Parliament approved the Artificial Intelligence Act that ensures safety and compliance with fundamental rights, while boosting innovation.

EU Regulation COM (2021) 206 – AI Act

The AI Act aims to protect fundamental rights from high-risk AI, while boosting innovation and establishing Europe as a leader in the field. The regulation establishes obligations for AI based on its potential risks and level of impact.

AI systems that can be used in different applications are analysed and classified according to the risk they pose to users. The different risk levels are related to more or less regulation.

The new rules establish obligations for providers and users depending on the level of risk from artificial intelligence.

The AI Act bans the unacceptable-risk AI systems, considered a threat to citizens' rights, including: biometric categorisation systems based on sensitive characteristics and untargeted scraping of facial images from the internet or CCTV footage to create facial recognition databases, emotion recognition in the workplace and schools, social scoring, predictive policing (when it is based solely on profiling a person or assessing their characteristics), and AI that manipulates human behaviour or exploits people's vulnerabilities.

The high-risk AI systems potential harm to health, safety, fundamental rights, environment, and democracy. Such systems must assess and reduce risks, maintain use logs, be transparent and accurate, and ensure human oversight. Citizens will have a right to submit complaints about AI systems and receive explanations about decisions based on high-risk AI systems that affect their rights. All high-risk AI systems should be assessed before being put on the market and throughout their lifecycle.

General-purpose AI (GPAI) systems and the GPAI models they are based on must meet certain transparency requirements, including compliance with EU copyright law and publishing detailed summaries of the content used for training. The more powerful GPAI models that could pose systemic risks will face additional requirements, including performing model evaluations, assessing, and mitigating systemic risks, and reporting on incidents.

Additionally, artificial or manipulated images, audio, or video content ("deepfakes") need to be clearly labelled as such.

The law aims to offer start-ups and small and medium-sized enterprises opportunities to develop and train AI models before their release to the public.

That is why it requires that national authorities provide companies with a testing environment that simulates conditions close to the real world.

Italian Bill on Artificial Intelligence

The Council of Ministers, n. 78 of April 23, 2024, approved a bill that regulates the use of artificial intelligence in the sectors entrusted by the Regulation to the normative autonomy of the Member State.

The bill was presented to the Senate for approval on May 20 (AS 1146).

The objective of the bill is to promote "a correct, transparent and responsible use, in an anthropocentric dimension, of artificial intelligence, aimed at seizing the opportunities" (Article 1) to improve the living conditions of citizens and social cohesion.

The measure introduces regulatory criteria, principles and sector- specific rules, in order to find a balance between the use of new technologies and the risk associated with their improper use.

The rules intervene in the five areas of the national strategy:

- National authorities;
- Promotion actions;
- Protection of copyright;
- Criminal sanctions;
- Delegation to Government for adaptation to the European Regulation and for the regulation of hypotheses of the use of artificial intelligence for illicit purposes.

The text consists of 26 articles, among which the rules that dictate the principles that must govern the entire life cycling of AI systems and models are particularly relevant, for the research, experimentation, and development phase to the application and use phase (Articles 3,4,5,6).

Article 3 provides that life cycle of AI systems and models is based on respect for fundamental rights and principles of transparency, security, protection of personal data, robustness, accuracy, non-discrimination, and sustainability.
Development and concrete application must take place respecting the autonomy and decision-making power of human, based on the anthropocentric approach of the bill and the European Regulation.

The use of AI must not jeopardize the democratic life of the country, cybersecurity must be guaranteed throughout the life cycle of AI systems and models and people with disabilities must have full access to AI systems without discrimination.
The use of AI must respect media pluralism, freedom of expression, and impartiality and completeness of information, to ensure data, subjects must have the right to object to the incorrect processing of their data (Article 4).

The State and the public authorities promote the use of AI to improve productivity and start new economic activities to increase the competitiveness of the national economic system (Article 5).
The presidency of the Council of Ministers plays a central role in defining and implementing the national AI strategy (Article 17), designates the Agency for digital Italy (AgID) and the National Cybersecurity Agency as the national Authorities for AI (Article 18), delegates the Government to adopt the necessary legislative decrees for the adaptation of national regulation to the European regulation, particularly in the area of the literacy in AI within the school and university curricula, and to define the discipline in cases of use of artificial intelligence for illicit purposes.

Article 3 contains the fundamental principles and stipulates that the life cycle of AI systems and models must be based on the respect of fundamental rights and freedoms of the Italian and European legal systems, as well as the principles of transparency, proportionality, security, personal data protection, confidentiality, robustness, accuracy, non-discrimination, and sustainability.

Development and practical application must respect human autonomy and decision-making power, as imposed by the anthropocentric approach that characterizes the bill and the European regulation. It is established that the use of AI must not prejudice the democratic life of the country and its institutions, ensure cybersecurity throughout the entire life cycle of AI systems and models, and provide full access to AI systems for people with disabilities without discrimination.

Article 4 on information and confidentiality stipulates that the use of AI must respect, among other things, the pluralism of media, freedom of expression, and impartiality and completeness of information; information related to personal data processing must be clear and accessible to everyone, to guarantee the right of those concerned to object to their incorrect processing.

In the healthcare sector, article 7 applies the anthropocentric approach, stipulating that the use of AI:

- must contribute to improving diagnostic and treatment processes in a supportive role, without prejudicing the decision-making power of the professional;
- cannot establish discriminatory criteria for access to healthcare services;
- must contribute to improving the lives and social inclusion of people with disabilities.

The prescription extends the basis of informed consent to the use of AI systems.

The processing of data, including personal data, carried out by public and private non-profit entities for research and scientific experimentation in the creation of AI systems for therapeutic and pharmacological purposes is declared to be of significant public interest (Article 8), resulting in legal authorization for secondary use of personal data without direct identification elements, without the need to replicate the data holder's consent request, provided that the data holder has already consented to another research area, always notifying the Data Protection Authority.

In the field of labour, Article 10 applies the anthropocentric principle, stipulating that the use of AI:

- must be functional to improving working conditions, protecting the physical and mental integrity of workers, and enhancing productivity;
- must guarantee respect for workers' fundamental rights and not result in discriminatory treatment.

Article 13 regulates the use of AI in public administration activities as a tool capable of ensuring good performance and efficiency of administrative activity while emphasizing the principle of self-determination and responsibility of the person using it.

Article 14 stipulates that AI can only be used for support activities in the area of judicial activities such as organization and simplification of work or for legal and doctrinal research. Always within the logic of an anthropocentric vision of AI, the principle is established that the interpretation of the law, evaluation of facts and evidence, and adoption of any measure, including the judgment, is always reserved for the magistrate.

The principles outlined are in line with what is established at the European level in the AI Act, where AI systems intended for justice administration have been classified as high risk, and with the Ethical Charter for the use of AI in judicial systems, developed by the CEPEJ (European Commission for the Efficiency of Justice).

The government is delegated (Article 22) to adopt, within twelve months from the date the law comes into force, one or more legislative decrees to adapt national legislation to the regulation of the European Parliament and Council on AI, approved by the European Parliament in the session of March 13, 2024, especially concerning AI literacy in school and university.

The approval process began with the presentation of the bill to the Senate (May 20) and will conclude with the approval of both branches of Parliament.