

RocaJunyent Informs

Data Protection, Cybersecurity and Technology Department
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European Regulation on Artificial Intelligence

On 13 March 2024, the European Parliament has adopted the Regulation on Artificial Intelligence ("Regulation" or "RIA") laying down harmonising rules on Artificial Intelligence ("AI") and obligations on operators of AI systems through a risk-based approach to the fundamental rights of data subjects and the values of the European Union.

What is the scope of application?

The scope of the Regulation extends beyond organisations established in the European Union ("EU") to those using Artificial Intelligence in the **European market**. This means that many multinationals, with a presence or commercial interactions in the EU, will also have to apply it.

When will it be applicable?

The Regulation will be published in the Official Journal of the European Union and will enter into force 20 days later, becoming fully applicable after **two years**. This deadline is subject to certain exceptions determined by the categorisation of the risk associated with AI systems:

- ☐ After **6 months**, the ban on cases of use of AI systems deemed to pose an unacceptable risk to fundamental rights will apply.
- ☐ At **12 months**, the obligations for the governance of General Purpose IA ("GPAI"), which are considered systemic risk, will apply.
- ☐ After **24 months** the Regulation will be fully applicable, except for products already requiring third party conformity assessments (such as medical devices or toys), which are granted **36 months**.
- ☐ Existing high-risk IA systems on the market today will only be subject to the Regulation when they undergo significant design changes. In addition, LRM systems already on the market will have **an additional year** to comply with the regulations.

What is AI?

According to the Regulation, an AI system is considered to be an AI system when it is machine-based, designed to operate with different levels of autonomy, demonstrates adaptive capabilities and can infer from the input it receives, for explicit or implicit objectives, how to generate outputs such as content, predictions, recommendations or decisions that can be inferred in physical or virtual environments.

How does it regulate AI systems?

The Regulation establishes regulation based on risk levels, imposing more obligations on higher risk systems:

- ☐ **Unacceptable risk systems.** All AI systems that violate fundamental rights and public safety are prohibited, as well as those that have a high potential to manipulate people through subliminal techniques, exploit their vulnerabilities and alter their behaviour, or that contravene existing privacy, consumer and digital services legislation (such as facial recognition in public places).
- ☐ **High-risk systems.** High-risk systems are those that may have a negative impact on fundamental rights. Their use is allowed provided that they meet certain requirements (such as risk assessment and mitigation, human supervision, transparency, fundamental rights impact assessment, etc.) and that they obtain a favourable outcome of the conformity assessment to be carried out *ex ante*.
- ☐ **Limited risk systems.** These are general purpose systems, such as *chatbots*. Their use is allowed as long as they comply with specific transparency obligations towards users, among others.

- ☐ **Low or minimal risk systems.** This is a residual category applicable to all AI systems that do not pose a high risk to fundamental rights.

What should companies do now?

It is recommended that companies undertake the following actions with regard to AI:

- ☐ **Audit** the development and use of AI both within the company and in the supply chain.
- ☐ **Define** the ethical principles and limits of AI.
- ☐ **Assess** risks and improve existing controls for the use of AI.
- ☐ **Appoint** internal IA risk officers and establish governance and compliance teams.
- ☐ **Review** due diligence processes with suppliers related to AI procurement and AI-generated services/products.
- ☐ **Review** current contract models and update them to mitigate AI risks.
- ☐ **Maintain** vigilance on legislation and regulatory guidelines.

How is innovation to be supported?

With the aim of strengthening European competitiveness in the field of AI, a *sandbox* is set up to provide a controlled environment for developing, testing and validating innovative AI systems under real-world conditions. The Regulation aims to establish common rules for the creation of a *sandbox* and a framework for cooperation between the supervisory authorities involved. However, the specific requirements for access to *sandboxes* will be determined by the local supervisory authorities. In Spain, Royal Decree 817/2023 of 8 November aims to create the first controlled environment to test the application of certain requirements set out in the Regulation.

Sanctioning regime and supervisory authorities

Penalties for non-compliance with the Regulation may amount to up to EUR 35 million or 7% of the total turnover of the previous financial year. Penalties will be graduated according to the seriousness of the infringement committed. The Regulation requires Member States to establish rules and sanctioning procedures to ensure proper compliance. In Spain, the Spanish Agency for the Supervision of Artificial Intelligence ("AE-SIA") has been created for this purpose.

In addition, the European IA Office has been established to support EU Member States' governing bodies and enforce the standards for the GPAI models.