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SHAPING EUROPE'S DIGITAL FUTURE

Introduction to the Artificial Intelligence Act proposal

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Key regulatory concepts

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
- Aligned to vast EU acquis on product safety which shall be jointly applied (e.g. AI embedded in products)

Excluded: AI developed used exclusively for military purposes

Layered risk-based approach

- No regulation of the technology as such, but of **concrete high-risk use cases**
- Covers **risks to health, safety and fundamental rights**

Level playing field for EU and non-EU players

- Independent of origin of producer or user

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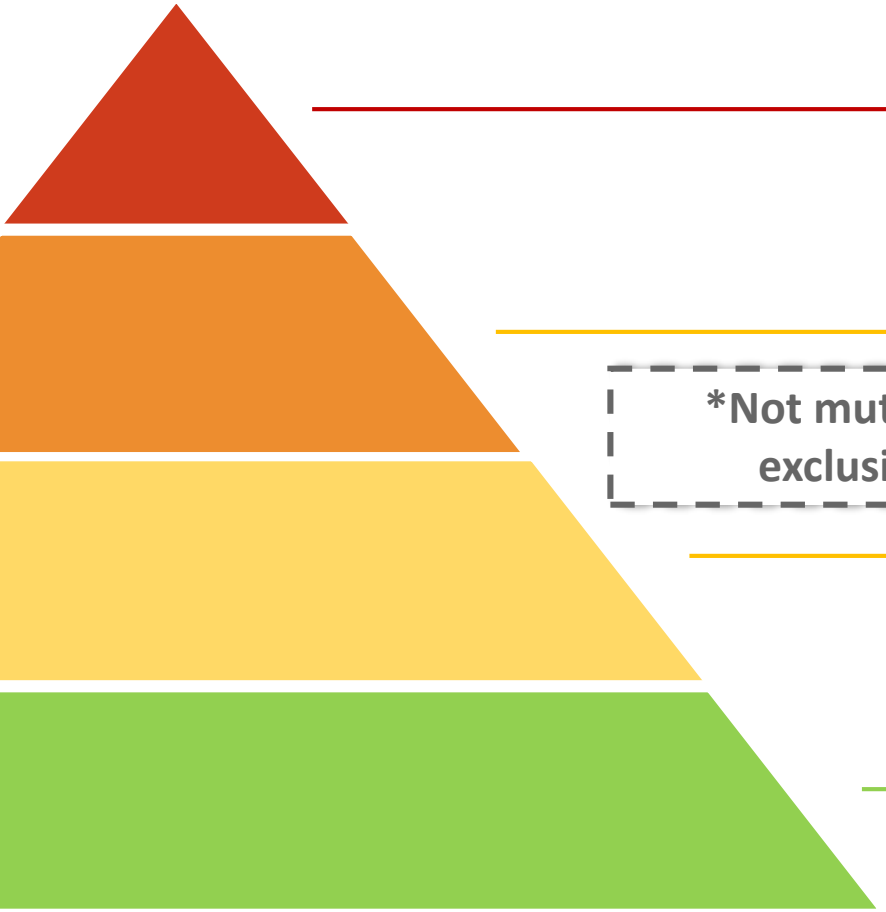
Definition of Artificial Intelligence

> *"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"*

- 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 risk-based approach



*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

'Transparency' risk
'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)

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 they are **exposed to emotional recognition or biometric categorisation systems**
- Apply **label to deep fakes**

Possible voluntary codes of conduct (Art. 69)

- No mandatory obligations
- Commission and Board to encourage drawing up of codes of conduct (**voluntary application of requirements for high-risk AI systems or other requirements)**

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High-risk Artificial Intelligence Systems (Title III, Chapter 1 & Annexes II and III)

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 AREAS

- ✓ 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

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

Establish and implement **risk management system**

&

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

- Use high-quality **training, validation and testing data** (relevant, representative etc.)
- Draw up **technical documentation** & set up **logging capabilities** (traceability & auditability)
- Ensure appropriate degree of **transparency** and provide users with **information** on capabilities and limitations of the system & how to use it
- Ensure **human oversight** (measures built into the system and/or to be implemented by users)
- Ensure **robustness**, **accuracy** and **cybersecurity**

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

CE marking = indication that product complies with requirements of applicable Union legislation

In order to affix a CE marking, 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 of AI systems are **in compliance with the AI Regulation**

3 **Undergo conformity assessment procedure** to assess and demonstrate 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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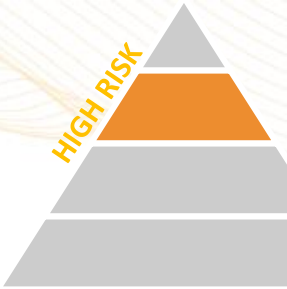
Overview: obligations of operators (Title III, Chapter 3)



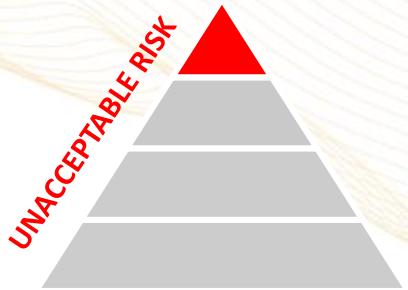
Provider obligations

- Establish and implement **quality management** system in its organisation
- **Register AI system** in EU database
- 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)

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



EXAMPLES

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

Extended Reality (XR) applications controlling the sensory experience of users

✗ **Exploitation of vulnerabilities** resulting in physical/psychological harm

Addictive AI-enabled applications intended for children (i.e., gambling-like random rewards or sending systematic push-notifications when 'off')

✗ **'Social scoring'** by public authorities

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

✗ **'Real-time' remote biometric identification for law enforcement purposes in publicly accessible spaces** (with exceptions)

All faces in the town square captured live by cameras are **cross-checked, in real time,** against a **database of terrorists** held by the law enforcement agencies

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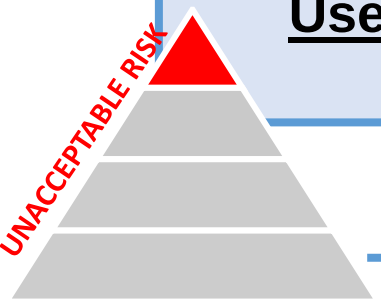
Remote biometric identification (RBI)



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

The governance structure (Titles VI and VII)

European level

Artificial Intelligence Board

- National Supervisory Authorities
- EDPS
  - European Commission Secretariat

- Collect and **share best practices & expertise**
- Contribute to **uniform administrative practices** in the MS
- Provide **advice, opinions, recommendations** on AI issues:
  - Standards (including harmonized standards) & technical specifications
  - Preparation of guidance documents

National level

National Competent Authorities, incl. National Supervisory Authority

- Responsible for the application and implementation of the Regulation
  - Oversight of conformity assessment bodies
  - Market surveillance activities ex Regulation (EU) 2019/1020

Thank you

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