

EUROPEAN UNION LAW SERIES

THE EUROPEAN AI ACT

Summary, Key Points and Article-by-Article Analysis

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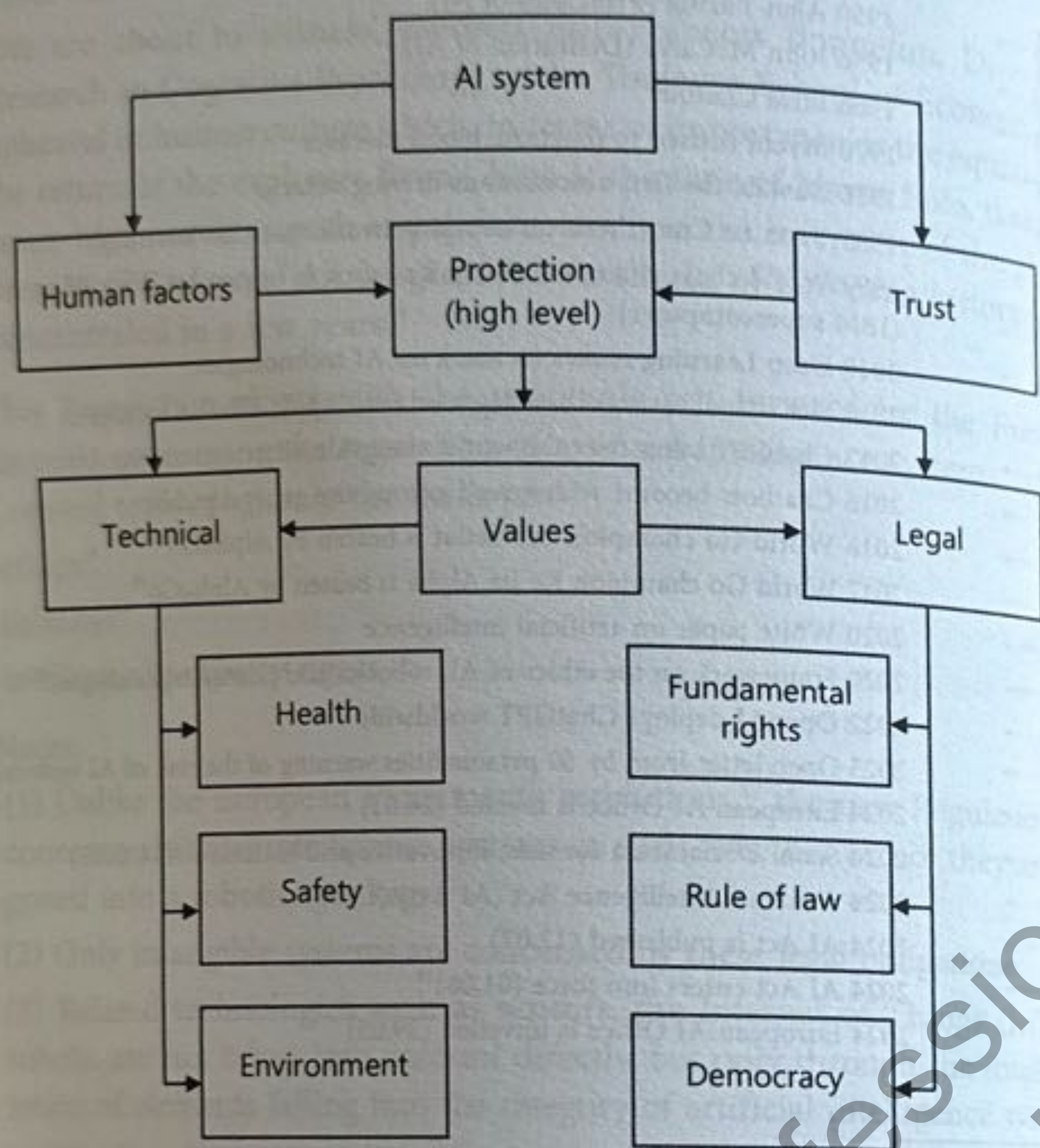
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1.3. General Architecture of the Regulation¹⁹

7. The Regulation is structured as follows:



1.4. Objectives

8. The objectives are set out below:

- to make the EU a global leader in the development of secure, trustworthy and ethical AI;²⁰
- to ensure the protection of ethical principles, as specifically requested by the European Parliament;²¹
- to establish a high level of protection;
- to organise the smooth functioning of the single market by creating the right conditions for the development and use of trustworthy AI in the European Union;

¹⁹ AI Act, Art. 1.
²⁰ AI Act, Rec. 8.
²¹ AI Act, Rec. 8.

- to ensure that AI systems are safe and respect law on fundamental rights and European Union values;
- to ensure legal certainty to facilitate investment and innovation in AI;
- to enhance governance and effective enforcement of existing law on fundamental rights and safety requirements applicable to AI systems;
- to facilitate the development of a single market for lawful, safe and trustworthy AI systems and prevent market fragmentation;²²
- to align EU Regulation with the achievement of the United Nations Sustainable Development Goals (SDGs).

9. The main challenges facing the Regulation can be summarised under the following headings, listed in alphabetical order:

NO.	THEME	CHALLENGES
1.	Creation	Plundering of works during the training phase of large language models ²³
2.	Economic model	Shift from work value to creation value
3.	Employment	Bipolarisation of the market between highly skilled individuals and others, along with associated conflicts
4.	Intelligent divide	Widening of the digital divide
5.	Production	Stereotyped outputs ²⁴ and associated loss of human skills
6.	Technological eugenics	Confrontation between humans, natural humans vs. augmented or enhanced humans
7.	Technological slavery	Dependence on AI systems

1.5. Approach

10. In 2024, regulations concerning AI systems worldwide follow a vertical approach, i.e. they address:

- autonomous cars;
- industrial robots;
- autonomous ships;
- etc.

²² Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain union legislative acts {SEC(2021) 167 final} – {SWD(2021) 84 final} – {SWD (2021) 85 final}, explanatory memorandum, p. 3, Brussels, 21 April 2021.

²³ AI Act, Art. 51: general-purpose AI system model such as ChatGPT (OpenAI) or Gemini (Google).

²⁴ S. DURANTON, 'IA générative et productivité: pour le meilleur et pour le pire' ['Generative AI and productivity: for better or for worse'], *Les Échos*, 3 October 2023.

11. In contrast, the Regulation follows a horizontal approach, by introducing horizontal rules that apply to all AI systems,²⁵ onto which vertical or sector-specific rules will be added.

12. The framework is based on managing the risks posed by AI systems, which could represent '[a]n extinction risk for humanity'.²⁶

13. This approach results from coordinated legal management based on EU values and the risks of harm to those values.²⁷

1.6. Values-Based Management

1.6.1 Introduction

14. The purpose of the legal framework is to protect natural persons, undertakings and democracy.²⁸

1.6.2 Health

15. The concept of health covers the physical and psychological protection of individuals.

1.6.3 Safety

16. This concept covers:

- the protection of individuals, corporate bodies and property;²⁹
- cybersecurity.³⁰

1.6.4 Environment

17. Environmental protection is one of three values, along with the rule of law and democracy, that have been included in the latest versions of the new Regulation. The concept of environment is not defined as such.

²⁵ With some exceptions, see below.

²⁶ Sam Altman, OpenAI CEO, quoted by J. LE BOLZER, in 'Risques, régulation, éthique: état des lieux des enjeux qui questionnent l'IA' ['Risks, regulation, ethics: an overview of the issues surrounding AI'], *Les Échos*, 12 October 2023, p. 32 (paper), 20 September 2023 (online).

²⁷ C. CRICHTON, 'Règlement sur l'intelligence artificielle: premiers éléments d'analyse' ['AI Act: Initial points for discussion'], HAL, 23 July 2024.

²⁸ AI Act, Rec. 1.

²⁹ The technical aspects of AI technology safety are dealt with in a separate section. See section 6.14 Safety.

³⁰ AI Act, Art. 15.

18. The expected benefits of AI technologies in this field include:

- environmental monitoring;
- the conservation and restoration of biodiversity;
- climate change mitigation and adaptation.³¹

1.6.5 Fundamental Rights

19. These rights are those referred to in the Charter of Fundamental Rights of the Union.³²

20. They are taken into account in two ways:

- the obligation to respect the fundamental values of European democracy;³³
- the need to implement these requirements in such a way that AI systems integrate these imperatives into their 'natural behaviour'.

21. 'The use of AI with its specific characteristics (e.g. opacity, complexity, dependency on data, autonomy) can adversely affect a number of fundamental rights enshrined in the EU Charter of Fundamental Rights.'³⁴

22. Notes:

- (1) The requirement of alignment with human intentions is a decisive element in the consideration of fundamental rights.
- (2) This requirement is one of the essential obligations of providers of general-purpose AI models with systemic risk.³⁵
- (3) The Regulation does not establish any principles or rules on the methods or type of solutions to achieve such alignment.³⁶

1.6.6 Rule of Law

23. AI systems must be framed in such a way as not to lead to dictatorships of a technological nature within the European Union.

³¹ AI Act, Rec. 4.

³² Charter of Fundamental Rights of the European Union (2016), [2016] OJ C202/389, https://eur-lex.europa.eu/eli/treaty/char_2016/oj.

³³ Council Decision (EU) 2024/2218 of 28 August 2024 on the signing, on behalf of the European Union, of the Council of Europe Framework Convention on Artificial Intelligence and Human Rights, Democracy and the Rule of Law, <http://data.europa.eu/eli/dec/2024/2218/oj>.

³⁴ EDPS, Opinion 44/2023 of 23 October 2023 on the Proposal for Artificial Intelligence Act in the light of legislative developments, p. 7.

³⁵ AI Act Annex XI, section 2(2).

³⁶ P. MOLGA, 'L'intelligence humaine progresse toujours' ['Human intelligence continues to progress'], *Les Échos*, 23 October 2023, p. 13.

24. This would undermine:

- the principle of separation of powers;
- the independence of the judiciary;
- access to rights;
- participation in public debate.

1.6.7 Democracy

25. AI systems may not be designed and implemented throughout their entire lifecycle on a basis that could:

- undermine the integrity of the institutions of the European Union or of individual Member States;
- jeopardise the independence of democratic institutions;
- explicitly or implicitly bias or block democratic processes as a whole.

1.7. Risk-Based Management

1.7.1 Introduction

26. In the Regulation, risks are classified as follows:

NO.	RISK	SPECIFICATION	REFERENCE
1.	Unacceptable	AI systems that contradict EU values	AIA, Art. 5
2.	Systemic	General-purpose AI system	AIA, Art. 51 ³⁷
3.	High	AI systems that can lead to serious consequences	AIA, Art. 6
4.	Specific	Transparency obligation	AIA, Art. 50
5.	Minimal	Optional adherence to a code of practice	AIA, Art. 56
6.	Exclusion	Special cases	AIA, Art. 2

³⁷ OpenAI's ChatGPT, Google's Gemini, or Anthropic's Claude.

1.7.2 A Product and Risks View

27. The general framework for AI technology 'products' is subject to cross-cutting legislation on market surveillance and product compliance (hereafter referred to as 'MS&PC').³⁸

28. However, the main concepts concerning products and risks are much broader.

29. These include:

NO.	THEME	MSR (MS&PC)	AI ACT	COMMENT
1.	Product	Definition None	Definition None	In the AI Act, the term is cited 122 times in connection with AI systems
2.	Operator	Economic operator Regulation (EU) 2019/1020 Art. 3(13)	Economic operator AI Act (EU) 2024/1689 Art. 3(8)	The AI Act integrates deployers and end-users as entities or individuals acting in the course of a professional activity
3.	Product presenting a risk	Regulation (EU) 2019/1020 Art. 3(19)	No definition as such	Concepts relating to protection in the face of risk: • health; • safety; • environment; • fundamental rights; • rule of law; • democracy. AIA, Art. 1(1)
4.	Risk	Regulation (EU) 2019/1020 Art. 3(18)	AI Act (EU) 2024/1689 Art. 3(2)	The notion of risk is more limited in the AIA: 'danger' for one (Reg. 2019/2020) and 'harm' for the other (AIA)

³⁸ AI Act, Art. 74(1): 'Regulation (EU) 2019/1020 shall apply to AI systems covered by this Regulation. For the purposes of the effective enforcement of this Regulation:
(a) any reference to an economic operator under Regulation (EU) 2019/1020 shall be understood as including all operators identified in Article 2(1) of this Regulation;
(b) any reference to a product under Regulation (EU) 2019/1020 shall be understood as including all AI systems falling within the scope of this Regulation.'

1.8. Values-Based and Risk-Based Management

1.8.1 Introduction

30. This approach is determined by guiding principles.³⁹ Each of these principles is broken down into specific principles.⁴⁰ The principles are the subject of legal obligations. Each legal obligation is then articulated around of technical,⁴¹ organisational⁴² or legal⁴³ requirements.

31. The provider should determine its solution in such a way that it complies with these requirements.

1.8.2 Management Structure

NO.	THEME	SPECIFICATION
1.	Initial phase	Implementation of requirements according to the AI system type and the general-purpose AI model <i>ex ante</i>
2.	Compliance phase	Compliance checks for certain high-risk AI systems ⁴⁴ Self-compliance for others
3.	Market phase	National market surveillance authority Self-surveillance for high-risk AI systems

1.9. Harm

32. This covers both material and immaterial damage,⁴⁵ including physical psychological, societal and economic harm.⁴⁶

³⁹ See section 7.3 Guiding Principles.

⁴⁰ See section 7.4 Specific Principles.

⁴¹ Risk management system for high-risk AI systems. AI Act, Art. 9.

⁴² Documentation keeping. AI Act, Art. 18.

⁴³ Written mandate for relations between a provider and an authorised representative. AI Act, Art. 22.

⁴⁴ High-risk AI systems, AI Act, Art. 6(1), Section A of Annex I List of Union harmonisation legislation.

⁴⁵ AI Act, Rec. 5.

⁴⁶ See section 6.6 Damage and Harm.

1.10. Missing Concepts

33. Many concepts in the sphere of artificial intelligence have not been included in the Regulation. This is the case for the following concepts:

NO.	TECHNOLOGY	SPECIFICATION
1.	Robot	See section 3.8 Robotic Systems below
2.	Sensor	See section 3.8 Robotic Systems below
3.	Algorithm	See section 3.2.3 Algorithm below

2. SCOPES

34. The scopes include:

- the geographical scope;
- the historical scope.

2.1. Geographical Scope

2.1.1 Introduction

35. The Regulation applies to:⁴⁷

- providers established within the EU;
- manufacturers of products embedding AI technologies;
- providers established or located in a third country placing on the market or putting into service in the EU;
- providers established or located in a third country, where the output produced by the AI system is used in the EU;
- deployers of AI systems located within the EU;
- deployers established or located in a third country, where the output produced by the AI system is used in the EU;
- affected persons located in the EU.

2.1.2 Extraterritorial Scope

36. The Regulation has an extraterritorial effect through a ripple effect.

⁴⁷ AI Act, Art. 2.

37. It applies to:

- providers established in a third country and operating within the EU; and
- output generated outside the EU and used in the EU.

2.1.3 Global Influence

38. As with the GDPR, the extraterritoriality rules of the Regulation initiate a process of universality that will ultimately lead to a homogenisation of the key principles and general terms of implementation of AI systems around the world.

2.1.4 EU Providers

39. The concept of establishment implies the exercise of activity through stable arrangements. The form of such arrangements may be a body with a legal personality or a mere establishment.

40. Only AI systems operated within the EU are concerned. AI systems intended for export are not subject to these requirements.

41. The activities of providers include either or both of the following:

- the placing on the market;
- the putting into service.

42. Notes:

- (1) Design and development activities are not relevant for the scope.
- (2) However, these two phases are subject to obligations and associated requirements for high-risk AI systems. These include:
 - o record-keeping;⁴⁸
 - o accuracy, robustness and cybersecurity.⁴⁹

2.1.5 Product Manufacturers

43. Product manufacturers are comparable to providers when they integrate an AI system into a product under their own name or trademark.⁵⁰

44. The status of provider applies when the product is put into service.

⁴⁸ AI Act, Art. 12.

⁴⁹ AI Act, Art. 15.

⁵⁰ AI Act, Art. 2(1)(e).

2.1.6 Non-EU Providers

45. Where providers that are not established within the EU operate in one or more Member States, AI systems must comply with all the obligations.

2.1.7 Non-EU Providers of Outputs

46. The use of output produced by AI systems originating from third countries is subject to the Regulation; the main purpose is to protect deployers.

2.1.8 Deployers

47. A deployer is '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'.⁵¹

48. All uses of AI systems located in the EU must comply with the requirements relating to AI technologies. The same applies when these uses are limited to output produced by AI systems from countries outside the EU.

2.1.9 Affected Persons

2.1.9.1 Introduction

49. The protection applies to:

- natural persons;
- undertakings.⁵²

2.1.9.2 Natural Persons

50. They are protected as individuals⁵³ or as a group of individuals.⁵⁴

⁵¹ AI Act, Art. 3(4).

⁵² AI Act, Rec. 2.

⁵³ AI Act, Art. 5(1)(a) referring to 'a person's consciousness'.

⁵⁴ AI Act, Art. 5(1)(b) referring to groups of vulnerable persons.

51. This applies in particular in the following cases:

NO.	PROTECTION	SPECIFICATION
1.	AI literacy	Awareness-raising and training obligations ⁵⁵
2.	Automated decisions	Information on the use of high-risk systems covered by Annex III ⁵⁶
3.	Human/AI interface	AI systems subject to a transparency obligation ⁵⁷
4.	Testing in real-world conditions	High-risk systems ⁵⁸

2.1.9.3 Undertakings

52. Focused on competition law,⁵⁹ the term 'undertaking' means all entities engaged in an activity, whether natural persons or legal persons governed by private or public law.⁶⁰

2.1.9.4 Criterion

53. The affected persons are those 'that are located in the Union'.⁶¹

2.1.10 Other Actors

54. They are as follows:

NO.	ACTORS	SPECIFICATION
1.	Distributor	'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' ⁶²
2.	Importer	'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' ⁶³

⁵⁵ AI Act, Art. 4.

⁵⁶ AI Act, Arts. 26(11) and 86(1).

⁵⁷ AI Act, Art. 50(1).

⁵⁸ AI Act, Art. 60(1).

⁵⁹ TFEU, Arts. 101 and 102: 'Rules applying to undertakings'.

⁶⁰ This does not apply to activities in the exercise of public powers, such as those of Member States, local authorities or specific bodies.

⁶¹ AI Act, Art. 2(1)(g).

⁶² AI Act, Art. 3(7).

⁶³ AI Act, Art. 3(6).

NO.	ACTORS	SPECIFICATION
3.	Exporter	No legal rules as such ⁶⁴
4.	Authorised representative	'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' ⁶⁵
5.	Operator	'A provider, product manufacturer, deployer, authorised representative, importer or distributor' ⁶⁶
6.	Subject	'A natural person who participates in testing in real-world conditions' ⁶⁷
7.	Staff (or personnel)	Employees of providers and deployers ⁶⁸

2.1.11 Institutions of the European Union

55. The Regulation applies to EU institutions, bodies, offices and agencies when acting as a provider or deployer of an AI system.⁶⁹

2.1.12 Exclusions

56. They are as follows:

NO.	ACTIVITIES	SPECIFICATION	REFERENCE
1.	Personal activity	Deployers that are natural persons who use AI systems in the course of a purely personal non-professional activity ⁷⁰	AIA, Art. 2(10)
2.	Scope of the EU	Systems that do not fall within this scope	AIA, Art. 2(4)

⁶⁴ The terms exporter and export are not used in the AI Act.

⁶⁵ AI Act, Art. 3(5).

⁶⁶ AI Act, Art. 3(8).

⁶⁷ AI Act, Art. 3(58).

⁶⁸ AI Act, Art. 4.

⁶⁹ AI Act, Rec. 23.

⁷⁰ The same applies to 'systems that are based on the rules defined solely by natural persons to automatically execute operations' (AI Act, Rec. 12 and 13). These two elements are not really aligned.

NO.	ACTIVITIES	SPECIFICATION	REFERENCE
3.	Design (Phase)	The 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: Notes: • (1) This exclusion is distinct from that concerning scientific research as such. • (2) Testing in real-world conditions are excluded	AIA, Rec. 20 AIA, Art. 2(8)
4.	International cooperation	Special agreements	AIA, Art. 2(4)
5.	Provision of intermediary services	Liability system	AIA, Art. 2(5)
6.	Scientific research and development	The 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	AIA, Art. 2(6) AIA, Rec. 25
7.	Output of AI systems for defence or national security purposes	Use 'in the Union exclusively for military, defence or national security purposes, regardless of the type of entity carrying out those activities' ⁷¹	AIA, Art. 2(3)
8.	AI systems for defence purposes	Purposes exclusive to such purposes As is or with modifications ⁷²	AIA, Art. 2(3)
9.	AI systems for military purposes	Purposes exclusive to such purposes As is or with modifications ⁷³	AIA, Art. 2(3)
10.	AI systems for national security purposes	Purposes exclusive to such purposes As is or with modifications ⁷⁴	AIA, Art. 2(3)

57. Notes:

- (1) Issues relating to areas in which Member States' have exclusive competence and prohibited practices are examined during the presentation of these practices.

⁷¹ Private or public entities.⁷² Private or public entities.⁷³ Private or public entities.⁷⁴ Private or public entities.

2.1.13 Coordinated Activities

2.1.13.1 Introduction

58. Subject to a reassessment of the situation, in the light of developments in high-risk AI systems by the European Commission, the areas listed below are not subject to the Regulation despite the implementation of AI technologies, in the form of safety components or products.⁷⁵

2.1.13.2 Modifications

59. This list of activities is coordinated in Articles 102 to 109.

60. This coordination requires the European Commission to apply the requirements applicable to high-risk AI systems in these areas, which are as follows:

NO.	THEME	REFERENCE
1.	Compliance with the requirements	AIA, Art. 8
2.	Risk management system	AIA, Art. 9
3.	Data and data governance	AIA, Art. 10
4.	Technical documentation	AIA, Art. 11
5.	Record-keeping	AIA, Art. 12
6.	Transparency and provision of information to deployers	AIA, Art. 13
7.	Human oversight	AIA, Art. 14
8.	Accuracy	AIA, Art. 15
9.	Robustness	AIA, Art. 15
10.	Cybersecurity	AIA, Art. 15

2.1.13.3 List of Activities

61. It is as follows:

NO.	THEME	SPECIFICATION	REFERENCE
1.	Regulation (EC) No 300/2008	11 March 2008	Common rules in the field of civil aviation security
2.	Regulation (EU) No 168/2013	15 January 2013	Approval and market surveillance of two- or three-wheel vehicles and quadricycles

⁷⁵ AI Act, Section B of Annex I.

NO.	THEME	SPECIFICATION	REFERENCE
3.	Regulation (EU) No 167/2013	5 February 2013	Approval and market surveillance of agricultural and forestry vehicles
4.	Directive No 2014/90/EU	23 July 2014	Marine equipment
5.	Directive (EU) No 2016/797	11 May 2016	Interoperability of the rail system within the European Union
6.	Regulation (EU) No 2018/858	30 May 2018	Approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles
7.	Regulation (EU) No 2018/1139	4 July 2018	Common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency
8.	Regulation (EU) No 2019/2144	27 November 2019	Type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users

2.1.13.4 Architecture

62. This exclusion list concerns AI technologies relating to high-risk systems. It corresponds to Section B (List of other Union harmonisation legislation of Annex I (List of Union harmonisation legislation).

2.1.13.5 Special Rules

63. The areas concerned by the adjustments and referred to in Section B of Annex I are as follows:

NO.	THEME	REFERENCE
1.	Civil aviation	Application of Article 102 amending Regulation (EC) No 300/2008
2.	Agricultural and forestry vehicles	Application of Article 103 amending Regulation (EU) No 167/2013
3.	Two- or three-wheel vehicles and quadricycles	Application of Article 104 amending Regulation (EU) No 168/2013
4.	Marine equipment	Application of Article 105 amending Directive 2014/90/EU

NO.	THEME	REFERENCE
5.	Rail system	Application of Article 106 amending Directive (EU) 2016/797
6.	Motor vehicles and their trailers	Application of Article 107 amending Regulation (EU) No 2018/858
7.	European Union Aviation Safety Agency	Application of Article 108 amending Regulation (EU) No 2018/1139
8.	Motor vehicles and their trailers (approval)	Application of Article 109 amending Regulation (EU) No 2019/2144
9.	Evaluation and review procedure	Trajectory for updating legislation to take into account developments in AI technologies. Application of Article 102
10.	Regulatory sandboxes (Art. 57)	Application if EU harmonisation legislation has taken into account the AI Act requirements for high-risk AI systems
11.	National competent authorities	They are those competent for the aforementioned areas

64. Notes:

- (1) The regulations for activities covered by Section A of Annex I concerning high-risk AI systems are in line with the requirements of the new European legislative framework.⁷⁶
- (2) This is not yet the case for the regulations of the activities covered by Section B of Annex I, for which the European Commission has been mandated to take into account the AI technologies implemented in these areas.

2.2. Historical Scope

2.2.1 Introduction

65. The key dates of the Regulation are as follows:

- entry into force: on the twentieth day following that of its publication in the OJEU, i.e. 1 August 2024;⁷⁷
- application: 24 months after entry into force, i.e. 2 August 2026, except in special cases.

66. Within this period, the milestones are set out in the timetable below.

⁷⁶ See section 7.2 Legal Basis of the Union.

⁷⁷ The twentieth day following that of its publication in the *Official Journal of the European Union* (12 July 2024), i.e. 1 August 2024.