



**Scope Art 2**

(a) providers placing on the market or putting into service AI systems in the Union, irrespective of whether those providers are established within the Union or in a third country;

(b) deployers of AI systems that have their place of establishment or who 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 either Member State law applies by virtue of public international law or the output produced by the system is intended to be used in the Union;

(ca) providers placing on the market or putting into service AI systems referred to in Article 5 outside the Union where the provider or distributor of such systems is located within the Union;

(cb) importers and distributors of AI systems as well as authorised representatives of providers of AI systems, where such importers, distributors or authorised representatives have their establishment or are located in the Union;

(cc) affected persons that are located in the Union and whose health, safety or fundamental rights were adversely impacted by the use of an AI system that was placed on the market or put into service in the Union.

**Definitions Art 3**

**Legal entities** - may be one or more of these. Different obligations for each.

- **'provider'**: means a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed with a view to placing it on the market or putting it into service under its own name or trademark, whether for payment or free of charge or that adapts general purpose AI systems to a specific intended purpose;; (Note that there may be multiple providers along the AI lifecycle and that there are obligations on former providers (Art 28(2)))
- **'deployer'** (formerly **'user'**): means any 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;
- **'authorised representative'**: means any natural or legal person established in the Union who has received a written mandate from a provider of an AI system to, respectively, perform and carry out on its behalf the obligations and procedures established by this Regulation;
- **'product manufacturer'**: a manufacturer within the meaning of any of the Union harmonisation legislation listed in Annex II 'importer' means any natural or legal person physically present 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 outside the Union;
- **'distributor'**: any 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;
- **'importer'** means any natural or legal person established in the Union that places on the market or puts into service an AI system that bears the name or trademark of a natural or legal person established outside the Union;
- **'operator'**: means the provider, the deployer, the authorised representative, the importer and the distributor;
- **'affected person'** means any natural person or group of persons who are subject to or otherwise affected by an AI system.

**Systems**

**'artificial intelligence system'** (AI system) means a machine-based system that is designed to operate with varying levels of autonomy and that can, for explicit or implicit objectives, generate outputs such as predictions, recommendations, or decisions that influence physical or virtual environments;

**'foundation model'** means an AI model that is trained on broad data at scale, is designed for generality of output, and can be adapted to a wide range of distinctive tasks;

**'general purpose AI system'** means an AI system that can be used in and adapted to a wide range of applications for which it was not intentionally and specifically designed.

Also: **'significant risk'** means a risk that is significant as a result of the combination of its severity, intensity, probability, probability of occurrence, and duration of its effects, and its the [sic] ability to affect an individual, a plurality of persons or to affect a particular group of persons.

**High-Risk AI Systems Art 6**

Legislation in **Annex II** which requires a conformity assessment, including: Machinery Directive 2006/42/EC; Safety of Toys Directive 2009/48/EC; Medical devices Regulation (EU) 2017/745

EU regulation listed in **Annex II Section B**, including: EU harmonised legislation on Civil Aviation Security, vehicles (e.g. agricultural and forestry, motor vehicles), marine equipment.

AI systems listed in **Annex III** including: AI Systems used for: biometrics; critical infrastructure; educational and vocational training; employment and workers management; access to essential services; law enforcement; migration and border control; and judicial and democratic processes.

**Obligations on high-risk AI Systems**

In complying with the requirements, due account shall be taken of guidelines produced under the Act, generally acknowledged state of the art, including common specifications. **Art 8**

Different obligations depending upon the type of legal entity. In summary, may include obligations regarding: risk management; quality management; data and data governance; logs; technical documentation; record-keeping; transparency; human oversight; security; corrective actions; duties to provide information; co-operation with authorities; produce conformity assessments and declarations; registering the AI system on an EU database; post-market monitoring.

Note presumptions of conformity with: 1) specified existing EU legislation (Art 8(2a));2) when meeting common specifications made pursuant to Art 41(1) (Art 41(3)); 3) Art 10(4) (data and training obligations) (Art 42(1)); 4) Art 15 (cybersecurity obligations (Art 42(2))).

Additional responsibilities along the AI value chain of providers, distributors, importers, deployers or other third parties **Art 28**

There are specific obligations for former providers who no longer meet the definition of provider **Art 28(2)**, and also providers of a foundation model **Art 28b**

**Additional considerations**

Providers of AI systems intended to interact with natural persons shall ensure that they are designed and developed in such a way that the AI system, the provider itself or the user informs the natural person exposed to an AI system that they are interacting with an AI system in a timely, clear and intelligible manner, unless this is obvious from the circumstances and the context of use. **Art 52(1)**

The Commission, AI Office and Member States shall facilitate drawing up codes of conduct to encourage the voluntary application of the obligations on high-risk AI systems to non-high-risk AI systems. **Art 69**

All operators subject to the Regulation shall make their best efforts to develop and use AI systems or foundation models in accordance with general principles, including: human agency and oversight; technical robustness and safety; privacy and data governance; transparency (including explainability); diversity, non-discrimination and fairness; and social and environmental well-being. These are met by complying with the obligations for AI systems and foundation models. **Art 4a**

Parts of the AI Act are without prejudice to specified existing legislation, including those related to data protection, consumer protection and safety, and workers rights.

**Want to know more?**

Contact Tom Whittaker, Brian Wong or another member of our Technology Team. Also, follow our AI and Law blog here. For our one-page flowchart to navigate the UK's AI regulation framework, click here. For our one-page horizon scan of existing and anticipated AI regulation in the UK, EU and US, click here.