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SHAPING EUROPE'S DIGITAL FUTURE

A European Strategy for Artificial Intelligence

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AI is good …

- For citizens
- For business
- For the public interest

… but creates some risks

- For the safety of consumers and users
- For fundamental rights

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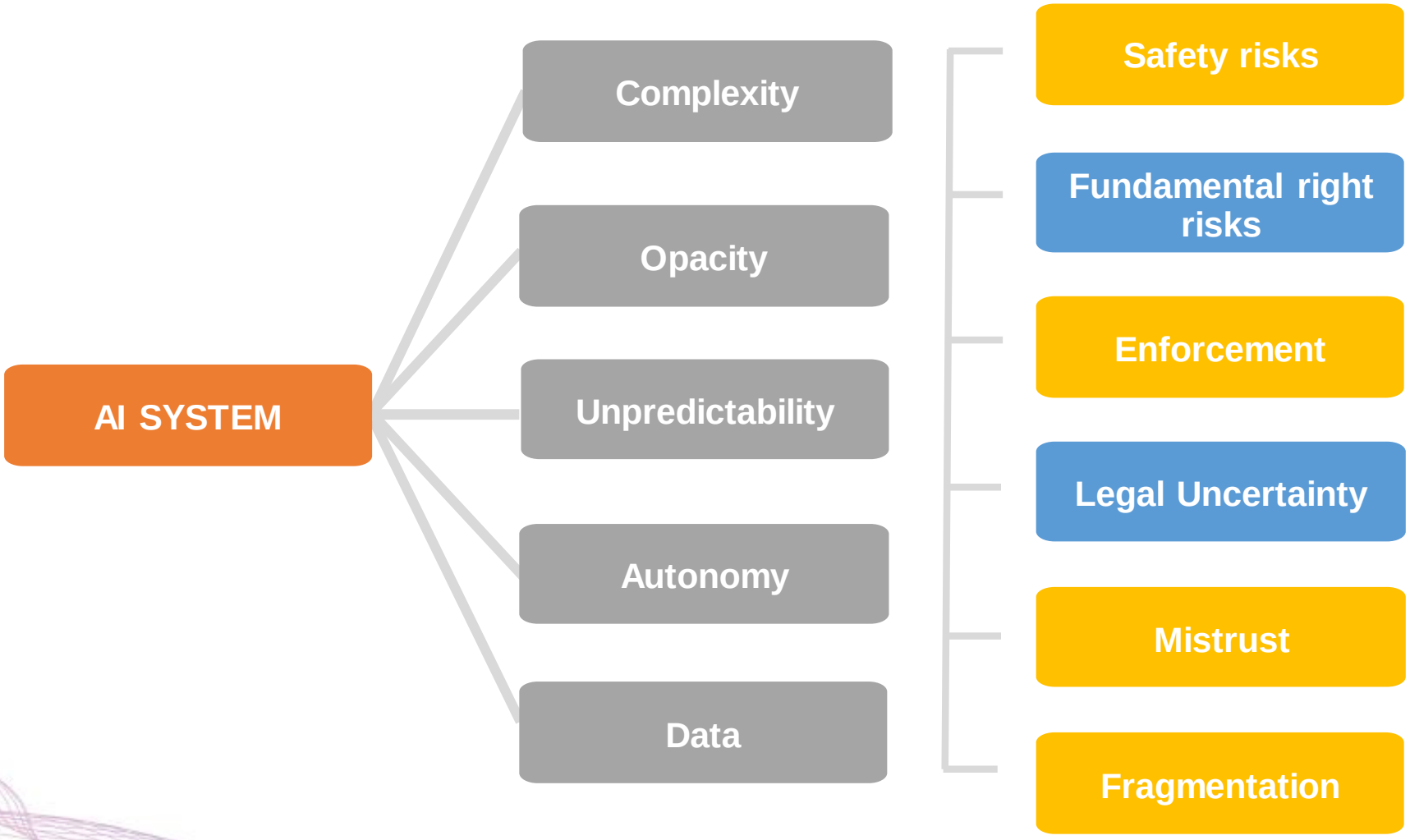
1. Proposal for a legal framework on AI

Why do we regulate AI use cases?



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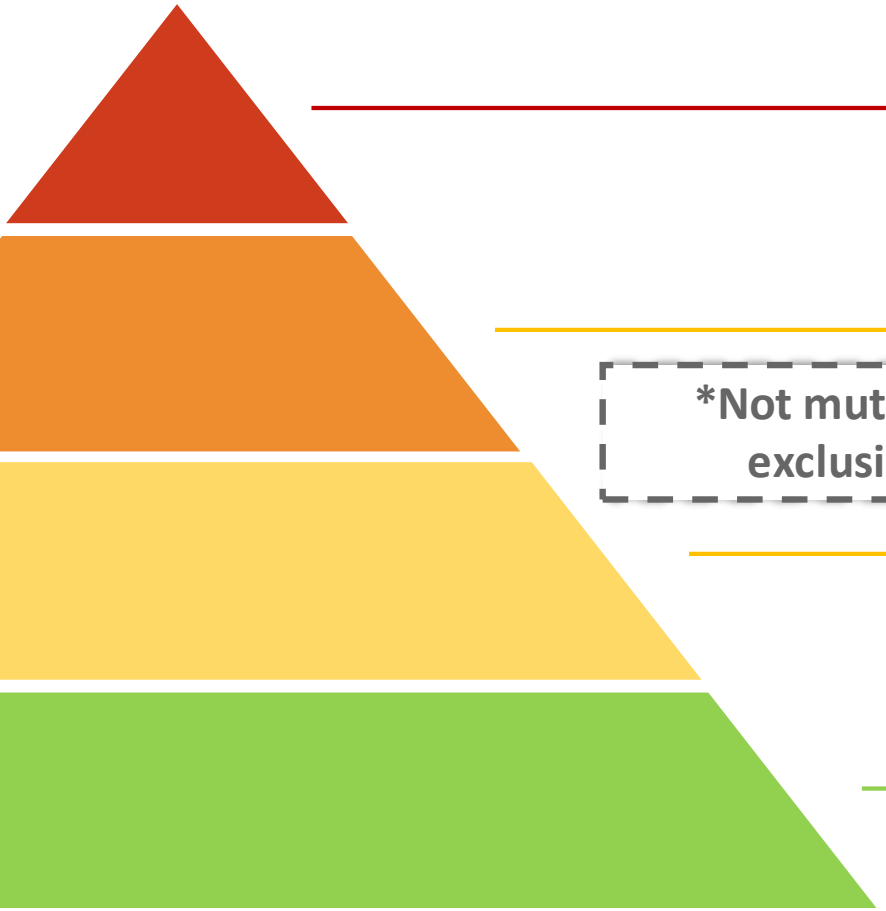
Definition and technological scope of the regulation (Art. 3)

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



*Not mutually exclusive

Unacceptable risk
e.g. social scoring

Prohibited

High risk
e.g. recruitment, medical devices

Permitted subject to compliance with AI requirements and ex-ante conformity assessment

AI with specific transparency obligations
'Impersonation' (bots)

Permitted but subject to information/transparency Obligations

Minimal or no risk

Permitted with no restrictions

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Most AI systems will not be high-risk (Titles IV, IX)

New transparency obligations for certain AI systems (Art. 52)

- **Notify humans** that they are **interacting with an AI system** unless this is evident
- Notify humans that emotional recognition or biometric categorisation systems are applied to them
- Apply **label to deep fakes** (unless necessary for the exercise of a fundamental right or freedom or for reasons of public interests)

Possible voluntary codes of conduct for AI with specific transparency requirements (Art. 69)

- No mandatory obligations
- Commission and Board to encourage drawing up of codes of conduct intended to foster the **voluntary application of requirements to low-risk AI systems**

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

Certain applications in the following fields:

1 **SAFETY COMPONENTS OF REGULATED PRODUCTS**

(e.g. medical devices, machinery) which are subject to third-party assessment under the relevant sectorial legislation

2 **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
- ✓ Law enforcement
- ✓ Migration, asylum and border control management
- ✓ Administration of justice and democratic processes

CE marking and process (Title III, chapter 4, art. 49.)

CE marking is an indication that a product complies with the requirements of a relevant Union legislation regulating the product in question. In order to affix a CE marking to a high-risk AI system, a provider shall undertake **the following steps:**

1 **Determine** whether its AI system **is classified as high-risk** under the new AI Regulation

2 **Ensure** design and development and quality management system are **in compliance with the AI Regulation**

3 **Conformity assessment procedure**, aimed at assessing and documenting compliance

4 **Affix the CE marking to the system** and sign a declaration of conformity

5 **PLACING ON THE MARKET or PUTTING INTO SERVICE**

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

Establish and implement **risk management** processes

&

In light of the **intended purpose** of the AI system

- Use high-quality **training, validation and testing data** (relevant, representative etc.)
- Establish **documentation** and design logging features (traceability & auditability)
- Ensure appropriate certain degree of **transparency** and provide users with **information** (on how to use the system)
- Ensure **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)

Provider obligations

- Establish and Implement **quality management** system in its organisation
- Draw-up and keep up to date **technical documentation**
- **Logging** obligations to enable users to monitor the operation of the high-risk AI system
- Undergo **conformity assessment** and potentially re-assessment of the system (in case of significant modifications)
- Register AI system in EU database
- Affix CE marking and sign declaration of conformity
- Conduct **post-market monitoring**
- **Collaborate** with market surveillance authorities

User obligations

- Operate AI system in accordance with **instructions of use**
- Ensure **human oversight** when using of AI system
- **Monitor** operation for possible risks
- **Inform the provider or distributor about any serious incident** or any malfunctioning
- **Existing legal obligations** continue to apply (e.g. under GDPR)

Lifecycle of AI systems and relevant obligations

Design in line with requirements

Ensure AI systems **perform consistently for their intended purpose** and are **in compliance with the requirements** put forward in the Regulation

Conformity assessment

Ex ante conformity assessment

Post-market monitoring

Providers to **actively and systematically collect, document and analyse relevant data** on the reliability, performance and safety of AI systems throughout their lifetime, and to **evaluate continuous compliance of AI systems with the Regulation**

Incident report system

Report serious incidents as well as malfunctioning leading to breaches to fundamental rights (as a basis for investigations conducted by competent authorities).

New conformity assessment

New conformity assessment in case of **substantial modification** (modification to the intended purpose or change affecting compliance of the AI system with the Regulation) by providers or any third party, including when changes are **outside the "predefined range" indicated by the provider for continuously learning AI systems.**

AI that contradicts EU values is prohibited (Title II, Article 5)

✗ **Subliminal manipulation** resulting in physical/ psychological harm

Example: An **inaudible sound** is played in truck drivers' cabins to push them to **drive longer than healthy and safe**. AI is used to find the frequency maximising this effect on drivers.

✗ **Exploitation of children or mentally disabled persons** resulting in physical/psychological harm

Example: A doll with an integrated **voice assistant** encourages a minor to **engage in progressively dangerous behavior** or challenges in the guise of a fun or cool game.

✗ **General purpose social scoring**

Example: An AI system **identifies at-risk children** in need of social care **based on insignificant or irrelevant social 'misbehavior'** of parents, e.g. missing a doctor's appointment or divorce.

✗ **Remote biometric identification for** law enforcement purposes in publicly accessible spaces (with exceptions)

Example: All faces captured live by video cameras checked, in real time, against a database to identify a terrorist.

Remote biometric identification (RBI) (Title II, Art. 5, Title III)

Use of real-time RBI systems for law enforcement (Art. 5)

Prohibition of use for law enforcement purposes in publicly accessible spaces with exceptions:

- Search for victims of crime
- Threat to life or physical integrity or of terrorism
- Serious crime (EU Arrest Warrant)

Ex-ante authorisation by judicial authority or independent administrative body

Putting on the market of RBI systems (real-time and ex-post)

- **Ex ante third party conformity assessment**
- Enhanced logging requirements
- "Four eyes" principle

No additional rules foreseen for use of real-time and post RBI systems: existing data protection rules apply

Supporting innovation (Title V)

Regulatory sandboxes Art. 53 and 54

Support for SMEs/start-ups Art. 55

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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

*Not foreseen in the regulation but the Commission intends to introduce it in the implementation process

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2. Coordinated Plan on AI 2021 Review

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The Coordinated Plan on AI 2021 review

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

The Coordinated Plan 2018

- Some **70 individual forward-looking actions**
- Developed together with the **Member States**
- Member States were encouraged to develop **national AI strategies**
- Set up as **a rolling plan** to be updated regularly

Why a 2021 review?

- **Covid-19 pandemic**
- **The Green Deal**
- **The RRF (+ DEP and HE) as game changer**
- **Policy alignment** with 2020 White Paper on AI (human-centric and trustworthy AI)
- **Technological developments** (new components, computing concepts, data infrastructure, new applications)
- **Lessons learned** from last two years of implementation, moving from 'intention' to 'action'

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FOUR KEY POLICY OBJECTIVES FOR ARTIFICIAL INTELLIGENCE IN EUROPE

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

Thank you