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From: General Secretariat of the Council

To: Delegations

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Subject: 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

Delegations will find in annex the 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, as adopted by written procedure on 16 November 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

THE COUNCIL OF THE EUROPEAN UNION:

1. RECALLS its Conclusions of February 2020¹ which HIGHLIGHTED that Better Regulation is one of the key drivers of sustainable, inclusive growth, fosters competitiveness, innovation, digitalisation and job creation, increases transparency and ensures public support for EU legislation; and REITERATED the need to ensure that EU regulation is transparent and simple and is achieved at minimum cost, while always taking into account a high level of protection of consumers, employees, health, climate and the environment. REAFFIRMS its commitment to promoting the most efficient regulatory instruments, such as harmonisation and mutual recognition.²
2. UNDERLINES that especially in order for the EU to emerge stronger from the COVID-19 crisis, which has had a severe impact on the majority of businesses in the EU, particularly small and medium-sized enterprises (SMEs) including micro-enterprises as well as start-ups, many of which face an existential threat, the EU regulatory framework needs to be as competitive, effective, efficient, coherent, predictable, innovation-friendly, future-proof, sustainable and resilient as possible. It needs to be evidence-based and has to protect and support both citizens and businesses in the context of the aim of a fully functioning EU Single Market without imposing new unnecessary burdens and while reducing existing unnecessary burdens.

¹ 6232/20.

² Interinstitutional Agreement on Better Law-Making, point 47.

3. RECALLS the principles of subsidiarity and of proportionality, as well as the precautionary principle, and its Conclusions of May 2016³ which STRESSED that, when considering developing or updating EU policy or regulatory measures, the ‘Innovation Principle’ should be applied, which entails taking into account the impact on research and innovation in the process of developing and reviewing regulation in all policy domains; which CALLED on the Commission and Member States to include the perspective of innovation-friendly and future-proof regulation as part of their discussions on existing regulation within REFIT; and which CALLED on the Commission and Member States to explore and exchange best practices as to how regulation can be made more future-proof and enabling for research and innovation, including possibilities for experimentation and flexibility. RECALLS the Best Practice Exchange organised in 2017 by the Maltese Presidency of the Council, which revealed that many Member States already consider experimentation and other innovation-related tools in their policy-making.⁴
4. HIGHLIGHTS that flexibility and experimentation can be important elements for an agile, innovation-friendly, future-proof, evidence-based and resilient regulatory framework which fosters competitiveness, growth, sustainability, regulatory learning as well as European technological sovereignty and leadership, and which helps to master systemic shocks and disruptive as well as long-term future challenges.
5. NOTES that regulatory sandboxes are increasingly used in a range of sectors, for example in finance, health, legal services, aviation, transport and logistics as well as energy, often including the use of new, emerging technologies – such as artificial intelligence (AI) and blockchain/distributed ledger technologies (DLT) – or the innovative use of existing technologies.⁵

³ 9580/16.

⁴ WK 6474/2017.

⁵ Attrey, A., Leshner, M. and Lomax, C., ‘The role of sandboxes in promoting flexibility and innovation in the digital age’, Going Digital Toolkit Policy Note 2, 2020.

6. NOTES the ‘Study supporting the interim evaluation of the innovation principle’ prepared for the Commission in 2019, which highlighted the need to improve the EU’s innovation-friendliness by strengthening the Commission’s approach to design experimental regulation, including regulatory sandboxes.⁶ NOTES that the Commission’s Science, Research and Innovation Performance Report 2020 states that the acceleration of technological development also calls for less traditional approaches to regulation and policy, such as regulatory sandboxes.⁷
7. RECOGNISES that the Commission announced in its Communication ‘SME Strategy for a sustainable and digital Europe’ to encourage Member States to develop proposals for regulatory sandboxes by launching a pilot.⁸ NOTES that the Commission in collaboration with European Blockchain Partnership is planning a pan-European blockchain regulatory sandbox to become operational in 2021/22. NOTES that the Commission’s Directorate-General for Structural Reform Support assists the European Bank for Reconstruction and Development in supporting regulatory sandboxes in Greece, Estonia and Poland.⁹
8. 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.¹⁰

⁶ https://ec.europa.eu/info/publications/study-supporting-interim-evaluation-innovation-principle_en.

⁷ https://ec.europa.eu/info/publications/science-research-and-innovation-performance-eu-2020_en.

⁸ 6783/20 (COM (2020)103).

⁹ Parenti, R., ‘Regulatory Sandboxes and Innovation Hubs for FinTech’, Study for the committee on Economic and Monetary Affairs, Policy Department for Economic, Scientific and Quality of Life Policies, European Parliament, Luxembourg, 2020.

¹⁰ European Commission, TOOL #21. Research & Innovation, Better Regulation Toolbox; European Commission; 6783/20 (COM (2020)103).

9. UNDERSTANDS 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.¹¹ NOTES 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.
10. HIGHLIGHTS that regulatory sandboxes can provide the opportunity for advancing regulation through proactive regulatory learning, enabling regulators to gain better regulatory knowledge and to find the best means to regulate innovations based on real-world evidence, especially at a very early stage, which can be particularly important in the face of high uncertainty and disruptive challenges, as well as when preparing new policies.
11. UNDERLINES that regulatory sandboxes can offer significant opportunities particularly to innovate and grow for all businesses, especially SMEs, including micro-enterprises as well as start-ups, in industry, services and other sectors.
12. UNDERLINES that regulatory sandboxes and experimentation clauses always need to respect and should foster the application of the principles of subsidiarity and of proportionality, as well as of the precautionary principle. A high level of protection of inter alia citizens, consumers, employees, health, climate and the environment, as well as legal certainty, financial stability, a level playing field and fair competition always need to be ensured and existing levels of protection need to be respected.
13. Regarding experimentation clauses:
 - a) ENCOURAGES the Commission to continue considering the use of experimentation clauses on a case-by-case basis when drafting and reviewing legislation, as well as to evaluate the use of experimentation clauses in ex-post evaluations and fitness checks;

¹¹ European Commission, TOOL #21. Research & innovation, Better Regulation Toolbox, point 1 on experimentation clauses, p.151.

- b) HIGHLIGHTS that experimentation clauses can be important in several current and forthcoming legislative proposals;
 - c) SUPPORTS the Regulatory Scrutiny Board to continue to check that due consideration is given to the impact of regulation on innovation, which may include amongst others the use of experimentation clauses, when scrutinising impact assessments, evaluations and fitness checks;
 - d) EMPHASISES its intention to assess the possible inclusion of experimentation clauses when discussing legislative proposals;
 - e) CALLS on the Commission to create an overview of the main existing experimentation clauses in EU law;
 - f) CALLS on the Commission to identify policy areas and regulations in which additional experimentation clauses could possibly help to foster innovation and advance regulation; ENCOURAGES the Commission to consult in this respect with Member States and stakeholders, for instance via the Fit for Future Platform or targeted consultations.
14. Regarding regulatory sandboxes: CALLS on 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.

15. CALLS on the Commission to present a progress report on this exchange of information and good practices regarding regulatory sandboxes as well as on the overview of existing experimentation clauses in EU law in the first half of 2021 in order to enable its discussion in the Working Party on Better Regulation under the Portuguese Presidency of the Council; and to present the final results and analysis together with practical recommendations on the possible future use of regulatory sandboxes and experimentation clauses in the EU and at EU level in the second half of 2021 in order to enable their discussion and follow up in the Working Party on Better Regulation under the Slovenian Presidency of the Council.
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