



Legal Flash

Human-led | AI-powered



March 2024

In brief

New Artificial Intelligence Act: What You Need to Know

On 13 March 2024, the European Parliament and the Council adopted the Regulation on laying down harmonized rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts. This is the first comprehensive legal framework for artificial intelligence (AI) in the EU, aiming to promote the development and uptake of trustworthy and human-centric AI, while ensuring a high level of protection of health, safety, fundamental rights and the environment.

In detail

Scope, Definitions, and Risk-based Approach

The Regulation applies to providers, deployers and users of AI systems in the EU, as well as to providers and users located outside the EU when the output produced by the AI system is used in the EU. It defines an AI system as "software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with".

The Regulation establishes a risk-based approach, distinguishing between unacceptable, high-risk and low or minimal risk AI systems. Unacceptable AI systems are those that contravene the values and rights of the EU, such as those that manipulate human behavior, exploit vulnerabilities, or use social scoring for general purposes. These AI systems are prohibited.

Regulatory Framework for High-Risk AI Systems: Requirements and Obligations

High-risk AI systems are those that pose significant risks to health, safety, fundamental rights or democracy, such as those used for critical infrastructure, law enforcement, education, employment, essential private and public services, migration, asylum and border control, and administration of justice. These AI systems are subject to strict requirements, such as:

- compliance with mandatory quality criteria, such as data quality, technical robustness, accuracy, human oversight and transparency;
- conformity assessment procedures, involving internal checks or external audits, depending on the type of AI system and product;
- registration in an EU database before placing on the market or putting into service;
- provision of clear and meaningful information to users and affected persons;

- establishment of risk management and quality management systems;
- cooperation with market surveillance and competent authorities;
- performance of fundamental rights impact assessments by public authorities or private operators providing public services.

Low or minimal risk AI systems are those that pose limited or no risks to health, safety, fundamental rights, or democracy, such as those used for entertainment, marketing, video games, or spam filters. These AI systems are subject to transparency obligations, such as informing users when they interact with an AI system or when the content they see is generated or manipulated by an AI system.

General-Purpose AI Models: Classification, Obligations, and Supervision

The Regulation also introduces specific rules for general-purpose AI models, which are AI systems that can be used for multiple purposes, some of which may be high-risk. These AI models are subject to classification rules and procedures, based on their capabilities and potential systemic risks at the EU level. General-purpose AI models with systemic risk are those that can cause significant harm to the health, safety, fundamental rights or democracy of a large number of persons in the EU. These AI models are subject to additional obligations, such as:

- notification to the Commission when they meet certain thresholds or benchmarks;
- inclusion in a list of general-purpose AI models with systemic risk, published and updated by the Commission;
- provision of technical documentation and transparency information to the Commission and the public;
- adherence to codes of practice, developed by the Commission with the assistance of the European Artificial Intelligence Board and the scientific panel;
- cooperation with the European Artificial Intelligence Office, which is the EU body responsible for the supervision and enforcement of the Regulation as regards general-purpose AI models.

Governance Framework: Roles, Responsibilities, and Oversight

The Regulation establishes a governance system, involving the Commission, the European Artificial Intelligence Board, the scientific panel, the national competent authorities, the market surveillance authorities, and the notified bodies. These actors have different roles and tasks, such as:

- providing guidance, advice, opinions and recommendations on the implementation and interpretation of the Regulation;
- developing standards, specifications, benchmarks and methodologies for AI systems;
- monitoring and evaluating the compliance, performance and impact of AI systems;
- conducting investigations, inspections, evaluations and audits of AI systems;
- imposing sanctions and remedies for non-compliance with the Regulation;
- facilitating the exchange of information, best practices and cooperation among stakeholders;
- supporting innovation and experimentation through AI regulatory sandboxes, which are controlled environments for testing innovative AI systems under regulatory oversight.

Implementation Timeline and Implications for Stakeholders

The Regulation will enter into force 20 days after its publication in the Official Journal of the EU, and will apply two years after its entry into force, with some exceptions for certain AI systems and models. It will have a significant impact on the development, deployment and use of AI systems in the EU, and will require market stakeholders, legal practitioners and public authorities to adapt to the new rules and obligations.

[The section you just read is entirely powered by AI]

Catalysts for AI Compliance

Imminent actions for companies and organizations

Strategic AI Assessment

Companies should Evaluate their organization's current and planned usage of AI systems. Such an evaluation is not merely a technical review but should play the role of a strategic analysis that involves understanding the nuances of informed decision-making, the influence of human behavior, the potential for bias, and the recognition of technological limitations inherent in AI systems.

Categorizing AI Assets

All organizations should conduct a thorough categorization of AI applications used, under the Act. It is important to review IT assets to identify what qualifies as AI under the EU AI Act. Such AI systems must then be sub categorized based on risk as defined in the Act. This latter categorization is crucial as it determines the level of scrutiny and regulatory requirements applicable for each system.

Implementing Internal Guidelines

Companies should create and implement internal guidelines and policies regarding the use of AI, to ensure ongoing compliance and accountability for all employees and stakeholders. This should include the collection of relevant information and the maintenance of required documentation.

Ensuring Ethical AI Use

It is of utmost importance for all organizations to ensure responsible use and assess ethical implications of their AI usage. By setting up comprehensive safeguards, companies can ensure that their use of AI is not only compliant with the law but also aligns with ethical standards, thereby safeguarding their reputation and avoiding potential legal entanglements.

Compliance Roadmap

The takeaway

In conclusion, compliance with the AI Act requires a proactive and methodical approach. Businesses must review, categorize, document, and ethically align their AI systems with the new regulations. By doing so, they can ensure that their use of AI is responsible, compliant, and ultimately a tool for growth and long-term success.

Let's talk

For a deeper discussion of how EU AI Act might affect your business,
please contact:



Vassilios Vizas

Partner, Leader of Tax & Legal Services, PwC Greece

Tel: +30 210 6874019
E: vassilios.vizas@pwc.com



Kalliopi Vlachopoulou

Head of Regulatory, Digital Law & Innovation, PwC Greece

Tel: +30 21 0811 4388
E: kalliopi.vlachopoulou@pwc.com

www.pwc.gr This information is intended only as a general update for interested persons and should not be used as a basis for decision-making. For further details please contact PwC: 268, Kifissias Avenue 15232 Halandri tel. +30 210 6874400 © 2024 PricewaterhouseCoopers Business Solutions AE. All rights reserved. PwC refers to the Greece member firm, and may sometimes refer to the PwC network. Each member firm is a separate legal entity. Please see www.pwc.com/structure for further details.