







European Commission Al Policy 2018-2021

Key initiatives:

- **European Strategy on Al** (April 2018)
- Guidelines for Trustworthy AI developed in 2018/2019 by the High-Level Expert Group on Artificial Intelligence (HLEG), Followed by the ALTAI in 2020
- First Coordinated Plan on Al (December 2018)
- The Commission's **White Paper on AI** (February 2020) Ecosystem of trust & ecosystem of excellence Followed by a **public consultation**
- Al package (April 2021)







Proposal for the Artificial Intelligence Act Why a EU regulation on Al?

Complexity — Opacity
Unpredictability — O
Autonomy — Data

Solid framework
of EU legislation
already in place
at EU and
national level

HOWEVER



can make application and enforcement of the existing rules more challenging and generate risks to safety and fundamental rights



The
Commission's
proposal for a
regulatory
framework on Al



A tailored regulatory response needed





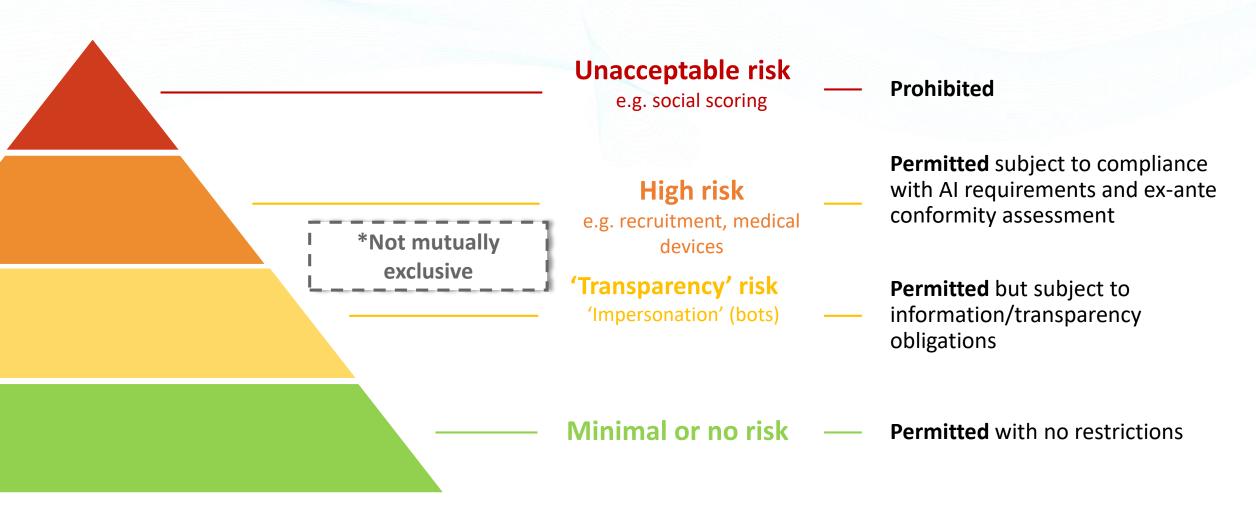
Proposal for the Artificial Intelligence Act- Foundations

- Al Act follows harmonisation legislation (Product Safety approach)
- Protection of safety and fundamental rights
- A risk based approach & Global level playing field
- A horizontal act
- Coherence and complementarity with existing legislation
- Al Act is innovation friendly





Proposal for the Artificial Intelligence Act Risk-based approach: overview







Proposal for the Artificial Intelligence Act Requirements for high-risk AI systems

Establish and implement **risk** management processes

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In light of the intended purpose of the Al 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**





The compliance and enforcement system

Pre-market – conformity assessment

Al that is safety
component of
products
(regulated by product
legislation)

Third-party ex ante conformity assessment (already existing under the relevant sectoral legislation)

Other high-risk AI systems ("stand-alone")

Ex ante conformity assessment through internal checks (except biometrics)

Post-market

Market surveillance (authorities)

Human oversight and monitoring (users)

Post-market monitoring (providers)

Reporting system for serious incidents brought to the attention of the providers

Re-assessment by the provider in case of substantial changes to AI systems

Registration (EU database)





The governance structure

European level

Commission to act as Secretariat

- Day-to-day business
- ▶ Prepare/follow-up Board meetings

Artificial Intelligence Board

- One member per Member State,
- European Data Protection Supervisor and representative of the Commission

Expert Group

- Not foreseen in the regulation but may be introduced in the implementation process
- Independent experts recruited and paid by the Commission for technical and scientific advice.

Main tasks

- ► Facilitate consistent application of the legal framework by Member States
- Contributing to market monitoring
- ► Collect and share best practices
- Contribute to standards / AI policy
- Provide advice on Al issues

National level

National Competent Authority/ies

Responsible for the application and implementation of the regulation, including for notified bodies, market surveillance

Main tasks

Responsible for implementation and application of the regulation within each relevant Member State territory







Most Al systems will not be high-risk

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)

MINIMAL OR NO RISK

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



Proposal for the Artificial Intelligence Act The scope – what is covered?

Definition of Artificial Intelligence

"a software that is developed with one or more of the techniques and approaches listed in Annex I (machine learning, logic and knowledge based, statistical approaches) 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.



Proposal for the Artificial Intelligence Act Risk-based approach: high risk Al systems

High-risk AI Systems

SAFETY COMPONENTS OF REGULATED PRODUCTS

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



- 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







Overview: obligations of operators

Provider obligations

- ► Undergo conformity assessment and potentially re-assessment
- ► Establish and Implement quality management system
- ▶ Draw-up and keep up to date **technical documentation**
- ► Conduct **post-market monitoring**
- ▶ Collaborate with market surveillance authorities
- ► Logging obligations to enable users to monitor the operation of the high-risk AI system

User obligations

- ▶ Operate AI system in accordance with instructions of use
- ► Ensure **human oversight** when using of AI system
- ▶ Monitor operation for possible risks
- ► Existing legal obligations continue to apply (e.g. under GDPR)

Other operators with certain obligations to providers include:

- Authorised representatives
- ► Importers
- ▶ Distributors
- Other third parties substantially changing the system





Proposal for the Artificial Intelligence Act Al that contradicts EU values are prohibited

Subliminal manipulation resulting in physical/ psychological harm

Exploitation of children or mentally disabled personsresulting in physical/psychological harm

General purpose social scoring

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

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

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.

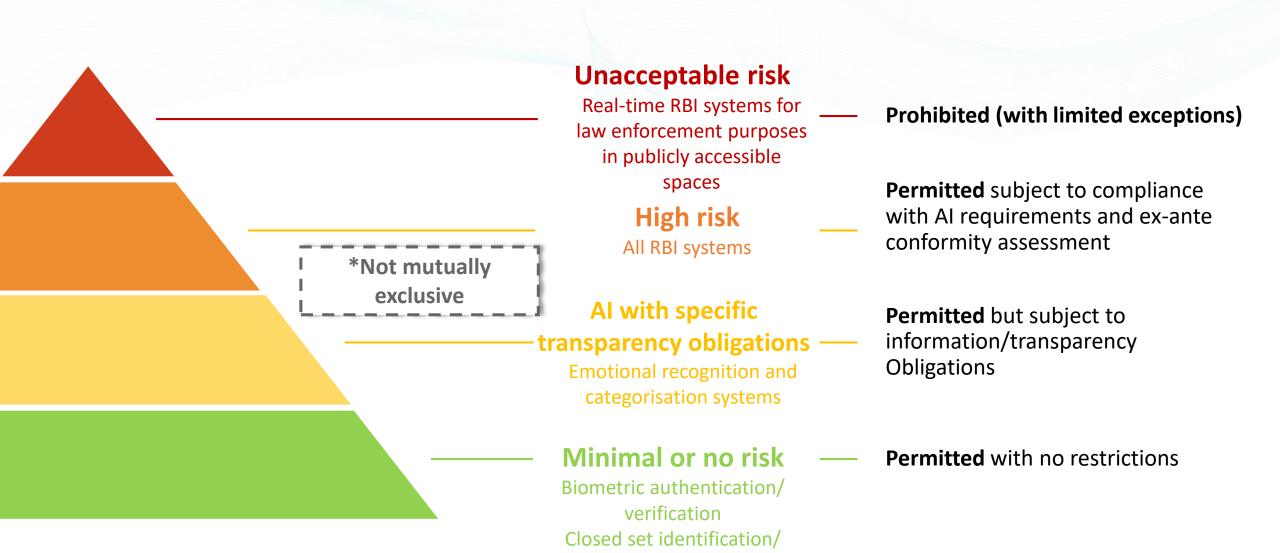
Example: An AI system **identifies at-risk children** in need of social care **based on insignificant or irrelevant social 'misbehavior'** of parents, e.g. missing a doctor's appointment or divorce.

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





Regulatory approach to biometrics



controlled environment