



Al is good ...

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- For citizens
- For business
- For the public interest

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... but creates some risks

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



1. Proposal for a legal framework on Al





Why do we regulate AI use cases?



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



Most AI systems will not be high-risk (Titles IV, IX) New transparency obligations for certain AI systems (Art. 52)

MINIMAL OR NO RISK



- 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)



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
- 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:**



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

Use high-quality training, validation and testing data (relevant, representative etc.) Establish and implement **risk** Establish **documentation** and design logging features (traceability & auditability) management processes Ensure appropriate certain degree of **transparency** and provide users with **information** & (on how to use the system) In light of the intended Ensure **human oversight** (measures built into the system and/or to be implemented by purpose of the users) Al system Ensure **robustness**, accuracy and **cybersecurity**

Overview: obligations of operators (Title III, Chapter 3)

- ▶ 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

Provider obligations

User obligations

- ► Affix CE marking and sign declaration of conformity
- Conduct post-market monitoring
- Collaborate with market surveillance authorities
- 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)



European Commission

Lifecycle of AI systems and relevant obligations



Design in line with requirements

Conformity assessment

Post-market monitoring

Incident report system

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

Ex ante conformity assessment

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

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 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

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

General purpose social scoring

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.

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)



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

Supporting innovation (Title V)





The governance structure (Titles VI and VII)

European level

National level

European Commission to act as Secretariat

Artificial Intelligence

National Competent Authority/ies



Expert Group*

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



2. Coordinated Plan on Al 2021 Review



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 Al 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 (humancentric 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'



FOUR KEY POLICY OBJECTIVES FOR ARTIFICIAL INTELLIGENCE IN EUROPE



Investments: Horizon Europe, Digital Europe, Recovery and Resilience Facility

