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### **The European Union's Artificial Intelligence Act and Strategic Vision**

In April 2021, the European Union introduced the world's first comprehensive artificial intelligence regulation proposal, placing the secure and responsible use of innovative technologies at the heart of its digital strategy. Adopted in July 2024 and entering into force in August, this regulation marks a significant milestone that reinforces Europe's ambition to lead globally in the digital domain.

Beyond imposing restrictions on certain AI applications, the Artificial Intelligence Act (AI Act) establishes a comprehensive governance framework aimed at shaping Europe's digital future based on public interest and ethical principles. The two-year transition period granted to Member States has been structured to ensure balanced and consistent implementation of this transformation.

Aligned with its objective of strengthening digital sovereignty, the European Union positions the AI regulation not merely as a technical framework but as a tool for long-term strategic capacity building. Reflecting this approach, the AI Act transcends regulatory boundaries to present a holistic policy framework centered on public interest, ethical values, and sustainable competitiveness.

Meanwhile, the Draghi Report emphasizes the critical role of digital public infrastructure in enhancing Europe's competitiveness. This highlights that the EU's efforts to shape its digital future encompass not only legal but also structural and economic dimensions.

## Background

In response to the rapid advancement of artificial intelligence technologies in recent years, the European Union has adopted a multi-layered policy approach that focuses not only on economic benefits but also on the ethical, social, and governance-related risks associated with these technologies.

The digital transformation process has necessitated the development of an inclusive governance model capable of addressing society's increasing demands for data security, justice, transparency, and accountability. The "Digital Strategy for Europe" published in 2020, together with the "White Paper on Trustworthy Artificial Intelligence," outlined the initial framework of a regulatory approach that simultaneously promotes innovation while safeguarding fundamental rights. These documents provided a roadmap for the EU's value-based digital governance.

The European Parliament, within the scope of this regulatory process, has advocated not only for technical standards but also for prioritizing value-driven principles such as human dignity, environmental responsibility, and ethical design. The Parliament emphasized principles such as transparency, traceability, human oversight, and the prevention of discrimination in AI applications, and supported the inclusion of a principle-based, adaptable definition of AI systems within the legal framework. This approach prioritizes not only the technical safety of AI systems but also their design in a way that contributes to public benefit. AI has the potential to directly contribute to various fields, from the efficiency of healthcare systems to environmental sustainability, from transportation safety to energy savings.

This regulation not only provides a technical framework for Europe's digitalization process but also legally secures the Union's determination to reflect its own values and strategic autonomy within the digital realm.

## Scope, Application Areas, and Risk-Based Structure of the AI Act

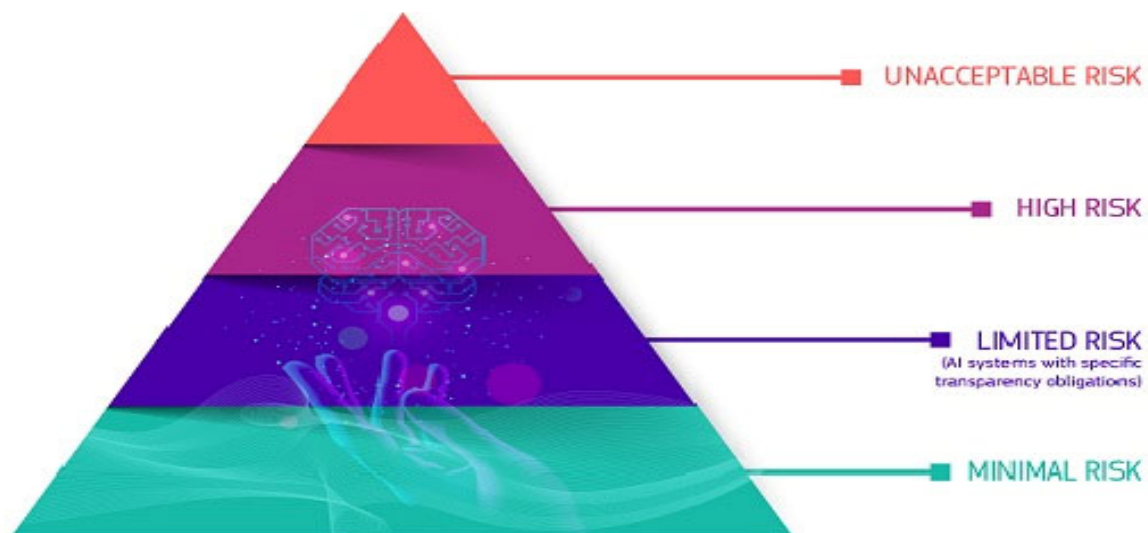
### Implementation

The European Parliament has established a Working Group to oversee the implementation of the AI regulation and support the development of the digital sector. This Group operates in coordination with the European Union Artificial Intelligence Office. The scope of the AI Act is not limited to actors developing these technologies; it also includes all parties involved in the marketing or professional use of AI systems. Developers, importers, distributors, and professional users are explicitly included within the regulatory framework, with clearly defined obligations.

The regulation mandates that companies outside the European Union must comply with the same rules if they place products or services on the EU market. In this respect, the AI Act is not merely a domestic market regulation; similar to the General Data Protection Regulation (GDPR), it constitutes a normative framework with cross-border effects, exemplifying the EU's strategy of achieving global influence through regulation. Moreover, certain areas, such as the defense industry, are excluded from the regulation; limited exemptions are foreseen for systems developed for experimental purposes. However, if such systems are commercialized, full compliance with the regulation becomes mandatory.

## Risk Categories

The AI Act follows a differentiated regulatory approach based on the potential impact of systems on individuals and society, prescribing intervention and oversight mechanisms appropriate to each risk level.



Kaynak: European Commission. A Risk-Based Approach. Retrieved from <https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai>

### 1- Unacceptable Risk Systems

Under EU legislation, certain AI systems are entirely prohibited due to their potential to seriously violate fundamental rights. Systems that subconsciously manipulate individuals' behavior or thought processes—for example, toys encouraging children to engage in dangerous activities—are included in this category. Additionally, systems that assign scores to individuals based on social behavior or economic status (social scoring), as well as applications that enable real-time facial recognition of individuals in public spaces, are also prohibited.

Although specific exceptions are granted for law enforcement agencies, these are subject to strict conditions and judicial oversight.

## 2. High-Risk Applications

AI systems that directly affect public safety, fundamental rights, and individual freedoms are classified as high-risk. These systems are utilized not only in technical sectors such as healthcare or transportation but also in public-impact areas such as education, recruitment, access to social benefits, judiciary processes, and border control. High-risk AI applications are subject to comprehensive conformity assessments before being placed on the market and are monitored and controlled regularly throughout their operational use. Users also retain the right to lodge formal complaints with national authorities regarding such systems.

## 3. Limited Risk Systems

Although some AI systems do not pose direct physical or legal threats, they carry the risk of information manipulation and misleading users. In such applications—for instance, chatbots or content-generating tools—users are legally required to be informed that they are interacting with AI. Accordingly, transparency and user notification obligations have been mandated for limited-risk systems.

## 4. Minimal Risk Systems

Certain AI applications are used in areas such as entertainment or automated message filtering and carry virtually no serious risk. These systems are not subject to direct legal supervision; however, guiding principles and best practice recommendations based on voluntary compliance are proposed to enhance ethical alignment.

## The AI Act's Implementation Timeline and Phased Compliance Process

The European Union adopted the world's first comprehensive regulatory framework in the field of artificial intelligence when the European Parliament approved the AI Act on March 13, 2024. It was finalized with the Council's approval on May 21. While the AI Act will become fully applicable 24 months after its entry into force, certain provisions will take effect earlier.

In particular, the prohibitive provisions regarding artificial intelligence systems classified as posing unacceptable risks entered into force on February 2, 2025. The implementing rules of the Act will generally enter into force nine months after the regulation becomes effective. Provisions concerning general-

purpose artificial intelligence systems, which must comply with transparency obligations, will apply 12 months after the regulation's entry into force.

For systems falling under the high-risk category, the compliance obligations will become applicable at the end of a 36-month period, resulting in a longer phased compliance timeline for such systems.

### **Sanctions Applicable Under the AI Act**

The AI Act requires Member States to establish effective, proportionate, and dissuasive sanctions for non-compliance with its rules concerning artificial intelligence systems. The regulation explicitly sets out upper thresholds for financial penalties.

In cases involving prohibited practices or violations of data management rules, fines can reach up to 7% of a company's total worldwide annual turnover from the previous financial year, or €35 million, whichever is higher. For breaches of other regulatory obligations, this limit is set at 3% of turnover or €15 million. Furthermore, incomplete, misleading, or incorrect responses to official information requests may result in fines of up to €7.5 million or 1.5% of turnover.

For small and medium-sized enterprises, the applicable thresholds are set at lower levels, calculated based on the lesser of the two options defined for each category. Developers of general-purpose artificial intelligence who fail to comply with obligations defined by the European Commission may also face proportionate administrative sanctions. EU institutions, agencies, and bodies are subject to the regulation as well. Within this scope, the European Data Protection Supervisor holds the authority to impose fines on relevant organizations in cases of non-compliance.

### **Conclusion and Assessment**

The AI Act constitutes a comprehensive governance vision aimed at shaping Europe's digitalization process not only through technical measures but also with ethical and strategic considerations. By adopting a risk-based regulatory approach that differentiates between systems based on potential impacts, the Act prioritizes safety and ethical standards while simultaneously promoting innovation in a sustainable manner.

The regulatory approach adopted by the AI Act seeks to position Europe not merely as a technological regulator, but as a global actor that establishes norms and generates value in the digital domain. The Act, structured around principles such as human dignity, accountability, and transparency, offers a strategic framework designed to anticipate the societal impacts of artificial intelligence applications and to foster public responses to such impacts.

However, the success of the regulation will depend not only on the quality of its legal provisions but also on the governance capacity demonstrated during its implementation phase. In particular, the compliance process for small and medium-sized enterprises, the level of guidance provided by national authorities, and oversight practices related to general-purpose AI models will directly influence the framework's effectiveness. Moreover, considering its cross-border effects, Turkish companies engaged in economic and technological interactions with Europe will inevitably need to update their compliance strategies in accordance with this new framework.

In conclusion, the AI Act is not merely a legislative instrument underpinning Europe's digital strategy; it is also a long-term vision document aiming to establish a participatory and sustainable digital order centered on ethical values. Combined with an effective and inclusive implementation process, this regulation has the potential to become a global reference framework for artificial intelligence governance, extending its influence beyond the European continent.



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