Baker McKenzie.

Product Risk Radar
EU Regulation on AI

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Overview

In April 2021, the European Commission published a proposal for a Regulation laying down harmonised rules on artificial intelligence (the "**AI Act**"). Following this, the Council of the European Union put forth their common position on the AI Act and, in June 2023, the European Parliament adopted their negotiating position. This has triggered interinstitutional negotiations aimed at finalising the text of the AI Act, which is stated to be completed by the end of 2023, for voting by early 2024. No other jurisdiction has yet taken a step of this nature; Europe seems determined to lead the world in this important area of technology policy.

If implemented in line with the Commission's proposal, the AI Act will lead to significant changes to the way in which companies develop, market and use smart digital technologies in virtually all its forms. 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.

AI Act in focus

- **Definitions** - The definition of AI in the Commission's proposal is very broad, with the aim of helping to *"future proof"* the regulation. The AI Act will apply to <u>any</u> software developed using certain broadly defined AI approaches and techniques that can generate outputs "*influencing the environments they interact with*". As such, the AI Act may encompass technologies that many may not consider to be <u>true</u> AI. However, the EU Council and Parliament, in line with the OECD's definition of AI, have adopted a narrower definition that is focused on machine-learning capabilities to avoid including traditional computational software within the remit of the definition. The Parliament also proposes allowing AI systems to be, *"used as stand-alone software system, integrated into a physical product (embedded), used to serve the functionality of a physical product without being integrated therein (non-embedded) or used as an AI component of a larger system"*.

- **Risk based approach** – The AI Act proposed by the Commission takes a risk-based approach to regulating AI, which is echoed by the Parliament's negotiating position. It identifies AI practices that are too high risk and are prohibited. The Commission and Parliament's positions differ as to which should be banned in their entirety; for example, the Commission's proposal allows some exceptions to their proposed ban on the use of real time remote biometric identification systems in publicly accessible spaces by law enforcement agencies while the Parliament proposes prohibiting this entirely. Both bodies set out detailed regulatory requirements for "high-risk" AI systems, provide transparency requirements for some AI systems (e.g., those intended to interact with people, emotion recognition or biometric systems), and envisage voluntary regulation of low-risk AI systems via codes of **conduct**.

- **Regulatory framework for "high-risk" AI systems** – AI systems which have an adverse impact on people's safety or their fundamental rights are considered high risk by the Commission. This includes where: (i) the AI system is intended to be used as a safety function in certain products, or which is covered by legislation in Annex II (including IoT products, robotics and other 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. AI systems in Annex III are also high risk (e.g., systems relating to management of critical infrastructure). The Parliament proposes that AI systems in Annex III that pose 'significant risk' to the health, safety and rights of individuals, are also considered high risk. Additionally, it suggests that social media engines classified as Very Large Online Platforms (**VLOPS**), as defined under the Digital Services Act (**DSA**), be included as well, alongside election-influencing systems.

Pursuant to the AI Act, there are heightened requirements for these high-risk AI systems, for example the need for:

- risk management systems to be in place;

- human oversight to be maintained;

- those AI systems to be designed and developed with capabilities enabling automatic recording of events while the system is operating, e.g. to enable monitoring of when an AI system presents a risk or leads to substantial modification;

- certain high-risk AI systems to be registered, with specified information about the system stored on a publicly available database;

- providers of high-risk AI systems to establish and document post-market monitoring systems to cover the whole product life cycle; and

- reporting to the authorities, within 15 days, incidents caused by the failure of a high-risk AI system that have, or potentially could have, resulted in serious injury or damage to property.

Obligations of "Providers" in relation to high-risk AI systems

A "Provider" is defined to include a person that develops an AI system or has an AI system developed with a view to placing it on the market or putting it into service under its name / trademark. Pursuant to the Commission's draft of the AI Act, a provider has various obligations, including:

- to put a quality management system in place (e.g., with a strategy for regulatory compliance and test procedures for post development of the system), to draw up technical documentation, and to ensure the systems undergo the conformity assessment procedure.

- to establish and document a post-market monitoring system (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 Regulation. If the authorities find that an AI system is in compliance with the Regulation but presents a risk to health or safety, the authorities can require the operator to take measures including to recall it.

Under the Parliament's proposal, providers of foundational models would be required to register them in an EU database, mitigate any risks detected, and comply with certain design and environmental requirements. Providers of general purpose AI that use large language models would need to comply with strict regulations surrounding transparency, including informing those who receive AI-generated content that it was AI-generated and providing information about the model's training data. Providers also need to make available all information needed for downstream providers to be able to comply with the Act.

- **Obligations of "product manufacturers" in relation to high-risk AI systems:** Where a high-risk AI system relating to a product under Annex II (e.g. the Machinery Directive) is placed on the market or put into service with that product, under the name of the product manufacturer, the manufacturer of the product has responsibility for compliance with the AI Regulation (and the product manufacturer has the same obligations as the Provider).

- **Regulatory Sandbox:** The Commission and the Parliament have envisaged the creation of regulatory sandboxes 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.

- **Conformity Assessments:** High-risk AI systems are to undergo a new conformity assessment procedure whenever they are substantially modified, regardless of whether the modified system is intended to be further distributed or continues to be used by the current user. For high-risk AI systems that continue to learn after being placed on the market / put into service, changes to the system and its performance that have been pre-determined from the initial conformity assessment do not constitute a substantial modification.

- **Extraterritorial effect:** Obligations will extend to providers and users based outside of the EU where, for example, the output produced by the system is used in the EU.

- **Enforcement:** The Commission's proposal for the AI Act imposes very significant administrative fines for particular breaches of the regulation including, for example, non-compliance of the AI system with requirements or obligations which could lead to administrative fines of up to 20 million Euros or 4% of a company's worldwide annual turnover. The Parliament has proposed harsher penalties; those who do not comply with the regulations are fined up to 40 million Euros or 7% of global turnover, whichever is the larger amount.

Why is this development important?

Businesses that are involved in the development of AI systems (of any sort) will be obliged to comply with the provisions of the AI Act. This means that they will be legally required to meet a defined list of criteria before those AI systems can be introduced into the single market. The extent to which the AI Act will truly support a thriving and innovative digital economy, rather than stifle progress in this area, remains to be seen.

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What is the current status?

'Trilogue' negotiations between the Council, Commission and Parliament have been completed and a provisional agreement has been reached. Once finally approved, the AI Act will become effective 20 days after publication in the Official Journal and will then need to be implemented by Member States within 24 months, except for some specific provisions; (i) prohibitions will be applicable after 6 months from the date of entry and (ii) the General Purpose AI obligations will apply after 12 months from the date of entry.

To assist companies and individuals throughout the transition period, the Commission will be launching an 'AI Pact' to assist companies and individuals to comply on a voluntary basis ahead of the deadline.

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