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Proposal for a

COUNCIL RECOMMENDATION

on common principles on regulatory sandboxes to support innovation and a future-proof regulatory framework

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Across Europe, there is a strong political focus on competitiveness and innovation-friendly regulation, while boosting global market access for businesses. The European Union wants to remain a place where breakthrough innovation can emerge and scale, while maintaining high standards for safety, trust and fairness. At the same time, innovative companies that want to scale up in Europe may be hindered by regulations that are not sufficiently flexible¹, posing certain challenges for innovators. The fragmented landscape across Member States in areas where no harmonised EU legislation exists also creates an uneven level playing field and higher compliance costs for innovators to test solutions under real world conditions in different Member States.

In response, the Commission adopted the EU Startup and Scaleup Strategy² in May 2025, outlining plans to enhance the Union's regulatory agility. Among other measures, regulatory sandboxes can provide businesses, including SMEs, startups, and other interested parties, with testing environments and accelerate market entry. At the same time, regulators can better understand the needs of emerging innovations and adjust rules to respond more effectively to challenges they face. Regulatory sandboxes are usually set up on a case-by-case basis with a clear scope. Importantly, this experimentation tool is not about deregulation. Rather, it is about creating a safe space where innovation and regulatory learning can evolve together. Regulatory sandboxes provide a practical way to learn by doing and offer firsthand insights into emerging innovation – including their risks and impact. They may also reduce market entry barriers for innovators and enhance communication and coordination between different public authorities and innovators, especially in relation to cross-sectoral innovation.

In 2025, the Commission also conducted a survey of Member States on their national experience with regulatory sandboxes³. The collective insights from the responding Member States emphasised the need for political backing, open communication, adequate resource allocation, and flexible, well-defined frameworks in achieving regulatory sandbox success. Continuous collaboration, iterative adjustments, and close stakeholder engagement remain vital to capitalise on regulatory sandboxes fully. Collectively, these insights point to the necessity of clear procedural frameworks, strong stakeholder collaboration, flexible design, effective communication, and strategic alignment with broader economic and social goals.

The objective of this proposal for a Council Recommendation is to contribute to an environment where innovation and regulation drive growth, competitiveness, and resilience across the EU. It sets out a common EU reference framework for regulatory sandboxes in areas where there is no Union legislation, with a definition and principles for their establishment, supervision and cross-border operation. This will provide a common understanding of this regulatory experimentation tool across the Union, enabling its more effective and efficient use that builds on existing experiences and best practices from the Member States and existing initiatives. In practice, this also clarifies access to regulatory

¹ The Draghi report: A competitiveness strategy for Europe, 2024, p. 6, https://commission.europa.eu/topics/competitiveness/draghi-report_en#paragraph_47059.

² COM/2025/270final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025DC0270>

³ European Commission: Directorate-General for Research and Innovation, Vuorinen, H., Isakovic, S. M. and Bonel, E., *Use of regulatory sandboxes in EU Member States – 2025 survey report*, Publications Office of the European Union, 2026, <https://data.europa.eu/doi/10.2777/9535645>

sandboxes and helps to reduce fragmentation between Member States. The Commission proposal promotes regulatory learning and will further strengthen the dialogue with Member States in the future. For innovators, well implemented regulatory sandboxes can improve regulatory clarity and facilitate the development of innovative solutions, such as technologies, products, services, and business models.

- **Consistency with existing policy provisions in the policy area**

The Council conclusions of 30 September 2025 on ‘The importance of research and innovation for the EU Startup and Scaleup Strategy’⁴ recognised the importance of regulatory sandboxes to facilitate market entry of innovations by supporting innovative startups and innovative scaleups in developing and testing new ideas, assessing regulatory compliance of new solutions, improving regulatory learning, and issuing recommendations for overcoming regulatory hurdles. To ensure the rapid and effective implementation of regulatory sandboxes, these Council conclusions encouraged the Union to develop clear and efficient rules in the for regulatory sandboxes in the upcoming European Innovation Act, including for Union-wide regulatory sandboxes.

This proposal for a Council Recommendation is adopted together with the proposal for European Innovation Act⁵.

The proposal follows up on the 2020 Council Conclusions on the role of regulatory sandboxes and experimentation clauses in an innovation-friendly, future-proof, sustainable and resilient EU regulatory framework⁶. These conclusions called upon the Commission to organise, in cooperation with Member States, an exchange of information and good practices regarding regulatory sandboxes between Member States and itself in order to:

- (a) establish an overview of the state of play regarding the use of regulatory sandboxes in the EU;
- (b) identify experiences regarding the legal basis, implementation and evaluation of regulatory sandboxes;
- (c) analyse how learning from regulatory sandboxes at national level can contribute to evidence-based policy making at EU-level.

In response, the Commission has already adopted the 2023 staff working document on regulatory learning in the EU⁷, one of the actions on the New European Innovation Agenda (NEIA)⁸, and conducted a follow-up survey of Member States in 2025 on regulatory sandboxes.

⁴ The importance of research and innovation for the EU Startup and Scaleup Strategy – Council conclusions <https://data.consilium.europa.eu/doc/document/ST-13357-2025-INIT/en/pdf>

⁵ Commission proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL - European Innovation Act – COM(2026) 567

⁶ 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 <https://data.consilium.europa.eu/doc/document/ST-13026-2020-INIT/en/pdf>

⁷ SWD(2023) 277/2 final, https://research-and-innovation.ec.europa.eu/document/download/fc6f35cd-a8d6-4770-aefe-c09ca85cff8c_en?filename=swd_2023_277_f1.pdf

⁸ 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, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022DC0332>

- **Consistency with other Union policies**

This proposal recognises all policy areas where the Union and Member States have shared competence. It takes into account that regulatory sandboxes have already been introduced in legislation or form part of pending legal proposals, including:

- **artificial intelligence**, with Regulation (EU) 2024/1689 (‘AI Act’)⁹ requiring Member States to establish at least one regulatory sandbox in this field providing national coverage,
- **biotechnology**, following the Commission Proposal for the European Biotech Act¹⁰ in 2025 which outlined five regulatory sandbox frameworks and builds on the Strategic Framework for a Competitive and Sustainable EU Bioeconomy¹¹,
- **cybersecurity**, where the Cyber Resilience Act¹², adopted in 2024 introduced provisions on regulatory sandboxes for products with digital elements,
- **public sector interoperability**, where cross-border regulatory sandboxes were introduced in the Interoperable Europe Act¹³, adopted in 2024,
- **energy, climate and environmental transitions**, following the adoption of the 2024 Net-Zero Industry Act¹⁴ which also includes provisions on regulatory sandboxes. Contributing to Europe’s maritime technological leadership, industrial sovereignty and twin transition objectives, the 2026 Industrial Maritime Strategy “encourages Member States to further support the rapid uptake of innovation including tests beds and regulatory experimentation”¹⁵. In the same vein, the 2026 Strategy for the development and deployment of Small Modular Reactors (SMRs) in Europe specifies that the Commission “will assist Member States in developing regulatory

⁹ 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) (OJ L, 2024/1689, 12.7.2024, ELI: <http://data.europa.eu/eli/reg/2024/1689/oj>)

¹⁰ Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing a framework of measures for strengthening Union’s biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act) COM(2025) 1022 final, [EUR-Lex - 52025PC1022\(01\) - EN - EUR-Lex](#)

¹¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions A Strategic Framework for a Competitive and Sustainable EU Bioeconomy COM(2025) 960 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52025DC0960>

¹² Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) (Text with EEA relevance) <https://eur-lex.europa.eu/eli/reg/2024/2847/oj/eng>

¹³ Regulation (EU) 2024/903 of the European Parliament and of the Council of 13 March 2024 laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act), [Regulation - EU - 2024/903 - EN - EUR-Lex](#)

¹⁴ Regulation (EU) 2024/1735 of the European Parliament and of the Council of 13 June 2024 on establishing a framework of measures for strengthening Europe’s net-zero technology manufacturing ecosystem and amending Regulation (EU) 2018/1724 (Text with EEA relevance), [Regulation - EU - 2024/1735 - EN - EUR-Lex](#)

¹⁵ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the EU Industrial Maritime Strategy COM(2026)111final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52026DC0111>

sandboxes for SMRs”, building on the regulatory sandboxes provided for under the Net-Zero Industry Act¹⁶,

- **financial sector**, where market infrastructures based on distributed ledger technology benefitted from a pilot regime of Regulation (EU) 2022/858 (‘DLT Pilot Regime Regulation’)¹⁷,
- **mobility**, as regulatory sandboxes are addressed in the Industrial Action Plan for the European automotive sector, aiming to boost market readiness and commercialisation of autonomous vehicles. Moreover, they are included in the Commission proposal aiming to facilitate a more rapid and autonomous development of innovative, dual-use transport solutions in cooperation between civil and military authorities¹⁸,
- **life sciences and pharmaceutical sectors**, with regulatory sandbox provisions included in the politically agreed regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency¹⁹, as well as in the proposed revision of the EU Regulations on medical devices and *in vitro* diagnostic medical devices²⁰ and in the proposal for a European Biotech act, which also addresses regulatory sandboxes in the area of food chain.²¹ The Commission’s Strategy to position the Union as the world’s most attractive place for life sciences by 2030 indicated that “regulatory systems need to be responsive to emerging technologies and keep pace with scientific progress. Future legislation should integrate experimentation clauses, derogations and the use of test environments such as regulatory sandboxes”²².

¹⁶ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Strategy for the development and deployment of Small Modular Reactors (SMRs) in Europe, COM(2026) 117 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52026DC0117>

¹⁷ 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, and amending Regulations (EU) No 600/2014 and (EU) No 909/2014 and Directive 2014/65/EU (Text with EEA relevance) [Regulation - 2022/858 - EN - dlt - EUR-Lex](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52022R0858)

¹⁸ Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing a framework of measures to facilitate the transport of military equipment, goods and personnel across the Union COM(2025) 847 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC0847>

¹⁹ Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 [EUR-Lex - 52023PC0193 - EN - EUR-Lex](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52023PC0193)

²⁰ Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and *in vitro* diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I [EUR-Lex - 52025PC1023 - EN - EUR-Lex](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC1023)

²¹ Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing a framework of measures for strengthening Union’s biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938

²² Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Choose Europe for life sciences A

This proposal focuses on national regulatory sandboxes set up by Member States and is without prejudice to existing Union legislative provisions on regulatory sandboxes or Commission proposals for new legislative initiatives. It encourages Member States to build on the existing legislative framework for regulatory sandboxes made under Union law, when relevant.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The legal bases for this initiative are Articles 173(3) and 292 of the Treaty on the Functioning of the European Union (TFEU). In accordance with Article 292 TFEU, the Council can adopt recommendations and acts on a proposal from the Commission in all cases where the Treaties state that it must adopt acts on the basis of a proposal from the Commission.

In accordance with Article 173 TFEU, the Union and the Member States must ensure that the necessary conditions for competitiveness of the Union's industry exists. This includes fostering better exploitation of the industrial potential of policies of innovation, research and technological development. In particular, according to Article 173(3), the Union shall contribute to the achievement of the objectives set out in Article 173(1) through the policies and activities it pursues under other provisions of the Treaties.

The initiative does not propose any extension of Union regulatory power or binding commitments on Member States. It is the Member States who will decide, based on their national circumstances, how they implement this Council Recommendation, taking into account relevant applicable Union legislation.

• Subsidiarity (for non-exclusive competence)

The present proposal is in conformity with the principle of subsidiarity as provided for in Article 5(3) of the Treaty on the European Union (TEU).

The use of regulatory sandboxes, including cross-border regulatory sandboxes, is expected to grow across the Union in the coming years. In this evolving context, different interpretations and applications of the concept of a “regulatory sandbox” have started to emerge across sectors and among Member States. Action by Member States alone, in non-harmonised areas, is likely to result in divergent approaches, creating substantial coordination costs for Member States seeking to cooperate or develop common practices. A coordinated approach is therefore necessary to minimise transaction costs for European businesses and public authorities using this tool.

The proposal provides an efficient means of establishing a common EU reference framework, reducing fragmentation across Member States, and ultimately supporting the Single Market.

By promoting favourable framework conditions and a common approach to regulatory experimentation, this proposal seeks to foster collective action. It aims to deliver more targeted and effective results than isolated national initiatives. A common approach would ease establishing regulatory sandboxes across borders by several Member States while remaining flexible enough to accommodate the different degrees of experience and

strategy to position the EU as the world's most attractive place for life sciences by 2030 COM/2025/525 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025DC0525>

preparedness among Member States in accelerating innovation and taking into account relevant applicable Union legislation.

The proposed approach is consistent with the logic underpinning recent Union legislative initiatives, notably the AI Act and the Interoperable Europe Act, both of which recognise that purely national regulatory sandboxes cannot by themselves ensure cross-border regulatory learning, mutual recognition of outcomes, or the scaling of innovative solutions across the Single Market.

The proposal therefore generates Union added value by fostering joint regulatory experimentation across jurisdictions and reducing the costs for innovators of engaging with multiple national regimes, while leaving the design and operation of national regulatory sandboxes to Member States.

- **Proportionality**

The present proposal is in conformity with the principle of proportionality as provided for in Article 5(4) TEU. Neither the content nor the form of this proposed Council Recommendation exceeds what is necessary to achieve the objective of achieving a minimum level of consistency of approach across the Union.

The legal status of this initiative should ensure ownership of and endorsement by the Member States.

The recommendation helps Member States and the Union to develop and implement regulatory sandbox frameworks and to promote regulatory learning. A minimum level of consistency of approach across the EU is essential. It underscores the importance of transparency of establishment and implementation, following the principle ‘as open as possible, as closed as necessary’. It also recommends considering risk management measures for experimentation.

- **Choice of the instrument**

The proposed Council Recommendation provides guidance to Member States about how to define regulatory sandboxes and agree on common principles for their establishment, design, operation, including in cross-border context, and evaluation and regulatory learning. It recommends that Member States support their innovation sector and public authorities, taking appropriate steps to raise awareness.

The choice of a Council Recommendation ensures that all Member States are actively involved and committed at political level, while at the same time it allows for sufficient flexibility, considering that Member States may depart from different starting points in terms of regulatory frameworks, availability of resources, and maturity of the innovation ecosystem.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

This is a new initiative so there was no preceding evaluation.

- **Stakeholder consultations**

The current initiative is covered by a comprehensive stakeholder consultation plan carried out for the European Innovation Act.

Of the respondents to the stakeholder consultation that expressed an opinion²³ on regulatory sandboxes, a majority agreed that an EU-level definition of ‘regulatory sandbox’ would help achieve a better common understanding across Europe, and that more possibilities for “cross-border EU-level regulatory sandboxes” would facilitate their wider implementation, as well as that there should be regulatory sandboxes for newly emerging technologies to facilitate their wider adoption.

Respondents that have declared experience in participating in or setting up regulatory sandboxes show higher agreement with the above statements than those that have not.

In the position papers submitted in response to the call for evidence on the European Innovation Act, stakeholders highlighted the lack of sufficient opportunities to test innovative solutions, identified regulatory sandboxes as essential for overcoming limited testing opportunities in the Union and described Union funding and regulatory procedures as slow, duplicative, and inaccessible. Other submissions argued that existing regulatory systems in Member States are outdated and slow to keep pace with technological change, often applying old rules to new technologies such as AI and biotechnology.

During stakeholder interviews, industry, SME, and startup associations discussed the idea of harmonising regulatory sandboxes positively to allow innovative products to enter the market under controlled conditions, reducing time-to-market. Financial-sector representatives proposed a sandbox jurisdiction for start-ups with simplified incorporation, licensing and harmonised business codes to enable easier cross-border operation.

In April 2025, the Commission survey of Member States on the national use of regulatory sandboxes was launched at the Council Working Party on Competitiveness and Growth – Better Regulation, under the Polish presidency for the Council of the European Union. It builds on a similar survey conducted in 2021 by the Slovenian Council Presidency. In September 2025, the latest data were presented at the same Working Party²⁴ under the Danish Council Presidency. During the discussion that followed the presentation, two Member States provided additional data on regulatory sandbox practices in their national context and other responses were accepted until January 2026. The final report published by the Commission in March 2026 presents all the data received²⁵.

- **Collection and use of expertise**

In addition to the input received during the consultation process, the proposal is underpinned by extensive evidence, reports and studies collected over recent years. Key sources of evidence include two surveys of Member States conducted by the Commission in 2021 and 2025, the 2026 Assessment of the state of play of the innovation principle in the preparation of EU legislation, as well as the Commission’s biennial report on Science, Research and Innovation Performance of the EU.

In 2025, the Commission conducted a **survey of Member States** on the use of regulatory sandboxes at national level²⁶. This second survey identified 132 regulatory sandboxes at

²³ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14593-European-Innovation-Act/public-consultation_en

²⁴ <https://data.consilium.europa.eu/doc/document/WK-12252-2025-INIT/en/pdf>

²⁵ European Commission: Directorate-General for Research and Innovation, Vuorinen, H., Isakovic, S. M. and Bonel, E., *Use of regulatory sandboxes in EU Member States – 2025 survey report*, Publications Office of the European Union, 2026, <https://data.europa.eu/doi/10.2777/9535645>

²⁶ *Ibid.*

national level, across 15 Member States but primarily in Germany and France (up from 40 identified in the 2021 survey). This report shows the diversity of approaches in the Member States, for example in terms of legal basis (horizontal or sector-specific), geographic limitations of regulatory sandbox frameworks (i.e. in some cases enabling experimentation only in some specific regions), openness to companies registered in other Member States, monitoring and evaluation, as well as other aspects.

Looking at the inclusion of regulatory sandboxes and innovation more generally in the **preparation of EU legislation**, a 2026 assessment²⁷ found that experimentation clauses, pilot schemes or regulatory sandboxes appear in approximately 10–15% of impact assessments conducted in 2020–2025, primarily in digital, financial, and emerging technology policy areas. According to the experts, regulatory sandboxes appear to have permeated the better regulation agenda of the European Commission more than other tools.

In addition, the Commission’s biennial **Science, Research and Innovation Performance of the EU (SRIP)** report highlighted the opportunities provided by regulatory sandboxes in the most recent two editions. In 2024, the report underlined that “an adaptable regulatory framework and a proactive standardisation strategy remain key to foster innovative activities”²⁸. The authors explain that the EU’s focus on regulatory sandboxes aims to streamline the integration of research into the market, while ensuring the legislative agility needed to keep pace with rapid technological advances. In 2022, the authors underlined that the “emergence of new practices, technologies and business models, and the acceleration of innovation call for more flexible and experimental approaches to regulation, such as regulatory sandboxes”²⁹.

- **Impact assessment**

The current proposal does not require an individual impact assessment given the non-binding legal nature of the proposed instrument.

Nevertheless, each of the Union regulations and proposals that include regulatory sandbox provisions as of July 2026 were accompanied by an impact assessment or analytical staff working document.³⁰

- **Fundamental rights**

One of the proposal’s main objectives is to support Member States and organisations participating in regulatory sandboxes, ensuring that authorised experimentations support innovation while preserving trust and protecting fundamental rights and values. Safeguards of ethical and legal nature (e.g. data collection, transparency, protection of fundamental rights, fair competition) need to be in place, and risks related to, for example health, safety or fundamental rights, need to be managed properly. The proposal is based on a non-discriminatory approach and promotes transparency of regulatory sandboxes.

²⁷ European Commission: Directorate-General for Research and Innovation, Renda, A., Dell’Aquila, M., Nyoka Rukudzo, I., Vu, H. et al., *Assessment of the state of play of the innovation principle in the preparation of EU legislation*, Publications Office of the European Union, 2026, <https://data.europa.eu/doi/10.2777/8779303>

²⁸ SRIP, 2024, p. 349, https://ec.europa.eu/assets/rtd/srip/2024/ec_rtd_srip-report-2024-chap-05.pdf

²⁹ SRIP, 2022, p. 17, <https://data.europa.eu/doi/10.2777/78826>

³⁰ SWD/2020/201 final; SWD/2020/201 final; SWD/2022/721 final; SWD(2023)219 final; SWD/2022/282 final; SWD(2023) 192 final; SWD/2025/1050 final; SWD/2026/450 final.

4. BUDGETARY IMPLICATIONS

It is difficult to estimate cost changes brought by this Council Recommendation due to its non-binding nature. Monitoring its application in Member States and evaluating its implementation can provide cost estimates in the future.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

To support Member States and stakeholders as they implement the recommendation, full use will be made of the existing governance structures, for example the Council Working Party on Competitiveness and Growth.

The proposal underlines the importance of monitoring, evaluation and reporting on regulatory learning that results from regulatory sandboxes and should be used to ensure legislation remains fit for purpose.

- **Explanatory documents (for directives)**

Not applicable.

- **Detailed explanation of the specific provisions of the proposal**

The proposed Council Recommendation contains the following sections:

- After introducing the issue at stake and the political background of the proposal in the recitals, its scope is explained. A definition of ‘regulatory sandbox’ is proposed, which draws on the main elements of the various definitions in use internationally. Other relevant terms are also defined, including experimentation, controlled environment, competent authority and cross-border regulatory sandboxes.
- Then, principles for the establishment of regulatory sandboxes are proposed as a recommendation to the Member States to agree on these minimum aspects for a common framework in the Union. These principles are conceived in such a way that they can be used to underpin the formulation and design of a regulatory sandbox at any level and sector. These principles were formulated based on available best-practice and taking into account results of the 2025 Survey of Member States³¹.
- A separate point outlines the minimum aspects that should be agreed related to any cross-border regulatory sandbox to help innovative companies scale up across the Union as it would enable larger scale testing in the different Member States. Cooperation among competent authorities in cross-border regulatory sandboxes can facilitate coordinated supervision, enhance regulatory coherence, and exploit cross-border innovation synergies. They can also promote shared learning and sharing of costs for the establishment, management and supervision of regulatory sandboxes for innovations that are of relevance to multiple Member States.
- The duration and other conditions of experimentation and participation in regulatory sandboxes that should be outlined are listed subsequently. To ensure regulatory sandboxes to function effectively, the competent authorities should use transparent

³¹ European Commission: Directorate-General for Research and Innovation, Vuorinen, H., Isakovic, S. M. and Bonel, E., *Use of regulatory sandboxes in EU Member States – 2025 survey report*, Publications Office of the European Union, 2026, <https://data.europa.eu/doi/10.2777/9535645>

and objective processes governing participation including eligibility criteria, application procedures, and clear terms and conditions for participation, as well as conditions regarding the handling of intellectual property rights and liabilities to ensure a predictable environment that supports the development of innovative solutions. Any relevant support measures for participants, such as regulatory advice, training and where appropriate funding, should be also clearly defined in advance in the participation conditions. By doing so, it is ensured that innovation within the regulatory sandboxes can be adequately nurtured and innovative solutions that successfully complete experimentation in the regulatory sandbox can be guided towards successful integration in the wider market. Dedicated points are then provided on transparency and non-discriminatory access to regulatory sandboxes.

- The recommendation on regulatory learning and follow-up outlines that Member States should require that after the completion of the regulatory sandbox, competent authorities should analyse the available information and assess the need to amend the regulatory framework. It also states that regulatory sandbox participants should be able to obtain the exit report with the aim of accelerating the conformity assessment, standardisation or national market approval of their innovations that were tested within the regulatory sandbox.
- The final section specifies how the follow-up to the recommendation is facilitated and monitored.

Proposal for a

COUNCIL RECOMMENDATION

on common principles on regulatory sandboxes to support innovation and a future-proof regulatory framework

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292, in conjunction with Article 173(3), thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) Innovation fuels the Union's competitiveness and prosperity. However, existing legal frameworks in certain areas do not stand the test of time in face of rapidly changing and emerging technologies. Innovators face legal uncertainty when bringing new products and services to the market which do not neatly fit into existing regulatory frameworks.
- (2) Innovation is built on experimentation and testing. Regulatory sandboxes are a targeted form of experimentation which can help the Commission and Member States assess whether existing legal requirements remain fit for purpose or need adaptation due to rapidly evolving technology. They are usually set up on a case-by-case basis with a clearly defined scope. They offer a practical way to learn by doing and provide firsthand insights into emerging innovation – including their risks and impact. They may also reduce market entry barriers and enhance communication and coordination between different public authorities and innovators, especially in relation to cross-sectoral innovation. Nevertheless, participation in regulatory sandboxes should not be considered as a permanent exemption from regulatory requirements or an alternative pathway to regulatory authorisations in the Union.
- (3) In recent years, regulatory sandboxes have been increasingly promoted as a tool to foster innovation throughout the Union, including by Council conclusions¹ encouraging knowledge sharing of best practices, Member State initiatives and the incorporation of regulatory sandbox provisions in key Union legislation². Those

¹ 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 <https://data.consilium.europa.eu/doc/document/ST-13026-2020-INIT/en/pdf>

² Regulation (EU) 2024/903 of the European Parliament and of the Council of 13 March 2024 laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act) (OJ L, 2024/903, 22.03.2024, ELI: <http://data.europa.eu/eli/reg/2024/903/oj>); 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) (OJ L, 2024/1689, 12.07.2024, ELI: <http://data.europa.eu/eli/reg/2024/1689/oj>); Regulation (EU) 2024/1735 of the European Parliament and of the Council of 13 June 2024 on establishing a framework of measures for strengthening Europe's net-zero technology manufacturing ecosystem and amending Regulation (EU) 2018/1724 (OJ L,

initiatives have underscored the value of regulatory sandboxes in supporting small and medium-sized enterprises (SMEs), as defined in Commission Recommendation 2003/361/EC³, innovative startups and innovative scaleups, as defined in Commission Recommendation (EU) 2026/720⁴ and informing evidence-based policymaking. The Commission has reaffirmed its commitment to preparing legislative proposals containing innovation-friendly, future-proof rules, balancing legal certainty with adaptability to technological developments⁵, without compromising the high level of protection of public interest objectives.

- (4) As a result of the increasing focus on regulatory sandboxes, differing interpretations on their purpose, scope and concept have become more visible. The definition of regulatory sandboxes and the conditions for their establishment and operation vary between Member States, an element which adds to the complexity faced by innovators. A common understanding could facilitate the development of innovative solutions across the internal market and reduce regulatory barriers resulting from divergent national approaches to experimentation. At the same time, such an understanding would allow sufficient flexibility while recognising Member States' different starting points, capacities and sectoral differences, as well as the existence of the Union legislation which defines regulatory sandboxes for specific sectors.
- (5) To help innovators and other interested parties identify opportunities to participate in regulatory sandboxes, it is necessary to lay down common and transparent principles across the Union concerning the establishment of, conditions for participation in and the outcomes of regulatory sandboxes. Such principles would contribute to building public trust and facilitate knowledge-sharing between competent authorities across the Union while preserving a level playing field. Participation criteria and operating conditions should be transparent, objective and proportionate, ensuring that regulatory sandboxes do not create unjustified competitive advantages or hinder the free movement of goods in areas that have been subject to Union harmonisation.
- (6) To ensure a predictable environment that supports the development of innovative solutions in the internal market, the competent authorities in the Member States should use transparent and objective processes governing regulatory sandboxes, including eligibility criteria, application procedures, clear terms and conditions for participation and operation, as well as regulatory learning. To ensure legal certainty, any possibility of granting derogations from existing legal requirements should be explicit, clearly defined and consistent with Union legislation.

2024/1735, 28.06.2024, ELI: <http://data.europa.eu/eli/reg/2024/1735/oj>; Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) (OJ L, 2024/2847, 20.11.2024, ELI: <http://data.europa.eu/eli/reg/2024/2847/oj>). See also 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, and amending Regulations (EU) No 600/2014 and (EU) No 909/2014 and Directive 2014/65/EU (OJ L 151, 2.6.2022, p. 1, ELI: <http://data.europa.eu/eli/reg/2022/858/oj>).

³ Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: <http://data.europa.eu/eli/reco/2003/361/oj>).

⁴ Commission Recommendation (EU) 2026/720 of 18 March 2026 on the definition of innovative enterprises, innovative startups and innovative scaleups (OJ L, 2026/720, 24.3.2026, ELI: <http://data.europa.eu/eli/reco/2026/720/oj>).

⁵ Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, A Simpler, Clearer and Better Enforced EU Rulebook, COM/2026/380 final [EUR-Lex - 52026DC0380 - EN - EUR-Lex](#)

- (7) With a view to enabling a common understanding of regulatory sandboxes, it is necessary to raise further awareness, align communication and facilitate peer learning between Member States and their competent authorities, as well as to contribute to a learning approach that is both flexible and agile.
- (8) Sharing information with conformity assessment bodies, standardisation organisations, market surveillance authorities and other relevant actors about the outcomes of a regulatory sandbox, for example in the form of an exit reports, could help accelerate the conformity assessment, standardisation or national market approval of the innovative solutions. As a result, innovation could be adequately supported and innovative solutions that successfully complete experimentation in the regulatory sandbox could be guided towards successful integration into the market.
- (9) Non-discriminatory access to regulatory sandboxes throughout the Union would promote fair competition and encourage broad participation by all relevant stakeholders, including economic operators, which can provide useful input to competent authorities for the purpose of regulatory learning. Regarding the possibility to restrict access or grant priority access to regulatory sandboxes, which should be in line with the obligations of the Union set out in applicable international agreements, it is recommended to carefully consider the necessity for such restriction or priority based on objective elements, such as the country of registration and size of participating entities.
- (10) Regulatory sandboxes and the evidence generated through the experimentation performed therein should support the evolution of regulatory frameworks. Systematic analyses of insights from experimentation activities should enhance the adaptability of regulatory frameworks to changing circumstances and technological advancements. Regulatory sandboxes should also provide an opportunity for advancing regulation in the case of high uncertainty and disruptive challenges, as well as when preparing new policies.
- (11) In light of the experience gained from existing Union and national regulatory sandboxes, the Council welcomes the Commission's intention to monitor relevant developments and assess where appropriate whether further measures at Union level may be necessary. Any such measures should be innovation-friendly and designed to avoid unnecessary administrative burden or overly prescriptive requirements,

HEREBY RECOMMENDS:

- 1. For the purposes of this Recommendation, the following definitions should apply:
 - (1) ‘regulatory sandbox’ means a structured framework that allows regulatory sandbox participants to experiment with innovative solutions for a limited time in a controlled environment, under the supervision of one or several competent authorities, and that results in evidence-based regulatory learning;
 - (2) ‘experimentation’ means any combination of development, testing, and validation of innovative solutions in real-world conditions in a controlled environment, prior to making them available or otherwise putting into service or use;
 - (3) ‘controlled environment’ means a physical, digital or hybrid environment inside or outside of a laboratory or an otherwise simulated environment in which experimentation in regulatory sandboxes may take place under the supervision of one or several competent authorities, subject to predefined conditions, safeguards and measures to address and mitigate potential risks;

- (4) ‘competent authority’ means any public sector body of a Member State at national, regional or local level, which is entrusted under Union or national law with responsibilities for the supervision or enforcement of legislation that is related to or affects innovations that may be experimented or supervised within a regulatory sandbox;
 - (5) ‘cross-border regulatory sandbox’ means a regulatory sandbox established, operated or supervised jointly by competent authorities from more than one Member State.
2. In developing national provisions on regulatory sandboxes, Member States should consider the following:
 - (a) assess whether a regulatory sandbox is necessary in a particular sector;
 - (b) apply the Union legal provisions in force regarding the establishment and operation of regulatory sandboxes where relevant;
 - (c) state the reasons for the necessity of including provisions on regulatory sandboxes in the relevant national legal act and clearly define the regulatory sandbox’s objectives within that act;
 - (d) where derogations from existing legal requirements are envisaged, ensure that such derogations are explicit, clearly defined and duly justified;
 - (e) ensure that derogations from applicable Union secondary law are envisaged only where the possibility for such derogations is provided for in applicable Union acts;
 - (f) provide in the national legal act that regulatory sandboxes may be established on the competent authority’s, or authorities’ initiative or at the request of an applicant, subject to the competencies of that authority or those authorities under Union and national law;
 - (g) check, where relevant, whether test facilities, including those accredited for conformity assessments under Regulation (EC) No 765/2008 of the European Parliament and of the Council⁶, could be made available for experimentation in regulatory sandboxes;
 - (h) cooperate with research infrastructures and technology infrastructures⁷ to provide participants in regulatory sandboxes with access to the facilities and services of those infrastructures, where relevant.
3. Member States and their competent authorities should specify the conditions under which experimentation is allowed, covering at least the following aspects:
 - (1) the objectives and scope of the experimentation, which should include fostering innovative solutions that cannot be developed in accordance with the currently applicable rules, and promoting regulatory learning;
 - (2) the types of experimentation that are authorised to be carried out;

⁶ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30, [ELI: http://data.europa.eu/eli/reg/2008/765/oj](http://data.europa.eu/eli/reg/2008/765/oj))

⁷ The European Strategy on Research and Technology Infrastructures, https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/our-digital-future/european-strategy-research-and-technology-infrastructures_en

- (3) any restrictions on experimentation, including its maximum duration or any geographical limitations;
 - (4) an assessment of potential risks, mitigation measures and the safeguards necessary to ensure protection of the public interests, fundamental rights, the rights guaranteed by national constitutions and rights guaranteed by the Treaties, in particular those relating to protection of the safety of persons and property, of consumers and of the environment, as well as to public health and public order, also in accordance with international obligations and fair competition;
 - (5) the terms of the evaluation of experimentation;
 - (6) the conditions of extension, renewal, suspension, modification, or termination of experimentation, including the reporting of serious incidents;
 - (7) the conditions for applying any derogation from the legislation applicable to the area in which the experimentation is proposed.
4. Member States should ensure that the duration of the experimentation in a regulatory sandbox is proportionate to its objectives and allows for the achievement of the intended purpose and the generation of sufficient regulatory learning.
5. Member States should ensure that participation in and the operation of regulatory sandboxes are subject to clearly defined conditions covering, to the extent relevant, the following aspects:
- (a) eligibility criteria, the application procedure, selection criteria and procedures, the conditions for participating in and exiting the regulatory sandbox, and, where applicable, the conditions for access to a specific experimentation environment, including any financial conditions for such access, as well as the modalities governing the provision of the explicit and prior consent from participating natural persons;
 - (b) the liability of participants and other parties involved in the regulatory sandbox, in accordance with applicable Union and national law, for any damage caused to third parties, including users, subjects of the testing and consumers as a result of the experimentation;
 - (c) the management of intellectual property rights, data protection and measures safeguarding the right to privacy, and the protection of confidential information;
 - (d) any provisions specifying the materials and resources which participants or the competent authority, or both, will make available to the regulatory sandbox project;
 - (e) the arrangements for monitoring, reporting, evaluation and knowledge sharing; as a minimum, the actors to be involved in the evaluation process should be identified in the national provisions on regulatory sandbox, as well as, if relevant, any reporting obligations;
 - (f) an exit strategy, including pathways for the deployment of the innovative solutions that successfully complete the experimentation within the regulatory sandbox, and a process for the orderly termination of experimentations that produce unsuccessful or potentially harmful effects;

- (g) any relevant support measures, including guidance and advice on regulatory expectations, training, awareness-raising, and, where appropriate, funding, tailored to the needs of innovative startups, innovative scaleups, small and medium-sized enterprises (SMEs), potential public or private customers or other end-users of the innovations.
6. Member States and their competent authorities are encouraged to establish and facilitate participation in cross-border regulatory sandboxes. When setting up a cross-border regulatory sandbox, competent authorities should conclude an agreement setting out at least the following aspects:
 - (a) the conditions under which experimentation is allowed;
 - (b) the allocation of the respective roles and responsibilities of the competent authorities from different Member States for the establishment, operation, supervision, monitoring and termination of the regulatory sandbox;
 - (c) the legal provisions and administrative arrangements applicable to the cross-border regulatory sandbox (including those listed in point 5), taking into account the allocation of the respective roles and responsibilities among the relevant competent authorities.
 7. Member States should ensure that all requests to establish and to participate in regulatory sandboxes are assessed on a transparent and non-discriminatory basis.
 8. However, subject to the obligations of the Union set out in applicable international agreements, Member States may, to the extent necessary and provided that objective grounds are given:
 - (a) restrict the possibility of participating in regulatory sandboxes and provide that possibility exclusively to Union citizens and to entities established in the Union;
 - (b) give priority to SMEs, innovative startups, or innovative scaleups established in the Union for participation in a regulatory sandbox; or
 - (c) require participants in a regulatory sandbox to carry out in the Union certain research, development and innovation activities necessary for experimentation within the regulatory sandbox.
 9. With the support of the competent authorities, Member States should collect and analyse the results of, and lessons learnt from, the experimentation within a regulatory sandbox. Based on that analysis, Member States should assess the need to integrate those learnings into the national regulatory framework applicable to the innovation that was subject to the experimentation.
 10. Member States should require competent authorities to issue, upon request from a regulatory sandbox participant, an exit report detailing the activities carried out in the regulatory sandbox, the results of the experimentation and the learning outcomes, with the aim of accelerating the conformity assessment, standardisation or national market approval of the innovations.
 11. Member States should make available to the public any information related to the establishment and outcomes of the experimentation, while fully protecting business secrets or otherwise confidential information, including lessons learnt for the purposes of regulatory learning, unless this would be contrary to national security interests or the Union's security interests.

12. It is recommended that Member States implement this Recommendation as soon as practicable.
13. Member States are invited to monitor, with the support of the Commission, the progress in the implementation of this Recommendation.

Done at Brussels,

*For the Council
The President*