Council of the European Union
General Secretariat

Brussels, 05 July 2021

WK 8842/2021 INIT

LIMITE

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WORKING DOCUMENT

From:	European Commission
To:	Working Party on Competitiveness and Growth (Better Regulation - Attachés) Working Party on Competitiveness and Growth (Better Regulation)
Subject:	Draft Non-paper on Regulatory Sandboxes as Tools for Innovation-Friendly Regulation - Preliminary Findings

DRAFT NON-PAPER ON REGULATORY SANDBOXES AS TOOLS FOR INNOVATION-FRIENDLY REGULATION

PRELIMINARY FINDINGS

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Introduction

This report presents the preliminary findings of the European Commission's ongoing work to follow up to the Council conclusions of 16 November 2020 on regulatory sandboxes and experimentation clauses. Specifically, the Council asked the Commission to compile an overview of the main existing experimentation clauses and regulatory sandboxes in EU law and, in relation to sandboxes, to also share experiences with the Member States.

Regulatory sandboxes and, to a certain extent, experimentation clauses are a relatively new phenomenon in the EU and beyond. Therefore, following up to the Council conclusions required – as an initial step – reaching an agreement on what to look for. The steps undertaken to do so are described below in Section I, and take as a starting point the definition included in the Council conclusions. The Commission further specified and complemented this definition, to reflect the EU level experience more accurately. Section I also outlines the activities undertaken by the Commission to ensure an adequate follow-up.

The remainder of the report is structured as follows: Section II provides an overview of EU-level provisions identified by the Commission and that allow setting up regulatory sandboxes. Additional details on selected examples are also included. Section III instead covers other forms of experimentation identified at EU level and that could be of interest to Member States. Finally, Section IV concludes and raises open questions for the future that emerged from this exercise.

Section I: Definitions applied and organisation of work

In its conclusions of 16 November 2020, the Council lists some elements that characterise regulatory sandboxes:

- the existence of a structured context for experimentation,[1] e.g. the possibility to get exemptions from certain rules in order to allow for incubation of new ideas,
- planned testing of innovative technologies, products, services or approaches in a real-world environment,
- application for a limited time and in limited parts of a sector or area,
- under regulatory supervision. [2]

The Council further notes (recital 8) that experimentation clauses are often the legal basis for regulatory sandboxes, and are already used in EU legislation and in Member States' legal frameworks. It also describes experimentation clauses as (recital 9):

> "*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*" .

[1] Note that in the Council conclusions the 'structured context' is not defined further. For the purposes of this non-paper it could mean the possibility to get exemptions under pre-defined conditions and/or by a competent authority.

[2] Specifically, the conclusions explain that the Council "*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*".

To follow-up on the Council's request, the European Commission set up a temporary Interservice Group (ISG) on regulatory sandboxes and experimentation clauses, open to all Directorates-General (DGs) and active until the end of 2021. The main task of the ISG is to collect and analyse details on existing (i.e., operating or planned) regulatory sandboxes at EU level and on experimentation clauses.

As mentioned, the ISG initially concentrated on reaching a common understanding of the **concept of regulatory sandbox**. In this respect, the working definition of regulatory sandboxes used by the Commission is broadly in line with the Council's definition. It should be noted however that sandboxes do not imply a systematic lifting of regulatory requirements. Indeed, there could be cases where sandboxes are used to test innovations in yet unregulated fields. This should also be checked against the practice that Member States will report.[3] Thus, sandboxes do not necessarily need to fulfil all the criteria listed in the Council Conclusions.

Given the **broader remit of experimentation clauses**, it was necessary to refer to the Better Regulation toolbox that already contains elements on experimentation clauses and regulatory sandboxes. These elements follow the same logic of the Council conclusions, in allowing a certain degree of flexibility during implementation, and leave room for innovative forms of compliance. The definition is however somewhat broader and covers narrower applications, including prototypes, testing and piloting schemes:

> *"An experimentation clause enables the authorities tasked with implementing and enforcing the legislation to exercise a degree of flexibility in relation to innovative technologies, products or approaches, even if they do not conform to all existing legal requirements. Experimentation clauses can be appropriate when detailed product or technological characteristics have to be defined in legislation, but the policy goal could be met in the future by different, innovative solutions. They may also be proposed with the express intention of encouraging innovation and experimentation".* Better Regulation toolbox (tool #21)

Therefore, the ISG decided to sift through EU legislation from the past 10 years with two objectives: 1) to get a more accurate understanding of the variety of clauses allowing for other forms of experimentation that are not – strictly speaking – sandboxes and 2) establish what does not constitute an experimentation clause. Classical examples of the latter include longer transposition deadlines for specific provisions in a Directive, and flexible lifting of requirements for other purposes than experimentation.

The ISG has taken stock of experimentation clauses falling under this broader definition, should they be of use, also for future sharing of experience with the Member States.

To compile the preliminary overview included in this draft report, the ISG circulated to all Commission DGs a questionnaire covering both regulatory sandboxes and experimentation clauses, as described above. The aim of the questionnaire circulated to ISG members was twofold:

i) to establish an overview of **experimentation clauses expressly foreseen** in EU legislation and of regulatory sandboxes that operate based on such clauses (Part 1), and

[3] Relevant examples from Member States to be included here, based on answers provided to questionnaire prepared by the Slovenian Presidency.

ii) to collect information on **provisions allowing for other forms of experimentation** in the EU acquis, and on concrete projects concluded, on-going or planned to test new technologies and solutions following those provisions (Part 2).

The answers to the questionnaire were subsequently analysed and discussed in dedicated meetings of the ISG and the most relevant examples explored further, to start reflecting on outstanding questions and lessons learned from experimentation at EU and national level. So far, the ISG met three times between January and May 2021.

The Commission also shared the questionnaire with the Portuguese Presidency, as a basis for additional data collection by Member States, if deemed appropriate by the Council. An adapted version of the questionnaire is under preparation in the Council.

Section II: EU legislation allowing the setup of regulatory sandboxes

This section includes the preliminary findings on EU legislation allowing the setup of regulatory sandboxes, as described in **Part 1 of the questionnaire** circulated to Commission DGs. As shown below, examples of legal provisions explicitly foreseeing the setup of regulatory sandboxes (or an equivalent scheme that predates the use of the sandboxes terminology) remain limited at EU level.

In some policy fields, no example could be identified. Relevant initiatives may however exist at Member State level. In this respect, when referring to regulatory sandboxes, it is important to bear in mind that EU law is different from national law. Specifically, Member States have greater freedom to legislate in their territory as they see fit; the Union instead has to act and can only act within the boundaries of the competencies given by the Treaties.

In other policy fields however, the ISG identified very recent examples of experimentation clauses, and clauses dating back some years, in both cases potentially paving the way for sandboxes. Table 1 summarises these examples. For reference, the relevant part of the questionnaire on which these findings are based is included at the top of the Table.

Table 1: Preliminary overview of EU legislation allowing the setup of regulatory sandboxes

Part 1. Experimentation clauses and regulatory sandboxes expressly foreseen in EU legislation ***Question 1.1***: Are there examples of experimentation clauses from the last 10 years setting up sandboxes and falling in the remit of your DG? ***Question 1.2***: Are there any examples of regulatory sandboxes being implemented or planned at EU level based on such an experimentation clause? ***Question 1.3***: If you have answered YES to one or both questions above, please indicate the relevant legislation and article(s) below.	
Yes at EU level	***Yes at national level*** (IN PROGRESS: to be checked with Member States/Council Secretariat)
Digital The **Commission proposal for a Regulation on Artificial Intelligence (AI)**[4] provides a common framework for the establishment and implementation of AI regulatory sandboxes by one or more Member States competent authorities or the European Data Protection Supervisor, and the coordination of those schemes within the European Artificial Intelligence Board (Article 53). Article 54 also provides the legal basis for the further processing of personal data for the development of certain innovative AI systems in the public interest	**Digital** **Energy** **Financial Services** Very recent experience at national level in 10 Member States. **Transport**

[4] Proposal for a Regulation of the European Parliament and of the Council of 21 April 2021 laying down harmonised rules on artificial intelligence (artificial intelligence act) and amending certain union legislative acts, COM/2021/206 final.

subject to certain conditions.

The **Commission Communication** "**An SME Strategy for a sustainable and digital Europe**"[5] provides a basis to launch a pilot for live testing of innovative solutions with supervisors and regulators in order to "encourage Member States to develop proposals for regulatory sandboxes." The blockchain regulatory sandbox (with the support of the European Blockchain Partnership) under the Digital Europe Program is implementing this commitment under the SME Strategy.

Financial Services

The **pilot regime** for market infrastructures based **on distributed ledger technology (DLT) regulation**.[6] This proposal is part of a package of measures to further enable and support the potential of digital finance in terms of innovation and competition while mitigating the risks. The digital finance package included a new Strategy on digital finance for the EU financial sector, as well as a proposal for a regulation to build markets in crypto-assets, a proposal for digital operational resilience, and a proposal to clarify or amend certain related EU financial services rules. One of the strategy's identified priority areas is ensuring that the EU financial services regulatory framework is innovation-friendly and does not pose obstacles to the application of new technologies. This proposal, together with the proposal for a bespoke regime for crypto-assets, represents the first concrete actions within this area, seeking to provide appropriate levels of consumer and investor protection, legal certainty for crypto-assets, enable innovative firms to make use of blockchain, DLT and crypto-assets and ensure financial stability.

Health and Food Safety

Existing

- Article 13a Directive 66/402/EEC on marketing cereal seed.[7]

Under consideration

- "*Initiative for regulatory pilots in a 'sandbox' environment provided by the European Medicines Agency (EMA) and the Commission to test the adaptability of the pharmaceuticals framework for new cutting-edge product developments – 2022*" in COM/2020/761[8] - 3.2. Enabling innovation and digital transformation – EMA.
- The **European Health data space** (EHDS) could be part of this "sandboxing scheme" in the sense that the EHDS would be providing data that are GDPR compliant, of high quality and quickly accessible to be used in these AI regulatory sandboxes

[5] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *An SME strategy for a sustainable and digital Europe*, of 10 March 2020, COM/2020/103 final.

[6] Proposal for a Regulation of the European Parliament and of the Council of 24 September 2020 on a pilot regime for market infrastructures based on distributed ledger technology, COM/2020/594 final.

[7] Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed. Article 13a states that "for the purpose of seeking improved alternatives to certain provisions set out in this directive, it may be decided to organise temporary experiments under specified conditions at Community level in accordance with the provisions laid down in Article 21".

[8] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Pharmaceutical Strategy for Europe*, 25 November 2020, COM/2020/761.

for testing purposes. **Transport** Chapter 12.8 of the **Aviation Security Regulation**[9] on *methods of screening using new technologies* foresees the possibility for Member States to experiment new screening methods.	

A selection of cases from Table 1 – either because of their legal basis or because of relevant implementation experience, is further described below.

Artificial intelligence (AI) regulatory sandboxes

In the Commission proposal for Artificial Intelligence Regulation, Article 53 provides the general framework for the formal establishment and operation of AI regulatory sandboxes by one or more Member States competent authorities or the European Data Protection Supervisor, who are responsible for the supervision of the proposed regulation. The sandboxes are designed as a controlled environment that facilitates the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service, pursuant to a specific plan. This shall take place under the direct supervision and guidance by the competent authorities, with a view to ensuring compliance with the requirements of the AI Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox. The objectives are to foster AI innovation, to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. Any significant risks to health and safety and fundamental rights identified during the development and testing of such systems shall result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place. Member States' competent authorities that have established AI regulatory sandboxes should associate other relevant regulators (e.g. data protection authorities). They should also coordinate their activities and cooperate within the framework of the European Artificial Intelligence Board and submit annual reports on the results from the implementation of those schemes. The concrete modalities and the conditions of the operation of the AI regulatory sandboxes will be set out in implementing acts. Article 54 also provides a special legal basis for the processing of personal data lawfully collected for other purposes that can be re-used for the development in the sandbox of certain AI systems in the public interest, subject to additional safeguards and conditions.

Pilot regime for Distributed Ledger Technology (DLT) market infrastructure

This proposal is part of a package of measures to further enable and support the potential of digital finance in terms of innovation and competition while mitigating the risks. The digital finance package included a new Strategy on digital finance for the EU financial sector, as well as a proposal for a regulation to build markets in crypto-assets, a proposal for digital operational resilience, and a proposal to clarify or amend certain related EU financial services rules.

[9] Commission Implementing Regulation (EU) 2015/1998 of 5 November 2015 laying down detailed measures for the implementation of the common basic standards on aviation security.

One of the strategy's identified priority areas is ensuring that the EU financial services regulatory framework is innovation-friendly and does not pose obstacles to the application of new technologies. Indeed, digital transformations beg the question of how the financial acquis handles new technologies such as DLT and related instruments (e.g. crypto-assets).

This proposal, **together with the proposal for a bespoke regime for crypto-assets**[10], represents the first concrete actions within this area, seeking to provide appropriate levels of consumer and investor protection, legal certainty for crypto-assets, enable innovative firms to make use of blockchain, DLT and crypto-assets and ensure financial stability.

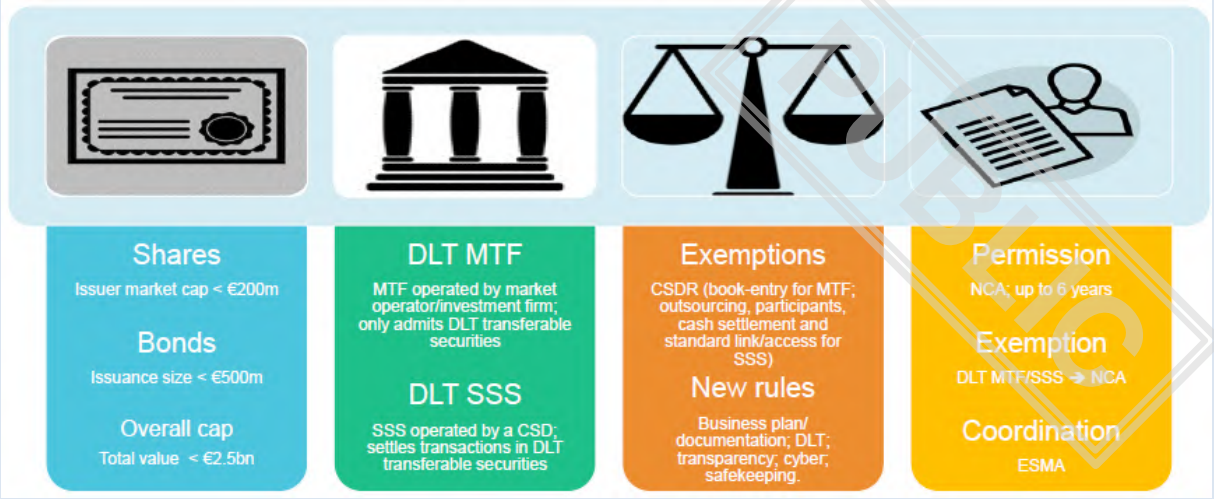
Main features and implementation of the pilot regime for DLT market infrastructures

The pilot regime aims to enable market participants to operate a DLT market infrastructure (either a DLT multilateral trading facility or a DLT securities settlement system) by establishing clear and uniform operating requirements and by creating the possibility for certain firms to seek permission from national competent authorities to operate so-called DLT market infrastructures, and to seek exemptions from specific requirements set out in EU legislation in order to be able to test issuing, trading and settling securities on DLT.

- The overall objective is for stakeholders to gain experience on the application of DLT in market infrastructures and for policymakers to learn more about regulatory hurdles to the issuance, trading and post-trading of financial instruments in crypto-asset form.
- The proposal is based on Article 114 TFEU, which confers to the European institutions the competence to lay down appropriate provisions for the approximation of laws of the Member States that have as their objective the establishment and functioning of the Internal Market. The proposal aims to allow for experimentation through derogations for the use of DLT in the trading and post-trading of crypto-assets that qualify as financial instruments, where existing legislation may preclude or limit their use.
- The pilot regime establishes conditions for acquiring a permission to operate a DLT market infrastructure, sets limitations on the transferable securities that can be admitted to trading, and frames the cooperation between the DLT market infrastructure, competent authorities and the European Securities and Markets Authority (ESMA). The Regulation mandates ESMA to carry out a review on the application of the pilot regime three years after its entry into force.
- The proposed pilot regime will enable DLT market infrastructures to request National Competent Authorities (NCAs) for exemptions from certain provisions in the Markets in Financial Instruments Regulation (MiFIR) and the Central Securities Depositories Regulation (CSDR) that have proven to be difficult to apply for DLT-based infrastructures.
- The pilot regime proposes safeguards to ensure consumer protection, market integrity and financial stability. It proposes a controlled environment for a limited set of assets and transactions. It will not be a large-scale operation that replaces current markets and their infrastructures. All participants will also have to provide a clear exit strategy, to ensure smooth transitions once they pilot period is over.

[10] Proposal for a regulation of the European Parliament and of the Council of 24 September 2020 on Markets in Crypto-assets, and amending Directive (EU) 2019/1937, COM/2020/593 final.

Pilot regime attributes (Articles 3-9)



The proposal for a Regulation on Markets in Crypto-Assets would help the innovative crypto projects in finance. It would provide common schemes for experimentation and for the regulation of specific activities, thereby overcoming the current impediments faced by firms when seeking to scale their activities cross-border, whilst ensuring risks to consumers and to operational resilience are effectively mitigated.

Whether financial products and services provided using decentralised means will become widely used, and whether these would require specific rules, remains to be seen. The European Commission and the European Supervisory Authorities are monitoring continuously the regulatory perimeter.

The proposal would ensure consistency and a level-playing field by granting powers to the ESMA to monitor and coordinate experimentations as Member States' competent authorities submit evaluated applications from market participants.

The long-term objective of gaining experience on the application, and limits of, the existing financial services legislation to DLT market infrastructures, necessitates that this is done at EU level. Thus, the ESMA will evaluate the outcomes on a yearly basis and ESMA, together with the Commission, will evaluate and report to the Council and Parliament on the pilot regime at the latest after a five-year period.[11]

The pilot regime will promote the development of DLT market infrastructures, which could enable the transition to tokenised financial instruments and DLT market infrastructures, supporting innovation and ensuring the EU's global competitiveness.

Pan-European blockchain regulatory sandbox

The Commission Communication on "*An SME Strategy for a sustainable and digital Europe*" provides a basis for launching a pilot for the live testing of innovative solutions with supervisors and regulators, in an effort to "encourage Member States to develop proposals for

[11] Specifically, Article 10 of the pilot regime proposal requires the Commission to report to Council and Parliament on whether the pilot regime should be: i) extended for another period; ii) extended to other types of financial instruments; iii) made permanent with or without amendments; iv) terminated; v) used as a base to inform future reviews of underlying trade/post-trade legislation.

regulatory sandboxes." The blockchain regulatory sandbox under the Digital Europe Program is implementing this commitment.

This Digital Europe regulatory sandbox at the EU level (under the auspices of the European Blockchain Partnership) aims to clarify the legal framework and provide legal certainty to European start-ups and market players that innovate with blockchain-based solutions. The goal is to facilitate cooperation and dialogue between innovators as well as EU and national regulators and experts, with a view to develop a harmonised interpretation of regulations, with flexibility to allow for innovation. It will also collect best practices and support the assessment of legal, as well as business obstacles that arise in deploying such solutions. In terms of scope, the sandbox will clarify legal and regulatory issues both for use cases within EBSI and also - more generally, for innovative start-ups using blockchain technologies.

Directive 66/402/EEC on marketing cereal seeds

For the purpose of seeking improved alternatives to certain provisions set out in Directive 66/402/EEC, it may be decided to organise temporary experiments under specified conditions at Community level in accordance with the provisions laid down in Article 21. In the framework of such experiments, Member States may be released from certain obligations laid down in the Directive. The extent of that release shall be defined with reference to the provisions to which it applies. The duration of an experiment shall not exceed seven years. Examples are:

- Implementing Decision (EU) 2020/1106 on the organisation of a temporary experiment under Council Directives 66/401/EEC, 66/402/EEC, 2002/54/EC and 2002/57/EC as regards the official checking rate for field inspection under official supervision for basic seed, bred seed of generations prior to basic seed and certified seed,
- Decision 2017/547 on the organisation of a temporary experiment under Council Directive 2002/56/EC as regards seed potato tubers derived from true potato seed,
- Implementing Decision 2014/150/EU on the organisation of a temporary experiment providing for certain derogations for the marketing of populations of the plant species wheat, barley, oats and maize pursuant to Council Directive 66/402/EEC,
- Implementing Decision 2012/340/EU on the organisation of a temporary experiment as regards field inspection under official supervision.

Section III: Other forms of experimentation at EU level – preliminary findings[12]

As explained, **Part 2 of the questionnaire** cast a wider net, searching for **other forms of experimentation** at EU level, going beyond the terms indicated by the Council conclusions.

The questionnaire results point to two groups: i) policy fields where no other forms of experimentation could be identified, and ii) policy fields with existing and planned testing, piloting and other schemes. Some of these schemes have the potential to evolve into sandboxes in the future. This could be the case for instance of the JRC Living Labs, under certain circumstances.

Interestingly, the ISG initially identified a longer list of experimentation clauses. However, filtering those clauses based on the questionnaire's definition led to a narrower list. The excluded examples featured e.g. longer transition periods for implementation.

Table 2 provides an overview of experimentation clauses and initiatives at EU level that broadly fall under the scope of 'different forms of experimentation'. The relevant part of the questionnaire on which these findings are based is included at the top of the Table.

Table 2: Preliminary overview of other forms of experimentation foreseen at EU level

Part 2. Other forms of experimentation and tests
Question 2.1: Are there other forms of experimentation clauses (e.g. flexibility in national implementation, to run pilot schemes other than sandboxes, etc.) included in the legislation from the past 10 years and managed by your DG? ***Question 2.2a***: If you have answered YES to question 2.1, please indicate the relevant legislation and article(s) ***Question 2.2b***: Please provide below any additional observations, as needed.
Digital **European Blockchain Services Infrastructure (EBSI)** to build a pan-European blockchain infrastructure for the delivery of public services. While not a formal sandbox, EBSI is moving into the pilot phase and provides an informal testing environment for currently up to seven use cases. In addition, a formal blockchain regulatory sandbox (under the auspices of the European Blockchain Partnership) is being set up under the **Digital Europe Program** for the testing of EBSI use cases and beyond, i.e. for other key blockchain use cases (see Section II above). **Environment** Article 15(5) of the **Industrial Emissions Directive**[13] (IED) includes a mechanism to support innovation in the IED through the concept of "emerging techniques" and a related Innovation Observatory. **Industry** Article 9.2 of the **Radio Equipment Directive**[14] lays down that "At trade fairs, exhibitions and similar events, Member States shall not create any obstacles to the display of radio equipment which does not comply with this Directive (…)". In addition, the obligations of the Directive are not applicable to certain equipment used for

[12] This section is still under preparation and might be subject to changes.
[13] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control).
[14] Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

R&D purposes, as laid down in Annex I: "Custom-built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes"

Some **targeted provisions on vehicles and machinery** that go beyond traditional product harmonisation. These have to be put into context and include:

- CO2 emission performance standards for new passenger cars and for new light commercial vehicles (Art. 10 derogations for certain manufacturers, art. 11 eco-innovation);[15]
- Approval and market surveillance of agricultural and forestry vehicles (Art. 35 exemptions for new technologies or new concepts);[16]
- Approval for internal combustion engines for non-road mobile machinery (Art. 35 exemptions for new technologies or new concepts);[17]
- Approval and market surveillance of two- or three-wheel vehicles and quadricycles (Art. 40 exemptions for new technologies or new concepts).[18]

Transport

Article 4.5 of Directive 96/53/EC (**Weights and Dimensions Directive**).[19] This provision allows Member States to authorise the use in their territories of vehicles or vehicle combinations incorporating new technologies or new concepts, which cannot comply with one or more requirements of the Weights and Dimensions Directive, to carry out certain local transport operations for a trial period. This possibility was used in all cases to allow new concepts, consisting of vehicle combinations exceeding the maximum length, and sometimes the maximum weight, in freight transport.

Article 71 of Regulation 2018/1139 (**EU Civil Aviation Regulation**).[20] This Article could be seen as an example of provision allowing for forms of experimentation. In detail, Article 71 allows Member States to grant exemptions from aviation safety requirements (other than the essential requirements laid down in the same Regulation), in the event of urgent unforeseeable circumstances or urgent operational needs, where certain conditions are met. The Article provides for a clear procedure of notifications and assessment at EU level. These provisions leave room for innovative forms of compliance. Recently, there has been the practical example of exemptions filed by several Member States for the electric-powered Pipistrel aircraft, in the domains of Aircrew, OPS, and Continued Airworthiness, since the current Implementing Provisions could not fit an electric-powered aircraft.

Cross-cutting examples: Joint Research Centre **Living Labs**.

[15] Regulation (EU) 2019/631 of the European Parliament and of the Council of 17 April 2019 setting CO2 emission performance standards for new passenger cars and for new light commercial vehicles, and repealing Regulations (EC) No 443/2009 and (EU) No 510/2011.

[16] Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles.

[17] Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC.

[18] Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles.

[19] Council Directive 96/53/EC of 25 July 1996 laying down for certain road vehicles circulating within the Community the maximum authorized dimensions in national and international traffic and the maximum authorized weights in international traffic.

[20] Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91.

As indicated, some of these initiatives have the potential to be framed as regulatory sandboxes, depending on their implementation modalities and/or possible link with existing legislation. The rest of this section focuses on some relevant examples from Table 2.

The European Blockchain Services Infrastructure (EBSI)

EBSI aims to build a pan-European infrastructure for the delivery of public services while meeting the highest standards of security, privacy, sustainability and compliance with EU laws. The Commission is working with technical experts from the 27 EU Member States, Norway and Liechtenstein under the auspices of the European Blockchain Partnership (EBP) to develop the EBSI. While not being a formal sandbox, EBSI is now moving into the pilot phase and provides an informal testing environment for currently four use cases that are at an advanced stage and three additional use cases selected for deployment on EBSI. There will also be a formal regulatory sandbox at the EU level under the Digital Europe Program (in collaboration with the European Blockchain Partnership), that aims to accompany the deployment of decentralized solutions on blockchain within the EBSI and beyond (see above under Section II, EU level examples).

The Commission is closely cooperating with EBSI on the diploma use case for the implementation of its **European Digital Credentials** (launched under the 2018 Digital Education Action Plan). European Digital Credentials have been piloted by 18 countries and are currently in the launch phase. EBSI can provide a test environment for new technologies that can support European Digital Credentials, and in the longer term provide (parts of) the infrastructure needed for digital credentialing.

In the area of employment, the Commission is also co-convenor of the **European Social Security Pass pilot** project, which was announced in the European Pillar of Social Rights Action Plan and will be developed within the framework of EBSI. The pilot project aims at exploring by 2023 the feasibility of a digital solution to facilitate the interaction between mobile citizens and national authorities, and improve the portability of social security rights across borders.

There are also plans for sandboxes, where appropriate, under various projects under the **Digital Europe Programme**, in particular:

- ***Data space for media:*** the data space will provide a sandbox environment and interface services to foster pilots for and host innovative media services developed through initiatives other than Digital Europe such as Horizon 2020 and Horizon Europe;
- ***Testing and Experimentation Facility for Manufacturing:*** the manufacturing TEF may include regulatory sandboxes. The manufacturing TEFs will provide physical and virtual access to real-life manufacturing resources (e.g., model factories, combining different technologies) that can be used for testing and experimenting with AI solutions;
- ***Testing and Experimentation Facility for Health:*** the health TEF may include regulatory sandboxes for technologies based on Artificial Intelligence (AI) and robotics for health care;
- ***Testing and Experimentation Facility for Agri-Food:*** regulatory sandboxes are provided where relevant;

- ***Testing and Experimentation Facilities Smart Cities and Communities***: the smart cities and communities TEF could advance through experimentation and sandboxing the EU regulatory framework for AI and robotics. In particular, the action will result in four facilities to be deployed for an extended period, to be used in pilots, testing, experimentation, as well as for sandboxing and to support standardisation and the implementation of the AI regulatory framework.

The JRC Living Labs

The JRC is hosting living labs on two of its research sites in Ispra (Italy) and Petten (Netherlands), positioning them as testbeds and demonstrators to co-create innovative smart city solutions. The ongoing living lab projects focus on digital energy and future mobility solutions, but there is strong interest and potential to extend the initiative to other JRC sites and policy areas related to urban environments, e.g. air quality, health and wellbeing, smart buildings, waste management. The JRC sites in Ispra and Petten simulate urban environments with a large number of staff, buildings, roads and utilities, dedicated experimental facilities and high-speed communication networks. As such, they offer an environment for JRC scientific teams, in collaboration with SMEs and start-ups, to test and demonstrate in almost-real-life settings a variety of innovative technologies (e.g. connected and automated vehicles, delivery droids, and smart e-charging platforms) and research methodologies (e.g. user-centric research design, co-creation and citizen engagement methods). At the moment, the collaboration projects are selected through an open call for expressions of interest. The JRC Living Labs involve users early in the innovation and research process, which considerably shortens product/service development cycles, allows piloting of development based on rapid feedback loops, facilitates early identification of policy and regulatory challenges, and enables the exploration and validation of approaches for addressing them. Thus, the JRC Living Labs can improve the provision of high quality, policy-relevant and people-oriented research.

In terms of regulatory support, there are significant similarities between living labs and regulatory sandboxes, but crucially also several promising complementarities. Both provide a framework for experimentation of innovations in real-life environments. While living labs are designed with a stronger focus on technology innovation, they necessarily provide insights – just like regulatory sandboxes – into the regulatory and policy implications of such innovation. In terms of complementarities, living labs add to the regulatory sandbox an in-built focus on users, and especially on the social implications of innovations. In view of both similarities and complementarities, the JRC Living Labs initiative is therefore well-placed to support and guide the development of regulatory frameworks alongside the development of innovative technologies and solutions. The JRC Living Labs can take on the role of a regulatory sandbox for the European Commission in selected areas. They can offer an environment for regulatory learning and discovery, where the regulatory implications of innovative technologies can be observed and shaped, especially over longer timeframes. When developed into an in-house regulatory sandbox, the JRC Living Labs can anticipate and respond to the needs for regulatory support, and thereby contribute to improving design and implementation of regulations, policies and standards, enabling to assess their benefit and efficiency, and providing feedback on their performance.[21]

[21] More information about the JRC Living Labs and the open call for expressions of interest at: https://ec.europa.eu/jrc/en/research-facility/living-labs-at-the-jrc; https://ec.europa.eu/jrc/en/research-facility/living-labs-at-the-jrc/call-expression-interest-future-mobility-and-digital-energy-solutions

Section IV: Preliminary conclusions

This section concludes with some preliminary findings from the follow-up activities undertaken by the Commission to respond to the Council conclusions. Work is still in progress, including possible additional data collection at Member State level. Despite these caveats, some preliminary messages could already be identified. In particular:

- In light of the relative novelty of regulatory sandboxes in the EU and globally, there is currently no established legal definition of this practice. The term encompasses different types of experimentation, with some common features such as the set-up of a controlled environment under supervision by a competent authority; a link with legislation; possible temporary derogations and exemptions from those parts of the legislation that are relevant for a specific sandbox; and the use of appropriate safeguards.
- Rather than trying to find an all-encompassing definition, a more helpful approach would be to establish – on a case-by-case basis – what purpose should a given sandbox serve and what are its expected outcomes.
- In order to establish the purpose of a sandbox, an important question to ask is: (i) would the sandbox operate in a field that is already regulated, or (ii) would the sandbox be in a field where there is no legislation yet? In the second case, the likely purpose of the sandbox is to learn and establish whether regulation in the field under examination is possible/desirable at all. Conversely, in the case of existing legislation, the purpose of the sandbox is to experiment, test, and try to understand whether an exemption would make sense, under what conditions, and with which requirements.
- In addition to these general remarks on the nature of regulatory sandboxes, when referring to the EU context, it is important to keep in mind that EU law is different from Member States' law. Member States have greater freedom to legislate in their territory as they see fit. The Union, however, has to act and can only act within the boundaries of the competencies given by the Treaties.
- Finally, the co-existence of sandboxes and other types of experimentation at EU and national level (subject to further updates from the Member States), raises the question of the link (if any) between these national experiences and EU legislation in the same sector or on the same topic. These national experiences may also have implications from an Internal Market perspective and in terms of implementation and enforcement of existing EU legislation in the same sector.

To conclude, this interim report includes some open and important questions that the Commission would like to share with Member States as a basis to advance this exchange of views and information on regulatory sandboxes and experimentation clauses.

Open questions/ important questions:

1. Internal Market dimension: how can experimentation be reconciled with the need to ensure consistency in implementation and enforcement within the Internal Market? In what policy domains do Member States have experience with implementation and enforcement of regulatory sandboxes? What is the purpose of each regulatory sandbox case?
2. Do Member States have examples of national experiences that link up with EU legislation in the same sector or on the same topic? If this is the case, what is their experience and lessons learned?

3. What conditions or safeguards could apply to reconcile the need for experimentation at e.g. local level, specific sector, with the proper functioning of the Internal Market?
4. When do sandboxes make more sense to be undertaken at EU level? When instead at Member State level?
5. Are some sectors better suited for experimentation and sandboxes (e.g. financial services, digital technologies, mobility, and energy)? If so, why?
6. What are the criteria for success of a sandbox from a legal perspective? Can we draw some lessons from existing experience?
7. In light of EU-level goals in climate and environment, including climate neutrality objectives for 2050, could experimentation/regulatory sandboxes become more prominent to contribute to reaching these objectives? If so under which conditions?