



Executive Brief: Understanding the EU AI Act

Prepared by Dynamic Comply

The **European Union Artificial Intelligence Act (AI Act)** (Regulation (EU) 2024/1689) is the world's first comprehensive legal framework for AI. Its primary goal is to ensure that AI systems used in the EU are **safe, transparent, accountable, and respect fundamental rights**. The Act entered into force on **August 1, 2024**, with provisions applying gradually over the following months and years. Most provisions will apply from **August 2, 2026**.

Risk-Based Approach

The core of the AI Act is a **risk-based approach**, classifying AI systems based on their potential to harm health, safety, and fundamental rights.

- **Unacceptable Risk: Banned systems** that violate fundamental rights. This includes real-time biometric identification in public spaces, with limited law enforcement exceptions requiring prior authorization. Prohibition applies from **February 2, 2025**.
- **High Risk:** Permitted but subject to **mandatory requirements** and **conformity assessment** before market entry. These include AI systems as safety components or those with fundamental rights implications listed in Annex III. Obligations cover risk management, data governance, technical documentation, record-keeping, transparency, human oversight, accuracy, robustness, and cybersecurity. Providers and deployers have distinct duties. Public authorities using certain high-risk systems must register them in an EU database. These rules largely apply from **August 2, 2026**.
- **Limited Risk:** Subject to **transparency obligations**, such as labelling AI-generated content (e.g., chatbots, deepfakes).
- **Minimal Risk:** Generally **no specific obligations** (e.g., spam filters).

Key Requirements & Concepts

- **Risk Management System:** High-risk AI system providers must establish and maintain a continuous, iterative risk management system throughout the system's lifecycle.
- **Human Oversight:** High-risk systems require human oversight measures. Deployers must assign human oversight to competent, trained individuals.
- **Fundamental Rights Impact Assessment:** Deployers of high-risk AI systems must conduct this assessment. The AI Office will provide a template questionnaire to assist.

- **General-Purpose AI (GPAI) Models:** Specific rules apply, especially for GPAI models with systemic risks. Providers must make publicly available a summary of the training data, including copyrighted material, using a template from the AI Office.
- **Transparency:** Obligations for certain AI systems. Content modified or generated by AI must be labelled.
- **Post-Market Monitoring:** Providers of high-risk AI systems must implement systems to monitor their performance over their lifetime.
- **Conformity Assessment:** High-risk AI systems must undergo this assessment before market placement or service. Certificates from notified bodies are valid for up to four years for most Annex III systems.
- **AI Literacy:** Measures to ensure sufficient AI literacy for those dealing with AI systems are required. Applies from **February 2, 2025**.
- **EU Database:** A public EU database for registering high-risk AI systems will be established.

Governance & Scope

Governance involves the **AI Office**, the **European Artificial Intelligence Board**, and **National Competent Authorities**. The Act applies to **providers and deployers** of AI systems within the EU, and potentially extraterritorially if their systems affect people in the EU. Exceptions exist for military, national security, research, and non-professional use.

Support for SMEs

The Act includes measures to support SMEs and start-ups, such as priority access to AI regulatory sandboxes, simplified documentation, proportionate compliance costs, and targeted guidance. SMEs are defined based on employee count and turnover/balance sheet total. Microenterprises may have simplified quality management system obligations.

Penalties

Non-compliance can lead to significant fines. The highest fines are for prohibited AI systems (up to €35M or 7% of global annual turnover). Lower fines apply for other infringements. Fines for SMEs are capped at the lower threshold.

Dynamic Comply helps organizations align with these requirements through tailored audits and advisory services.