

Context – Making Europe fit for digital age

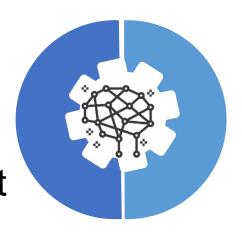
- Priority of von der Leyen Commission: "Europe must now lead the way on digital or it will have to follow the way of others, who are setting these standards for us."
- EU Digital Finance Strategy: "Europe must drive digital finance with strong European market players in the lead, to make the benefits of digital finance available to European consumers and businesses, based on European values and a sound regulation of risks."



Al - the baseline....

Al is good ...

- For consumers
- For business
- For the public interest



... but certain use cases create some risks

- For safety of consumers and users
- For fundamental rights



Al Package (April 2021)

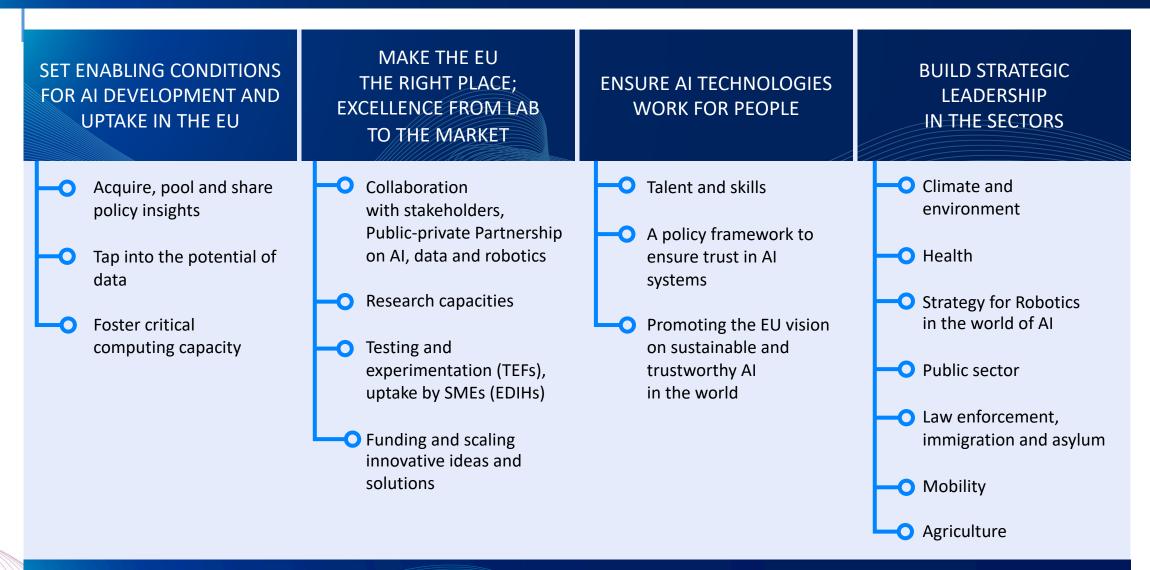
EXCELLENCE AND TRUST

- Communication: "Fostering a
 - European approach to Al"
- Coordinated Plan on AI (review)
- Proposal for a legal framework on Al





Coordinated Plan on AI: joint commitment between the Commission and Member States that by working together, Europe can maximise its AI potential to compete globally



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

Proposal for a legal framework - Definition and technological scope (Art. 3)

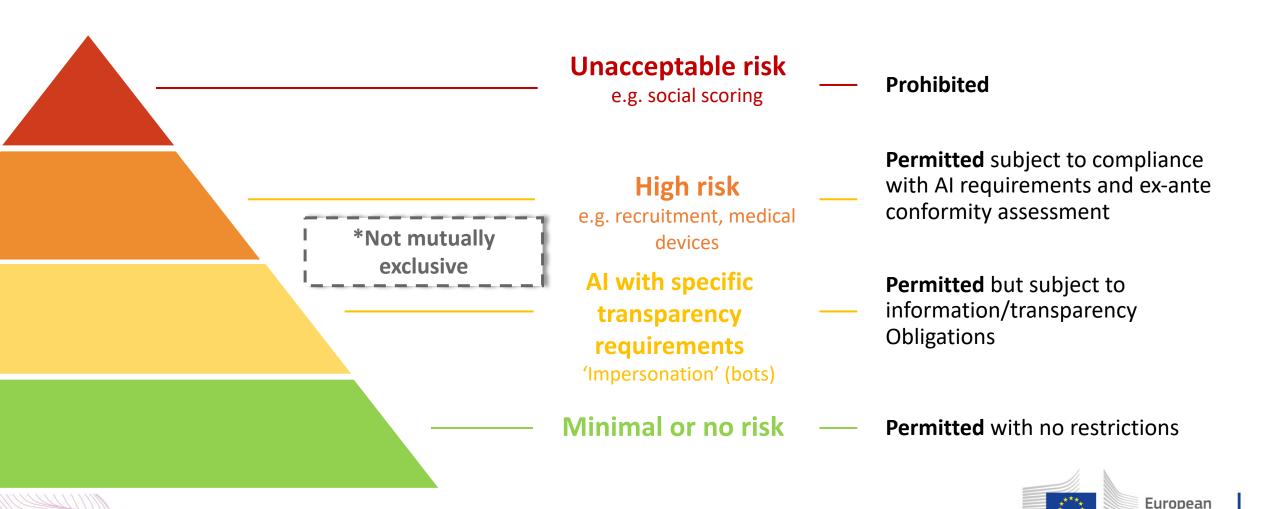
Definition of Artificial Intelligence

- Definition of AI should be as neutral as possible in order to cover techniques which are not yet known/developed
- Overall aim is to cover all AI, including traditional symbolic AI, Machine learning, as well as hybrid systems
- ► Annex I: list of AI techniques and approaches should provide for legal certainty (adaptations over time may be necessary)

"a software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with"



A risk-based approach to regulation



Commission

High-risk Artificial Intelligence Systems (Title III, Annexes II and III)



Certain applications in the following fields:

- > Safety components of regulated products (e.g. medical devices, machinery) which are subject to third-party assessment under the relevant sectorial legislation
- Certain (stand-alone) AI systems in the following fields:
 - ✓ Biometric identification and categorisation of natural persons
 - ✓ Management and operation of critical infrastructure
 - Education and vocational training
 - ✓ Employment and workers management, access to self-employment
 - ✓ Access to and enjoyment of essential private services and public services and benefits, including creditworthiness assessments of natural persons
 - ✓ Law enforcement
 - ✓ Migration, asylum and border control management
 - Administration of justice and democratic processes



Requirements for high-risk AI (Title III, chapter 2)



Use high-quality training, validation and testing data (relevant, representative etc.)

Establish and implement risk management processes (in light of the intended purpose of the Al system)

Establish documentation and design logging features (traceability & auditability)

Ensure appropriate degree of **transparency** and provide users with **information** (on how to use the system, its capabilities and limitations)

Enable **human oversight** (measures built into the system and/or to be implemented by users)

Ensure robustness, accuracy and cybersecurity

Overview: obligations of operators of high-risk AI (Title III, Chapter 3)

- ► Establish and Implement quality management system in its organisation
- ▶ Draw-up and keep up to date **technical documentation**
- ▶ Undergo conformity assessment and potentially re-assessment of the system (in case of significant modifications)
- ▶ Register standalone AI system in EU database (listed in Annex III)
- ► Sign declaration of conformity and affix **CE marking**
- ► Conduct **post-market monitoring**
- ▶ **Report serious incidents &malfunctioning** leading to breaches to fundamental rights
- ▶ Collaborate with market surveillance authorities

User obligations

- ▶ Operate high-risk AI system in accordance with instructions of use
- ► Ensure human oversight & monitor operation for possible risks
- ► Keep automatically generated logs
- ▶ Inform any serious incident & malfunctioning to the provider or distributor
- ► Existing legal obligations continue to apply (e.g. under GDPR)



How will it work in the financial sector?

- ▶ 1 high risk use case: "AI systems intended to be used to evaluate the creditworthiness of persons or establish their credit score, with the exception of AI systems developed by small scale users for their own use"
 - ► Entities not regulated and supervised under EU rules (for example credit bureaus), subject to full set of rules
 - ► Credit institutions regulated by EU law the supervision of compliance would be integrated into our financial supervisory system
- ► ESAs will continue to give guidance on AI & financial services rules



Next steps

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The European Parliament and the Council as colegislators will negotiate the proposal and agree on a compromise in the ordinary legislative procedure

Once adopted, there will be 2 years of transitional period before the Regulation becomes directly applicable across the EU.

In parallel, harmonized standards of CEN/CENELEC should be ready and support operators in the practical implementation of the new rules& conformity assessment procedures



