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

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AI Regulatory sandboxes – Article 53 (1)

> "*AI regulatory sandboxes established by **one or more Member States competent authorities** or the **European Data Protection Supervisor** shall provide a <u>controlled environment that facilitates the development, testing and validation</u> of innovative AI systems for a limited time <u>before</u> their placement on the market or putting into service pursuant to a specific plan.*
> *This shall take place under the <u>direct supervision and guidance</u> by the competent authorities <u>with a view to ensuring compliance</u> with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.*"

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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

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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)

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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

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Thank you