

Bonn, Bucharest, Dublin, Lisbon, Madrid, Milan, Paris, The Hague, Vienna, Warsaw

How to Define an AI System under the AI Act

CEDPO AI and Data Working Group

Micro-Insights Series

October 2025

Authors:

Marc Bellon

Lionel Capel

Maria Moloney

Laura Morató Pascual

Alessandro Vasta

Contact information:

<https://cedpo.eu>

info@cedpo.eu



About the Micro-Insights Series

The Micro-Insights Series is a publishing initiative by the CEDPO AI and Data Working Group. It will provide digestible, definitive, short-form papers on key areas of interest at the intersection between data and artificial intelligence. With a practical focus, keeping one eye on explaining complex topics and the other on implementation, it will outline the significance of key areas and advise practitioners on impact, and next steps. With the EU Artificial Intelligence Act (the 'AI Act') coming into law in 2024, the scene is now set for all practitioners, and it is possible to discuss the regulation of data and AI with much greater clarity.

The Micro-Insights Series will follow the evolution of AI and data over the coming years, and as the clock winds down on the crucial implementation period for the AI Act, and as AI technologies evolve in ever-more novel and unexpected ways, the Series will respond with up-to-date, authoritative guidance on the core areas of concern.

Amongst others, the series will include papers on:

- Regulation of General-Purpose Artificial Intelligence under the AI Act
- Explaining the AI Pact.
- Educating practitioners on how to conduct Fundamental Rights Impact Assessments under the AI Act.
- Outlining the role that data protection regulators will have in AI regulation.
- Examining whether or not the data protection officer is the right person to be the AI officer.
- The lawful basis for using training data in machine learning.
- Readiness toolkit for the AI Act.

Table of Contents

1. Introduction	4
2. AI Systems Criteria	5
A machine-based system.....	5
Varying levels of autonomy	5
Adaptiveness after deployment.....	6
Objectives.....	6
Inference	6
Outputs	6
Influence on environments	7
3. Conclusion	7

1. Introduction

One of the principal aims of the AI Act is to foster AI innovation while ensuring high levels of protection for health, safety, and fundamental rights within the EU. It is essential to understand the scope of the AI Act regulation because it allows us to recognise exactly what falls within the reach of the regulation and what does not. Only systems meeting the regulation's definition of an AI system fall within its scope. Given the complexity of the regulation, the European Commission is required to provide guidelines to help stakeholders understand and apply the AI system definition outlined in the Act.

For this reason, on 6 February 2025, the European Commission published guidelines to help all stakeholders better understand the definition of AI systems contained within the EU AI Act and to support the initial implementation of the Act's rules, which came into effect the same month.

The guidelines are an aid but are not legally binding. The Court of Justice of the European Union (CJEU) holds the authority for definitive interpretations of the AI Act. Given the rapid evolution of AI technology, the guidelines emphasize the need for a flexible, non-mechanical application of the AI system definition.

Article 3(1) of the AI Act defines an AI system as a **machine-based** system with **varying levels of autonomy**, potentially exhibiting **adaptiveness** after deployment, that **infers outputs** (predictions, content, recommendations, decisions) from **inputs** to **influence physical or virtual environments**.

If we break down this definition, we can see there are seven main criteria for AI systems:

1. It must be a machine-based system.
2. There are varying levels of autonomy.
3. It may exhibit adaptiveness after deployment.
4. There must be (at least one or more) objectives.
5. Inference must exist.
6. There must be (one or more) outputs.
7. It must have an influence on its environment.

The remainder of this article gives very brief explanations of each of these seven criteria to help the reader to practically ascertain the nature of an AI system as defined under the AI Act.

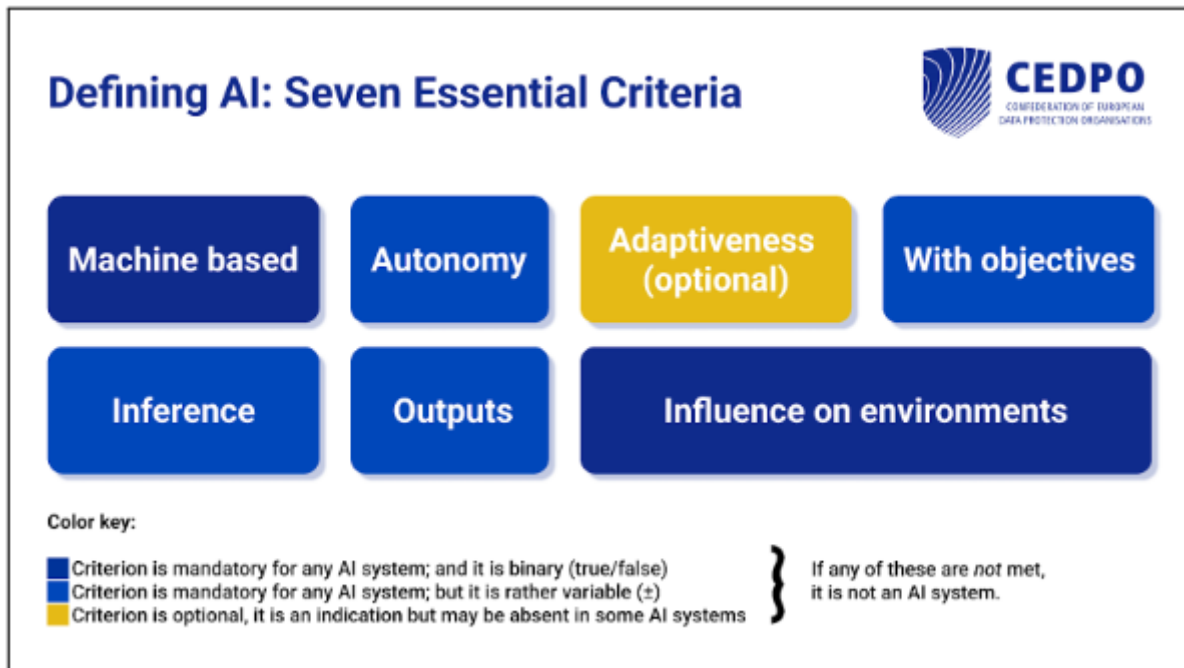


Figure 1 The Seven Criteria for AI Systems

2. AI Systems Criteria

A machine-based system

All AI systems are developed with and run on machines: hardware (physical elements) and software (computer code, instructions, programs, operating systems and applications). AI systems may rely on many such components.

Machine-based is understood widely and includes emerging systems that depart from traditional computing, including:

- quantum computing systems; and
- biological or organic computational systems (biological computing)

Varying levels of autonomy

To determine whether a system qualifies as an AI system, the level of autonomy is a crucial factor. Systems designed to operate with a reasonable degree of independence in their actions meet the autonomy criterion in the definition of an AI system.

A key aspect of autonomy involves the level or degree of human involvement and intervention. For instance, a system like ChatGPT that requires manually provided inputs to generate an output independently, demonstrates 'some degree of independence of action.' This is because the system is capable of producing an output without it being precisely specified by a human.

Adaptiveness after deployment

An AI system 'may exhibit adaptiveness after deployment'. This refers to self-learning capabilities, meaning the system may automatically learn, discover new patterns, or identify relationships in data beyond what it was initially trained on. This allows the system to change behaviour while in use, potentially producing different results for the same inputs.

In contrast to other criteria, all of which are essential to define an AI system, adaptiveness after deployment is not a decisive criterion, but more an indicator. Therefore, a system that has been initially trained and that does not exhibit adaptiveness once deployed, is not excluded from the definition of an AI system.

Objectives

The 'objectives' of an AI system refer to its internal goals, which determine how the system operates. These objectives may be explicitly defined through optimisation functions or implicitly derived from learned patterns of interaction with its environment. These objectives may differ from the 'intended purpose' assigned by the provider in a specific context, as they focus on the outcomes the system should achieve, without necessarily implying how it is integrated or used. Consequently, AI can develop unformulated objectives, as is the case with reinforcement learning models or large language models. While this characteristic is essential for describing an AI system, it is not sufficient by itself to distinguish it from other algorithms.

Inference

'Inference' in AI refers to the ability of a system to generate outputs, such as predictions, content, recommendations, or decisions, based on the input it receives. This process involves deriving conclusions from data, often using AI techniques like machine learning or knowledge-based approaches. In the context of AI, inference encompasses both the generation of results from inputs (during the system's use phase) and the derivation of models or algorithms from data during the building phase. This capability to infer distinguishes AI systems from traditional software, which rely on predefined rules and do not generate outputs based on learned or derived patterns.

Outputs

The ability of a system to generate outputs, such as predictions, content, and recommendations that can influence physical or virtual environments, based on inputs it receives and using machine learning and logic and knowledge-based approaches, is fundamental to what AI systems do and what distinguishes those systems from other forms of software. These outputs fall into four main categories: **predictions, content, recommendations, and decisions**. **Predictions** involve estimating unknown values with minimal human intervention. **Content** refers to the creation of new material like text and images. **Recommendations** suggest actions or products based on user data. **Decisions** are conclusions made by the system, which, in effect,

automate human judgement. AI systems, especially those using machine learning, can excel in handling complex data and generating more nuanced outputs compared to non-AI systems.

Influence on environments

An important element in defining an AI system is its ability to produce outputs that can influence both physical and virtual environments. This highlights that AI systems are active agents, impacting the environments in which they operate. The term 'physical or virtual environments' encompasses both tangible, physical objects (such as a robotic arm) and virtual settings, including digital spaces, data flows, and software ecosystems. An AI agent that books airline tickets is an example of an AI system influencing a physical environment.

3. Conclusion

The EU AI Act offers a comprehensive definition of AI systems. It describes such systems as having seven key criteria as outlined in this article. The key takeaway from the exercise of defining AI systems according to the EU AI Act is that these systems are essentially software-code-developed using techniques like machine learning, statistical methods and/or other logic-based approaches, that result in decisions, predictions, or recommendations, which have the potential to influence our physical and virtual environments.

This complex definition seeks to capture the dynamic and ever-evolving nature of AI, while at the same time trying to establish clear legal foundations to supervise them. By anchoring AI systems within this regulatory framework, the EU is looking to establish a balance between fostering innovation and safeguarding health, safety and fundamental rights. This in turn will promote transparency, accountability, and trust in the development and deployment of AI technologies across the Union and into the future.