thermonuclear ones.[218] What is more, current research on LENR is unable to detect excess radiation, making this form of energy appear very safe.[219] As such, the CleanHME project is important because it lays the foundation for the development of a clean technology, which can ultimately help steer the EU towards carbon neutrality.

More specifically, the CleanHME project aims to test a hydrogen-metal and plasma system, a potential new source of clean and efficient energy, which could be used to power small mobile systems or stand-alone generators for private use and industrial applications. The project will do so by testing and prototyping a single nuclear fusion reactor for heat and electricity. Throughout this, partners will also formulate a working theory of hydrogen-metal energy.[220]

The project is coordinated by the University of Szczecin, and partners include universities, research organisations, private for-profit entities and international partners. The partners include four univiersities, four research organisations, seven private for-profit entities and two interntional partners.[221]

Background and context

---

[216] European Commission. "Energy and the Green Deal," April 8, 2022. https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal/energy-and-green-deal_en.

[217] *ibid*

[218] "CleanHME – CleanHME Project Webpage." CleanHME Project. https://www.cleanhme.eu/#home.

[219] *ibid*

[220] *Ibid;* Cordis, 2020. "Clean Energy From Hydrogen-Metal Systems." CORDIS | European Commission. July 15, 2020. https://cordis.europa.eu/project/id/951974.

[221] The partner universities are Politechnika Morska W Szczecinie, Uppsala Universitet, Politecnico Di Torino, and Universita Degli Studi Di Siena. The partner research organisations are Institut für Festkörper-Kernphysik gGmbH, Institut Jozef Stefan, Istituto Nazionale Di Fisica Nucleare, and Centre National De La Recherche Scientifique (Cnrs). The partner private for-profit entities are Futureon SRL, Broadbit Energy Technologies SRO, Vegatec SA, Sart Von Rohr, Lifco Industrie, and Lakoco. The international partners are Massachusetts Institute of Technology and Lakeheard University.

See: Cordis, 2020. "Clean Energy From Hydrogen-Metal Systems." CORDIS | European Commission. July 15, 2020. https://cordis.europa.eu/project/id/951974.

There are three policy and regulatory dimensions to the CleanHME project. These include the broader dimension of policies and regulations relating to the green transition, the narrower policies and regulations related to nuclear energy and the most specific being those related to nuclear fusion. This section will provide a brief overview of both these dimensions, as they relate to the CleanHME project.

The European Green Deal outlines the EU's strategy to achieve climate neutrality by 2050.[222] One approach to achieving this climate goal, is through the transition to green energy sources. For example, under the REpowerEU plan[223], the Clean Energy for All Europeans package[224] and 'A hydrogen strategy for a climate-neutral Europe'[225] the EU creates a pathway towards clean energy. One-quarter of the world's low-carbon electricity is generated by nuclear power, making it the second largest source of low-carbon electricity[226] and pointing to its increasing relevance in green transition. This too is reflected in the establishment of the first-ever Nuclear Energy Summit, held in March of 2024, during which the world leaders discussed the importance of nuclear energy in reducing dependency on fossil fuels and bolstering energy security.[227] With nuclear power as a critical and stable low-carbon energy source, the goals set out by the European Green Deal, and the policies that have emerged in response to it, underscore the motivation for the CleanHME project and others similar to it.

Nuclear energy at the European level is regulated under the Treaty on the European Atomic Energy Community (Euratom).[228] This treaty, dating back to 1957, establishes a common nuclear energy market and serves as a mechanism that facilitates progress within the nuclear energy sector. In doing so, the treaty promotes research and facilitates investment into nuclear energy, working to ensure a stable and equally distributed supply of nuclear energy for all Member States.[229] The treaty does not apply to military applications of nuclear energy, concerning itself only with the peaceful use of nuclear materials.[230] The Euratom treaty establishes uniform health and safety regulations across Member States under the 2013 'Basic Safety Standards Directive'.[231]

For nuclear fusion, the EU has yet to create a regulatory framework dedicated to such technology, leading to a regulatory vacuum.[232] Instead, nuclear fusion is regulated under policies that were designed for nuclear fission, and because nuclear fission poses higher safety

---

[222] "The European Green Deal." 2021. European Commission. July 14, 2021. https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en.

[223] "REPowerEU." 2022. European Commission. May 18, 2022. https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal/repowereu-affordable-secure-and-sustainable-energy-europe_en.

[224] "Clean Energy for All Europeans Package." n.d. Energy. https://energy.ec.europa.eu/topics/energy-strategy/clean-energy-all-europeans-package_en#energy-performance-in-buildings.

[225] European Commission. 2020. "A Hydrogen Strategy for a Climate-neutral Europe." https://energy.ec.europa.eu/system/files/2020-07/hydrogen_strategy_0.pdf.

[226] "Nuclear Power in a Clean Energy System – Analysis - IEA." 2019. IEA. May 1, 2019. https://www.iea.org/reports/nuclear-power-in-a-clean-energy-system.

[227] "Nuclear Energy Summit 2024." 2024. IAEA. https://www.iaea.org/events/nuclear-energy-summit-2024.

[228] "Treaty on the European Atomic Energy Community (Euratom) | EUR-Lex." n.d. https://eur-lex.europa.eu/EN/legal-content/summary/treaty-on-the-european-atomic-energy-community-euratom.html.

[229] *ibid*

[230] *ibid*

[231] "COUNCIL DIRECTIVE 2013/59/EURATOM." 2014. Official Journal of the European Union, January. http://data.europa.eu/eli/dir/2013/59/oj.

[232] Eriksson, Lars-Goran, Maria Papadopoulou, Roberto Passalacqua, and Christopher Ibbott. 2021. "Exploring regulatory options for fusion power plants." Publications Office of the European Union. https://op.europa.eu/en/publication-detail/-/publication/e79311c5-265a-11ec-bd8e-01aa75ed71a1.

risks, when applied to nuclear fusion these regulations tend to be overly conservative.[233] Despite this regulatory vacuum, nuclear fusion has been recognised by policymakers in other ways. Since 2007 the EU established its own consortium, Fusion for Energy, to act as the EU's representative to the International Thermonuclear Experimental Reactor (ITER) project the world's largest nuclear fusion experiment.[234] In a recent amendment to the 'Net Zero Industry Act', the EU included 'fusion energy technologies' among the list of net-zero technologies that promote decarbonisation.[235]

At the national level, most EU Member States have also yet to create a regulatory framework dedicated to nuclear. However, in 2020 the United Kingdom (UK), launched the Spherical Tokamak for Energy Production (STEP) which acts to develop the UK's first nuclear fusion powerplant by 2040 and in 2021 the UK published its first strategy for fusion energy.[236] More recently, Germany announced a nuclear fusion strategy, 'Fusion 2040', which included a nuclear fusion research funding program and plans to build Germany's first fusion powerplant by 2040 as well.[237] Such actions suggest that progress in the regulation of nuclear fusion is forthcoming.

Key regulatory challenges of the project

The key regulatory challenges of the CleanHME project concern the rigidity of safety regulations and discrepancies between regulations inside and outside of the EU. While most project members were not aware of standing legislation, several interviewed project partners expressed that the requirements of the project proposal and the next steps of the project's completion were sources of uncertainty. This section will explore these regulatory challenges and areas of under-regulation and uncertainty.

Nuclear energy is renowned for its strict regulation, especially concerning safety standards. Project participants and coordinators noted in interviews that, even in the experimental stages of their work, safety regulations affected their ability to access materials and at times conduct experiments. Some interviewed stakeholders highlighted that such regulations make the development of nuclear technology very costly and, as they see it, undermine competition in the nuclear energy market.[238]

According to one interviewed participant, SMEs in particular struggle to comply with stringent safety regulations. It was suggested that SMEs are typically resource-constrained and lack funding, and therefore cannot afford to invest in their research and in the monitoring and compliance of the safety regulations.[239] As such, these safety regulations make the cost of

---

[233] *ibid*

[234] "Fusion Energy and ITER." n.d., Energy. https://energy.ec.europa.eu/topics/research-and-technology/fusion-energy-and-iter_en.

[235] "Fusion in EU Net Zero Industry Act." Fusion Industry Association. November 21, 2023. https://www.fusionindustryassociation.org/fusion-in-eu-net-zero-industry-act/.; Ehler, C. 2023. "Consolidated Compromise Amendment On Net Zero Industry Act." https://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/COMMITTEES/ITRE/DV/2023/10-25/05-CA_NZIA_EN.pdf.

[236] Rincon, By Paul. 2020. "UK Fusion Experiment Used in Hunt for Clean Energy." October 29, 2020. https://www.bbc.com/news/science-environment-54741375.

[237] "Fusion 2040 – Forschung Auf Dem Weg Zum Fusionskraftwerk - BMBF." 2024. Bundesministerium Für Bildung Und Forschung - BMBF. https://www.bmbf.de/SharedDocs/Downloads/de/2024/fusion2040_programm.html.

[238] Clean energy from HME. Interview with project participant. May 27, 2024.; Clean energy from HME. Interview with project participant. May 30, 2024.

[239] Clean energy from HME. Interview with project participant. May 27, 2024.

entering the nuclear sector, as an SME, too high and contributes to the low participation of SMEs in the nuclear energy sector.[240]

Similarly, some interviewed participants felt that private companies, as opposed to public institutions, were better able to overcome such barriers to access. According to one interviewee, this is because public institutions, unlike private ones, are hampered by stricter monitoring due to their use of public funds.[241] According to another interviewee, this was because private laboratories are willing to take more risks in terms of safety compared to public ones.[242]

Interestingly, both interviewees cited the benefit of a strong network within the nuclear energy sector, as a means to overcome these barriers.[243] In their experience, a strong network provides team members with more resources, so that when the team does face a barrier, the project is able to overcome it. For example, if one laboratory is not comfortable conducting a particular experiment, a less risk-averse laboratory could help the project team to overcome this.[244]

A similar sentiment was expressed for accessing materials, whereby having a reliable network can better help project teams to source materials.[245] Participants also attributed the EU's single market, and common nuclear energy market under Euratom, as mitigating some of the challenges they faced in accessing materials.[246] One interviewee stressed the importance of establishing strong networks in less populated Member States, noting the importance of reputation in smaller nuclear sectors.

Although interviewees faced regulatory challenges at the EU level, regulatory barriers mostly occurred at the international level. This is because discrepancies between the regulations of countries inside and outside the EU pose challenges to international trade and collaboration. For example, one interviewed project member was unable to purchase lithium 6, a material used for the construction of nuclear reactors, because the sellers, based in the United States, were not permitted to make the sale under national regulations.[247] Similarly, when creating the project's consortium, though coordinators wanted to partner with institutions outside of the EU they were unable to do so successfully due to differences between the regulation of Intellectual Property Rights in the EU and in the United States and Canada.[248]

Most interviewees stated that they were not confident in their knowledge of the key regulations and legislation relevant to the CleanHME project or its sector.[249] Some explained this by the fact that that their institution had a separate department dedicated to navigating such issues.[250]

---

[240] *ibid*

[241] Clean energy from HME. Interview with project participant. May 30, 2024.

[242] Clean energy from HME. Interview with project participant. June 10, 2024.

[243] Clean energy from HME. Interview with project participant. May 30, 2024.; Clean energy from HME. Interview with project participant. June 10, 2024.

[244] Clean energy from HME. Interview with project participant. June 10, 2024

[245] Clean energy from HME. Interview with project participant. May 30, 2024

[246] Clean energy from HME. Interview with project participant. May 30, 2024.; Clean energy from HME. Group interview with project coordinators. June 05, 2024.

[247] Clean energy from HME. Interview with project participant. May 30, 2024.

[248] Clean energy from HME. Group interview with project coordinators. June 05, 2024.

[249] Clean energy from HME. Interview with project participant. May 30, 2024. ; Clean energy from HME. Group interview with project coordinators. June 05, 2024.; Clean energy from HME. Interview with project participant. June 10, 2024.

[250] Clean energy from HME. Interview with project participant. May 30, 2024. ; Clean energy from HME. Group interview with project coordinators. June 05, 2024.; Clean energy from HME. Interview with project participant. June 10, 2024.

Across all interviews, the only specific policy cited was Euratom.[251] In this regard the, one project member felt that the Euratom treaty holds too much power over which research receives funding.[252] In their view, this is because the projects and labs who receive the most substantial funding are those that operate under Euratom.

Importantly, though there is a clear lack of awareness amongst project members about the current regulations, this did not appear a cause for concern. This is partially because project members felt that the regulatory framework would be better established and applied by the time the technology reaches later stages of development.[253] Though there was no clear regulation specific to nuclear fusion, one project member explained that at the current stage of the technology's development, the standard safety regulations applied and that these standards were to be expected.[254] Another participant argued that it was important that these standard safety regulations were in place.[255]

The regulations that did raise concern amongst interviewees pertained to the technicalities of the project itself. Specifically, the requirements that the project's consortium perceived to be challenging included the need for a balance of countries from across the Horizon Europe ecosystem as well as a gender balance amongst team members. This proved challenging because such requirements do not reflect the realities of the nuclear physics sector, and project members felt they could not satisfy them.[256]

Moreover, the inability of the project to reach a higher TRL so that it could secure ongoing funding through, for example, EIC Transition program funding was a source of uncertainty amongst project members.[257] One project coordinator stated that they feel the current TRL is 3.5, and as the project comes to completion, they are uncertain about how to proceed at this level.[258] Many interviewees made the argument that the project needed more time so that a higher TRL could be reached.[259] The project coordinators suggested there should be an additional funding mechanism between Pathfinder and Transition projects to account for projects which have not met the TRL requirements.[260]

Uncertainty was also felt by project members regarding intellectual property and patents.[261] Some interviewees reported feeling uncertain about how intellectual property is being handled and whether the technology would be patented at a later stage.[262] According to one participant, this is because when the technology is developed under EU projects there is no guarantee

---

[251] Clean energy from HME. Interview with project participant. May 30, 2024.

[252] *ibid*

[253] Clean energy from HME. Interview with project participant. May 27, 2024

[254] Clean energy from HME. Interview with project participant. June 10, 2024.

[255] Clean energy from HME. Interview with project participant. May 30, 2024.

[256] Clean energy from HME. Group interview with project coordinators. June 05, 2024.; Clean energy from HME. Interview with project participant. June 10, 2024.

[257] Clean energy from HME. Group interview with project coordinators. June 05, 2024.; Clean energy from HME. Interview with project participant. June 10, 2024.

[258] Clean energy from HME. Group interview with project coordinators. June 05, 2024.

[259] Clean energy from HME. Interview with project participant. May 30, 2024.; Clean energy from HME. Group interview with project coordinators. June 05, 2024; Clean energy from HME. Interview with project participant. June 10, 2024.

[260] Clean energy from HME. Group interview with project coordinators. June 05, 2024.

[261] Clean energy from HME. Group interview with project coordinators. June 05, 2024.; Clean energy from HME. Interview with project participant. June 10, 2024.

[262] Clean energy from HME. Group interview with project coordinators. June 05, 2024.; Clean energy from HME. Interview with project participant. June 10, 2024.

that it will be patented, in part because of the high cost of patenting.[263] To address this, that same participant suggested that a mechanism for patenting be integrated into the project itself, or that the EU develop a governmental body which can help facilitate the patenting of technology developed under EU projects.

Opportunities for regulatory experimentation and innovative legislation practices

Nuclear fusion is increasingly recognised for its potential as a stable source of clean energy and one which can help the EU fulfil its climate agenda. With the research into nuclear fusion still underway there lies an opportunity to craft policy and legislation, specific to nuclear fusion, which will help foster its growth in the current and the later stages of the technology's development.

Fostering this development could take the form of regulatory experimentation spaces. During the interviews, none of the project members stated that they had participated in these experimentation spaces, and most were entirely unfamiliar with experimentation spaces such as regulatory sandboxes, living labs and testbeds.[264] One participant doubted that such spaces would be made available to them in their Member State.[265] However, most participants felt that such spaces would be useful, but at later stages of the technology's development. Specifically, regulatory sandboxes[266] and testbeds[267] were thought to be able to attract partners and facilitate entry into the market.

One project participant who was familiar with such spaces before the interview, specifically regulatory sandboxes, expressed keen interest in the potential of this legislative practice for the CleanHME project and nuclear technology in general. It was indicated that a regulatory sandbox would help SMEs in the nuclear energy sector overcome the high cost of complying with safety regulations, which they felt would create equal competition within the sector.

Key takeaways

Desk research and interviews with project members unveiled the following key takeaways:

- The EU has yet to create a robust regulatory framework dedicated to nuclear fusion, thus creating a regulatory vacuum.
- Stringent safety regulations do pose regulatory challenges for the development of hydrogen-metal and plasma systems, but these challenges tend to be larger when collaborating with countries outside of the EU.
- A strong network inside the nuclear energy sector mitigates the challenges that arise from regulations.
- For interviewed project members, the project's consortium requirements, the TRL level and intellectual property were all sources of uncertainty. A funding mechanism in between TRLs and a governmental body to facilitate patenting could help address this uncertainty.

[263] Clean energy from HME. Interview with project participant. June 10, 2024.

[264] Clean energy from HME. Interview with project participant. May 30, 2024.; Clean energy from HME. Group interview with project coordinators. June 05, 2024.

[265] Clean energy from HME. Interview with project participant. May 30, 2024.

[266] Clean energy from HME. Interview with project participant. June 10, 2024.

[267] Clean energy from HME. Group interview with project coordinators. June 05, 2024.

- If implemented regulatory sandboxes have to potential to mitigate the barriers that stringent safety regulations pose, particularly for SMEs.

Case P3: A Ready-to-fly deorbit device based on electrodynamic tether technology

Case in brief

The long-term sustainability of space activities is a major concern within the scientific community. Most satellites remain in orbit at the end of their operational life because of the high costs associated with their removal. This results in the accumulation of space debris in Low Earth Orbit (LEO), increasing the probability of in-space collision and posing a threat to operational satellites and the space environment. The European Innovation Council (EIC) funded project 'A ready-to-fly deorbit device based on electrodynamic tether technology' (hereafter E.T.PACK-F) is developing a device deisgned to facilitate spacecraft to de-orbit from space. The successful development and deployment of the E.T. PACK- F Deorbit Device will open a market for new de-orbit technologies that provide a lighter and cheaper solution for mitigating space debris and therefore enhance the safety and sustainability of space operations. The Deorbit Device is based on electrodynamic tether (EDP) technology which facilitates de-orbiting of space craft upon the completion of missions. Unlike conventional de-orbiting systems, which de-orbit via chemical propulsion or electrical thrusters, EDP technology does not use a propellant. Instead, a thin aluminium tape generates an electrical current, creating a natural drag which, over time, reduces the altitude of the spacecraft and allows it to more swiftly re-enter the atmosphere. Once re-entered into the earth's atmosphere the space craft then burns-up and is eliminated.

The E.T.PACK-F, an EIC Transition project, builds on the Pathfinder E.T.PACK project, which developed and tested the prototype of the Deorbit Device (TRL 4). The current project aims to continue with this framework and prepare a flight-ready model (TRL 8) for an in-orbit demonstration (IOD) in 2025. A business model for E.T.PACK-F technology commercialisation is also being developed. See Table 1 for additional and specific project information.

The five partner organisations for the project include three universities working directly on the tethering technology: the project coordinator, University Carlos III of Madrid (UC3M), and project participants TU Dresden (TUD), and University of Padova (UNIPD). Two additional participants include SENER Aeroespacial and Rocket Factory Augsburg (RFA) that signed a Launch Service Agreement for the devices first flight and that are the product developers and end-users of the DD.

Background and context

Relevant policies and regulations for the E.T.PACK-F project are those in the space sector which primarily involve those relating to de-orbiting practices and sustainability and safety in space. This section provides an overview of the key policies and regulations in this sector and their relevance to the E.T.PACK-F project.

At the EU level, the ESA Zero Debris Charter and the Space Debris Mitigation Requirements reduce de-orbiting time from 25 years to a maximum of five years. The charter promotes environmental sustainability and industrial competitiveness, encouraging the development of debris-neutral technologies with the goal of making such technologies the standard by 2030. While not mandatory, ESA partners are expected to support the Charter. This Charter was also highlighted in an interview with the project coordinator of the E.T.PACK-F, who noted that

it had encouraged deorbiting and environmental consciousness in the sector, which has been highly beneficial for the EDT technology because the technology can meet these goals.

The ESA Zero Debris Charter aligns with international regulations, such as the US Federal Communications Commission's requirement of reducing de-orbiting time from 25 years to five years, and is viewed by an interviewed project coordinator as the convergence of standards, and they anticipate that the EU will introduce similar regulation. This approach also reflects wider international objectives, including recommendations from the Inter-Agency Space Debris Coordination Committee (IADC) that member agencies (which includes the ESA) improve end-of-life disposal design on space craft; the UN Committee on the Peaceful Uses of Outer Space (UNCOPUOS) guidelines for the Long-term Sustainability of Outer Space Activities which promotes space debris management measures; and the United Nations' Working Group on Long-Term Sustainability of Outer Space Debris recommendations on stricter and more timely de-orbiting practices. The interviewed project coordinator also noted that such guidelines influence legislation, in particular the IADC recommendations which are often adopted into law.

Adhering to timely-deorbiting requirements also enables missions to avoid legal liability and navigate complex international regulatory landscapes. Space debris from collisions can be considered as pollution and subject to the "polluter pays" principle which is embedded in the EU Environmental Liability Directive, and international law, including US environmental law. The principle promotes accountability for space pollution and prevention of environmental damage.

At national level, currently, no country requires that space craft must be removed from space upon completion of their mission. However, security and sustainability issues related to space debris are key elements of many national space strategies and complement the objectives of the E.T.PACK-F to reduce collisions and the creation of harmful space debris. Spain's National Aerospace Security Strategy (2019) highlights the challenges of the increasing volume of space debris for the security of space missions. The Italian Space Strategy similarly promotes the resilience of space infrastructure against space debris. The German Federal Government's Space Strategy also emphasis avoiding the creation of space debris and specifically supports the advancement of new advanced solutions for the removal of space objects. Notably, these examples of national space policy all promote the importance of international cooperation and compliance to ensure sustainable and safe space activities.

Key regulatory challenges of the project

No regulatory challenges were found to have been encountered during the project. However, some general challenges related to regulation were identified which impact on the space sector and market uptake of E.T.PACK-F technology. These are discussed in more detail in this section.

An interviewed project coordinator highlighted the need for a regulatory framework and funding to ensure that space objects can be de-orbited. It was suggested that while a lack of regulation is harmful to the industry, there is also a lack of incentive to regulate as it reduces the competitiveness of the industry. Regulation enforcing de-orbiting requirements means that those implementing space missions must consider expensive and heavy de-orbiting solutions. The interviewee suggested that the availability of lighter and cheaper de-orbiting technology (such as the E.T.PACK-F) could address some of these challenges by providing a viable option for missions to meet regulatory or agency requirements for de-orbiting.

Despite the lower cost offered through E.T.PACK-F developed technology, de-orbiting devices are still expensive. The interviewee suggested that a potential mitigating strategy to meet the changing policy landscape would be a plan of short-term incentives to facilitate the transition from 25-year de-orbit requirements to five-year de-orbiting requirements, which are

anticipated. Currently, it was elaborated, that the industry views this recommendation as costly and burdensome. Incentives, such as financing, would better enable the industry to adjust to new requirements and integrate technologies (e.g. the uptake of de-orbiting technologies in their space craft) to meet future regulation.

Moreover, by incentivising the uptake of electrodynamic tethering, there is an opportunity to increase research and development opportunities across the sector and create a more favourable regulatory environment. For example, EDTs can be used to collect data in orbit which can be used by scientists or sold by operating companies and used to fund the cost of de-orbiting and overcome the associated costs or meeting regulations. Incentives could spur innovation and growth of the sector as well as introduce commercial opportunities which are aligned with regulatory and sustainability goals.

Regulatory gaps in international space law are challenging for debris removal. Current guidelines are voluntary and difficult to enforce, making it harder to coordinate efforts for space debris removal. Similarly, there is often ambiguity surrounding the liability and ownership of space debris, particularly when space crafts are owned and operated by multiple countries. As an example, if a dangerous object requires removal from space, a craft from another country with EDT technology may have the capacity to remove it but might not be legally able to do so if the craft originated from a different country. A cooperative framework would mean that space debris can be more easily removed, EDT technology more readily adopted, and ensure safety and sustainability in space, a key aim of the EU Space Strategy for Security and Defence.

These regulatory uncertainties and lack of enforcement are relevant for technologies such as EDTs because they present obstacles to compliance with de-orbiting requirements which are highly beneficial to the uptake of this technology.

Opportunities for regulatory experimentation and innovative legislation practices

As the regulatory landscape continues to evolve and as space policy becomes prioritised, it is likely that the technology developed through the E.T.PACK-F project will not only benefit from these conditions but support their enforcement. It was noted by an interviewee that EIC funding for this project was pre-emptive. When the project was initiated, de-orbiting technology was not a priority in the industry due to its cost and the additional weight of implementation. Throughout the project, de-orbiting recommendations and requirements have become more stringent and the EIC funded project is able to benefit from this new landscape.

Notably, the E.T.PACK-F project has not been involved in experimentation spaces. However, as indicated by an interviewee, the project's compliance with ESA requirements has positioned it well to adapt to future regulations. This proactive adherence to industry measures, which are often guided by international consensus, ensures that the technology is in step or even ahead of regulatory developments. In this way, the project coordinator felt that, due to a lack of regulation at EU or national level, adherence to ESA standards had acted as a proxy regulatory sandbox.

Key takeaways

From the desk research and stakeholder inputs, the following key takeaways have been gathered:

- Regulatory uncertainty and lack of regulation reduce industry competitiveness and hampers the market uptake of emerging technologies such as the E.T.PACK-F. As such, more stringent regulations which favour the timely de-orbiting of space craft would create beneficial conditions for the market uptake of the technology.

- Regulatory conformity at national, EU and international level would allow for a more sustainable and secure space environment and benefit collaborative research and innovation, enhancing knowledge and data sharing, and commercial opportunities.
- Funding incentives would help the industry meet current guidelines and the anticipated regulatory changes which would obligate space crafts to de-orbit in five years or less, which would entail the addition of costly de-orbiting devices.
- Proactive development of emerging technologies in anticipation of regulatory changes positions them well to benefit from and support an evolving regulatory environment.

Case P4: IQM Quantum Computers

Case in brief

IQM was founded in 2018 in Finland as a spin-out from Aalto University's Quantum Computing and Devices (QCD) group and the Finnish State Research Centre (VTT). It is the European leader for quantum computing and has commercialized superconducting qubits and quantum information processing technologies. In 2020, IQM received EUR 2.5 million (grant and equity based) in EU funding though Horizon 2020's Industrial Leadership pillar as a sole beneficiary. The aim of the Prometheus project is to develop the first commercial 1000-qubit quantum computer. In short term, the aim was to deliver 5- to 20-qubit devices to supercomputing centres. The processors developed in this project represent the order of magnitude required to run commercially viable quantum algorithms.[268] The development of the technology has taken further steps in recent years. In 2023, IQM and VTT launched Finland's second quantum computer – a 20-qubit superconductive device. Moreover, significant steps have been taken that will enable the scaling up of the now completed 20-qubit quantum computer to 50-qubits. VTT and IQM plan to complete the upgrade by the end of 2024.[269]

According to the IQM's informant, the EU funding was crucial in successful implementation of the project as well as raising additional funding from other private and public sources. Additionally, IQM has received funding though Finnish government, private financiers and participated in EU funded joint research programmes. In Finland, the quantum computer is located in Micronova, which is a national research infrastructure maintained by VTT.

IQM serves as an interesting case study for examining the impact of EU regulations on the development and market uptake of quantum computers. The Prometheus project underscores the transformative potential of quantum computing and the critical role of EU support in achieving technological milestones. The EU's strategic funding and support have been crucial in positioning IQM at the forefront of the quantum computing industry. Moreover, quantum computing, as a strategic and fast evolving technology, is a technology sector, where big part of the regulation is aiming at reducing risks of European economic security, leading into regulation that empowers development, funding and collaboration. In that sense, the recent developments in regulation regarding quantum technologies are changing fast as the global geopolitical tensions are increasing.

Background and context

The regulation of quantum computing in the EU involves a multi-faceted approach, addressing R&D funding, data protection, cybersecurity and trade controls. These regulations are

268 Cordis. https://cordis.europa.eu/project/id/959521

269 VTT: https://www.vttresearch.com/en/news-and-ideas/finland-launches-20-qubit-quantum-computer-development-towards-more-powerful-quantum

designed to foster innovation, secure Europe's competitiveness and economic security and ensure security and privacy of end-users. Regulation regarding quantum computing can be roughly classified into 4 types: 1) supporting and enabling regulation that aims to foster European economic security and competitiveness, 2) trade and export controls, 3) regulation aiming to mitigate quantum computing specific risks, such as quantum safe cryptography and 4) general regulation that impacts companies in all sectors, such as GDPR or ESG related matters.

The regulation in first and fourth categories is widely EU level, and the two others showcase significant variance across Member States, creating barriers due to lack of clarity and compatibility. Moreover, as the technology is still emerging and novel, there are vacuums in regulation, mainly in EU level joint regulation and standardization. The most important regulatory uncertainties are currently related to access to skilled research and development staff and employee retention, as the field is characterized by need for highly specialized research knowledge that is with high strategic importance for countries. Current increases in geopolitical tensions make firms anticipate on regulation regarding free flow of research staff. Firstly, there is a joint understanding in Europe on the strategic significance of quantum computing technologies, which has been determined as strategic and critical technology[270], underlying its high priority for EU's sovereignty. Both, EU level regulation and funding, are highlighting this importance and aim to foster European economic security and competitiveness though increased funding and collaboration. This aspect has been stressed as the global geopolitical tensions are intensifying though Russian war and trade war with China.

In 2018, the Council Regulation ((EU) 2018/1488[271], now replaced by Regulation (EU) 2021/1173)[272] on establishing the European High Performance Computing Joint Undertaking, stressed the need to develop a world-class ecosystem in supercomputing and quantum computing technologies and applications across Europe. In the aftermath of the regulation, the EU set up the Quantum Technologies Flagship, which is a ten-year initiative that aims to bring research results closer to industrial exploitation. In 2019, another initiative, the EuroQCI[273] (now part of IRIS), was launched to build and deploy an EU wide secure quantum communication infrastructure, enabling information and data to be transmitted and stored and to be capable of linking critical public communication assets throughout the Union. In 2023, EU launched another regulation ((EU) 2023/588)[274] for establishing the Union Secure Connectivity Programme for period 2023-2027, which aims to provide a satellite-based, multi-orbital communication infrastructure for governmental use and develop further and gradually integrate the European Quantum Communication Infrastructure (EuroQCI) initiative into the secure connectivity system. Secondly, also relating to enhancing European Economic security, EU has been negotiating about need for trade and export controls. A recent "European Economic Security Strategy" is based on a three-pillar approach: 1) promotion of the EU's economic base and competitiveness, 2) protection against risks and 3) partnership with the broadest possible range of countries to address shared concerns and interests. The strategy states that there is a need to expand the EU toolkit regarding exports and outward investments

270 Regulation of the European Parliament and of the Council establishing the Strategic Technologies for Europe Platform ('STEP') COM(2023) 335 final

271 Council Regulation (EU) 2018/1488 of 28 September 2018 establishing the European High Performance Computing Joint Undertaking

272 Council Regulation (EU) 2021/1173 of 13 July 2021 on establishing the European High Performance Computing Joint Undertaking and repealing Regulation (EU) 2018/1488

273 European Commission. https://digital-strategy.ec.europa.eu/en/policies/european-quantum-communication-infrastructure-euroqci

274 Regulation (EU) 2023/588 of the European Parliament and of the Council of 15 March 2023 establishing the Union Secure Connectivity Programme for the period 2023-2027

in some key enabling technologies with military applications. These dual-use technologies include quantum computers, semiconductors and artificial intelligence. These planned extensions of export controls are aiming to mitigate risks related to technology security and leakage.[275] The regulation has been noted also at IQM. Currently, the future impacts of the strategy are still uncertain, especially regarding its impacts on regulation on employment and international research collaboration. This was identified as a very significant regulatory uncertainty. Additionally, there are hopes that the future regulation will be able to balance correctly between the security issues and promotion of quantum technologies. There is a potential threat that too stringent regulation may crowd out skilled labour and investments and slow down the process of scaling up the technology.

EU has also specific regulation on limiting exports of dual-use technologies, which in some cases may include also quantum technologies.[276] So far, this has not had significant impacts on exports at IQM. However, such regulatory uncertainty has led to increased administrative costs as it creates needs to produce background studies. Additionally, many components or their raw materials (e.g. Helium-3) that are used in quantum computers, are a subject to import controls. According to the informants at IQM, trade regulation has significant variation across Member States, which creates uncertainty for developing and bringing quantum computers to markets. mThirdly, policymakers have globally realized potential risk of quantum computers' ability to break existing encryption protocols on internet, which endangers encrypted messaging and online banking services. To mitigate the risk, a need to develop post quantum cryptography (PQC) has been identified.

The need for developing PQC has been acknowledged in EU documents ((EU) 2023/588)[277], but it includes only recommendations instead of binding regulation. According to the interviews, some Member States have proceeded with national regulation regarding development of PQC, but there is lack of EU level regulation regarding this. In this regard, USA is in the forefront of the regulation. The US legislation[278] has mandated that the timeline to change to PQC will be from 2025 until 2033, by which time the cyber secure supply chain will have to have transitioned to using PQC by default. In 2025, web browsers and software updates will have to become post-quantum secure by default if they are sold to the US. The EU has also specific regulation on limiting exports of dual-use technologies, which in some cases may include also quantum technologies.[279]

So far, this has not had significant impacts on exports at IQM. However, such regulatory uncertainty has led to increased administrative costs as it creates needs to produce background studies. Additionally, many components or their raw materials (e.g. Helium-3) that are used in quantum computers, are a subject to import controls. According to the informants at IQM, trade regulation has significant variation across Member States, which creates uncertainty for developing and bringing quantum computers to the market. Finally, quantum computing is subject to many general, technology neutral EU level regulations, that are common to nearly all business sectors. Such regulations are e.g. General Data Protection

[275] Joint communication to the European Parliament, the European Council and the Council of "European Economic Security Strategy" JOIN(2023) 20 final

https://data.consilium.europa.eu/doc/document/ST-10919-2023-INIT/en/pdf

[276] Regulation (EU) 2021/821 of the European Parliament and of the Council setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items.

[277] Regulation (EU) 2023/588 of the European Parliament and of the Council of 15 March 2023 establishing the Union Secure Connectivity Programme for the period 2023-2027

[278] H.R.7535 - Quantum Computing Cybersecurity Preparedness Act

[279] Regulation (EU) 2021/821 of the European Parliament and of the Council setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items.

Regulation (GDPR) ((EU) 2016/679)[280] and regulation on ESG matters. Additionally, the Cybersecurity act (EU) 2019/881)[281] and NIS2 directive ((EU) 2022/2555)[282] may have direct impacts on quantum technologies, but they are also technology neutral. Due to their general nature, they are not investigated in-depth in this case study.

Key regulatory challenges of the project

Overall, the interviewee at IQM describes the impacts of regulation as a two-edged sword. On one hand, the EU is supporting and enhancing the development of quantum technologies through funding programmes, joint research efforts and policies, but on the other hand, especially in the current geopolitical situation, some regulation is severely hampering free flow of knowledge, skilled staff and financing, as well as making it more difficult to import necessary components and to export final products. Moreover, lack of coherent regulation and standards across Member States and other countries, creates uncertainty in both research and development as well as market uptake of the technologies. Despite some challenges, the interviewee sees the net impact of EU regulation and activities as positive and emphasizes that a right balance between supporting and limiting actions should be found.

As described in the previous chapter, large part of EU regulation regarding quantum technologies is related to setting up programmes that aim to support the development though funding, public procurement and collaboration. The informant highlights that these subsequent programmes, such as Quantum flagships, EuroQCI and Joint Undertakings have been playing a crucial role in supporting the development and commercialization of the technology. Also, the fact that Commission has defined quantum technology as a strategic and critical technology has spread the general knowledge about quantum computing and its importance. This has partly aided in receiving support and funding from public and private sources.

Finally, the programmes have facilitated collaboration and exchange of ideas across Member States, which has had a positive impact. However, the need for public sector support is continuous, as the quantum technology is currently in a lifecycle phase, where its past startup phase, but large-scale commercial applications or defence investments are still far in the future.

The challenges on the other hand rise largely from the geopolitical sphere, hampering imports and exports as well as collaboration with non-EU countries, particularly China and some extent also other grey-zone countries, such as India, which may be considered to have a backdoor to countries like Russia. All three aspect as highly important for development and commercialization of quantum computing. Firstly, many of the components or raw materials used in the hardware are subject to import controls, such as Helium3 and semiconductors, and the regulation varies across the country of origin. Secondly, export controls on items that have potential dual use properties hamper commercialisation of quantum technologies. Secondly, the informant highlights that the current geopolitical situation, is creating a significant barrier in collaborating with researchers and professionals from certain countries, hiring new staff and in general, free flow of ideas. Especially in terms of innovation, global exchange of ideas has a significant role. However, it must be noted, that not all tensions arising from geopolitical issues is regulation related. Some might be also related to e.g. financing institutions own policies. On

[280] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)

[281] Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (Text with EEA relevance)

[282] Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive)

the positive side, the informant points out that North Atlantic collaboration has increased somewhat, especially though institutions like NATO. Finally, there seems to be a lack of standardisation in the spere of quantum technologies and agreements on interfaces. The informant points out that due to lack of standards, even developing regulation is difficult. aSecond challenge in regulation, pointed out by the informant relates to alignment of regulation. Despite the EU regulatory efforts, there seems to be significant variance across the Member States, which creates significant uncertainty to both development and commercialisation. For instance, the trade controls are to some extent country specific and often require collaboration with the national Ministry for Foreign Affairs. The informant emphasised that uniform trade controls across Member States would improve the system significantly. Another quantum specific regulation that is varied across Member States, is the regulation regarding PQC. Despite being noted for its importance in EU level policy documents, a common regulatory framework is still missing. aIn summary, regulations' impact to development and commercialisation of quantum computers is two-fold. On one hand, the EU is highly involved in supporting it, but on other hand, the geopolitical risks are closing the world, which has a negative impact. Additionally, much of the regulation is heterogenous across Member States, which creates inefficiencies and uncertainties.

IQM has no experience in regulatory experimentation spaces as such. However, they have been participating in national research infrastructure and several joint research programmes. Overall, they see great benefits in all kinds of collaboration for research and development.

Opportunities for regulatory experimentation and innovative legislation practices

EU regulations, while providing essential support, also create barriers that impact the company's progress. On the supportive side, EU-level regulations have established programmes and activities that foster innovation through funding, collaboration, and the strategic positioning of quantum technology as critical for European sovereignty. Programs like the Quantum Technologies Flagship and EuroQCI have been instrumental in advancing research and promoting the commercialization of quantum computing, thereby enhancing European competitiveness.

However, the regulatory environment is also marked by considerable challenges. The fragmented and somewhat unpredictable or unclear regulatory landscape across EU Member States, particularly in areas such as trade and export controls, creates significant uncertainty. For IQM, navigating these regulatory challenges have led to increased administrative burdens. Regulation also has negative impacts in the operating environment – such as investments and labor market. Furthermore, geopolitical tensions, reflected in stringent regulations on the free flow of research talent, imports of raw materials and exports of dual-use technologies, exacerbate these challenges. Current or anticipated regulations designed to protect economic security, such as those limiting collaboration with non-EU countries, may restrict IQM's access to global expertise and materials critical for quantum computer development.

Additionally, the lack of standardized regulations and clear guidelines, especially in areas like post-quantum cryptography, hampers cohesive development across the EU. Variations in national regulations lead to inefficiencies. While EU regulations aim to balance promoting innovation with mitigating security risks, the current geopolitical climate and regulatory fragmentation often hinder the free exchange of ideas and resources, ultimately impacting the broader market adoption of quantum technologies.

Key takeaways

- In case of quantum computing, EU regulations' impact is two-fold. On one hand, several regulations have aimed at developing programmes, such as Quantum flagships, EuroQCI and Joint Undertakings that increase funding, public prcurement and collaboration, and hence greatly supported development and commercialization of the

technology. On the other hand, the current geopolitical challenges have led to protectionist regulation, which hampers imports, exports, collaboration and hiring qualified staff.

- The most important regulatory uncertainties are currently related to access to skilled research and development staff and employee retention, as the field is characterized by need for highly specialized research knowledge that is with high strategic importance for countries. Current increases in geopolitical tensions make firms anticipate on regulation regarding free flow of research staff.
- Another barrier is related to lack of coherence between regulation within Member States. This creates significant uncertainty and increases administrative burden.
- Regulatory experimentation spaces are not familiar for the informants. However, collaboration and joint efforts are seen as highly beneficial for development of quantum technologies.

Case P5: Humidity-to-energy technology of Cascatachuva

Case in brief

The Cascatachuva technology case draws on the “CATCHER” project (Creation of innovative "humidity to electricity" renewable energy conversion technology towards sustainable energy challenge) funded by the EIC[283].

The CATCHER is a 4-year project running from 1 April 2022 to 31 March 2026 with the total budget of EUR 2 996 550. It aims to develop an innovative technology exploiting the atmospheric humidity for direct conversion to the electricity, thus gaining a new sustainable source of renewable energy and contributing to priorities for strengthening the EU leadership on renewables. Overall new source potential is estimated at 500 times more of the current global energy needs (i.e. ca. 15 000 000 TWh of electricity generation) with one conversion module have the production capacity of 10kWh per day.

The project is implemented by a multidisciplinary consortium consisting of qualified research and businesses in material science, physics, nanoelectronics, green chemistry, nanoengineering, sustainability and research marketing from six countries, i.e. Portugal, Belgium, Austria, Spain, Poland and Ukraine[284]. The CASCATACHUVA startup was launched to be the leader of the project R&I and project results exploitation and business' plan development, go- to the market strategy elaboration and related aspects.

The project builds on the previously developed humidity-to-electricity converter device prototype (funded by the Horizon 2020 under 2016-2019 H2020-MSCA-RISE-2015 HUNTER project) and has the objective of advancement, optimization and scaling up of the technology with its further integration into the EU electricity grid. Currently, the project is at the TRL 4 stage with the work focused on the development of the Engineering Prototype (to be validated in 2025).

The project and the innovative technology it aims to develop is fully aligned with EU policy and objectives on renewables and sustainability. In particular, the project will allow applying recent advancements in nanotechnology science and engineering to address DIRECTIVE (EU) 2018/2001 on the promotion of the use of energy from renewable sources, EU Strategic Energy

---

[283] *‘Creation of innovative “‘humidity to electricity’” renewable energy conversion technology towards sustainable energy challenge’ | CATCHER Project | Fact Sheet | HORIZON* (no date) *CORDIS | European Commission*. Available at: https://cordis.europa.eu/project/id/101046307 .

[284] Ibid.

Technology Plan (SET Plan) and EU Re-thinking 2050 strategy. The results of the optimization and scaling up of the technology would allow to contribute to the EU's reputation as a global renewable leader.

Background and context

The EU regulation in the area of the renewable energy promotion consists of the DIRECTIVE (EU) 2018/2001 on the promotion of the use of energy from renewable sources[285]. The Directive stresses the important role of the increased use of energy from renewable sources for the reduction of greenhouse gas emissions and hence compliance with the EU's commitment under the 2015 Paris Agreement on Climate Change. The Directive establishes a common framework for the promotion of energy from renewable sources, set binding EU target of 32% of the share of renewable energy in total gross energy consumption by 2030, and emphasizes the benefits of moving towards a decentralized energy production.

Furthermore, in November 2023, the revised Renewable Energy Directive (2018), which includes faster and simpler permitting procedures for renewable energy projects and their related infrastructure projects, entered into force. Following the Russian aggression against Ukraine and the objective of the EU to cut down its dependence on Russian fossil fuels, a REPowerEU plan was introduced in 2022 with a set of measures to accelerate the renewable energy uptake by removing administrative barriers have been introduced. More generally, the renewable energy acceleration is part of the objectives of the European Green Deal and the corresponding European Climate Law with significant contribution of renewables to achieving the climate neutrality by the EU by 2050.

In addition, the EU Strategic Energy Technology Plan (SET Plan) (2007)[286] aims to accelerate the deployment of green technologies to enable the transition towards a climate-neutral energy system in the EU. The SET Plan is one of the main instruments of the Energy union's pillar 5 on research, innovation and competitiveness[287]. The SET Plan is currently being revised to ensure its objectives are harmonised with the EU Green Deal, REPowerEU and the Green Deal Industrial Plan. Finally, the SET Plan focuses on 10 actions for research and innovation across the whole innovation chain, including the research and market uptake, financing and regulatory frameworks, etc.

The regulation of the atmospheric humidity to electricity conversion type of technology for the moment is absent due to the absolute novelty of the solution proposed. However, solar energy regulation by the EU is being used by the project team to guide the assessment of commercial viability of the technology.

Key regulatory challenges of the project

Overall policy and legislative context focused on carbon-neutrality and increasing the share of the renewables presents a favourable environment for development of the technology and provides positive prospects for its commercialisation at scale.

The gap in regulation of the "humidity-to-electricity" technology at the European and national level is explained by the novelty of the proposed technology. The legal definition of such new

[285] Directive (EU) 2018/2001 of the European Parliament and of the Council of 11 December 2018 on the promotion of the use of energy from renewable sources (recast) (Text with EEA relevance.). Available at :https://eur-lex.europa.eu/eli/dir/2018/2001/oj .

[286] European Commission (no date) *Strategic Energy Technology Plan*. Available at: https://energy.ec.europa.eu/topics/research-and-technology/strategic-energy-technology-plan_en .

[287] European Commission (no date) *Energy union*. Available at https://energy.ec.europa.eu/topics/energy-strategy/energy-union_en .

source of energy is considered by the project team as a necessary first step towards facilitating the technology development and further adoption at scale.

To deal with the existing gap in legislation, the project team has been using the solar power technology regulation to assess the commercial potential of the power system and necessary regulatory compliance requirements. The similarity with the solar energy generation devices is based on the alike functional characteristics, including the mobility of the "humidity-to-electricity" device, much like the solar panels, but in this case the device will take the form of the box (conversion module of 1m3) that could be installed in the humid place in a household or industrial sites (indoor and/or outdoor).

As mentioned by the project team, the un-regulation of the novel technology creates some uncertainties in terms of compliance with regulations that might be applicable once the technology is deployed at a commercial scale. For instance, if the technology is installed by households, i.e. installation of the portable device in the form of the box of the volume of one cubic metre in the basement or balcony of a residential building, there is a need to comply with legislation on domestic health and security, the noise/vibration legislation (as the device is expected to produce noise). If the technology is to be installed on the industrial sites or be incorporated into the construction of buildings (as this is envisaged by the team for the next generation of such devices), additional compliance efforts are required.

The tentative list of the EU regulations to comply with might include:

- CE Marking[288] to ensure the product meet high safety, health, and environmental protection requirements.
- Low Voltage Directive (LVD) (2014/35/EU)[289] to ensure the electrical equipment provides a high level of protection for users and operates safely.
- Electromagnetic Compatibility (EMC) Directive (2014/30/EU) to ensure that electromagnetic disturbances of the device do not interfere with other equipment.
- Eco-Design Directive (2009/125/EC) to ensure the device comply with specific requirements to ensure energy efficiency and environmental performance.
- Restriction of Hazardous Substances (RoHS) Directive (2011/65/EU) in electrical and electronic equipment.
- Energy Labelling Regulation (EU 2017/1369) to indicate energy consumption and efficiency.
- General Product Safety Directive (2001/95/EC) to ensure safety of the device as a consumer product.
- Construction Products Regulation (EU) No 305/2011 in case the device is integrated into the building structure (at a later stage of the device development and commercialisation).
- Waste Electrical and Electronic Equipment (WEEE) Directive (2012/19/EU) to provide collection, recycling and recovery of the device once it is out of use.
- National Grid Connection Requirements in case the device will feed the electricity into the grid (which is expected under the project), etc.

---

[288] European Commission (no date) *CE marking*. Available at https://single-market-economy.ec.europa.eu/single-market/ce-marking_en

[289] European Commission (no date) *Low Voltage Directive (LVD).* Available at https://single-market-economy.ec.europa.eu/sectors/electrical-and-electronic-engineering-industries-eei/low-voltage-directive-lvd_en .

A testbed or a solution (for example, a dialogue platform as is the case for DLT in EBS) that would facilitate the navigation through these compliance requirements would help to accelerate technology deployment and commercialisation, save time and resources and support the necessary enhancements to the device, if required.

The project is looking for the supportive regulatory and standardization framework and in this respect the application for the EU Regulatory Blockchain Sandbox was submitted but the project was not selected as the result (i.e. given no prior experience in blockchain and the nature of technology).

Currently, the project team is currently looking to ensure the technology qualification according DNV RP A203* (Recommended practice, Edition 2019-09 - Amended 2021-09) and would benefit from assistance in this step and further steps as the technology is a demonstration and deployment stage.

Among major challenges for the future adoption of technology, the project team considers financial incentives for households and industry. Ensuring such incentives are in place would require introduction of relevant legislation at the EU level (e.g. tax credits, voucher schemes, opportunity to sell excess energy to the grid, etc.).

Opportunities for regulatory experimentation and innovative legislation practices

The testing of the new “humidity-to-electricity” technology could benefit from participation in the regulatory experimentation spaces such as testbeds or sandboxes in energy or “smart city” areas, as the proposed technology lends itself well to the application within the scope of the enhancements to urban mobility, sustainability in construction and energy efficiency and carbon neutrality of cities.

At the moment, the Cascatachuva case represents an unregulated technology that is in early stages of development. Given the novelty of the technology, the company has difficulties in perceiving potential regulatory compliance measures (burden) and also requires appropriate testing environment to enhance and prepare its technology for the scale up at the later stages. Currently, the reflexions and expectations of innovators on future regulation is guided by the EU regulation of solar panels, given the similarity of the devices. In this regard, there is merit in engaging into a dialogue with relevant regulatory authorities once the technology is at TRL5/6 in order to foster better understanding of the technology by the regulators and enhance understanding of the regulatory environment for such type of technology. This dialogue could take form of a loose “sandbox” or “regulatory dialogue”. In addition, since the company is to launch the “early adopters sales” at TRL 8, the participation in the sandbox could help to test the technology in real-world settings and facilitate the uptake of the technology in the market later, i.e. building the awareness and the demand in the market, and hence accelerate its scale up (and the benefits in entails for the carbon-neutral objectives). Finally, the benefits of using a sandbox to test new technologies also include regulatory learning and strengthening the preparedness of the regulatory frameworks for the similar future breakthrough technologies in energy sector.

Key takeaways

- The regulation of the humidity-to-electricity technology is non-existent due to the complete novelty of the technology and its early stages of development (currently, work conducted on Engineering Prototype). This regulatory gap is perceived as a barrier by innovators making them advance with the technology development in the context of the regulatory uncertainty. However, this uncertainty has so far been mitigated by application of the example of regulation of solar panels for the humidity-to-electricity technology due to similarities in operation of those technologies. Nevertheless,

regulatory gap will become more of an issue as the technology progresses to next stages of development and will most likely require specific legislative and regulatory provisions to enable its commercialisation.

- The participation in the suitable regulatory experimentation tool would make a strong contribution to Cascatachuva's technology commercialisation and deployment, save time and resources and support the necessary enhancements to the device. A sandbox would provide for the possibility to test the technology in real-world settings while also hold consultations with regulators on the regulatory framework and its potential changes when such technology is deployed in the market. In addition, the sandbox could help to enhance regulatory learning and build trust between regulators and innovators with contribution to faster tehnology development and uptake. For now, the, the company was not able to find such a regulatory experimentation space to meet its needs.
- In the case of novel ground-breaking technologies, such as the humidity-to-energy device proposed by Cascatachuva, it seems that finding a space to build better understanding of potential regulatory compliance costs and later fostering the demand in the market (through the "early adopter" phase) is particularly difficult as the technology simply does not "belong" to the standard boxes. Providing a space that would allow to engage in the discussions with the regulator early on in the process (e.g. at TRL5/6) would help to ensure more certainty for the next stages of technology development and enhance regulators' understanding of potential impact of such technology on the market early on (and develop relevant regulation).
- When it comes to technology deployment, the legislation, and in particular the establishment of the right financial incentives for adoption of the technology by households and industry is seen as an important enabler for the technology uptake. Ensuring such incentives are in place would require introduction of relevant legislation at the EU level (e.g. tax credits, voucher schemes, opportunity to sell excess energy to the grid, etc.) keeping in sight the limitations of potential sectoral regulations without considering change on a more systemic level.

Case P6: Best-in-class cancer diagnostic chip for patient stratification

Case in Brief

The BRIGHT project is executed by RUBYnanomed,[290] a Portuguese healthcare startup. The company aims to introduce breakthrough lab discoveries into the medical market.[291] For the BRIGHT project, RUBYnanomed is applying advanced microengineering and nanotechnology to develop a microfluidic-based liquid biopsy device, the RUBYchip (PCT/EP2016/078406). One of the most innovative features of the RUBYchip is its' non-invasive nature. Unlike traditional methods, such as biopsies, the RUBYchip utilises a liquid biopsy approach by analysing circulating tumour cells (CTCs) from a blood sample, making it minimally invasive compared to traditional biopsies which require taking a sample of body tissue.[292] By eliminating the need for more invasive procedures, the RUBYchip method is cost-effective as it reduces the need for surgical interventions and lowers hospitalisation costs. Moreover, RUBYnanomed's technology allows for non-invasive monitoring of tumour behaviour without

[290] "RUBYnanomed," Accessed 21 June 2024 https://rubynanomed.com/.

[291] 'RUBYnanomed - Portugal Ventures', 12 March 2021. https://www.portugalventures.pt/en/portfolio/rubynanomed/.

[292] 'Our Product – RUBYnanomed'. Accessed 21 June 2024. https://rubynanomed.com/our-product/.

the need for frequent invasive interventions. This leads to more targeted and appropriate treatments, reducing the need for costly repeat procedures and facilitating unprecedented frequent monitoring of cancer progression.

BRIGHT is an EIC Accelerator Challenges funded project, running from 2021 to 2025 (see Table 19 for additional project information). Notably, on top of the BRIGHT project, RUBYnanomed is also a partner in the ongoing Pathfinder Future and Emerging Technologies funded project '*Ultrasensitive BIOsensing platform for multiplex CELLular protein PHEnotyping at single-cell level'* (BIOCELLPHE) running from 2021 to 2025.[293] While the objective of the BRIGHT project is to further develop the RUBYchip, the aim of the BIOCELLPHE project is to develop a different kind of diagnostic technology that uses engineered bacteria to target and identify CTCs. As of 2024, the RUBYchip is at a Technology Readiness Level (TRL) of 6[294] and through the support of the BRIGHT project, RUBYnanomed is in the process of conducting pre-clinical trials across multiple hospitals in Europe for various cancer types.[295] The BRIGHT project therefore serves to prepare the technology for commercial deployment.

Background and context

The development and implementation of advanced diagnostic tools such as the RUBYchip are influenced by multiple policy and regulatory dimensions. Particularly, the RUBYchip aligns with several key EU health and technology agendas such as the Medical Device Regulation (MDR)[296] and the In Vitro Diagnostic Regulation (IVDR)[297]. This section describes the policy and regulatory context which relates to the BRIGHT project and the biotechnology sector.

The BRIGHT project operates within a robust regulatory framework established by the European Union, which significantly impacts the development and marketing of its innovative diagnostic technologies. The European Commission's Horizon Europe program underscores the importance of personalised medicine and advanced diagnostic tools in enhancing patient outcomes and reducing healthcare costs.[298] As part of this initiative, the EU's Cancer Mission aims to save more than three million lives by 2030 through improved cancer prevention, diagnosis, and treatment.[299] The RUBYchip™ technology, designed to enable early and accurate monitoring of cancer progression, aligns with these goals, contributing to better patient outcomes and supporting the broader EU agenda of combating cancer.[300]

---

[293] Cordis EU "Ultrasensitive BIOsensing Platform for Multiplex CELLular Protein PHEnotyping at Single-cell Level," CORDIS | European Commission, Accessed 21 June 2024, https://cordis.europa.eu/project/id/965018.

[294] INL News Website. 'RUBYNANOMED, INL Spin-off, One of 65 Innovative Start-Ups and SMEs to Receive €363 Million EIC Funding', 14 October 2021. https://www.news.inl.int/blog/rubynanomed-eicfund.

[295] "BRIGHT PT," RUBYnanomed. Accessed 21 June 2024. https://rubynanomed.com/portfolio-item/bright-pt/.

[296] "Regulation - 2017/745 - EN - Medical Device Regulation - EUR-Lex," April 5, 2017, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745.

[297] "Regulation - 2017/746 - EN - Medical Device Regulation - EUR-Lex," April 5 2017, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0746.

[298] 'Personalised Medicine - European Commission', 25 October 2023. https://research-and-innovation.ec.europa.eu/research-area/health/personalised-medicine_en.

[299] 'EU Mission: Cancer - European Commission', 14 May 2024. https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/eu-mission-cancer_en.; 'A Cancer Plan for Europe - European Commission'. Accessed 21 June 2024. https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union/cancer-plan-europe_en.

[300] "RUBYnanomed,"

To ensure compliance and market readiness, the BRIGHT project must adhere to stringent EU regulations. The MDR[301] and the IVDR[302] are critical in this regard. The MDR sets out comprehensive requirements for the safety and performance of medical devices, including provisions for clinical evaluation, post-market surveillance, and conformity assessment. It emphasises the necessity of clinical evidence to support manufacturers' claims.[303] Similarly, the IVDR governs in vitro diagnostic medical devices, mandating high standards of safety and performance through requirements for clinical performance studies and rigorous risk management protocols.[304] All in all, compliance with the MDR and IVDR ensures high safety and performance standards, crucial for effectively coping with cancer.[305]

Portugal, as an EU Member State, adheres to EU regulations and directives regarding medical devices, such as the MDR[306] or IVDR.[307] In addition, the Portuguese Health Products Regulatory Authority (Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. - INFARMED) oversees regulatory compliance of medical devices, ensuring they are in line with EU regulations and Portuguese safety and performance standards.[308]

Key regulatory challenges of the project

Medical devices are situated in a complex regulatory ecosystem, one which requires specialised expertise to navigate. This has only become more complex with the recent introduction of the IVDR. The key regulatory challenges which RUBYnanomed faces involve the lack of robust financial support, a lack of clarity in device classification and bottlenecks in certification processes. These challenges have led the project to take mitigating actions, which include hiring subcontractors and seeking medical certification outside of the EU.

Since RUBYnanomed has no prior experience in bringing a product to market, the firm lacked knowledge of the policies and regulations relevant to medical devices. Interviewees explained that the startup team tackled this challenge by attending numerous workshops, accelerators, and conferences dedicated to these topics. Additionally, they surrounded themselves with knowledgeable partners and policy experts in order to gain the necessary expertise.[309] Nevertheless, these mitigation strategies placed additional financial strain on the firm, as policy experts are costly, and subcontractor expenses are excluded from overhead costs under EIC project funding.[310] Interviewees felt that it was nonetheless necessary to incur these additional expenses, viewing policy experts as essential for obtaining regulatory approval of the device.[311]

---

[301] "Regulation - 2017/745 - EN - Medical Device Regulation - EUR-Lex," April 5, 2017, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745.

[302] European Commission - European Commission. 'Press Corner'. Text. Accessed 21 June 2024. https://ec.europa.eu/commission/presscorner/home/en.

[303] "Regulation - 2017/745 - EN - Medical Device Regulation - EUR-Lex,"; European Commission - European Commission. 'Press Corner'. Text. Accessed 21 June 2024. https://ec.europa.eu/commission/presscorner/home/en.

[304] 'Our Product – RUBYnanomed'. Accessed 21 June 2024. https://rubynanomed.com/our-product/.

[305] "New Regulations," Public Health, Accessed 24 September, 2024, https://health.ec.europa.eu/medical-devices-sector/new-regulations_en.

[306] "Regulation - 2017/745 - EN - Medical Device Regulation - EUR-Lex,"

[307] "Regulation - 2017/746 - EN - Medical Device Regulation - EUR-Lex," ; 'About Infarmed'. Accessed 21 June 2024. https://www.infarmed.pt/web/infarmed-en/about-infarmed.

[309] RUBYnanomed, Interview with employee 23 July 2024

[310] *Ibid*

[311] *Ibid*

They argued that the need to hire policy experts underscores the complexity of the regulations in the sector.[312]

A related issue is that, despite efforts to navigate the regulatory landscape via subcontractors, the device does not neatly fit into the device classifications delineated by the IVDR. This is because to classify a device the IVDR relies, in part, on the device's intended purpose and in having multiple applications the RubyCHIP could have different intended purposes.[313] Project members explained that in some applications the RUBYchip can be considered a class A because it is non-invasive, however, in other applications the device can be considered class C because it impacts patient management.[314] What is more, being a class C device, as opposed to a class A device,which would require it to follow a more demanding regulatory path to obtain certification.[315]

Additional challenges to product development arise from delays in device certification proccesses, caused by the capacity constraints of notified bodies following the introduction of the IVDR. In a 2021 position paper notified bodies expressed concern over the implementation of the IVDR, stating that because there were six IVDR-designated notified bodies, compared to the twenty one under the previous regulatory framework, and an increase the number of devices which required certification, there would be bottlenecks in certification process.[316] BRIGHT project members felt that notified bodies were still adjusting to IVDR, and that these bottlenecks were still present.[317]

The issue of delayed certification processes is compounded by a lack of sufficient funding in the field of diagnostic technologies. Interviewees reported that venture capitals favour investments in biotechnologies, pharmaceuticals and digital health.[318] According to the project team, the few investors in diagnostic technologies they identified were reluctant to invest in the firm because the device was outside of their specialisation and was yet to generating revenue. A more streamlined regulatory certification process would enable the project team to bring the RUBYchip to market faster, and therefore better position the team to attract and gain the trust of investors.

To combat certification delays of class C devices, RUBYnanomed decided to first pursue class C certification in the U.S., while concurrently pursuing class A device certification in the EU.[319] The decision to first pursue class C device certification in the U.S., as opposed to the EU, was made because the U.S. streamlines class C device certification with a 510(k) clearance pathway.[320] A 510(k) clearance pathway is a premarket submission made to the U.S. Food and Drug Administration (FDA) which expedites the market approval of a device if submitters can sufficiently demonstrate that their device is as safe and effective, therefore substantially

[312] *Ibid*

[313] "Regulation - 2017/745 - EN - Medical Device Regulation - EUR-Lex,"

[314] *Ibid ;* RUBYnanomed, Interview with employee 23 July 2024

[315] *Ibid*

[316] Sal Lucido, "EU Medical Device Regulation Still Presents Challenges and Opportunities," January 13, 2024, https://www.assurx.com/eu-medical-device-regulation-still-presents-challenges-and-opportunities/.; "Position Paper on MDR/IVDR Implementation," Team NB, December 1, 2021, https://www.team-nb.org/team-nb-position-paper-on-mdr-ivdr-implementation/.

[317] RUBYnanomed, Interview with employee 23 July 2024

[318] RUBYnanomed, Interview with employee 23 July 2024

[319] *Ibid*

[320] *Ibid*

equivalent, to an already legally marketed device.[321] The approval process takes approximately 90 day, and brings medical devices to market faster by allowing some firms to bypass certain clinical trials.[322] If approved as a class C device in the US, the team will seek reapproval as a class C device in Europe. In other words, the project team is relying on the US approval system to mitigate the slowness of the EU system.

Furthermore, one interviewee highlighted the transferability of FDA approval to other countries, particularly those in the Arab region. In their view, the FDA's approval had more international recognition than that of the EU, making FDA approval more desirable in the team's effort to penetrate new markets.[323]

By consulting with experts and taking advantage of other regulatory ecosystems, such as that of the US, RUBYnanomed was able to work around issues of regulatory complexity and delayed certification processes. With that said, the absence of robust funding networks for medical devices and the lack of clarity in device classification are challenges that remain.

Opportunities for regulatory experimentation and innovative legislation practices

BRIGHT project members participated in regulatory experimentation spaces, specifically living labs and testbeds, as a means to further develop the RUBYchip. Regarding living labs, project members felt that these spaces are made redundant by clinical trials, which are required for device certification. Regarding testbeds, project members explained that although these regulatory experimentation spaces had the potential to be helpful, they often did not provide them with sufficient support due to a disconnect in their specialised expertise and the realities of product development.[324] Interviewees suggested that testbeds would be more effective if they were managed by entities that were not primarily research-focused and if they dedicated more resources to technology transfer activities.[325] The challenges faced by project members could also be addressed by a regulatory sandbox.

According to one interviewee, the regulatory experimentation spaces availble to them during the BRIGHT project did not address their most pressing needs. Using the example of living labs, the interviewee explained that while these spaces were easily accessible, the requirement of the RUBYchip to undergo clinical trials in order to obtain medical certification meant that living labs provided limited additional value.[326] In their view, support should instead focus on economic means and active regulatory assistance.

Moreover, when regulatory experimentation spaces included partners with regulatory expertise, another project member noted that these experts remain too hermetic in their spheres of knowledge.[327] In their view, there is a need for more knowledge transfer between regulatory partners and those involved in product development, and these should happen at earlier stages of product development, perhaps even in university studies.[328] For example, via a testbed RUBYnanomed sought advice on how to classify their device under the IVDR, but because the regulatory expert lacked technical medical knowledge, they were unable to

---

[321] Center for Devices and Radiological Health, "Premarket Notification 510(K)," U.S. Food And Drug Administration, August 22, 2024, https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k.

[322] *Ibid*

[323] RUBYnanomed, Interview with employee 23 July 2024

[324] *Ibid*

[325] *Ibid*

[326] *Ibid*

[327] *Ibid*

[328] *Ibid*

provide satisfactory advice.[329] The lack of practical expertise among regulatory partners is aggravated by the increasing privatisation of testbeds, one interviewee stated that they work as typical consultants, but often charge the same amount with less experience.[330]

The project members agreed that some improvements could be made to testbeds.[331] For instance, they felt that testbeds should not be led by research institutes, but rather by those with more practical experience, as this would help close the knowledge gap between regulatory expertise and expertise in product development.[332] Additionally, interviewees stressed that there should be a greater focus on technology transfer and that more technology transfer offices should be established and made easily accessible. These changes would improve the practicality of testbeds, enabling them to better support firms in bringing their technologies to market. Notably, however, the needs of project members could also be met by a regulatory sandbox. This is because a regulatory sandbox would offer project members an opportunity to engage directly in a dialogue with regulators, express their challenges and be better informed on how to navigate the regulatory framework.

Key takeaways

The introduction of the IVDR has led to bottlenecks in approval processes, which further delays the efforts to bring the RUBYchip to market. This poses additional challenges to startups in diagnostic devices, particularly those bringing their first technologies to market, such as RUBYnanomed, relevant investors are limited, and reluctant to invest in firms that are yet to generate revenue.

The firm has participated in innovation testbeds and living labs, in a further the development of their device, but project members were nevertheless critical of these spaces. Interviewees felt that living labs were made redundant by the regulatory requirements for clinical trials. Furthermore, they were also critical of testbeds, arguing that despite their knowledge of regulations, policy partners lacked an understanding of the product and its development, rendering them ineffective advisors. RUBYnanomed has also sought external support from regulatory experts outside of testbeds, who they felt were better able to inform the firm on which regulatory pathway to take. However, because subcontractors are not covered under EIC overhead costs, the hiring of such experts causes the firm additional financial stress.

Changes to testbeds, for example, by designating their management to entities that are more practically oriented as opposed to research oriented, could offer firms better support and potentially reduce the need for subcontractors. Additionally, testbeds could be improved by integrating technology transfer offices into their spaces, and therefore build on their capacity to support firms in bringing their innovation's to market. However, the challenges faced by project members could also be addressed via a regulatory sandbox, as this would allow them to engage directly with regulators.

Improvements to testbeds are not universal solution, as they will not solve the bottlenecks in regulatory approval processes under the IVDR. Such bottlenecks influenced RUBYnanomed to pursue U.S. FDA approval for the RUBYchip's, as their 510(k) regulatory pathway streamlines approval processes and garners more international recognition.

[329] *Ibid*

[330] *Ibid*

[331] *Ibid*

[332] *Ibid*

Case P7: Making Superconducting power grids a feasible solution for Europe

Case in Brief

Making Superconducting power grids a feasible solution for Europe (SUBRACABLE) is a grant agreement between the European Innovation Council (EIC) and SUBRA, a superconductor manufacturer. SUBRA itself was formed as a spin-out from the Technical University of Denmark.[333] As part of the EIC's Accelerator programme, SUBRACABLE is a funding scheme to support and further the development of high-temperature superconductor (HTS) technology. The proprietary technology delivers electricity at lower resistance, meaning less electricity is lost in transmission, and requires fewer materials (copper) and less physical space for infrastructure. HTS provides lower costs for energy transmission and more sustainable use of resources and energy.[334]

Traditional transmission systems have electrical resistance, where the energy transmitted encounters atomic-level obstacles leading to the loss of electricity through heat. In 2020 during the transmission and distribution of electricity across Europe, 16% of energy was lost due to resistance.[335] The HTS cables being developed by SUBRA use an ultra-thin ceramic bundled in wires and conduct electricity with zero resistance.[336] Operating at 196ºC, SUBRA's conductor is classified as high temperature because, relative to traditional superconductors, which operate at -270 ºC, the temperature is much higher.[337] At this higher temperature, the conductor also requires 99% less copper than the average conductor and SUBRA estimates that their cables are 100 times more affordable than existing models.[338] Being both highly efficient and cost-effective, SUBRA's HTS cables have the potential to be a key part of the infrastructure required for Europe's transition to clean energy.[339]

Presently, no reports on the progress of HTS from SUBRA have been published, however, prototypes of the HTS are expected to be delivered in the coming months.[340]

Background and context

To satisfy carbon emission targets and make gains on the transition to clean energy, the European energy grid must be both expanded and modernised to efficiently transmit and distribute clean energy from wind and solar farms.[341] In various EU countries Transmission System Operators (TSOs), the organisations responsible for the transmission of energy, have demonstrated that planned network developments often do not align with the pace of the

---

[333] "Press Release: SUBRA Wins EIC Funding," SUBRA June 20, 2023, https://subra.dk/2023/06/press-release-subra-wins-eic-funding/.

[334] *Ibid*

[335] "New Power Cables in Europe to Make Energy Cheaper and More Sustainable," Horizon Magazine, May 29, 2024, https://projects.research-and-innovation.ec.europa.eu/en/horizon-magazine/new-power-cables-europe-make-energy-cheaper-and-more-sustainable.; Wołowiec, Tomasz, Svitlana Kolosok, Tetiana Vasylieva, Artem Artyukhov, Łukasz Skowron, Oleksandr Dluhopolskyi, and Larysa Sergiienko. 2022. "Sustainable Governance, Energy Security, and Energy Losses of Europe in Turbulent Times" *Energies* 15, no. 23: 8857. https://doi.org/10.3390/en15238857

[336] "New Power Cables in Europe to Make Energy Cheaper and More Sustainable."; "Press Release: SUBRA Wins EIC Funding,"

[337] "New Power Cables in Europe to Make Energy Cheaper and More Sustainable."

[338] *Ibid*

[339] "Press Release: SUBRA Wins EIC Funding,"

[340] *Ibid*

[341] Szymon Kardás "Gridlock: Why Europe&Rsquo;S Electricity Infrastructure Is Holding Back the Green Transition," ECFR, October 26, 2023, https://ecfr.eu/article/gridlock-why-europes-electricity-infrastructure-is-holding-back-the-green-transition/.

energy transition.[342] For instance, according to a recent SolarPowerEurope press release, countries such as Lithuania and Ireland have multiplied their solar power goals by 5 or 10 times respectively. However, these countries lag when it comes to making energy transition a reality through grid deployment, modernisation and flexibility. [343]

The 2030 climate and energy framework proposes new targets and measures to make the EU's economy and energy system more competitive, secure and sustainable.[344] It includes targets, such as reducing greenhouse gas emissions and increasing the use of renewable energies.[345] The misalignment, between climate goals and energy infrastructure, threatens necessary grid investments, which are crucial to achieving the EU's 2030 energy security and climate objectives. Efforts are being made under REPowerEU, the EU's strategy to reduce the EU's dependency on Russian fossil fuels and accelerate the transition to renewable energy sources.[346] Under REPowerEU the EU has devoted EUR 29 billion for grid infrastructure maintenance and upgrades until 2030.[347] That said, investment is estimated to be short by at least EUR 5 billion annually, assuming infrastructure remains technologically the same.[348]

According to the European Network of Transmission System Operators for Electricity's (ENTSO-E) Ten-Year Network Development Plan, the cross-border transmission infrastructure should double within the next seven years to accommodate the newly increased energy consumption standards which ought to increase by 60% by 2030.[349] This means that the infrastructure's capacity needs to be expanded so that it can support an additional 23 gigawatts (GW) by 2025 and a further 64 GW by 2030.[350] In practice, such would require the building of additional energy transmission grids, which are costly. However, superconductor power grids, which utilise similar technology as SUBRACABLE, can transfer more GW of energy without wasting additional energy, making it a cost-effective solution.

To meet these ambitious goals, the European Commission estimates that an investment of EUR 584 billion is necessary for the electricity grids within this decade,[351] though some have

---

[342] "Grid Operators: TSO and DSO Explained – gridX," Accessed July 11 2024, https://www.gridx.ai/knowledge/what-is-a-grid-operator.

[343] 'New Analysis: EU Countries Increase 2030 Solar Goals by 90% but Grid Planning Trails - SolarPower Europe'. Accessed 11 July 2024. https://www.solarpowereurope.org/press-releases/new-analysis-eu-countries-increase-2030-solar-goals-by-90-but-grid-planning-trails.

[344] "The 2030 Climate and Energy Framework," Consilium, October 23, 2014, https://www.consilium.europa.eu/en/policies/climate-change/2030-climate-and-energy-framework/.

345 Communication From The Commission To The European Parliament, The Council, The European Economic And Social Committee And The Committee Of The Regions A Policy Framework For Climate And Energy In The Period From 2020 To 2030 (2014). Https://Eur-Lex.Europa.Eu/Legal-Content/EN/ALL/?Uri=Celex%3A52014DC0015.

[346] "REPowerEU," European Commission, May 18, 2022, https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal/repowereu-affordable-secure-and-sustainable-energy-europe_en.

[347] "Questions and Answers on the REPowerEU Communication," European Commission - European Commission, May 18, 2022, https://ec.europa.eu/commission/presscorner/detail/en/qanda_22_3132.

[348] Elisabeth Cremona and Chris Rosslowe, "Putting the mission in transmission: Grids for Europe's energy transition," *Ember-Climate.Org*, Ember, March 13, 2024, https://ember-climate.org/app/uploads/2024/03/Grids-for-Europes-Energy-Transition-Report-1.pdf.

[349] Goyal, Khushboo. 'EU Grid Action Plan: Seeks to Address Missing Links of Energy Transition - REGlobal - Mega Trends & Analysis'. REGlobal, 8 January 2024. https://reglobal.org/eu-grid-action-plan-seeks-to-address-missing-links-of-energy-transition/.

[350] "Planning the Future Grid - TYNDP," Accessed September 10, 2024, https://tyndp.entsoe.eu/.

[351] Energy. "Energy," Accessed September 10, 2024. https://energy.ec.europa.eu/index_en.

argued that this is an underestimate.[352] Efforts to harmonise the EU's energy network are apparent in the Commission Regulation (EU) 2017/1485 of 2 August 2017[353] which establishes guidelines for the operational procedures and technical requirements necessary to ensure the secure, reliable, and efficient operation of the electricity transmission system. Furthermore, the publication of the Action Plan for Grids in November 2023 aims to address the missing links of the European green transition, by emphasising the need to make electricity grids more effective and their rollout both faster in construction and broader in geographic scope.[354]

SUBRA technology plays a pivotal role in addressing the current challenges and future demands of Europe's energy grid. This is because the technology being developed by SUBRA enhances the efficiency and capacity of power transmission while also supporting the integration of renewable energy sources. The HTS cables have the capacity to contribute to the EU's 2030 targets by connecting of offshore wind and solar farms to the onshore grid. The technology also has the potential to mitigate the substantial investment requirements by providing a more cost-effective alternative to traditional power grids, thereby ensuring a resilient and future-proof energy network.

Key regulatory challenges of the project

At this stage in the technology's development, a project coordinator reported that SUBRA faces no regulatory challenges or issues due to under regulation.[355] The EIC programme manager argued that was likely due to the stage of development that SUBRACABLE is in at the moment.[356] Nevertheless, the programme manager maintained that SUBRA is very likely to face regulatory challenges at later stages of the technology's development, such as differing standards for electricity across Member States, delays in testing due to environmental regulations and accessing sufficient financial support.

The energy system is regulated on the Member State level which means that the standards for power differ across different states. In practice, this poses challenges to technologies like SUBRA who need to adapt their technology's capabilities to comply with the set regulations. According to the programme manager, policymakers are aware of the need to standardise energy systems, and policy has been moving in this direction. They felt that this movement can even be seen on the micro-level with the standardisation of the USB-C as the phone cable in the common charger directive.[357] Nevertheless, in their view, because the changes for SUBRA need to happen at the macro-level, requiring synergies between energy infrastructure, it poses a much larger challenge and requires more time.[358]

---

[352] 'EU Energy Ministers Plan Power Grid beyond 2030. Šefčovič: "600 Billion Is Needed for Infrastructure."', 16 April 2024. https://www.eunews.it/en/2024/04/16/eu-energy-ministers-plan-power-grid-beyond-2030-sefcovic-600-billion-needed-for-infrastructure/.

[353] "Regulation - 2017/1485 - EN - EUR-Lex," August 2, 2017 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R1485.

[354] European Commission - European Commission. 'Press Corner'. Text. Accessed 8 July 2024. https://ec.europa.eu/commission/presscorner/home/en.

[355] SUBRA Interview with Employee August 21, 2024

[356] Interview with EIC Programme Manager September 4th, 2024

[357] "Directive - 2022/2380 - EN - EUR-Lex," November 3, 2022, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2022.315.01.0030.01.ENG&toc=OJ%3AL%3A2022%3A315%3ATOC.

[358] "Common Charger: EU Ministers Give Final Approval to One-size-fits-all Charging Port," Consilium, October 24, 2022, https://www.consilium.europa.eu/en/press/press-releases/2022/10/24/common-charger-eu-ministers-give-final-approval-to-one-size-fits-all-charging-port/.

SUBRA must also comply with environmental protection regulations and acquire permits for both the testing and implementation stages of their technology. This is in part because the technology requires the use of cryogenic nitrogen to reach the temperature (-196ºC) at which it operates. One interviewee explained that in some cases these permits can take years to access, and delays in testing creates further setbacks for firms that are trying to raise funds by demonstrating the capacity of their technology to investors.[359]

The setbacks in fundraising are critically important to the SUBRACABLE project because, according to an interviewee, SUBRA's greatest challenge is securing adequate financial support. Though the HTS cables themselves are less expensive than existing models, operating the cables requires a huge infrastructural investment. Not only is this very costly but it also takes a minimum of 20 years.[360] This means that returns on investment can only occur after this 20-year period, making it virtually impossible for SUBRA to secure funding through venture capitalists who, as explained by the interviewee, want to see returns on their investment in a five-year period.[361]

Though the EU acknowledges the need to synchronise the energy system across Member States, synchronisation is costly and can only occur over the course of many years. This too extends to innovation in the energy sector, where conflicting energy standards, rigid environmental regulations and costs serve as serious barriers to firms such as SUBRA who need to accommodate for large timelines.

Opportunities for regulatory experimentation and innovative legislation practices

SUBRA has yet to participate in any regulatory experimentation spaces. According to the project coordinator, the company's non-participation is due to scarce resources at the company level and because SUBRA already has several technologies on the market.[362]

At later stages of development, however, there is potential for the technology to benefit from regulatory sandboxes. In order to comply with the environmental regulations SUBRA needs to acquire permits to test and implement their technology. As this process can take upwards of 2 years, according to an interviewee, a regulatory sandbox which relaxed environmental regulations for testing would be instrumental in streamlining the technology's development.[363]

The programme manager argued that streamlining through regulatory sandboxes would be beneficial for all technologies that are trying to enhance the efficiency of the energy sector. In their view, this was because it would give firms the opportunity to fail faster, and therefore save time and resources on projects that will be ultimately unsuccessful. They also felt that these spaces would give firms the opportunity to gain the trust of potential investors, and therefore acquire the funding necessary to sustain their technology's development. With financial support as the biggest challenge that SUBRA faces, regulatory sandboxes could therefore play a critical role in mitigating this challenge.

Key takeaways

The energy sector, being highly complex and interdependent, requires years of infrastructural investment to integrate new technology. In the current stage of development, SUBRA is not facing many pressing regulatory challenges, but as a technology embedded in a greater energy system during later stages of implementation challenges are likely to be met. This is

[359] Interview with EIC Programme Manager September 4, 2024

[360] *Ibid*

[361] *Ibid*

[362] SUBRA. Interview with Employee August 21, 2024

[363] Interview with programme manager, September 4 2024

particularly true for abiding by environmental regulations, as well as attracting funding. These challenges are relevant beyond SUBRA but is relevant to all innovative technologies in the energy sector, as the EU works to further integrate the energy system, with for example REPowerEU and the 2023 Action Plan for Grids.[364]

Regulatory sandboxes have the potential to provide significant support to technologies that have the potential to improve the energy sector. This is because these firms are often burdened by stringent environmental regulations, that slow down the testing and implementation phases of the technology's development. Regulatory sandboxes would streamline these phases, and therefore benefit the energy sector because it would provide effective technologies more opportunities to demonstrate their capacity and attract investment, while also ensuring that unsuccessful projects fail faster.

Case P8: Kraftblock

Case in Brief

The Scalable, modular, high temperature, cost-efficient thermal energy and power storage and conversion system made of upcycled industrial by-products, also called Kraftblock, aimed to develop a container-based thermal energy storage system capable of storing 30 MWh of energy at extremely high temperatures (up to 1300°C). It addressed a critical environmental issue: pollution through flare gases emitted by industries like oil, gas, and steel, which account for a significant portion of global CO2 emissions. By capturing and storing this wasted energy, the project has the potential to greatly reduce emissions and improve energy efficiency in these industries. Key challenges included designing a system that can handle the high temperatures and power loads of flare gas stacks, while remaining compact and efficient for use in space-constrained industrial sites.

Over the first year, the project team focused on designing and testing a prototype system. They performed heat flow and stress simulations to optimize the storage unit, improving both its capacity and durability. The team also worked on creating a lightweight container structure to minimize costs and improve efficiency. Testing showed that the storage material could withstand high temperatures and many heating-cooling cycles without degradation. Currently, the design is being refined, with efforts focused on increasing storage capacity and further improving material performance, while ensuring safety and stability in real-world industrial settings.

Kraftblock was funded by EUR 1.7 million through a call from EIC accelerator programme, with a total project costs of EUR 2.5 million. The project was implemented with the help of two subcontractors who were responsible to develop specific engeneering solutions to improve the material of the container to ensure sufficient thermal insulation and reduce the overall weight of the container.

Background and context

Stationary energy storage technologies in the EU are regulated through a comprehensive framework designed to support their development, ensure environmental sustainability, and promote their integration into the energy market.

- **Renewable Energy Directive (RED III)**: RED III (Directive (EU) 2023/1791) builds on RED II by further advancing the integration of energy storage to accommodate the

[364] European Commission - European Commission. 'Press Corner'. Text. Accessed 8 July 2024. https://ec.europa.eu/commission/presscorner/home/en.

increasing share of renewables in the energy mix. It requires Member States to simplify and expedite the permitting process for energy storage projects, emphasizing faster approval timelines for both large-scale and distributed storage solutions. The directive mandates the removal of regulatory and market barriers to energy storage deployment, ensuring that storage systems, including behind-the-meter installations, can fully participate in electricity markets and grid services. Additionally, RED III promotes the use of storage to reduce renewable energy curtailment, enhance grid flexibility, and ensure security of supply, while also supporting decarbonization efforts across all sectors of the economy.

- **The Commission Recommendation on energy storage 2023/C103/01** emphasizes the need to streamline permitting processes and reduce administrative barriers to speed up storage deployment, particularly for innovative and smaller-scale projects. The recommendation also calls for reforms that enable energy storage systems to fully participate in energy markets, providing flexibility services and contributing to grid balancing. It encourages Member States to promote innovation in advanced storage technologies, such as batteries, hydrogen, and thermal storage, while fostering sector coupling to enhance grid flexibility and decarbonize difficult sectors like heating and transport. Additionally, the recommendation highlights the importance of ensuring storage systems are sustainable and recyclable, aligned with circular economy principles.
- **Electricity Market Directive and Regulation**: Adopted as part of the Clean Energy Package, the *Electricity Market Directive* (Directive (EU) 2019/944) and *Electricity Market Regulation* (Regulation (EU) 2019/943) set out rules for the operation of electricity markets, with a focus on ensuring market access for energy storage providers. They encourage the participation of energy storage in energy trading, capacity mechanisms, and ancillary services markets, enabling storage to contribute to grid flexibility and stability. These regulations also require grid operators to avoid discriminating against energy storage and promote fair grid connection conditions.
- **Environmental Impact Assessment (EIA) Directive**: Under Directive 2011/92/EU (amended by Directive 2014/52/EU), the installation of large energy storage systems, especially those with significant environmental or social impacts, must undergo an Environmental Impact Assessment (EIA). This ensures that potential environmental risks—such as land use, waste management, and pollution—are thoroughly evaluated and mitigated.

However, more important for the implementation of Kraftblocks' pilot project is the nationalisation of EU legislation, and how respective EU legislation is applied by national, regional and local authorities. For instance, the implementation act of the German federal government for implementing EU Directive 2023/2413 provides more detailed provisions for national regulations on construction, spatial planning, emission safety and renewable energies[365], all of which are relevant to developing and implementing themral energy storage systems in germany.

Key regulatory challenges

In the EIC-funded pilot project, a Kraftblock unit was installed on an ironworks industrial plants to reuse heat from flare gases to charge the thermal power storage. This pilot project of the Kraftblock thermal energy storage system is subject to multiple and different types of

[365] Deutscher Bundestag, Drucksache 20/12785: Entwurf eines Gesetzes zur Umsetzung der Richtlinie (EU) 2023/2413 in den Bereichen Windenergie an Land und Solarenergie sowie für Energiespeicheranlagen am selben Standort

regulation, that needed to be considered during the development and implementation of the project. For example, the building and construction permit for the storage system was difficult to achieve, as the system was labled as a third-party installation on the plant. This required additional administrative steps to be taken for receiving the building certification, environmental impact assessment and certification of the safety of the new system.

The installed system uses hot flare gases from the ironworks plant to heat the heat storage, that would otherwise be emitted into the atmosphere. As a result, the storage unit emits the cold flare gases. As per the regulation of flare gas emissions in Germany, the storage system required the installation of a 40m high exhaust pipe, as it needed to be higher than all other buildings and structures nearby.

Further regulatory challenges are posed by the German Renewable Energy Law (Erneuerbare Energien Gesetz EEG). Despite recent attempts to mitigate this challenge, renewable energy producers are still incentivised to shut off wind turbines in times of high energy production. As they are paid a premium during the time wind turbines are not running due to excess electricity production, there is no incentive to find solutions to use this excess electricity to charge stationary power storage systems.

In an interview with Kraftblock, it was emphasized that the EU Emissions Trading System (ETS) poses challenges to the economic competitiveness of utilizing excess heat for charging thermal storage containers. Under the current system, when utilising excess heat for charging thermal power storage containers, CO2 certificates must be purchased for the generation of heat at industrial plants, even when the heat is not immediately consumed but merely stored. This additional cost is factored into the price of the stored heat, reducing its competitiveness in the market. If CO2 certificates were only required at the point of energy consumption, rather than during storage, it could significantly enhance the market potential for using excess heat to charge thermal storage systems and sell the energy elsewhere.

A key innovation of Kraftblock is the mobility of charged containers. This enables to charge a container close to an energy source and transport the container to for example and industrial site to use the thermal energy. The container can be easily transported with conventional trucks. However, the regulatory environment for transporting goods at such high temperatures is not clear which leads to uncertainties for the transportation of charged Kraftblock containers. The current regulation has no definitions of mixed-phase hot materials, only for the transportation for hot liquid or hot solid materials. The German Federal Institute for Materials Research and Testing (BAM) however decided that the hot containers can be transported, while classified as hazardous material transport. However, it is not clear whether this decision is legally binding, and how a police officer would judge the situation if a truck were to be stopped on the road or in case of damage caused, as there is no corresponding regulation or legislation. tIn general, an interviewee from Kraftblock highlighted the willingness of authorities to cooperate when certifying and permitting novel technologies such as the Kraftblock thermal power storage system. However, it was highlighted during the interview that local and regional authorities have very little freedom to make decisions to apply regulatory practices to novel technologies within a legislative framework that is designed for existing technologies. Furthermore, it was mentioned during the interview that local or regional authorities may not have the technical knowledge or expertise in order to judge and assess environmental or safety implications of new technologies.

Opportunities for regulatory experimentation and innovative legislation practices

Interviewees highlighted the importance and success of EIC-funding for developing and improving the capacity of the thermal power storage system. The pilot project enabled the completion of the design of the energy system, which includes a charging device, thermal storage, and a discharging device. The main focus was on creating an efficient storage unit with a capacity of over 30MWh at 1,300°C. The regulatory challenges related to the saftey and and environmental regulations in the project caused extra costs and extended the project

timeline, as additional resources were required to understand the regulatory challenges and to plan the system to be in line with requirements from regulatory authorities. In other operations outside of the EIC-funded projects, regulatory challenges lead to legal uncertainties and risks (related to the unclear regulation regarding transportation of charged storage devices) and competitive disadvantages for thermal power storage systems.

During interviewees, representetives of Kraftblock also highlighted the importance of regulatory experiments or testbeds to test novel technologies in real life. While the KRaftblock project was not part of any such initiatives, interviewees agreed that it could have contributed to faster and more efficient mitigation of some of the regulatory challenges that the project faceds. A closer collaboration between innovation actors and regulatory authorities could help in future similar projects to enhance regulatory learning and provide for a more efficient implementation of innovation projects.

Key takeaways

The case study revealed regulatory barriers in the field of novel thermal power storage technologies, especially related to

- Building permits on industrial plants and integration into a plants energy system, and challenges in integrating the novel system into existing regulations regarding plant safety and environmental impact assessments
- Market disadvangtages due to ETS when storing excess heat, as well as lack of incentives for renewable energy producers to invest in storage technologies to store electricity during times of excess electricity production
- Legal uncertainties when transporting charged storage devices with hot materials with trucks on public roads

Despite these challenges, collaboration with authorities has helped the implementation of the project. While authorities have shown willingness to support the implementation of the project, lack of technical knowledge as well as very little room for maneuver for regional and local authorities made it difficult for regulatory authorities to adapt regulatory practices within existing legal frameworks for novel technologies for which no legislative guidance exists.

Appendix 6. Benchmarking case studies

Regulating AI: horizontal risk-based approach in the EU vs sectoral and principles-based approach in the UK and the US

The EU adopted a horizontal and risk-based approach to AI regulation in its AI Act (May 2024). It is horizontal as it puts similar regulatory standards for AI development, deployment and governance across all sectors[366], and it is risk-based as the law categorises risks associated with the AI applications with higher risks regulated through more stringent requirements[367]. The AI Act aims to harmonise the AI regulatory frameworks across the Member States through the

[366] Palmer, N. (2024) 'New study: UK should avoid EU-style AI regulation, but its current regulatory framework falls short'. Available at: https://www.brunel.ac.uk/news-and-events/news/articles/New-study-UK-should-avoid-EU-style-AI-regulation-but-its-current-regulatory-framework-falls-short#:~:text=%E2%80%9CThe%20UK%20is%20set%20to,sectors%2C%E2%80%9D%20explained%20Dr%20Gikay .

[367] *Diverging regulatory approaches for AI* (no date) *KPMG*. Available at: https://kpmg.com/xx/en/our-insights/regulatory-insights/diverging-regulatory-approaches-for-ai.html .

establishment of a dedicated AI-regulator and statutory obligations for all actors across the AI value chain (incl. extraterritorial reach of the regulation)[368]. The law received criticism because of these exact characteristics, i.e. horizontal, risk-based, but also due to heavy non-compliance costs. Such an approach is seen as much more restrictive than in the US and UK and is likely to slow down the development and deployment of the AI technologies in the EU leaving the EU lagging behind the two peers[369].

The UK, in contrast, has opted for a more flexible, sector and principles-based approach to AI regulation. This approach is outlined in the Government's response to the White Paper on a pro-innovation approach to AI regulation (2023) consultation[370]. There is no additional regulation in the area of AI envisaged. Rather, the approach is to rely on existing regulation and empower regulators to use five non-binding cross-cutting principles tailored to the specific sectors when dealing with AI[371]. There is, however, understanding that legislative action will be required but only once the risks associated with the AI-technology have matured, hence the regulatory system is currently focused on preparing itself for emerging and near-term risks[372]. This "context-based" and rather flexible approach has been criticised for the risks it poses to public safety as the AI technology rapidly develops.

In the US, the approach to the AI regulation is quite flexible and market-driven with major industry players largely responsible for the AI practices, although this has started to change recently. At the federal level, the Executive Order on AI (30 October 2023) establishes eight principles and priorities for the AI technology development focused on the safety, security and robustness of AI systems, along with investment in education and training, and a commitment to equity, civil rights, and workers' rights[373]. Federal regulators have restated their authority over the AI even absent a comprehensive law governing AI[374]. At the states' level, the AI has been regulated either through specific provisions as part of comprehensive privacy laws (e.g. the California Privacy Rights Act), separate laws (e.g. to enter into force in Colorado, Connecticut and Montana) or through specific company obligations regarding use of AI in certain contexts (such as employment)[375].

All the three approaches to regulation of AI envisage using regulatory sandboxes for AI testing and deployment. In fact, the AI Act promotes establishment of sandboxes and testbeds at the Member States level[376], the UK Government's White Paper on AI regulation envisages the

---

[368] Haie, A.-G., Cohen, T. and Golodny, A. (2024) 'A comparative analysis of the EU, US and UK approaches to AI regulation'. Steptoe. Available at: https://www.steptoe.com/en/news-publications/steptechtoe-blog/a-comparative-analysis-of-the-eu-us-and-uk-approaches-to-ai-regulation.html .

[369] Benizri, I. *et al.* (2023) 'A comparative perspective on AI regulation', *Default*. Available at: https://www.lawfaremedia.org/article/a-comparative-perspective-on-ai-regulation .

[370] GOV.UK (2024) *A pro-innovation approach to AI regulation: government response*. Available at: https://www.gov.uk/government/consultations/ai-regulation-a-pro-innovation-approach-policy-proposals/outcome/a-pro-innovation-approach-to-ai-regulation-government-response .

[371] The principles include i) safety, security, and robustness; ii) appropriate transparency and explainability, iii) fairness, iv) accountability and governance, and v) contestability and redress.

[372] *Regulating AI: Two steps forward for the UK as pro-innovation approach remains* (2024) *Herbert Smith Freehills*. Available at: https://www.herbertsmithfreehills.com/notes/data/2024-02/regulating-ai-two-steps-forward-for-the-uk-as-pro-innovation-approach-remains.

[373] EY (2024) 'The Artificial Intelligence (AI) global regulatory landscape'. Available at: https://www.ey.com/content/dam/ey-unified-site/ey-com/en-gl/insights/ai/documents/ey-gl-the-artificial-intelligence-global-regulatory-07-2024.pdf.

[374] For instance, "the Consumer Financial Protection Bureau, Department of Justice, Equal Opportunity Commission, and Federal Trade Commission (FTC) issued a Joint Statement on Enforcement Efforts Against Discrimination and Bias in Automated Systems, pledging vigorous use of their respective authorities to protect against discrimination and bias in automated systems". https://www.lawfaremedia.org/article/a-comparative-perspective-on-ai-regulation

[375] Ibid.

[376] *EU AI Act: first regulation on artificial intelligence* (2023) *Topics | European Parliament*. Available at: https://www.europarl.europa.eu/topics/en/article/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence .

creation of an AI sandbox, and the US has been using sandboxes and testbeds at the state and federal[377] levels to test AI innovations.

Overall, based on example of the AI regulation, the following can be observed:

- the EU has a more risk-based pre-emptive approach to regulation of emerging technologies privileging consumer protection and public safety over the potential gain from a faster development of technology;
- the adoption of a horizontal rather than a sectoral approach is more common for the EU which could be partially explained by the need to ensure better coordination across Member States; however, even if a horizontal regulation, coordination issues persist (see the DLT pilot regime case below);
- the more flexible approach adopted in the US and UK might contribute to a comparatively more favourable environment for the uptake of emerging technologies which to an extent explains the choice of some companies to test and develop their AI-enabled technologies in those jurisdictions.
- the flexible approach to emerging technologies regulation in the US contributes to high level of fragmentation of regulatory frameworks (e.g. federal and state level) with potential negative effects on the scale up of technologies (see the case of fintech below).
- the "wait and see" or incremental approach to regulating innovation in the UK while leaving more space for innovation entails public safety and consumer protection risks, if not addressed.

US regulatory experimentation in fintech – learnings for the EU?

In the U.S., the few existing examples of the federal regulatory sandboxes are concerned with the fintech[378]. This could be explained by the fintech sector modular and digital nature (easier to isolate for testing without impact on broader systems), dynamic regulatory landscape in financial services (tend to be more flexible and adaptable than in cleantech or biotech which are known to be very rigid due to health, safety and environment risks), fintech`s key role in driving economic growth in the U.S., and the rapid pace of innovations in fintech.

However, given the high level of **regulatory fragmentation** in the financial sector, operating a sandbox at the federal level is very challenging without amendments to legislation that would allow closer coordination between the federal and state regulators. Currently, no existing U.S. agency has the authority to impose a uniform state-federal sandbox framework and there is a lack of coordination between agencies in federal and state levels[379].

In fact, several acts were proposed to enable sandboxes in financial sector at federal level (i.e. Financial Services Innovation Act, introduced in 2016 and re-introduced in 2022[380], and the

[377] For example, US Department of Energy Aragonne Leadership Computing Facility AI testbed https://www.alcf.anl.gov/alcf-ai-testbed.

[378] This fact is also highlighted by Sherkow, Jacob S., Regulatory Sandboxes and the Public Health (February 1, 2022). University of Illinois Law Review, vol. 2022, pp. 357-410, Available at http://dx.doi.org/10.2139/ssrn.3792217 .

[379] Rossi Martins, A.C. (2021) *A Sandbox for the U.S. Financial System*. Available at: https://www.theregreview.org/2021/08/19/rossi-martins-sandbox-for-us-financial-system/.

[380] US Financial Services Committee (2024) *McHenry Reintroduces Legislation to Foster Greater Innovation in Financial Services* . Available at: https://financialservices.house.gov/news/documentsingle.aspx?DocumentID=409156 .

Advancing Innovation to Assist Law Enforcement Act[381], introduced in 2019), but they never made it into the law. The instances of regulatory relief to fintech companies include, the 2018 Act to promote economic growth, provide tailored regulatory relief, and enhance consumer protections, and for other purposes (became a law 05/24/2028). It contains broad provisions for regulatory relief to smaller financial institutions and provisions to facilitate the innovation by fintech firms. Other than that, specific regulators at federal and state level regulate the financial sector through orders and other instruments.

Regulatory innovation is mostly carried out by the innovation offices within the regulatory authorities, e.g. Office of Financial Technology of the Office of the Comptroller of the Currency[382], Office of Strategic Hub for Innovation and Financial Technology (FinHub) of the Securities and Exchange Commission[383], Office of Competition and Innovation of the Consumer Financial Protection Bureau[384]. These units often use **no-action letters and pilot programs** to allow for innovative technologies testing and ensure oversight and response regarding emerging technologies in relevant industries.

An example of a federal regulatory sandbox among very few cases is the federal Consumer Financial Protection Bureau (CFPB) which until recently was running two sandboxes and implementing a "no actional letter" policy. More specifically, the CFPB put in place a trial **disclosure program (TDP) and the compliance assistance sandbox (CAS)** in 2018-2019. The TDP allowed firms to design and improve existing disclosures to consumers (on the costs, benefits, and risks of various financial products and services) though experimentation with the context, format, or delivery of the disclosures. The sandbox provided companies an opportunity to do in-marketing testing of alternative disclosures for a determined period of time, benefitting from regulatory derogations. The CAS allowed firms to test a financial product or service in order to seek regulatory clarity on how it is regulated. The CFPB assessed whether a firm's product or service complies with relevant law, and if approved, that firm benefitted from liability protection under the Truth in Lending Act governing credit transactions, the Electronic Funds Transfer Act, governing electronic payments, or the Equal Credit Opportunity Act addressing discrimination in lending[385].

In addition, the CFPB introduced No Action Letter ("NAL") policy which allowed firms to receive a statement suggesting the CFPB would not bring a supervisory or enforcement action against a company for providing a particular consumer product or service under agreed circumstances. Finally, to address the noted fragmentation in the financial sector and related consumer protection, the CFPB launched the American Consumer Financial Innovation Network ("ACFIN") to coordinate efforts between federal and state regulators to further shared objectives of consumer access, financial inclusion, and competition to ensure that consumer markets are free from fraud, discrimination, and deceptive practices.

However, in September 2022, the CFPB announced **termination of the sandboxes** with the following argumentation "the policies do not advance their stated objective of facilitating consumer-beneficial innovation and failed to meet appropriate standards for transparency and

---

[381] Congress.gov. "Actions - H.R.2613 - 116th Congress (2019-2020): Advancing Innovation to Assist Law Enforcement Act." septembre 23, 2019. https://www.congress.gov/bill/116th-congress/house-bill/2613/all-actions.

[382] *OCC establishes Office of Financial Technology* (2023) *OCC.gov*. Available at: https://www.occ.gov/news-issuances/news-releases/2023/nr-occ-2023-31.html.

[383] SEC.gov (no date) *Office of Strategic Hub for Innovation and Financial Technology (FinHub)*, *SEC.gov*. Available at: https://www.sec.gov/about/divisions-offices/office-strategic-hub-innovation-financial-technology-finhub.

[384] *Competition and innovation at CFPB* (no date). CFPB. Available at: https://www.consumerfinance.gov/rules-policy/competition-innovation/.

[385] Kaplan, Lawrence and Kaplan, Lara (2019) 'CFPB FinTech Regulatory Innovation Initiatives Echo International Regimes', *Pall Hastings*. Available at: https://www.paulhastings.com/insights/client-alerts/cfpb-fintech-regulatory-innovation-initiatives-echo-international-regimes.

stakeholder participation". As noted by several experts, the reasons for "failure" of these sandboxes lay both in the inability of the CFTB to waive other agencies' rules and the fact that the no-action letters were not able to prevent other federal and state agencies from bringing enforcement actions against companies that receive the CFTB relief[386].

The termination of the sandboxes underscores the difficulty of effectively operating a federal sandbox in a highly fragmented regulatory environment with federal-state coordination problems. In the context where in the U.S. the most cumbersome financial regulations are imposed at the federal level, it seems that most impact for the uptake of the emerging technologies in financial sector could be achieved through the introduction of a federal sandbox in fintech.

At the state level, a lot of the experimentation is taking place in fintech with fintech sandboxes established in eight states (as of 2023). However, the potential impact of these sandboxes on fintech sector is rather limited, as most financial regulation is federal and federal laws are supreme over the state laws, making it impossible for the state regulators to nullify enforcement actions by federal agencies against companies that take part in the state-level sandboxes[387].

The **state-level fintech sandbox programmes** in the U.S. differ greatly in their scope, administration, and accessibility to applicants. The first state to develop a fintech sandbox was Arizona in 2018, followed by Florida, Hawaii, Nevada, North Carolina, Utah, West Virginia, and Wyoming[388]. The impact of the sandboxes on the state's fintech market also varies depending on internal state regulations and barriers to entry for new companies. For example, sometimes the sandbox is the only means for specific industry to enter the market in a state. A case in point is the Hawaii's cryptocurrency sandbox launched in 2020 in the context of the state's strict licensing rules (which made it too expensive for cryptocurrency trading platforms to do business there)[389].

In addition, as every state has its own regulations, the entry of a company having tested its technologies in one state's sandbox into a market of a different state is not guaranteed and might requires additional compliance efforts and testing. For a prospective fintech company this could pose an issue for the scale up and slow down its growth, hence having negative effects for the economy as a whole. Evidence suggests that many startups in fintech have found a way to get around these regulatory complications by selling their software to established banks and credit unions.

Furthermore, when comparing the number of companies admitted to state sandboxes in the US to the number in equivalent UK's Financial Conduct Authority fintech sandboxes, the significantly lower number of admissions in the US is observable. Thus, fintech sandboxes in Arizona, Hawaii, West Virginia, and the CFPB's Compliance Assistance Sandbox admitted 31 companies as of November 2021, as opposed to 178 companies in the two sandboxes in the UK[390]. Such low number could be partly explained by the high level of fragmentation of regulatory system in fintech in the US and its implications for companies' scale up. This also

[386] Ryan Nabil, *How Regulatory Sandbox Programs Can Promote Technological Innovation and Consumer Welfare. Insights from Federal and State Experience*. Competitive Enterprise Institute, Aug 17, 2022. Available at https://cei.org/wp-content/uploads/2022/08/Ryan_Nabil_-_Regulatory_Sandboxes-3.pdf

[387] Ibid.

[388] Ibid.

[389] Quiton, S. (2021) 'Fintech "sandboxes" in Arizona, other states, aim to attract companies'. Available at: https://azmirror.com/2021/06/16/fintech-sandboxes-in-arizona-other-states-aim-to-attract-companies/.

[390] Ryan Nabil, *How Regulatory Sandbox Programs Can Promote Technological Innovation and Consumer Welfare. Insights from Federal and State Experience*. Competitive Enterprise Institute, Aug 17, 2022. Available at https://cei.org/wp-content/uploads/2022/08/Ryan_Nabil_-_Regulatory_Sandboxes-3.pdf .

is part of the explanation of why the testbeds are far more popular regulatory innovation tools in the U.S. than the sandboxes.

Implications for the EU:

- High level of fragmentation of the regulatory system in the U.S., especially regarding the fintech, complicates the implementation of regulatory innovation tools such as sandboxes both at the federal and state level, requiring legislation to facilitate coordination and cooperation between the two jurisdictions to enable testing of new technologies. This puts the EU at a competitive advantage in terms of opportunities for testing of fintech, especially given the modular and digital nature of the solutions proposed.
- The autonomy that each state possess in creation and application of regulations and the establishment of sandboxes in fintech, provides innovators with a variety of choice of a sandbox, incl. when it comes to the "restrictiveness" of regulatory regimes, size of the potential market for product deployment after testing, industries and networks the sandbox provides access to, etc. presenting a tailored and relatively easy point of entry for a company into the market. The described diversity in sandbox approaches and factors related to the size of the market together with the importance of the fintech sector in the economy of the U.S., make the U.S. a potentially more attractive platform for testing of innovative financial technologies than the EU.
- The regulatory fragmentation in the U.S. acts as an important obstacle for the scale up of the company's solution in case the company wants to operate beyond the borders of the state it was able to test its technology in (under the derogatory regime of the sandbox). Hence, the EU which does not have this level of regulatory fragmentation in fintech is an attractive destination for the testing of innovative technologies and their further scale up, especially in the context of the UK leaving the EU and the implications for the financial sector it has had. The testing and deploying of technology in the **EU** also presents a **sizeable market opportunity for the fintech companies**, while the ongoing work of the European Commission on streamlining and adapting the legislation in financial market regulation (e.g. MiCA, MiFID) is aimed at facilitating the uptake of fintech.

Facilitating the blockchain technologies uptake through innovative regulatory tools: Digital Securities Sandbox (DSS) in the UK and the DLT pilot regime in the EU.

The UK is a pioneer in the regulatory sandbox approach with its first formal sandbox in fintech created in 2016 under the **UK Financial Conduct Authority (FCA).** The sandbox has known a resounding success since its establishment and served an inspiration for similar initiatives all over the world. As of 2023 and since 2016, the sandbox received more than 600 applications and a total of 173 companies were admitted to test their technologies. The evidence shows that 80% of firms participating in the sandbox are still in operation.

In 2021, the sandbox adapted it application approach to an "always open" model (instead of cohort application approach) to better cater to the needs of companies at different points in their development cycle. In **2023,** the UK introduced new legislation, the **Financial Services and Markets Act** to "harness the opportunities of innovative technologies in financial services" and as a response to the rapid technological development (e.g. AI, blockchain, etc). The legislation delegates the HM Treasury the power to introduce financial markets infrastructure (FMI) sandboxes to facilitate the testing of new technologies. But the legislation also goes one step further as it delegates the power to the HM Treasury to **disapply or modify certain legislation and regulations** based on the results of the FMI sandboxes. This is an important step signalling the determination to significantly adapt the regulation to the pace of technological development in financial sector, putting UK in a position to attract pioneer fintech

solutions. Thus, for instance, during the consultation on the first FMI sandbox under the Act – the **Digital Securities Sandbox (DSS**) to be implemented by the Bank of England and FCA, it was specifically stated that "the FMI sandboxes will allow UK legislation to be modified and permanently changed"[391], which has not been the case under the other FCA's fintech sandbox, for example. Furthermore, the recent changes in the Government of the UK lead to proposals by the Labor on a regulatory sandbox for financial products to reach underserved communities as part of its policy paper Financing Growth[392].

In the **EU**, similar reflexion on the opportunities to be seized in emerging technologies in financial sector took form of a **Distributed Ledger Technologies (DLT) Pilot Regime**[393]. The DLT Pilot Regime is in place in the EU since 23 March 2023 and it provides a sandbox environment allowing for regulatory flexibility for firms to seek permissions to test solutions using DLTs. The expectation is that the pilot regime will allow to elaborate a regulatory framework conducive to innovation in the sector. According to the current legislation, the regime is to run for three years (until 2026). The European Securities and Markets Authority (ESMA) implements the sandbox and is to provide annual reports to reflect on the experience of the sandbox and potential regulatory adjustments to be made.

According to the information provided by ESMA, no DLT market infrastructures have been authorised as of April 2024, but 4 applications were submitted to national competent authorities (NCAs) and at least 8 others are expected towards the year end[394]. So far, a number of challenges were identified by the ESMA for the sandbox implementation, chief among them being the **hesitation of potential applicants** because of a perceived uncertainty about the duration of the DLT Pilot Regime, i.e. according to the legislation it is to run for three years. The clarification by the Commission to ESMA in this regard specified that "no expiration date for the DLT pilot regime is envisaged"[395] and that a new legislative proposal had to be submitted and adopted to amend or terminate the regime.

In addition, challenges that were highlighted by ESMA concerned the coordination with other legislation recently introduced in financial sector, such as MiCA and MiFID. For instance, ESMA noted a timing mismatch of the DLT Pilot Regime with MiCA regulation (authorisations to start only in 2024) which disabled the possibility to test tokens for cash settlements (as one of the DLT applications). Furthermore the potential **overlap of the regime** was noted with the regulations when it comes to custody through self-hosted wallets, and finally, the challenges in interoperability between DLT market infrastructures and traditional market infrastructures, as well as among DLT market infrastructures themselves were brought to the front.

Implications for the EU:

- The current innovative approaches to fintech in the UK and the EU highlighted the importance of adapting the legislation to capture the benefits of latest technological developments for financial markets. However, the cases of DSS and DLT pilot regime

[391] Smethurst, J., Bernard, C. and Davies, O. (2024) 'The Digital Securities Sandbox: a new model for trading and settlement in the UK?', *Freshfields*. Available at: https://riskandcompliance.freshfields.com/post/102j6uf/the-digital-securities-sandbox-a-new-model-for-trading-and-settlement-in-the-uk.

[392] McEneny, G. and Yeo, A. (2024) 'The growth of regulatory sandboxes – extending the safe places to play', *Dentons*. Available at: https://www.dentons.com/en/insights/articles/2024/march/6/the-growth-of-regulatory-sandboxes-extending-the-safe-places-to-play.

[393] ESMA (no date) *DLT Pilot Regime*. Available at: https://www.esma.europa.eu/esmas-activities/digital-finance-and-innovation/dlt-pilot-regime .

[394] ESMA (2024) 'Letter to the EU institutions on the DLT Pilot Regime Implementation '. ESMA. Available at: https://www.esma.europa.eu/sites/default/files/2024-04/ESMA75-117376770-460_DLT_Pilot_Regime_-_Letter_to_EU_Institutions.pdf.

[395] ESMA (2024) 'Letter from the European Commission on the DLT Pilot Regime Implementation '. Available at: https://www.esma.europa.eu/sites/default/files/2024-05/3056562_030524_Reply_Verena_Ross_on_DLT_Pilot_Regime_Implementation.pdf.

differ in the certainty they provide to potential innovators with the UK featuring better than the EU. The **lack of certainty** has a direct effect on the potential uptake of the emerging fintech in the EU. Thus, in the UK case, innovators would be able to operate in a much more certain environment than in the EU which is ensured through the new legislation provisions on the HM Treasury's power to amend, repeal, and revoke existing legislation to accommodate new technologies[396]. Such certainty can be an important incentive for firms' applications once the DSS sandbox is established and could foster groundbreaking technologies in financial sector. Since the DLT Pilot Regime does not guarantee permanent changes to the EU financial services legislation, or at least this has not been specified in the legislation in a clear way, it creates important uncertainty for the companies who hesitate to apply as the result (i.e. the current report on the DLT pilot regime implementation by ESSA shows that there is a lot of hesitation).

- The format of the sandbox, including its duration and scope, is another important element of difference between the DSS and the DLT Pilot Regime. The ESMA implementing the DLT Pilot Regime raised the issue of hesitation of potential applicants to apply to DLT pilot regime stemming from the relatively short duration of the pilot regime – i.e. 3 years until 2026, according to the legislation. This **short period of operations** together with the lack of certainty around the permanence of regulatory changes resulting from the DLT pilot regime (as described above) seem to act as a deterrent for companies to test their technologies under the pilot regime. In addition, the DLT Pilot Regime has a much **narrower scope** compared to the FMI sandboxes which include, in addition to multilateral trading facilities, settlement systems, and trading and settlement systems, the recognised investment exchanges, and operators of organised trading facilities eligible to take part in the sandboxes. This could potentially lead to the EU missing out on the opportunities in fostering technologies across the whole spectrum of the financial services market.

The Ofgem`s Future Regulation Sandbox – moving to a combination of a product and policy-testing environment in one regulatory tool to advance UK's energy technologies

Since **2020**, the UK's Office of Gas and Electricity Markets (Ofgem) has been implementing an **Energy Regulation Sandbox (ERS**) that offers opportunity to the innovators to test new technologies in gas and electricity sector in a live market environment (with application of regulatory derogations for the defined trial period)[397]. The sandbox has also an explicit focus on facilitating the entry of new technologies and services into the market. These is done through a set of **four tools**, including i) bespoke guidance (and certainty about specific rules applicable for certain technologies), ii) letters of comfort (agreeing and specifying what a compliant behaviour is for the period of the trial), iii) letters of confirmation (not an endorsement) to support the launch into the market, iv) and a time-limited trial with the application of regulatory derogations.

The approach taken was to design a sandbox around an individual innovator proposal to allow the product testing and trial with five sandboxes granted in total (as of 2024) and one sandbox declined. The available evaluation of the sandboxes (2 out of 3 which are due at the end of 2024, and in 2025) note the usefulness of the sandbox regime for the innovators (the UK Power Networks' Charge Collective Sandbox and the F&S Energy Sandbox, both implemented over

---

[396] [396] Ryan Nabil, *How Regulatory Sandbox Programs Can Promote Technological Innovation and Consumer Welfare. Insights from Federal and State Experience*. Competitive Enterprise Institute, Aug 17, 2022. Available at https://cei.org/wp-content/uploads/2022/08/Ryan_Nabil_-_Regulatory_Sandboxes-3.pdf

[397] Ofgem (2020) 'Energy Regulation Sandbox: Guidance for Innovators'. Available at: https://www.ofgem.gov.uk/sites/default/files/docs/2020/07/sandbox_guidance_notes.pdf .

2021-2022)[398]. However, the ERS was not concerned with making change to the regulation on a permanent basis.

To move one step ahead, Ofgem proposed to establish a new sandbox - **the Future Regulation Sandbox (FRS),** completing the consultations on it in January 2024. It built on the feedback received from the innovators on the current (often outdated) regulations being the main obstacle for the uptake on new technologies in the energy sector and the ERS incapacity to ensure a permanent change to the regulations. The FRS aims to tackle these issues and to ensure that regulation is "fit for purpose" and "in step" with rapid innovation and technology development in the energy sector[399].

The FRS will not only allow **the innovators to test their ideas in a live energy environment** (i.e. involving consumers or interacting with market rules or the physical system), but also will allow **regulators to test and trial changes to the energy rulebook** in a controlled environment before introducing them to the regulatory framework. This would be enabled through a several set of trials, including i) open innovation challenge (i.e. setting a challenge to industry to submit proposals for innovation trials), ii) the innovation trial (trialling one or more innovations at the same time to find out which solve the given problem best), and iii) the regulation trial (the testing or one or more updated rules and methodologies to see whether they are fit for purpose). Hence, the FRS integrates **a policy-testing** (or adaptive) **feature** to its testing environment as opposed to the ERS which is limited to a product-testing (or advisory) environment only[400].

The FRS trials and wider policy work are expected to inform the decisions on removing, amending current regulation or introducing new rules or guidance[401], or in other words, improving the rulebook and making it fit for a net zero energy system that works in best interests of consumers[402]. In addition, the FRS will explore the opportunities for **partnerships building among innovators** (e.g. between a licensed and non-licensed entity) before the application submission to enhance the sandbox' accessibility, e.g. to non-licensed entities, and the impact of the technologies tested.

In the EU, the experience with the regulatory sandboxes in energy sector is rooted at the level of the Member States and has been marked by the **fragmentation of the energy regulatory framework at the EU and member-states level**, complemented by the competition regulation requirements. Given the stark "national-level" character of the energy regulatory sandboxes, the legislative frameworks at national level enabling such regulatory experimentation are important. The recent study by the European Commission [403] finds that only 12 Member States have the necessary frameworks for regulatory sandboxes in place and the experience in sandbox operations varies greatly across those Member States (for example, France is well-

---

[398] Ofgem (2022) 'Peer to Peer Matching Platform: F&S Energy Sandbox Evaluation Report'. Available at : https://www.ofgem.gov.uk/sites/default/files/2024-03/F%26S%20Energy%20-%20Sandbox%20Evaluation%20Report%20-%20redacted.pdf

[399] Ofgem (2023) 'Proposal to introduce the Future Regulation Sandbox'. Available at https://www.ofgem.gov.uk/call-for-input/proposal-introduce-future-regulation-sandbox

[400] UK Department for Business and Trade (2020) 'Regulator approaches to facilitate, support and enable innovation'. Available at https://www.gov.uk/government/publications/regulator-approaches-to-facilitate-support-and-enable-innovation

[401] Ofgem (2023) 'Proposal to introduce the Future Regulation Sandbox'. Available at https://www.ofgem.gov.uk/sites/default/files/2023-10/Proposal%20to%20introduce%20the%20Future%20Regulation%20Sandbox%20CfI%20final.pdf .

[402] Ibid.

[403] European Commission: Directorate-General for Energy, Gorenstein Dedecca, J., Ansarin, M., Afrodit Adsal, K. and Blind, K., *Regulatory sandboxes in the energy sector – Final report*, Publications Office of the European Union, 2023, https://data.europa.eu/doi/10.2833/848065

advanced in its practice and approach to regulatory sandboxes in energy[404]). Related to this is the issue of the lack of resources and skills of the national regulatory authorities to develop a regulatory sandbox (incl. financial and human resources)[405] constraining the deployment and the expected impact of sandboxes across the EU.

However, one of the most important obstacles for effective energy sandbox implementation as highlighted by the European Commission study is the high risk of conflicts between the derogations granted under the national regulatory sandboxes with the EU-level regulations[406]. Since the binding EU energy market regulations have effect on the competition in the energy market, the sandboxes must take into consideration **energy market and competition regulations both at the EU and Member States' level** when setting the derogations for testing of new technologies. This complicates the operation of the energy sandboxes at the national level potentially reducing the sandbox efficiency as a tool for fostering innovation in the energy sector.

Furthermore, the complexity of regulatory derogations setting and application resulting from such fragmentation can act as a deterrent for innovators willing to test their ideas in the sandbox environment with negative effect for the innovativeness of the EU energy market. The first step to address the fragmentation would be to **improve coordination and to clarify mandates of EU and Member State-level regulators**. For this, one option would be to provide EU-level guidance and assistance to Member States on elaboration of mandates of their relevant national regulatory authorities with regards to granting exemptions and regulatory derogations in the framework of energy sandboxes. In addition, European Commission could envisage actions to promote the best practice exchange on sandboxes implementation between the Member States and support implementing entities with limited resources to address the capability challenges some states face.

Coming back to the presented new sandbox by the Ofgem, i.e. Future Regulation Sandbox, that combines both product testing and policy-testing, while also focussed on the regulatory change based on the trials conducted in the experimentation environment, only a few similar initiatives at the member-state level in the EU could be noted. For instance, the French Regulatory Sandbox by Energy Regulation Commission created in 2020 aims to provide "a legal framework adapted to projects that allow testing of innovations that would ultimately require changes to the applicable regulatory and legislative framework"[407] . It does not focus on the opportunity for regulatory trials, however. Other initiatives in the EU, such as the four Regulatory Sandboxes for the Energy Transition funded by the German Federal Ministry for Economic Affairs and Climate Action[408] operate rather as testbeds as no regulatory derogations are granted for the testing of innovative solutions. One of these sandboxes, for example, the Northern German Regulatory Sandbox, gathers 14 partners across research and

[404] See the French Commision de régulation de l'énergie Regulatory Sandbox https://www.cre.fr/en/electricity/electricity-networks/regulatory-sandbox.html

[405] European Commission: Directorate-General for Energy, Gorenstein Dedecca, J., Ansarin, M., Afrodit Adsal, K. and Blind, K., *Regulatory sandboxes in the energy sector – Final report*, Publications Office of the European Union, 2023, https://data.europa.eu/doi/10.2833/848065

[406] Ibid.

[407] Commision de régulation de l'énergie Regulatory Sandbox https://www.cre.fr/en/electricity/electricity-networks/regulatory-sandbox.html

[408] Renewable Energies Hamburg, EEHH (no date) *Sandboxes of the energy transition*. Available at: https://www.erneuerbare-energien-hamburg.de/en/projects/sandboxes-of-the-energy-transition.html.

industry and allows to test integrated coupling of different sectors with hydrogen and energy efficient district solutions primary in the heating domain[409].

Implications for the EU:

- The experience of the UK's Ofgem in energy regulatory sandbox implementation shows that with the accelerated pace of technological progress, the net-zero objectives, and global energy crisis consequences, it is important to not only provide space for product testing but also address the "the pacing problem" (i.e. the fact that the technology develops quicker than the regulation that does not manage to capture and leverage in time these developments) through a **combination of product and policy-testing environment in the sandbox**. The FRS that allows for both product (service) testing and regulatory testing has the potential to accelerate regulatory learning and enable regulatory change necessary to accompany the deployment of new technologies in the energy market for the benefits of the economy and the consumers. Such an approach could be considered and promoted in the EU to ensure the EU's regulatory framework is fostering innovation. This action could take form of development of relevant **guidelines** for national regulatory authorities in the EU and relevant measures to support the implementation of sandboxes that comprise both product-testing and regulatory testing elements.
- In the EU, the fragmentation of regulatory frameworks between the EU and Member State (national) levels leads to **high risks of conflicts between the derogations granted under the national regulatory sandboxes and the EU-level** regulations both in energy and competition policies. This, together with legislative gaps for regulatory sandbox implementation and related capacity constraints of regulators across Member States, make the regulatory sandboxes in energy sector difficult to operate in the EU. The development of the **EU-level guidance and assistance** to Member States on elaboration of mandates of their relevant national regulatory authorities with regards to granting exemptions and regulatory derogations under the sandboxes would help to address this issue.

The US Emergency Use Authorisations and the EU Conditional Market Authorizations as regulatory experimentation tools with the effect of the "sandbox" for the uptake of new health technologies – the case of Covid-19 pandemic response

The medical sector is usually heavily regulated due to public health and safety concerns associated with the therapies and medical devices that are allowed into the market. The US`s Food and Drug Administration (FDA), much like European Medicines Agency (EMA), operates on a strict command-and-control principle whereby the regulator requires developers of new therapeutic technologies to first prove the safety and efficacy of their products under laboratory conditions before the technologies are authorised into the market. Hence, operating a regulatory sandbox in the health sector is rather a rare and difficult undertaking. However, some actions by relevant regulatory authorities in this sector that consist in relaxing the regulatory barriers temporarily under exceptional circumstances (i.e. health crisis or emergency) to allow new medicines or vaccines into the market, **have the effect the sandboxes** but in a heavily-regulated context. This argument is presented below drawing on the US and the EU experiences in deploying the Emergency Use Authorisation (EUA) and Conditional Market Authorizations (CMA) for therapeutic ana vaccines during the Covid-19 pandemic.

[409] Fraunhofer Institute for Wind Energy Systems (no date) *Northern German Regulatory Sandbox: Energy Transition Alliance for Innovations and Effective Climate Protection*. Available at: https://www.iwes.fraunhofer.de/en/research-projects/current-projects/northern-german-regulatory-sandbox.html.

In the case of the US, as of 2013, the FDA has the power to provide temporary authorisations of new technologies under the EUA program in the context of public health emergency[410]. The technologies are hence authorised for public distribution under the "totality of scientific evidence" principle which foresees regular reporting of the experimental data to the regulator by the innovator. The FDA's EUA were enacted on January 31, 2020 for Covid-19 vaccines resulting in development and authorisation of at least three new vaccines against Covid-19 in 2021[411]. Overall, FDA EUA authorisation under Covid-19 pandemic was the most expansive in the tool's history: more EUAs have been issued for COVID-19 than all of its previous EUAs combined[412]. However, EUAs application during the Covid-19 pandemic gathered quite a few criticisms, in particular, when it comes to inability to generate controlled, real-world evidence of effectiveness and safety of therapeutics (evidence suggests FDA issued EUAs several therapies even when their efficacy has been poor). Despite this, some experts call for considering the EUAs as a form of a regulatory sandbox. The reasons for this lay in the similarity of the EUA and regulatory sandboxes, including the **opportunity for experimentation** and collection of the resulting data, dialogue with the regulator, scalability of the proposed solution, together with limitations of the scope and duration, and specific participants' characteristics[413].

In the EU, in the context of the Covid-19 pandemic, the EMA resorted to the implementation of the **Conditional Market Authorisation (CMA) tool combined with the rolling reviews** to accelerate the authorisation of vaccines against Covid-19, such as, for instance Pfizer/BioNTech and Moderna. The CMA could be further converted to standard marketing authorisation (SMA) once the CMS holder fulfils necessary obligation and data gathered confirm medicine's benefits continue to outweigh risks[414]. On 26 April 2023, the European Commission adopted pharmaceutical legislation amendment proposal[415] which introduced temporary emergency marketing authorizations ("TEMAs") for use when there is a "public health emergency"[416] to prepare a better response in case of the next major public health crisis. Like the EUAs, the CMAs are subject to sandbox-like characteristics, including testing of a new health technology, limited scope and duration of the authorisation, comprehensive data provision (post-authorisation), scalability of the solution proposed (in case successful) and restrictions for selection of participants in the CMA programme.

Implications for the EU:

- Health sector remains heavily regulated due to safety and security concerns for public health and regulatory sandboxes are difficult to implement. However, certain actions by the regulators aimed at relaxing regulatory controls to enable innovative technology to be tested in the market for a limited period under exceptional circumstances, can be qualified as "sandboxes" in healthtech.

---

[410] Sherkow, Jacob S., Regulatory Sandboxes and the Public Health (February 1, 2022). University of Illinois Law Review, vol. 2022, pp. 357-410, Available at: https://ssrn.com/abstract=3792217

[411] Ibid.

[412] Ibid.

[413] Ibid.

[414] EMA (no date) *Conditional marketing authorisation*. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/conditional-marketing-authorisation.

[415] European Commission (2023) *Reform of the EU pharmaceutical legislation*. Available at: https://health.ec/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en.

[416] Handy, S.C., Ellie (2023) *EU Pharma Legislation Review Series: Temporary Emergency Marketing Authorizations*, *Inside EU Life Sciences*. Available at: https://www.insideeulifesciences.com/2023/05/03/eupharma-legislation-review-series-temporary-emergency-marketing-authorizations/ .

- The US' EUA and the EU's CMA used to respond against the Covid-19 pandemic could be considered as examples of regulatory sandboxes in healthtech with learnings to be drawn from the experience in their deployment for the wider regulatory experimentation in health-tech in the EU. In other words, there is merit in exploring more in detail the lessons learnt from the innovative technologies development during the Covid-19 pandemic, in particular through the CMAs in the EU and the EUAs in the US, to enable testing and experimentation of innovative healthtech outside the "emergency" contexts.

EA-01-25-014-EN-N

Publications Office
of the European Union

ISBN 978-92-9412-040-3