

Product Risk Radar

EU Regulation on AI

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Overview

The EU's Artificial Intelligence Act (Regulation (EU) 2024/1689) (the "**AI Act**") is a comprehensive legal framework aiming to enhance the development of AI and support its ethical use.

The AI Act is now in force. However, the provisions of the AI Act do not yet apply (with many not coming into force until August 2026 – see below). In the meantime, the European Commission is encouraging companies to sign voluntary pledges in connection with the AI Act (see some brief comments on the AI Pact below).

The AI Act will lead to significant changes to the way in which companies develop, market and use smart digital technologies which include AI. Given AI's reliance on data, the proposed regulation has drawn extensively from existing data protection and cybersecurity rules (most notably, the General Data Protection Regulation), echoing, among other concepts, data processing transparency, data retention limits, implementation of appropriate safeguards to protect data, and data breach notification duties.

Who does the AI Act apply to?

The AI Act has a broad scope, including some extra territorial effect, and applies to:

- (i) providers placing on the market or putting into service AI systems or placing on the market general purpose AI models in the EU, irrespective of whether the providers are established or located within the EU or not;
- (ii) deployers of AI systems that have their place of establishment or are located within the EU;
- (iii) providers or deployers of AI systems that have their establishment or location outside the EU where the output produced by the AI system is user in the EU;
- (iv) importers and distributors of AI systems;
- (v) product manufacturers placing on the market or putting into service an AI systems together with their product and under their own name or trademark;

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- (vi) authorised representatives or providers, which are not established in the EU; and
- (vii) affected persons that are located in the EU.

This note does not contain a complete list of all of the obligations set out in the AI Act. Instead, we have highlighted some of the key obligations in the AI Act, which apply in particular to providers of AI systems.

The AI Act does not affect the application of the provisions on liability of providers of intermediary services set out in the Digital Services Act (Regulation 2022 / 2065). Further, the AI Act is without prejudice to any applicable EU rules on consumer protection and product safety, which companies will need to ensure they comply with.

AI Act in focus

- **Definition** – Article 3(1) of the AI Act defines an AI system as "*a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments*". This definition is intentionally very broad, with the aim of helping to "future proof" the applicability of regulation, and differentiating AI from other software where output is already pre-determined.
- **Risk based approach** – The AI Act takes a risk-based approach to regulating AI. Article 5 of the AI Act sets out a number of AI practices that are considered too high risk and are prohibited. These include, among others:
 - i) AI systems that exploit peoples vulnerabilities due to their age, disability, or social or economic situations;
 - ii) AI systems that create or expand facial recognition databases through the untargeted scraping of facial images from the internet or CCTV footage;
 - iii) real-time remote biometric identification in publicly accessible places by law enforcement (with some exceptions that apply); and
 - iv) AI systems that deploy subliminal techniques beyond a person's consciousness or use purposefully manipulative or deceptive techniques.

The AI Act further distinguishes between high risk, limited risk and minimal or no risk AI systems.

- High risk AI systems are the most heavily regulated systems under the AI Act and are subject to strict obligations before they can be put on the market.
- Limited risk AI-systems are subject to transparency obligations (for example, deployers of an AI system that generates or manipulates image, audio or video content constituting a deep fake are required to disclose that the content has been artificially generated or manipulated).
- AI literacy obligations, for example, apply to minimal or no risk AI systems.

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- **Regulatory framework for “high-risk” AI systems** – An AI system is considered high-risk where:
 - i) the AI system is intended to be used as a safety component of a product, or the AI system is itself a product, which is covered by legislation in Annex I (including machinery, toys and medical devices); and
 - ii) the product is required to undergo a third party conformity assessment to place it on the market or to put it into service under the legislation in Annex I (see above).

AI systems in Annex III are also high risk (e.g., systems relating to management of critical infrastructure), provided that they pose "significant risk" of harm to the health, safety and fundamental rights of individuals (for example, this would not include an AI system which is intended to perform a narrow procedural task). This relates to AI systems deployed in the following specific areas; biometrics, critical infrastructure, education, employment, access to self-employment, access to public services, law enforcement, migration and border control, and the administration of justice and democratic processes.

Inevitably, there are heightened requirements for high-risk AI systems. These high-risk AI systems need, for example:

- to have a risk management systems in place;
- to be developed on the basis of training, validation and testing data that meets certain quality criteria (if they make use of techniques involving the training of AI models with data);
- to have technical documentation drawn up before they are placed on the market or put into service (and that documentation needs to be kept up to date);
- to be designed and developed in such a way as to ensure that their operation is sufficiently transparent so that deployers can interpret its output and use it appropriately;
- to be subject to human oversight;
- to allow automatic recording of events over the lifetime of the AI system (for example to enable situations to be identified which may result in a substantial modification);
- to achieve an appropriate level of accuracy, robustness and cybersecurity.

Regulatory Sandboxes: Article 57 of the AI Act provides that EU Member States shall ensure that their competent authorities establish at least one AI regulatory sandbox at a national level to foster AI innovation. This will provide a controlled environment to facilitate the development, testing and validation of innovative AI systems for a limited time before being placed on the market or being put into service.

High potential penalties: Each Member State is required to set out rules on penalties and enforcement measures. However, the AI Act sets out some requirements in relation to the penalties that can be imposed. For example, for non-compliance with the prohibition on AI practices in article 5 of the AI Act, a company can be subject to a fine of up to 35 million Euros or 7% of a company’s worldwide turnover for the preceding financial year.

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Obligations of “Providers” in relation to high-risk AI systems

A “Provider” is defined to include a person that develops an AI system or a general purpose AI model or has one developed and places it on the market / puts it into service under its name / trademark. Pursuant to the AI Act, a provider of an AI system has various obligations in relation to high-risk AI systems, including the following (this is not a complete list).

- To ensure that high-risk AI systems comply with the requirements set out in the AI Act (see, for example, the requirements set out above).
- To put a quality management system in place (e.g., with a strategy for regulatory compliance).
- To keep technical and other documentation and records (e.g. logs automatically generated by a high-risk AI system).
- To ensure the systems undergo the conformity assessment procedure, draw up a declaration of conformity and affix a CE marking.
- To comply with registration obligations.
- To inform users that they are interacting with an AI system (unless this is obvious).
- To establish and document a post-marketing monitoring system in a manner that is proportionate to the nature of the AI technologies and the risks of the high-risk AI system.
- To take corrective action if a high-risk AI system is not in conformity with the AI Act. If the provider becomes aware that a high-risk AI system presents a risk, it is required to immediately investigate the causes and inform the market surveillance authority of the nature of the non-compliance and any relevant corrective action taken.
- To report any serious incident to the market surveillance authorities of the Member States where the incident occurred (no later than 15 days after the provider or deployer become aware of the serious incident). A "serious incident" means an incident or malfunctioning of an AI systems that directly or indirectly leads to: (i) the death of a person or serious harm to a person's health; (ii) serious and irreversible disruption of the management or operation of critical infrastructure; (iii) infringement of obligations under EU law intended to protect fundamental rights; or (iv) serious harm to property or the environment.

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What is the current status?

The AI Act entered into force on 1 August 2024. Many provisions will apply from August 2026. However:

- some rules, for example, those on prohibited practices will apply from 2 February 2025;
- some rules apply from August 2025 (e.g. those relating to most penalties);
- some rules relating to "high-risk" AI systems will apply from August 2027.

The European Commission announced in September 2024 that over 100 companies have joined the AI Pact and agreed to voluntarily work towards future compliance with the AI Act (e.g. by identifying AI systems likely to be categorised as high-risk under the AI Act and promoting AI literacy and awareness amongst staff to ensure ethical and responsible AI development) (see [here](#)).

Next steps

Businesses that are involved in the development of AI systems (of any sort) should consider what action they need to take in order to comply with any applicable provisions of the AI Act (particularly, given the high penalties than can apply for non-compliance).

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