Regulatory sandboxes in the Artificial Intelligence Act

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Rationale for Regulatory sandboxes in the AI proposal

- Conducive to EU objectives to achieve to **excellence and trust in AI**

- **Council Conclusions on regulatory sandboxes** explicitly refer to AI as developing technologies that require flexibility and novel forms of supervision facilitating innovation

- Sandboxes received **strong support by stakeholders** (during public consultation)

- Inspired by the **success of existing regulatory sandboxes** (e.g. finance, data protection, energy)

- The AI Act proposes a **common framework for AI regulatory sandboxes across Europe** to ensure that the regulatory framework is innovation friendly, future-proof and resilient to disruption
“AI regulatory sandboxes established by one or more Member States competent authorities or the European Data Protection Supervisor shall provide 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 this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.”
Objectives of the AI regulatory sandboxes

▶ To foster AI innovation by establishing a controlled and safe experimentation and testing environment in the development and pre-marketing phase

▶ To enhance legal certainty for innovators and the competent authorities’ oversight and understanding of the opportunities, emerging risks and the impacts of AI use

▶ To accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups
Governance framework – Article 53

- Established by national **competent authorities** (designated under the AI regulation)

- Possibilities for **cross-border European sandboxes**

- At national level, **association of other relevant regulators** (i.e. data protection, authorities providing or supporting access to data, sectoral supervisory authorities)

- **Synergies with other initiatives** (testing and experimentation facilities funded under DEP)

- **Coordination and cooperation at EU level** under the European Artificial Intelligence Board

- Competent authorities should submit **annual reports** to the AI Board and the Commission (incl. good practices, lessons learnt and recommendations)
Operation of the sandbox - Article 53

▶ **No derogation** from the AI requirements, but special regime for certain further personal data processing (article 54)

▶ **Flexibility in the operation**: modalities and conditions to be set out in implementing acts (eligibility criteria, procedure for application, selection, participation and exiting from the sandbox, rights and obligations of the participants)

▶ Some key elements defined in the AI Act:
  - Participation to be based on a **specific plan**
  - Any **significant risks to health and safety and fundamental rights** identified during the testing should result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place
  - Participants **remain liable** under applicable liability legislation
  - The **conduct of the participants** must be taken into account when competent authorities decide whether to impose administrative fines under data protection law
Special regime for re-use of personal data in the AI regulatory sandbox

Art. 54 provides a legal basis for the further processing of personal data for developing certain AI systems in the public interest in one or more of the following areas:

i) Law enforcement under the control and responsibility of the competent authorities. The processing shall be based on Member State or Union law;

ii) Public safety and public health, including disease prevention, control and treatment;

iii) A high level of protection and improvement of the quality of the environment;

Subject to additional safeguards including:

- Data processed should be necessary for fulfilling one or more of the AI requirements
- Effective monitoring mechanisms to identify high risks to fundamental rights
- Processing should not lead to measures or decisions affecting the data subjects;
- Storage, security and documentation requirements
Thank you