



16 March
2022

BLSI Virtual breakfast – March 2022 Key Takeaways

*Policymaking embraces innovation –
Drafting and implementing regulatory sandboxes*



What you can find in the BLSI Webinar key takeaways



Link to the March BLSI Virtual breakfast [recording](#)



Slides presented by the hosted speakers



Summary of interaction with audience

Agenda



Welcome and introduction

Zsofia Sziranyi and Isa von Kalben, *European Commission, DIGIT D2*



Regulatory Sandboxes & experimentation clauses in EU legislation

Lorna Schrefler, *European Commission, DG RTD*



German Regulatory Sandbox Strategy: Experiences and next steps

Dr. Konstantin Kolloge, *German Federal Ministry for Economic Affairs and Climate Action*



Regulatory Sandboxing Clause in proposal for Artificial Intelligence Act

Yordanka Ivanova, *European Commission, DG CONNECT*



Final remarks and conclusions

Cécile Guasch, *European Commission, DIGIT D2*



Welcome and introduction

Zsofia Sziranyi and Isa von Kalben
DIGIT D2

Check the [webinar recording](#) from its start
until 13 min 10 sec.

Who we are

Better Legislation for Smoother Implementation (BLSI) community

A living and continuously growing multi-disciplinary community on better legislation to share good practices and co-create tools with interoperability in mind around

- Digital-ready policymaking
- Legislation and technology
- Streamlined regulatory reporting process in the EU

The Legal Interoperability team



Zsofia Sziranyi



Cecile Guasch



Isa Katharina Von Kalben

Visit our community on [JoinUp!](#)

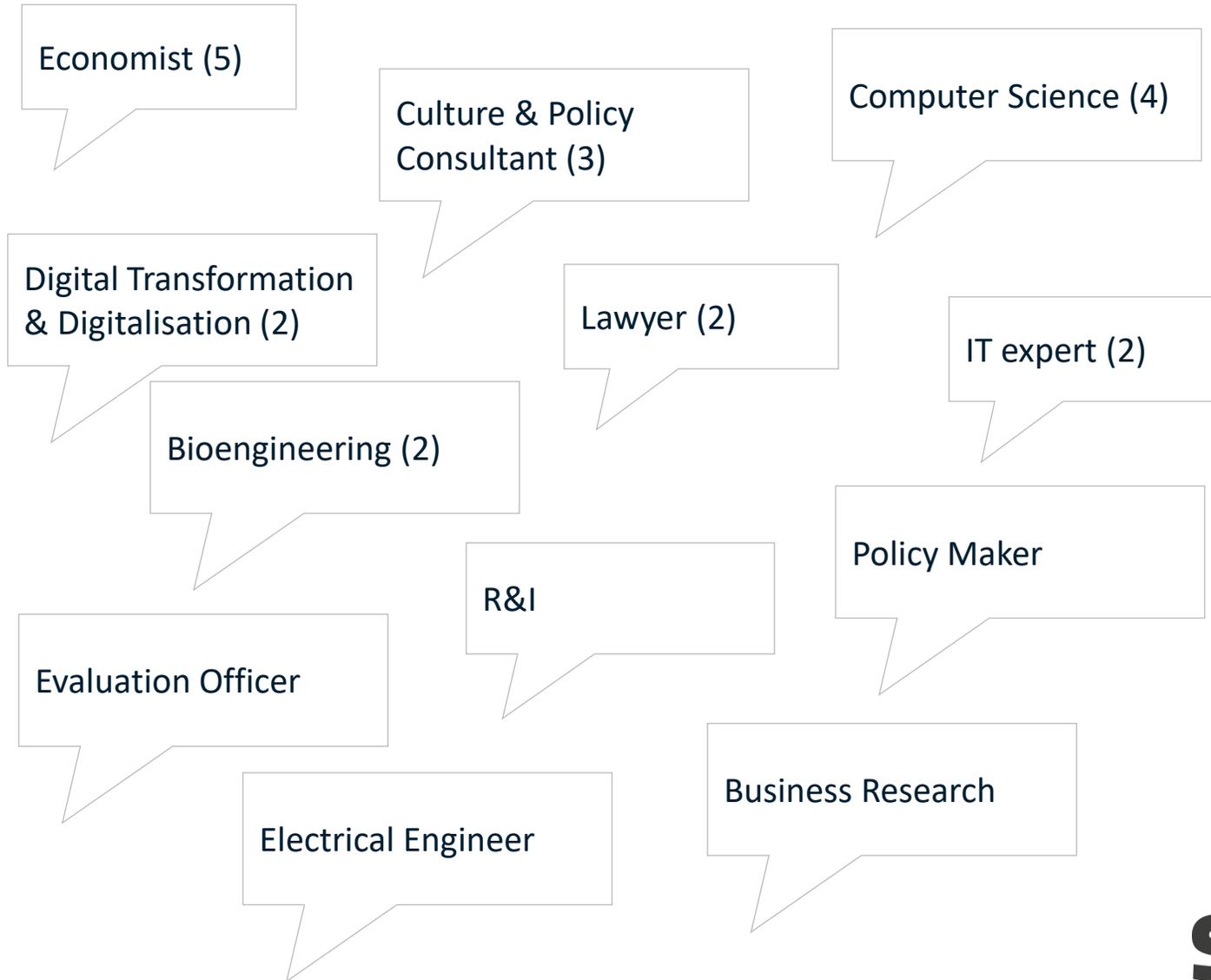
Why are regulatory sandboxes relevant for "better legislation for smoother implementation"?



Regulatory sandboxes allow public or private actors to test innovations in a controlled (real-world) environment, under a specific plan developed and monitored by a competent authority. They usually include a temporary loosening of applicable rules, and feature safeguards.

- They allow for testing digital implementation before drafting legal requirements.
- The need for a regulatory sandbox clause in the specific field should be assessed when drafting legal text.
- Opportunity to learn from each other: They are being implemented throughout Europe and beyond.

What is your professional background?



Join at
slido.com
#931 364

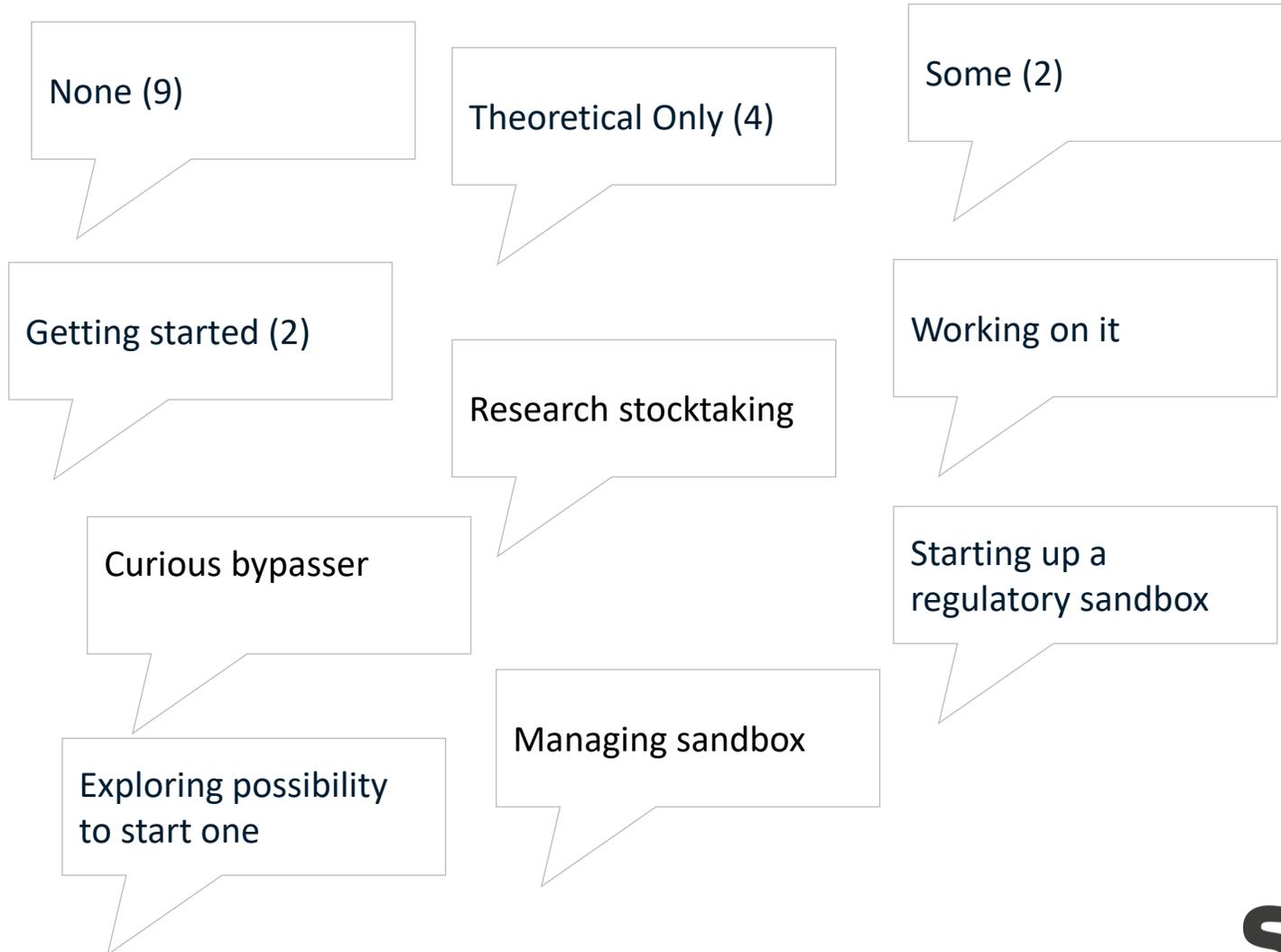
Active poll

What is your professional background?

- Computer and system analyst
- Policy Adviser
- Industry Association, R&I, Chemistry
- Economist, regulator agency
- Evaluation officer

slido

What is your experience with regulatory sandboxes?



Join at
slido.com
#931 364

Active poll

What is your experience with regulatory sandboxes?

No practical experience

None

only theoretical so far

No experience

Managing sandbox

slido

What is your experience with regulatory sandboxes?

To learn more, deeper understanding (5)

Exchange, connect, Share & Grow together (4)

Learn what regulatory sandbox are and how to implement it in my filed (3)

Learn what are the main legal barriers for experimentation a sandbox can solve (data privacy...)

Good overview about solutions and expected outcomes

Have constructive knowledge sharing

Hear about lessons learned

Understand the landscape and concept of sandboxes

To better understand the concept and learn about practical experience

Learn about concrete examples ideally in the area of agriculture/ food/ rural development



Join at
slido.com
#931 364

Active poll

What are your expectations for the webinar?

Learn what are the main legal barriers for experimentation a sandbox can solve (data privacy...)

To understand better the concept and learn about practical experience

Learn more, Deeper Understanding

better understanding how sandboxes can be used for policy innovation

slido

Regulatory Sandboxes & experimentation clauses in EU legislation

Lorna Schrefler,
European Commission DG RTD

Check the [webinar recording](#) from 13 min
10 sec until 37 min 10 sec



Regulatory sandboxes & experimentation clauses in EU legislation

Overview

DG Research & Innovation
Common Programme Analysis & Regulatory Reform

16 March 2022

Council conclusions of 16 November 2020

- Experimentation clauses (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.”

These clauses are often the **legal basis** for regulatory sandboxes.

- Regulatory sandboxes (recital 8):

“... 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.”

Follow-up to Council conclusions

- Develop a **common understanding** on experimentation clauses/regulatory sandboxes, both for cases based on an explicit legal provision and cases under a broader definition capturing other forms of experimentation;
- Establish which forms of flexibility are NOT experimentation clauses/regulatory sandboxes under any definition (e.g. longer transposition timelines, mitigating measures);
- Collect information through questionnaire & assess the examples identified, search for additional evidence/available lessons on ‘experimentation clauses’ in force for a certain number of years. Share experiences with the Member States.

Preliminary findings: regulatory sandboxes

- When sifting through EU legislation for regulatory sandboxes and underlying legal base:
 - Some experimentation clauses paving the way for sandboxes exist at EU level: Artificial Intelligence; Pilot regime for market infrastructures based on distributed ledger technology (DLT) + Markets in Crypto-Assets; food safety;
 - Various initiatives exist at national level in different sectors (e.g. fintech sandboxes operational in 10 Member States, energy under France Experimentation, transport in Germany).

Lessons from the exchange of practices

- EU experimentation clauses: implementation experience varies case-by-case
- ‘Older’ experimentation clauses may not have been looked at with today’s perspective until now
- Other existing/planned testing and piloting at EU level. Constantly evolving landscape: e.g., Sustainable and Smart Mobility Strategy, EU Digital Finance Platform
- Comparative reading of EU and national experiences with sandboxes highlights commonalities (e.g. sectors, role of the supervisor, innovative component, time limits).
- Open questions: link between EU and national level experiments; Internal Market; scaling up?

First conclusions and next steps

- Limited operational experience across the EU but common features and how they operate clearer after the stocktaking
- Regulatory sandboxes only one of the tools to make space for innovation. Overall quality of the regulatory framework, other forms of experimentation, and better regulation also contribute to the same objectives
- EU level: monitor proposals in the pipeline and revised Better Regulation Toolbox
- Continue stocktaking and exchange of information with the Member States.

BR Tool #69 – Emerging methods and policy instruments

- New Tool (#69) on *Emerging methods and policy instruments* will also cover regulatory sandboxes
- Tool #69 covers: 1. what is a sandbox and its relevance in policy-making; 2. operational guidance on elements to consider before setting up a sandbox; 3. links with better regulation
- Under point 2 elements to consider are grouped by focus area: innovation and the market; applicable rules and flexibility; access to the sandbox; design and implementation; evaluation and learning; time and resources needed
- Short selection of examples of existing/planned sandboxes in the EU.

Thank you

Questions addressed to Lorna Schrefler, European Commission DG RTD



Q1: *What has changed as a result of the sandbox?*

A1: All are very new – difficult to extract conclusions



Q2: *Based on this experience, do you have some examples or a hint on how feasible is to establish a sandbox to experiment with cross-border data exchanges containing personal data (and the role of the Data Protection Agencies) – involved in eIDs – impossible to have preoperational phase – to plug in citizens to the system. If we need to experiment, we need to exchange data and change data format – have you experienced it?*

A2: In MS we see that you might play with actual data. We have low experience in social security. The safeguard is that the participant agrees and the data privacy should be enforced. There is little purpose for experimenting, maybe an anonymized format. The data has to be solved.



Q3: *I can hardly think of a regulatory sector which will NOT have to face innovation in digitalisation. That means, that experimental clauses or regulatory sandboxes should be relevant to all sectors. If so, shouldn't they become "standard clauses" in all new regulations?*

A3: This would be an ideal scenario, but it is not always feasible because EU has different room for manoeuvre depending on the policy field. But some common elements came up from the stocktaking and can serve as a basis to know which elements need to be covered.

Questions addressed to Lorna Schrefler, European Commission DG RTD



Q4: *One of the main challenge at the member state level is that a lot of laws are based at European level and can not be derogated. What is the EU roadmap to deploy EU sandbox on European Law?*

A4: There is also sandboxing that is relatively local and ot always connected to EU level. So the derogation issue does not come up there. But in other areas there may be such an issue. Or there is the need to connect the national experiments so that e.g. the benefits of having a Single Market materialize. So more coordination - see financial services examples in the slide.

The German Regulatory Sandbox Strategy: Experiences and next steps

Dr. Konstantin Kolloge,
*German Federal Ministry for
Economic Affairs and Climate Action*

Check the [webinar recording](#) from 37 min
10 sec until 1 hr 5 min 50 sec

The German Regulatory Sandbox Strategy: Experiences and next steps

Dr. Konstantin Kolloge
Head of the Coordination Office for Regulatory Sandboxes
Federal Ministry for Economic Affairs and Climate Action

1. ***Regulatory sandboxes in practice***
2. *A closer look into experimentation clauses*
3. *What we do (and plan)*

Why do we need regulatory sandboxes?

Enabling innovation..

- Regulatory sandboxes enable the testing of innovations (which are often not fully compliant with the general legal framework) in a real-world environment

.. and advancing regulation

- Regulatory sandboxes allow regulators to learn about the effects of innovation and the appropriate legal framework.



Example: Hub Chain Osnabrück

- Testing of a driverless on-demand shuttle bus to connect rural regions to urban public transport
- Strengthening local public transport in rural areas, reducing emissions from individual traffic
- Legal basis: Experimentation clauses in the Passengers Transportation Act and in the Road Traffic Registration Regulations
- Development of an "approval roadmap"



© Stadtwerke Osnabrück AG

Example: SmaLa – smart load and delivery zones

- Virtual booking system for inner-city delivery and loading zones in the city of Hamburg
- Objectives: Reduce search traffic and pollutants, increase traffic safety
- Testing of 4 smart loading and delivery zones in autumn 2021, expansion to 45 planned
- Legal basis: exemption from the German Road Traffic Regulations (StVO)
- Development of recommendations for advancing road traffic regulations



© Getty Images/Obradovic

1. *Regulatory sandboxes in practice*
2. ***A closer look into experimentation clauses***
3. *What we do (and plan)*

Experimentation clause: Passengers Transportation Act § 2 (7)

*“In order to allow for the **practical testing of new modes or means of transport**, the **licensing authority** may, **upon request on a case-by-case basis**, authorise **exemptions from the provisions of this Act** or from provisions adopted on the basis of this Act for a period of **no longer than four years**, insofar as they do not conflict with public transport interests.”*

Positive experiences

- Open formulation allows regulatory sandboxes for different new types of transport (e.g. ride pooling services, on-demand transport)
- Frequently used in practice, many successful projects
- Results of the sandboxes helped to create general rules (regulatory learning); August 2021: Amended law allows regular operation of ride pooling services and on-demand transport
- Experimentation clause remains as „entry gate“ for new types of transport

Experimentation clause: Passengers Transportation Act § 2 (7)

*“In order to allow for the **practical testing of new modes or means of transport**, the **licensing authority** may, **upon request on a case-by-case basis**, authorise **exemptions from the provisions of this Act** or from provisions adopted on the basis of this Act for a period of **no longer than four** [as of August 2021: **five**] **years**, insofar as they do not conflict with public transport interests.”*

Challenges

- Licensing conditions vary widely between different authorities (Länder, municipalities)
- Selection procedures also differ
- Some companies complain about the short duration and missing possibility of extension
- No structured process of knowledge transfer

Amendment August 2021: Maximum test period extended to five years

Experimentation clause: Testing enhanced vehicle systems for autonomous driving (adopted by the Fed. Cabinet in Feb. 2022)

Regulations on the operation of motor vehicles with automated and autonomous driving functions § 16

“(1) [..]

(2) The test permit shall be limited in time and shall not normally exceed a period of four years. It shall be extended for further two years at a time if the conditions for granting the permit continue to apply and the progress of the testing to date does not prevent an extension. If third parties appeal against the trial permit or its extension, the period of validity of the trial permit shall be extended by the number of days on which the appeal has a suspensive effect. [..]

(4) The Federal Motor Transport Authority shall be entitled to collect, store and use the data required for the evaluation of road safety and technical progress and for the evidence-based development of the regulation [..]

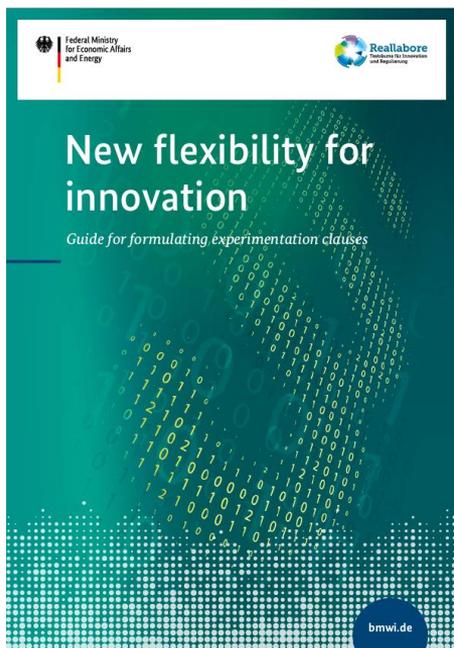
(5) The Federal Motor Transport Authority may approve exemptions from [..] 1. the provisions of § § 1a and 1e of the Road Traffic Act, 2. this Ordinance with the exception of § § 15 and 16 and the Road Traffic Licensing Regulations.”

1. *Regulatory sandboxes in practice*
2. *A closer look into experimentation clauses*
3. ***What we do (and plan)***

Creating the legal basis (1)

- **New experimentation clauses in national law** (for autonomous driving, digital identities)
- **“Experimentation clause check” in the legislative process:** In April 2021, the Federal Ministries committed to examine the possible inclusion of an experimentation clause for every draft law (non-obligatory)
- **Guide for formulating experimentation clauses:** Provides assistance to law makers in the formulation of experimentation clauses (published Dec 2020).

Creating the legal basis (2)



Model experimentation clause

SECTION 1: [Purpose of the testing]

SECTION 2: Constituent elements and legal consequences

General part: [Competence] [authorisation of authority] [operative part of decision], if [object of testing] and [material limitation].

Special part: [Procedural requirements for application]. [Scope (material and spatial) of the testing]. [Accompanying obligations]. [Time limit of permission/approval]. [Other ancillary provisions]. [Possibility of revocation].

SECTION 3: [Evaluation including transfer]. [Time limit for the clause].

SECTION 4: [Authorisation to issue ordinances or naming of the legal basis].

<https://www.bmwi.de/Redaktion/EN/Publikationen/Digitale-Welt/guide-new-flexibility-for-innovation-en-web-bf.html>

Creating the legal basis (3)

- **Council Conclusions on Regulatory Sandboxes and Experimentation clauses** adopted November 2020 during the German Presidency
- **Supporting the drafting of new EU experimentation clauses/regulatory sandboxes** (e.g. AI regulatory sandboxes)
- **Proposal for a national „Regulatory Sandbox Law“**

Information, Networking and support

- **Regulatory sandboxes network** (cross-cutting) with >500 members
- **Handbook regulatory sandboxes:** Manual for the design, implementation and evaluation of regulatory sandboxes
- **Practical guide to data protection** for regulatory sandboxes
- **Workshops, information, contact persons**
- **Regulatory sandbox competitions** („innovation prize“)



Information and contact

English Website:

<https://www.bmwi.de/Redaktion/EN/Dossier/regulatory-sandboxes.html>

E-Mail: konstantin.kolloge@bmwk.bund.de or
reallabore@bmwk.bund.de

Questions addressed to Dr. Konstantin Kolloge, German Federal Ministry for Economic Affairs and Climate Action



Q1: *What is the practical involvement of supervisory authorities in the Hubi example?*

A1: The main role of the authority was to allow for it and they had some safeguards. They also check if all safeguards were in place. Though they did not support and give guidance, we could see more in the regulatory sandboxes. With the AI regulatory sandboxes there could be a bigger role for these authorities.



Q2: *Working for the EC, we have pilot projects and preparatory actions proposed by the parliament. In the German examples have you made a proposal that a tested one can be a permanent service and generally benefit from it? Also looking at the variety of contexts in the transport sector how would you mitigate the risks of unsuitability of the experimentation arising from the potential variety of affected sectors?*

A2 (Dr. Konstantin Kolloge): We are thinking of scaling up. The companies don't want to invest if they don't know what comes after, they need security). We will try to take up the aspect of scaling after the sandbox in the standards, but it is very hard to install an "automatic process". On your second question: if other policy areas are affected, the relevant authorities must also be involved. In our example, these are often also security (the police), other environmental authorities.

A2 (Lorna Schrefle): One of the aspects that is indeed tricky with sandboxes is also that innovation cuts across different sectors that are usually under the competence of different regulators. So, the governance structure getting those regulators around the table is a key aspect.

The Regulatory Sandboxing Clause in the proposal for an Artificial Intelligence Act

Yordanka Ivanova,
European Commission, DG CONNECT

Check the [webinar recording](#) from 1 hr 5 min 50 sec until 1 hr 25 min 30 sec



Regulatory sandboxes in the Artificial Intelligence Act

Yordanka Ivanova
European Commission, CNECT A2
March 2022

Rationale for and objectives of the AI Regulatory sandboxes

- ▶ Conducive to our twin objectives to achieve **AI Excellence & Trust**
- ▶ [Council Conclusions on sandboxes](#) refer to AI as novel technologies that require flexibility
- ▶ Inspired by the success of existing regulatory sandboxes
- ▶ [AI proposal](#) creates a framework for **AI regulatory sandboxes** aimed to:
 - Foster AI innovation by establishing a controlled and safe experimentation and testing environment
 - Enhance legal certainty for innovators and the competent authorities' understanding of the opportunities, emerging risks and the impacts of AI use
 - Accelerate access to market, incl. for small and medium enterprises (SMEs) and start-ups

Key features of AI Regulatory sandboxes

Regulatory supervision

- Established by competent authorities under the AI Act (association of other regulators as well)
- Development under the direct supervision and guidance of regulators

Pre-marketing phase

- Facilitates the AI development, testing and validation for a limited time
- Testing in real conditions possible (without effects on people in actual decision-making)

Objective to ensure compliance

- With the requirements under the AI Act (data quality, transparency, accuracy, security)
- Possibility to supervise in the sandbox also GDPR and sectoral laws

Of specific AI projects

- AI systems must be 'innovative'
- Primarily 'high-risk' but can be also other AI systems under regulatory uncertainty

Variety of possible participants

- Public or private providers of AI systems (also in consortia)

Governance framework – Article 53

National level

- ▶ Established by **national competent authorities** under the AI Act
- ▶ Association of **other relevant regulators** (i.e. data protection, sectoral supervisory authorities)
- ▶ **Synergies with other actors** (data spaces, testing and experimentation facilities, hubs)

European level

- ▶ Possibilities for **cross-border European** and **EDPS sandbox**
- ▶ **Coordination and cooperation at EU level** under the EU AI Board
- ▶ **Competent authorities should submit annual reports** to the AI Board and the Commission (incl. good practices, lessons learnt and recommendations)
- ▶ **Single access point to sandbox** information for the whole EU

Operation of the sandbox - Article 53

- ▶ **No derogation from the AI requirements/conformity assessment**

- ▶ But margin of discretion how regulators apply them to specific AI use cases/projects
- ▶ Also special regime for re-use of personal data (art. 54)

- ▶ **Uniform conditions for the operation:** to be set out in implementing acts:

- ▶ Eligibility and selection criteria
- ▶ Procedure for application, selection, participation and exiting from the sandbox
- ▶ Terms and conditions

- a) *Prevent market fragmentation*
- b) *Ensure level playing field*
- c) *Flexibility (easily adapted)*

- ▶ **Key elements** defined in the AI Act:

- ▶ Participation to be based on a specific plan
- ▶ Risk management safeguards
- ▶ No administrative fines if guidance followed (recital 72)
- ▶ Participants remain liable for damage

Support measures under the 2021 Coordinated Plan on AI (review from 2018)

SET ENABLING CONDITIONS FOR AI DEVELOPMENT AND UPTAKE IN THE EU

- Acquire, pool and share policy insights
- **Tap into the potential of data**
- Foster critical computing capacity

MAKE THE EU THE RIGHT PLACE; EXCELLENCE FROM LAB TO THE MARKET

- Collaboration with stakeholders, Public-private Partnership on AI, data and robotics
- Research capacities
- **Testing and experimentation (TEFs), uptake by SMEs (EDIHs)**
- Funding and scaling innovative ideas and solutions

ENSURE AI TECHNOLOGIES WORK FOR PEOPLE

- Talent and skills
- A policy framework to ensure trust in AI systems
- Promoting the EU vision on sustainable and trustworthy AI in the world

BUILD STRATEGIC LEADERSHIP IN THE SECTORS

- Climate and environment
- Health
- Strategy for Robotics in the world of AI
- Public sector
- Law enforcement, immigration and asylum
- Mobility
- Agriculture

Investments: Horizon Europe, Digital Europe, Recovery and Resilience Facility



Thank you

Question addressed to Mrs. Yordanka Ivanova, European Commission, DG CONNECT



Q1: *Can you please elaborate more on the "EDPS sandboxes" and provide references?*

A1: On the EDPS question the reply can be simple: EDPS is the competent authority in the AI Act for EU institutions, bodies and agencies acting as providers of AI systems and it may decide to establish such a sandbox and supervise specific AI projects developed by us as Institutions

Conversations from the chat



The Italians already have a general clause on experimentations in their national law and it includes provisions around follow-up measures after the end of experimentation.



Q1: Can you please provide a link to the general clause on experimentation in Italy?

A1 a: <https://innovazione.gov.it/notizie/articoli/en/sperimentazione-italia/>

A1 b: Specifically, for Italy: Within 90 days from the date of the positive certification of the experimentation report, the President of the Council of Ministers, or the delegated Minister, in agreement with the Minister responsible for the matter, will promote the regulations and regulatory initiatives necessary to allow the experimentation activity to be carried out at full capacity.



Q2: But if you have a general law enabling experimentation/regulatory sandbox, and an older sector-specific legislation that does not include any experimental clause, I would guess that the latter takes priority (as *lex specialis*) and therefore the general law does not help here. Or do I miss something?

Do you have examples (even in Italian) on how this generic clause has been applied already in sectors/ projects?

A2 a: At this link you can find more information about the Italian sandbox: <https://innovazione.gov.it/notizie/articoli/en/sperimentazione-italia/>. Inside the link there the specific section excluded areas of application, that answer at your question.

Conversations from the chat



A2 b - Digital Transformation – ITA: We are still in an early phase. Few weeks ago, we authorized the first experimentation of autonomous shuttles (material is only in Italian: <https://innovazione.gov.it/notizie/articoli/innovazione-via-libera-alla-sperimentazione-di-navette-a-guida-autonoma-su-strada/>). If I understand well, this is the process: the innovation is blocked by an "older sector-specific legislation" with "Sperimentazione italia" we can allow the experimentation: the example, I think, is the older and specific "Codice della Strada" for the autonomous shuttles I posted before.



Thanks a lot, this is very useful to know. Anyway, even for areas of application that are not explicitly excluded, I think there might be still some friction with sectoral-specific legislation that requires some deeper legal analysis. For example, the reuse of telecom data is subject to the ePrivacy directive, that is very strict. But I'll certainly follow-up, thanks a lot for this information.



Final remarks and conclusions

Cécile Guasch

European Commission, DIGIT D2

Check the webinar recording from 1 hr 25
min 30 sec until its end

Final remarks and conclusions

Cécile Guasch, European Commission, DIGIT D2

- *Exciting topic where the Legal environment meets innovation,*
- *It is an emerging topic but fast evolutive,*
- *EU regulatory sandboxes will provide a frame*

BLSI community



Stay tuned for the upcoming:

- Virtual breakfast webinars
- Publication of case studies, issue papers, solutions and tools
- Legal Interoperability training



Join our ongoing discussions on:

- [Digital-ready policymaking](#)
- [Decision supporting tool on interoperability](#)



Stay informed:

[Subscribe to our newsletter](#) to stay tuned on what is coming and [become a member](#) of our community!



#BLSI = Better legislation for smoother implementation

Join us on [JoinUp!](#)



Thank you



interoperable europe

innovation ∞ govtech ∞ community

Stay in touch



[\(@InteroperableEU\) / Twitter](https://twitter.com/InteroperableEU)



[Interoperable Europe - YouTube](https://www.youtube.com/InteroperableEurope)



[Interoperable Europe | LinkedIn](https://www.linkedin.com/company/interoperable-europe/)



DIGIT-INTEROPERABILITY@ec.europa.eu



<https://joinup.ec.europa.eu/collection/interoperable-europe/interoperable-europe>