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 can bring benefits...

- For consumers
- For business
- For the public good

... but certain uses create some risks

- For safety and security
- For fundamental rights
Key initiatives:

- **European Strategy on AI** (April 2018)
- **Guidelines for Trustworthy AI** developed in 2019 by the High-Level Expert Group on Artificial Intelligence (HLEG)
- **First Coordinated Plan on AI** (December 2018)
- The Commission's **White Paper on AI** (February 2020) followed by a public consultation.
- **AI package** (April 2021)
### Updated Coordinated Plan on AI (review from 2018): joint commitment between the Commission and Member States

#### 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
Proposal for a regulation on Artificial Intelligence

Internal market legislation (mainly based on Art. 114 TFEU)

► “Classic” internal market rules for the **placing on the market and putting into service of** AI systems
► Horizontal in nature
► Aligned to vast EU acquis on product safety and services which shall be jointly applied; 

*Excluded:* AI developed or used exclusively for military purposes

Level playing field for EU and non-EU players

► Independent of origin of producer or user
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
  - AI with specific transparency requirements
    - ‘Impersonation’ (bots)
  - Permitted subject to compliance with AI requirements and ex-ante conformity assessment

- **Minimal or no risk**
  - Permitted but subject to information/transparency Obligations

- **Prohibited**

European 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
How will it work for 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 the existing financial supervisory system
Requirements for high-risk AI (Title III, chapter 2)

- Establish and implement risk management processes
  - 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 (Title III, Chapter 3)

<table>
<thead>
<tr>
<th>Provider obligations</th>
<th>User obligations</th>
</tr>
</thead>
<tbody>
<tr>
<td>▶ Establish and Implement <em>quality management</em> system in its organisation</td>
<td>▶ Operate high-risk AI system in accordance with <em>instructions of use</em></td>
</tr>
<tr>
<td>▶ Draw-up and keep up to date <em>technical documentation</em></td>
<td>▶ Ensure <em>human oversight &amp; monitor</em> operation for possible risks</td>
</tr>
<tr>
<td>▶ Undergo <em>conformity assessment</em> and potentially re-assessment of the system (in case of significant modifications)</td>
<td>▶ Keep <em>automatically generated logs</em></td>
</tr>
<tr>
<td>▶ Register standalone AI system in EU database (listed in Annex III)</td>
<td>▶ <em>Inform any serious incident &amp; malfunctioning</em> to the provider or distributor</td>
</tr>
<tr>
<td>▶ Sign declaration of conformity and affix <em>CE marking</em></td>
<td>▶ <em>Existing legal obligations</em> continue to apply (e.g. under GDPR)</td>
</tr>
<tr>
<td>▶ Conduct <em>post-market monitoring</em></td>
<td></td>
</tr>
</tbody>
</table>
Supporting innovation (Title V)

Regulatory sandboxes
Art. 53 and 54

Support for SMEs/start-ups
Art. 55
The governance structure (Titles VI and VII)

**European level**

- European Commission to act as Secretariat
- Artificial Intelligence Board
- Expert Group*

**National level**

- National Competent Authority/ies
- For the financial sector: existing financial supervisory authorities

*Not foreseen in the regulation but the Commission intends to introduce it in the implementation process*
The European Parliament and the Council as co-legislators 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.
Another chance for all voices to be heard

- Public consultation on the Commission proposal open until 6 August
- Commission ‘Have your say’ website:
  
  Artificial intelligence – ethical and legal requirements (europa.eu)
Thank you