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.”
AI - the baseline....

AI 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
Communication: “Fostering a European approach to AI”

Coordinated Plan on AI (review)

Proposal for a legal framework on AI
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.

<table>
<thead>
<tr>
<th>SET ENABLING CONDITIONS FOR AI DEVELOPMENT AND UPTAKE IN THE EU</th>
<th>MAKE THE EU THE RIGHT PLACE; EXCELLENCE FROM LAB TO THE MARKET</th>
<th>ENSURE AI TECHNOLOGIES WORK FOR PEOPLE</th>
<th>BUILD STRATEGIC LEADERSHIP IN THE SECTORS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acquire, pool and share policy insights</td>
<td>Collaboration with stakeholders, Public-private Partnership on AI, data and robotics</td>
<td>Talent and skills</td>
<td>Climate and environment</td>
</tr>
<tr>
<td>Tap into the potential of data</td>
<td>Research capacities</td>
<td>A policy framework to ensure trust in AI systems</td>
<td>Health</td>
</tr>
<tr>
<td>Foster critical computing capacity</td>
<td>Testing and experimentation (TEFs), uptake by SMEs (EDIHs)</td>
<td>Promoting the EU vision on sustainable and trustworthy AI in the world</td>
<td>Strategy for Robotics in the world of AI</td>
</tr>
<tr>
<td></td>
<td>Funding and scaling innovative ideas and solutions</td>
<td></td>
<td>Public sector</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Law enforcement, immigration and asylum</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mobility</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Agriculture</td>
</tr>
</tbody>
</table>

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

- **Unacceptable risk**
  - e.g. social scoring
  - **Prohibited**

- **High risk**
  - e.g. recruitment, medical devices
  - *Not mutually exclusive*
  - **Permitted subject to compliance with AI requirements and ex-ante conformity assessment**

- **AI with specific transparency requirements**
  - ‘Impersonation’ (bots)
  - **Permitted but subject to information/transparency Obligations**

- **Minimal or no risk**
  - **Permitted with no restrictions**

*Not mutually exclusive*
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 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)

<table>
<thead>
<tr>
<th>Provider obligations</th>
<th>User obligations</th>
</tr>
</thead>
</table>
| ➤ 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 | ➤ 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

1. The European Parliament and the Council as co-legislators will negotiate the proposal and agree on a compromise in the ordinary legislative procedure.

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

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