

- (b) prohibitions of certain AI practices;
- (c) specific requirements for high-risk AI systems and obligations for operators of such systems;
- (d) harmonised transparency rules for certain AI systems;
- (e) harmonised rules for the placing on the market of general-purpose AI models;
- (f) rules on market monitoring, market surveillance, governance and enforcement;
- (g) measures to support innovation, with a particular focus on SMEs, including start-ups.

Article 2

Scope

1. This Regulation applies to:

- (a) providers placing on the market or putting into service AI systems or placing on the market general-purpose AI models in the Union, irrespective of whether those providers are established or located within the Union or in a third country;
- (b) deployers of AI systems that have their place of establishment or are located within the Union;
- (c) providers and deployers of AI systems that have their place of establishment or are located in a third country, where the output produced by the AI system is used in the Union;
- (d) importers and distributors of AI systems;
- (e) product manufacturers placing on the market or putting into service an AI system together with their product and under their own name or trademark;
- (f) authorised representatives of providers, which are not established in the Union;
- (g) affected persons that are located in the Union.

2. For AI systems classified as high-risk AI systems in accordance with Article 6(1) related to products covered by the Union harmonisation legislation listed in Section B of Annex I, only Article 6(1), Articles 102 to 109 and Article 112 apply. Article 57 applies only in so far as the requirements for high-risk AI systems under this Regulation have been integrated in that Union harmonisation legislation.

3. This Regulation does not apply to areas outside the scope of Union law, and shall not, in any event, affect the competences of the Member States concerning national security, regardless of the type of entity entrusted by the Member States with carrying out tasks in relation to those competences.

This Regulation does not apply to AI systems where and in so far they are placed on the market, put into service, or used with or without modification exclusively for military, defence or national security purposes, regardless of the type of entity carrying out those activities.

This Regulation does not apply to AI systems which are not placed on the market or put into service in the Union, where the output is used in the Union exclusively for military, defence or national security purposes, regardless of the type of entity carrying out those activities.

4. This Regulation applies neither to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international cooperation or agreements for law enforcement and judicial cooperation with the Union or with one or more Member States, provided that such a third country or international organisation provides adequate safeguards with respect to the protection of fundamental rights and freedoms of individuals.

5. This Regulation shall not affect the application of the provisions on the liability of providers of intermediary services as set out in Chapter II of Regulation (EU) 2022/2065.

6. This Regulation does not apply to AI systems or AI models, including their output, specifically developed and put into service for the sole purpose of scientific research and development.
7. Union law on the protection of personal data, privacy and the confidentiality of communications applies to personal data processed in connection with the rights and obligations laid down in this Regulation. This Regulation shall not affect Regulation (EU) 2016/679 or (EU) 2018/1725, or Directive 2002/58/EC or (EU) 2016/680, without prejudice to Article 10(5) and Article 59 of this Regulation.
8. This Regulation does not apply to any research, testing or development activity regarding AI systems or AI models prior to their being placed on the market or put into service. Such activities shall be conducted in accordance with applicable Union law. Testing in real world conditions shall not be covered by that exclusion.
9. This Regulation is without prejudice to the rules laid down by other Union legal acts related to consumer protection and product safety.
10. This Regulation does not apply to obligations of deployers who are natural persons using AI systems in the course of a purely personal non-professional activity.
11. This Regulation does not preclude the Union or Member States from maintaining or introducing laws, regulations or administrative provisions which are more favourable to workers in terms of protecting their rights in respect of the use of AI systems by employers, or from encouraging or allowing the application of collective agreements which are more favourable to workers.
12. This Regulation does not apply to AI systems released under free and open-source licences, unless they are placed on the market or put into service as high-risk AI systems or as an AI system that falls under Article 5 or 50.

Article 3

Definitions

For the purposes of this Regulation, the following definitions apply:

- (1) 'AI system' means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments;
- (2) 'risk' means the combination of the probability of an occurrence of harm and the severity of that harm;
- (3) 'provider' means a natural or legal person, public authority, agency or other body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge;
- (4) 'deployer' means a natural or legal person, public authority, agency or other body using an AI system under its authority except where the AI system is used in the course of a personal non-professional activity;
- (5) 'authorised representative' means a natural or legal person located or established in the Union who has received and accepted a written mandate from a provider of an AI system or a general-purpose AI model to, respectively, perform and carry out on its behalf the obligations and procedures established by this Regulation;
- (6) 'importer' means a natural or legal person located or established in the Union that places on the market an AI system that bears the name or trademark of a natural or legal person established in a third country;
- (7) 'distributor' means a natural or legal person in the supply chain, other than the provider or the importer, that makes an AI system available on the Union market;
- (8) 'operator' means a provider, product manufacturer, deployer, authorised representative, importer or distributor;