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# People vs. Machines

## EUROPE'S NEW AI RULES

The European Commission has published its proposal for a new, dedicated Regulation on Artificial Intelligence. At the core of the proposal lies a risk-based regulatory approach, whereby certain AI practices are to be prohibited, others are to be labelled “high-risk” with correspondingly strict requirements, while other AI systems which pose “limited risk” and “minimal risk” will have to adhere to basic transparency requirements or can operate without facing additional rules, respectively.

The Commission’s aim is to balance the need to protect European citizens, an approach inspired by the General Data Protection Regulation (GDPR), while enabling (or at least not undermining) the uptake of AI systems needed to future-proof European industry.

While many further discussions are needed to establish whether the proposal achieves the right balance and constitutes an effective and feasible way forward, the text certainly provides a basis for discussions in Europe, as well as globally.

Hume Brophy has looked at the proposal in depth and outlines what you need to know.

### HOW ARE AI SYSTEMS CLASSIFIED

Rather than looking at the underlying technology, the proposal focuses on the use of the AI system and the risks and potential harm this implies to persons. Accordingly, four broad categories are created:

- 1 PROHIBITED AI PRACTICES** – which are understood to violate human rights and EU values. It includes AI systems that manipulate human behaviour, exploit vulnerabilities of specific groups, those used for social scoring of persons and the generalised use of AI systems for real-time biometric identification of persons.

*Much remains to be clarified on the ban of AI systems and practices. For example, how will “the use of an AI system that deploys subliminal techniques beyond a person’s consciousness” or that “exploits any of the vulnerabilities of a specific group” be measured in practice?*

- 2 HIGH-RISK AI SYSTEMS** – comprises a broad range of AI systems integrated as safety components of products and so-called stand-alone high-risk AI systems, which pose a high risk of harm to health, safety and fundamental rights of persons.

*Some examples of high-risk AI systems are AI systems used by a bank to assess a person’s creditworthiness, an AI system built as a safety component into an automated vehicle, or an AI system that is a safety component of machinery or toys.*

- 3 ‘LIMITED RISK’ AI SYSTEMS** - comprises AI systems that interact with humans, analyse emotions or provide a biometric categorisation of persons and those that are used to manipulate images, audio or video content, i.e., “deep fakes”.

- 4 ‘MINIMAL RISK’ AI SYSTEMS** - all other AI systems not captured by any of the above categories. No additional rules apply to these AI systems.

Additionally, the proposal contains an empowerment for the Commission to regularly update the list of stand-alone high-risk AI systems and therefore create a “living repository” of AI systems that will need to comply with the rules.

Inclusion in this list will be based on both the intended use of the AI system and its potential harm, with harm being measured through a combination of the severity of the impact and the probability of occurrence.

## WHAT REQUIREMENTS WILL HIGH-RISK AI SYSTEMS FACE?

High-risk AI systems will have to comply with a range of requirements.

*These will include:*



Establishment of a risk management system that runs throughout the lifecycle of the AI system



Data quality and governance



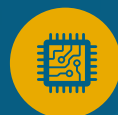
Documentation to make AI outputs verifiable and traceable



Transparency to enable users to understand and control high-risk AI systems



Appropriate safeguards that allow human oversight of the AI system



Robustness, accuracy and (cyber)security of the system

## WHO FACES OBLIGATIONS IN RELATION TO AI SYSTEMS?

First and foremost, providers of high-risk AI systems. The providers will be responsible for ensuring compliance with the requirements, maintaining an appropriate risk management system, ensuring pre-launch approval, drawing up documentation and putting in place an ongoing monitoring system.

**What is a provider?** By providers, the proposal refers to the person or company developing the AI system and placing it on the market or putting it into service. For example, a company that develops an AI system for its own use would be considered a provider. Likewise, a company that develops an AI system that is made available to others would also be considered a provider.

Users of AI systems are also captured. Users should be able to understand and control how the AI system produces outputs. Concretely, users face obligations in terms of managing the AI systems in accordance with the instructions of the provider, monitoring the output and keeping a record of the input data.

**What is a user?** By users, the legislation refers to a person or company under whose authority and responsibility the AI system is used. For example, a company that purchases an AI system to apply it to its own business operations would be considered a user.

In addition, importers of AI systems into the EU, distributors of AI systems, representatives of providers and relevant third parties are also captured by the proposal.

## WHAT HAPPENS IF THE REQUIREMENTS ARE NOT ADHERED TO?

The proposal foresees that EU Member States will lay down “effective, proportionate and dissuasive” penalties in case of infringement, specifying the nature and severity of the penalties.

However, for certain specific infringements the proposal foresees predetermined margins. This is the case when prohibited AI practices are developed or there is a breach of data governance obligations [up to EUR 30 million or 6% of total worldwide annual turnover, whichever

is higher], for the non-compliance of the AI system with any other requirements of the legislation [up to EUR 20 million or 4% of total worldwide turnover, whichever is higher], or in case of supply of incorrect information to relevant authorities [up to 10 million or 2% of total worldwide turnover, whichever is higher].

## WHO WILL OVERSEE AI SYSTEMS?

High-risk AI systems will be subject to both pre- and post-launch assessments. Pre-launch, these systems will be subject to a conformity assessment that may be undertaken by a third-party provider in the case of AI systems integrated as product safety components and AI systems for biometric identification, or via a self-assessment in case of all other stand-alone AI systems.

Once launched, AI systems will be subject to post-market monitoring to review the experience gained and assess whether these systems comply with the rules on an ongoing basis.

National competent authorities and notified bodies will be designated to supervise and accredit AI systems. Stand-alone high-risk AI systems will also have to be registered in a new EU Database before being placed on the market or put into service. This public database is to be established and managed by the European Commission.

## WHAT ABOUT NON-HIGH-RISK AI SYSTEMS?

While the proposal principally targets high-risk AI systems, transparency requirements are also foreseen for certain other AI systems (i.e., “limited risk” AI systems). These refer mainly to notification requirements when an AI system interacts with a person, analyses emotions or provides a biometric categorisation of persons and is used to manipulate images, audio or video content.

All other AI systems (i.e., “minimal risk” AI systems) do not face additional legal requirements.

The European Commission intends to encourage the voluntary uptake of Codes of Conduct for all AI systems, other than high-risk.

## DO THE REQUIREMENTS APPLY TO NON-EUROPEAN AI SYSTEMS?

The legislation is built around the concept of use cases and potential risks and harm to persons. Consequently, the proposal also applies to providers and users of AI systems even if they are based outside the EU, as long as the AI system affects people located in the EU.

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## WHAT ABOUT INNOVATIVE AI SYSTEMS?

The proposal makes provision for national competent authorities and/or the European Data Protection Supervisor to set up AI regulatory sandboxing schemes. These will allow innovative AI systems to be developed and tested under regulatory oversight.

## WHAT HAPPENS NEXT?

This proposal constitutes the beginning of a long journey. It will be heavily scrutinised by both the European Parliament and EU Member States over the coming year before becoming law.

If you would like to hear more about the EU's Digital Agenda, the EU's AI Strategy and how to best engage with EU stakeholders, don't hesitate to get in touch.



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