



BDO Legal Practical Steps for

# Responsible AI Adoption





# #Future

## Introduction

**Regulation (EU) 2024/1689, establishing rules on artificial intelligence** (hereinafter referred to as the "Regulation" or "AI Act"), represents a milestone in the regulation of emerging technologies. It ensures that Artificial Intelligence (hereinafter, "AI") is developed and used in a safe and ethical manner within the European Union, while simultaneously supporting technological innovation without imposing unnecessary restrictions.

**The AI Act ensures that Artificial Intelligence is developed and used in a safe and ethical manner.**

## 1 Who does it apply to?

The AI Act applies to all organisations within the European Union, as well as foreign entities that intend to use, develop, or market AI products in the EU market.

Only certain areas are excluded, such as military, defence, national security, scientific research, and purely personal activities, among others.

## 2 What is meant by Artificial Intelligence?

An AI system is defined as any machine-based system that operates autonomously and learns from its environment.

Any company may assume one of the following two main roles in relation to an AI system:

- **Developer/Provider of the system:** the company or individual who develops and offers the AI system.
- **Deployer:** the entity that uses or implements an AI system within its organisation.

## 3 What obligations does the AI Act impose?

The AI Act classifies AI systems according to their risk level. Systems deemed high-risk must comply with stricter requirements to ensure safety and reliability, whereas low-risk systems are subject to more flexible obligations.

It also introduces a list of prohibited practices which will be banned within the European Union six months after the Regulation enters into force.

Obligations vary depending on the company's role regarding the AI system (provider or deployer), and include: notifying and registering AI systems, conducting conformity assessments, drafting and approving internal use policies, informing users about the AI system, ensuring product and data security, creating supervisory authorities and regulatory sandboxes, among others.

## 4 How does the AI Act affect all companies?

To assess their obligations, all companies must understand the risk level of the AI systems they develop or use.

It is essential for companies to be prepared to meet the relevant requirements, and to protect both users and employees.

### Companies developing AI:

If your company is developing AI systems, you must adapt to the AI Act by:

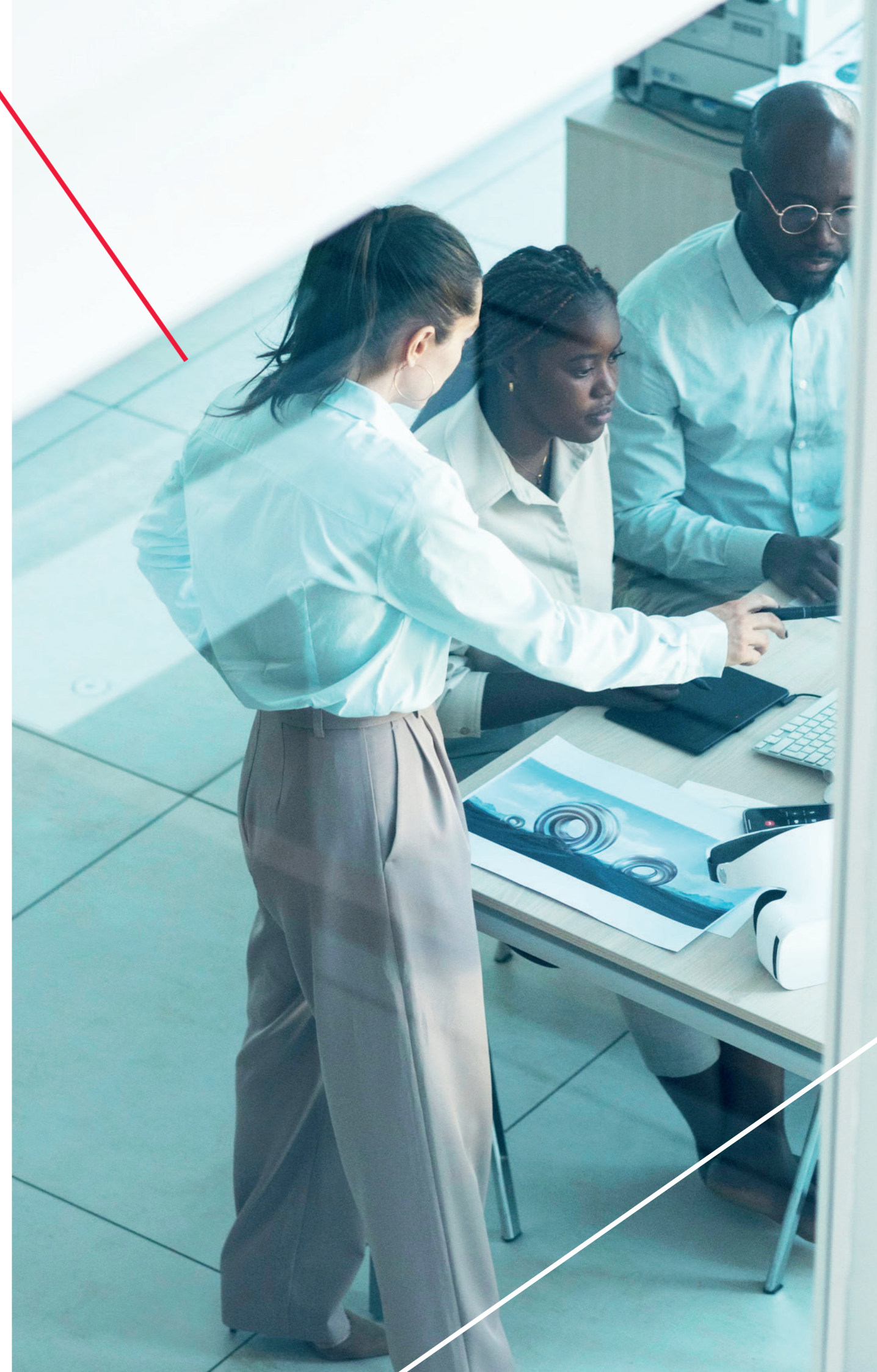
- Carrying out risk assessments to ensure systems meet safety requirements.
- Demonstrating compliance with the Regulation and submitting products for audits if necessary.
- Implementing ethical and transparency principles from the early development stages.

### Companies deploying AI:

If your business activities involve using AI systems developed by third parties, your company is responsible for ensuring their safe use and compliance with the provider's guidelines. This includes:

- Training staff to properly oversee AI usage.
- Ensuring the data used is representative and appropriate for the tasks carried out by the AI.
- Monitoring the system and reporting incidents to the relevant authorities.

**All companies must understand the risk level of the AI systems they develop or use.**



## 5 What is the timeframe for companies to adapt to this regulation?

Although the general deadline for compliance is two years from the AI Act's entry into force (2 August 2026), some key dates precede this and should be noted:

### 2 February 2025

- **Prohibited practices:** unacceptable risk AI practices banned from this date.

### 2 August 2025

- Rules for general-purpose AI models.
- AI-related sanctions (excluding fines for general-purpose model providers).
- Appointment of competent authorities in Member States.
- Establishment of EU governance bodies for AI and their confidentiality obligations.

### 2 August 2027

- Obligations concerning AI systems that are part of safety components in products regulated under EU harmonisation legislation and subject to third-party conformity assessments.

## 6 Consequences of non-compliance: Sanctioning regime

The Regulation sets out a sanctioning regime to ensure compliance with AI rules.

- **For prohibited practices**, fines can reach up to €35 million or 7% of the company's annual global turnover, whichever is higher.
- **For other breaches**, fines may go up to €15 million or 3%.
- **For providing misleading information**, penalties may reach €7.5 million or 1%.

For small and medium-sized enterprises, including start-ups, the lower of the amounts or percentages will apply.

## The Regulation sets out a sanctioning regime to ensure compliance with AI rules.

## 7 How can BDO Legal help?

The European AI Regulation not only imposes obligations but also opens up significant opportunities, strengthening companies' positions in an increasingly regulated and demanding market. Proactively complying with regulations will not only help avoid penalties but also enhance a company's reputation and foster trust among customers and business partners through the safe and ethical use of AI.

BDO Legal supports companies in adapting efficiently to the new regulations by offering assistance in key areas:

### Defining Scope, Roles and Legal Duties

Determine whether your systems fall under the AI Regulation and clarify your organisation's role – provider, deployer, or user – along with associated legal responsibilities.

### Transparency and Ethical Use

Fulfil transparency obligations with clear, accessible explanations of AI's role in decisions, reinforcing ethical and responsible use.

### Strategic AI Integration

Identify business areas where AI can enhance operations and support the seamless implementation of suitable AI tools.

### Registration and Compliance Checks

Expert assistance with system registration where required, plus verification of regulatory compliance and identification of any gaps or shortcomings.

### Governance and Internal Policies

BDO Legal supports the development of internal AI policies, establishes governance frameworks, and helps define responsibilities for oversight and compliance.

### Executive Training and Awareness

Training programmes tailored for leadership teams to build awareness of AI's regulatory, ethical, and strategic dimensions.

### Risk, Rights and Impact Assessments

Assessments of high-risk AI systems' impact on individual rights, combined with proactive risk management to reduce exposure to bias, data misuse and sanctions.

### Contractual Support

Drafting and reviewing of AI-related agreements, including service contracts, licences, terms of use, and technology partnerships.

### Compliance and Maturity Assessments

BDO Legal evaluates your organisation's readiness for AI regulation, providing a roadmap for reaching full compliance and operational maturity.

### GDPR and Confidentiality Compliance

Ensure alignment with GDPR while protecting intellectual property and safeguarding confidential information across the AI lifecycle.

### Quality Management Documentation

Preparation and review of QMS documentation required by the AI Regulation, including procedures and written controls for high-risk systems.

### Leveraging Compliance for Growth

Transform regulatory alignment into a competitive edge by positioning your business as a trusted, ethical innovator in AI-driven markets.

With BDO Legal's assistance, your company can not only ensure compliance with the Regulation but also fully capitalise on the opportunities that AI offers in a safe and ethical regulatory environment. Assessing the Regulation's impact and taking the appropriate steps is crucial to remaining competitive in the global market.



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Taking the appropriate steps is crucial to remaining competitive in the global market.

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