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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Revised draft Council Conclusions on Regulatory Sandboxes and Experimentation Clauses

In view of the informal videoconference of the Working Party on Competitiveness and Growth (Better Regulation) on 28 October 2020, delegations will find attached the revised draft Council Conclusions on the above subject.

Revised draft Council Conclusions on Better Regulation**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.
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, especially 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, innovation-friendly, future proof, sustainable and resilient as possible. It needs to **be evidence-based and has to** protect and support citizens as well as businesses **in the context of a fully functioning EU-Single Market** without imposing **[new]** unnecessary burdens **[and while reducing existing unnecessary burdens]**.

¹ **6232/20**

3. RECALLS its Conclusions of May 2016² 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 domains³; 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 **regulatory** flexibility and experimentation **are can be** important elements **of for an agile,** innovation-friendly, future proof and resilient regulatory framework which fosters competitiveness, growth, sustainability as well as European technological sovereignty **and leadership,** and which helps to master systemic shocks and disruptive as well as long-term future challenges.
- 5.9.** NOTES that regulatory sandboxes are increasingly used **across the OECD and beyond** in a range of sectors, for example in finance, health, legal services, aviation, transport and logistics and 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

² 9580/16

³ **9580/16: The Council recalls the Precautionary Principle.**

⁴ **WK 6474/2017**

⁵ **Attrey, A., M. Leshner and C. Lomax (2020)OECD, “The role of sandboxes in promoting flexibility and innovation in the digital age”, OECD Going Digital Toolkit Policy Note 2, 2019.**

6. NOTES the "Study supporting the interim evaluation of the innovation principle" that has been prepared for the Commission in 2019, which highlighted the need to improve the EU's innovation-friendliness by strengthening the Commissions 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 RECOGNIZES that the Commission has announced in the "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

7.5. UNDERLINES that PERCEIVES regulatory sandboxes as concrete frameworks which, by providing a structured context for experimentation, enable in a real-world environment the testing of innovative technologies, products, services or approaches especially in the context of digitalisation for a limited time and generally in a limited part of a sector or area under regulatory supervision of the respective authority 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, An SME Strategy for a sustainable and digital Europe, COM/2020/103 final.

- 8.6.** ~~ACKNOWLEDGES that UNDERSTANDS~~ experimentation clauses as legal provisions, which enable the authorities tasked with implementing and enforcing the legislation to exercise a degree of flexibility in relation to testing innovative technologies, products, services or approaches.¹¹ ACKNOWLEDGES that experimentation clauses are often the necessary legal basis for regulatory sandboxes, and are already used in EU legislation and in many Member States' legal frameworks.
- 9.7.** HIGHLIGHTS that regulatory sandboxes can provide the opportunity for advancing regulation through proactive regulatory learning, enabling the regulators to gain better regulatory knowledge and to find the best means to regulate innovations based on real world evidence at a very early stage, which is can be particularly important in the face of high uncertainty and disruptive challenges, as well as when preparing new policies.
- 10.8.** UNDERLINES that regulatory sandboxes can offer significant opportunities to innovate and grow for all businesses, especially ~~small and medium-sized enterprises~~ SMEs, including micro-enterprises as well as start-ups, in industry, services and other sectors significant opportunities to innovate and grow.
- 11.10.** UNDERLINES that regulatory sandboxes and experimentation clauses always need to respect and should foster the application of the Principles of Subsidiarity, Proportionality and Precautionary. 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.
- 12.** Regarding experimentation clauses:
- a.13.** ENCOURAGES the Commission to continue considering ~~systematically~~ 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.14. HIGHLIGHTS that this experimentation clauses can be particularly important in several current or forthcoming legislative proposals such as the legislative framework for the governance of common European data spaces, and the regulatory framework for Artificial Intelligence;

c.15. ENCOURAGES 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 for the use of experimentation clauses when scrutinising impact assessments, evaluations and fitness checks;

d.16. EMPHASISES its commitment intention to systematically assess the inclusion of experimentation clauses when discussing legislative proposals;

e.11. CALLS on the Commission to create an overview of all-existing experimentation clauses in the-EU acquis law especially in the field of finance, health, legal services, aviation, transport and logistics and energy;

f.11. 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].

13.11 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.11. establish an overview of the state of play regarding the use of regulatory sandboxes in the EU [especially in the field of finance, health, legal services, aviation, transport and logistics and energy];

b.11. identify ~~experiences best practices~~ regarding the legal basis, implementation and evaluation of regulatory sandboxes;

c.11. analyse how learning from regulatory sandboxes at national level can contribute to evidence-based policy making at EU-level.

11 ~~investigate the possibility of setting up regulatory sandboxes at EU-level and their possible usage as instruments for evidence-based policy making at EU-level.~~

14.12 CALLS on the Commission to present ~~a the~~ first ~~results~~ **short progress report** of this exchange of information and good practices **[as well as regarding the overview of existing experimentation clauses]** in the first half of 2021 [in order to enable their 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.
