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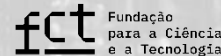


# Understanding the AI Act and Its Approach to AI Governance

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BSC AI Factory Partners



Affiliated entities





**BSC AIF Market Research Survey**  
<https://form.typeform.com/to/XDNmDVCW>



<https://www.bsc-aifactory.eu>



<https://www.linkedin.com/company/bsc-ai-factory/>



# Plan

1. Introduction to the AI Act
  1. Nature of the AI Act
  2. Scope of the AI Act
  3. Obligations and Requirements under the AI Act
  4. Governance and Enforcement of the AI Act
2. Digital Omnibus Package
3. Q&A

# Introduction to the AI Act

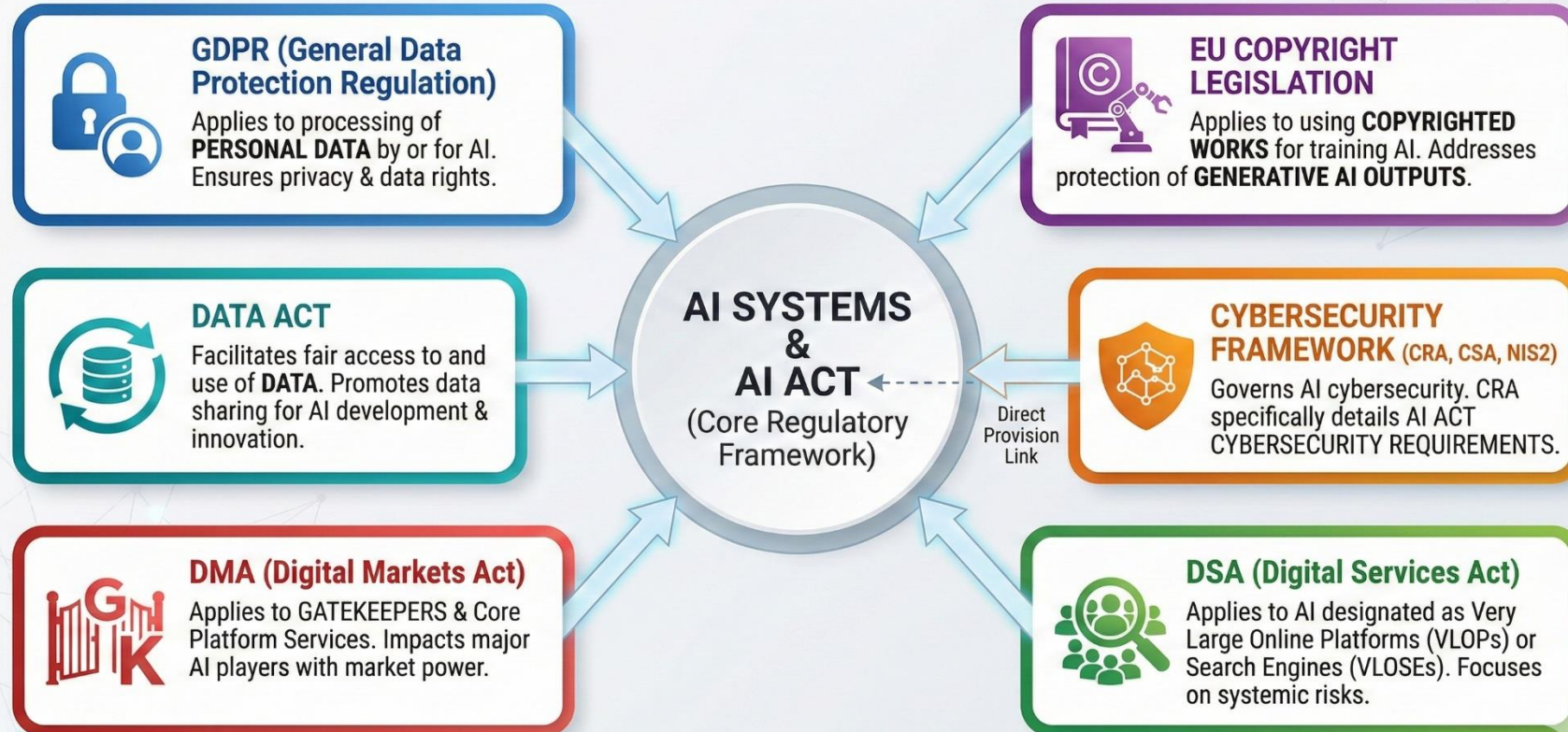


# What is the AI Act?

- First-ever AI-specific and legally binding, comprehensive framework in the EU.
- Is only a part of a more general framework applicable to AI in the EU
- Directly applicable without a requirement for transposition.
- Primarily a product safety legislation, with references to the protections of fundamental rights.
- Framework by nature, adopting a risk-based approach and not offering detailed practical steps per se.

# AI Related Framework in the EU

## EU Legislation Intersecting with AI and the AI Act



# What the AI Act is NOT:

- An all-encompassing, one-fit-for-all AI governance solution.
  - It does not contain almost any reference to liability.
  - It just refers to the existing EU legislation in highly-debated fields such as privacy or intellectual property.
- A practical compliance roadmap.
  - It provides the general framework required to market AI systems and GPAI models in the EU.
  - While it names the technical requirements, actions that will trigger compliance are not in the AI Act itself but left to technical standards.

# General Structure of the AI Act

<b>Chapter 1</b>	General provisions (Article 1-4)
<b>Chapter 2</b>	Prohibited AI practices (Article 5)
<b>Chapter 3</b>	High-risk AI systems (Article 6-49)
<b>Chapter 4</b>	Transparency obligations for providers and deployers of certain AI systems (Article 50)
<b>Chapter 5</b>	General-purpose AI models (Article 51-56)
<b>Chapter 6</b>	Measures to support innovation (Article 57-63)
<b>Chapter 7</b>	Governance (Article 64-70)
<b>Chapter 8</b>	EU database for high-risk AI systems (Article 71)
<b>Chapter 9</b>	Post-market monitoring, information sharing and market surveillance (Article 72-94)
<b>Chapter 10</b>	Codes of conduct and Guidelines (Article 95-96)
<b>Chapter 11</b>	Delegation of power and committee procedure (Article 97-98)
<b>Chapter 12</b>	Penalties (Article 99-101)
<b>Chapter 13</b>	Final provisions (Article 102-113)

## AI Act risk-based approach for AI systems:



GPAI models with or without systemic risk, and GPAI Codes of practice

AI regulatory sandboxes and measures for providers and deployers, in particular SMEs, including start-ups

## 13 different annexes, including:

- Annex 3:** High-risk AI systems referred to in Article 6 on classification rules for high-risk AI systems, paragraph 2
- Annex 4:** Technical documentation referred to in Article 11 on technical documentation, paragraph 1
- Annex 11 (and 12):** Technical documentation for providers of GPAI models (and transparency information)

**EPRS | European Parliamentary Research Service**

Author: Tristan Marcelin with Lucille Killmayer, Members' Research Service  
PE 772.906 – June 2025

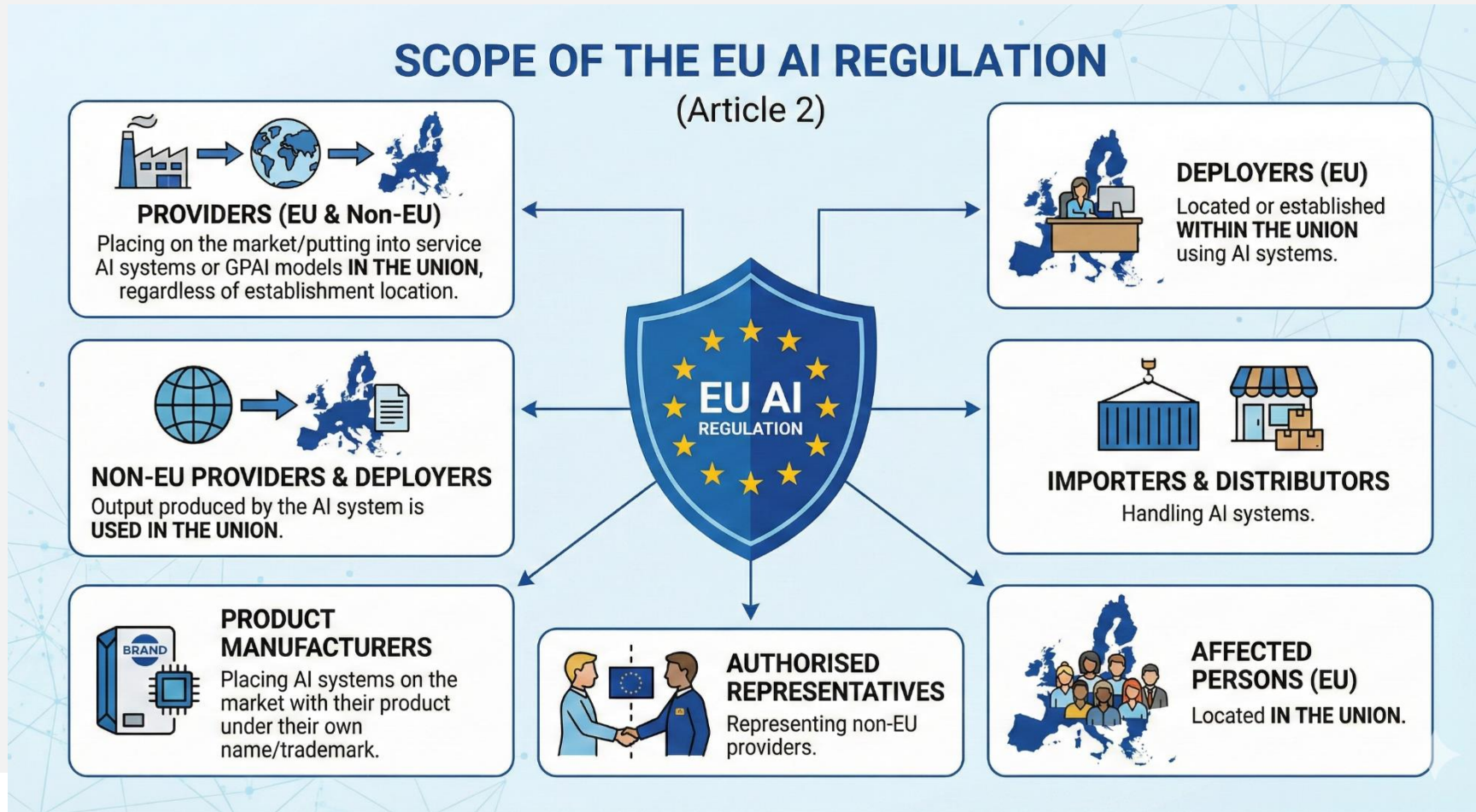


# What does this structure mean?

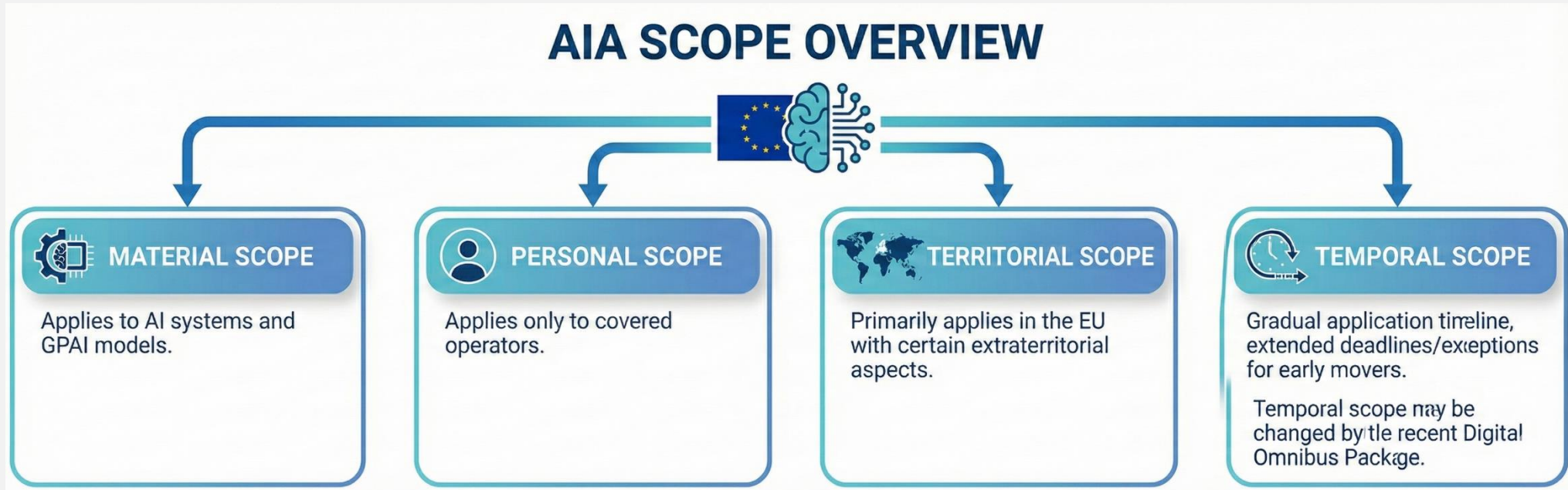
- Not every AI system or model is covered.
- Even among the covered AI systems and models, requirements and obligations are different.
- Using or developing AI system or a model does not automatically get you in the scope.
- There is a need for a scope assessment.

# The Scope of the AI Act

# What is the scope of the AI Act?



# What is the scope of the AI Act?

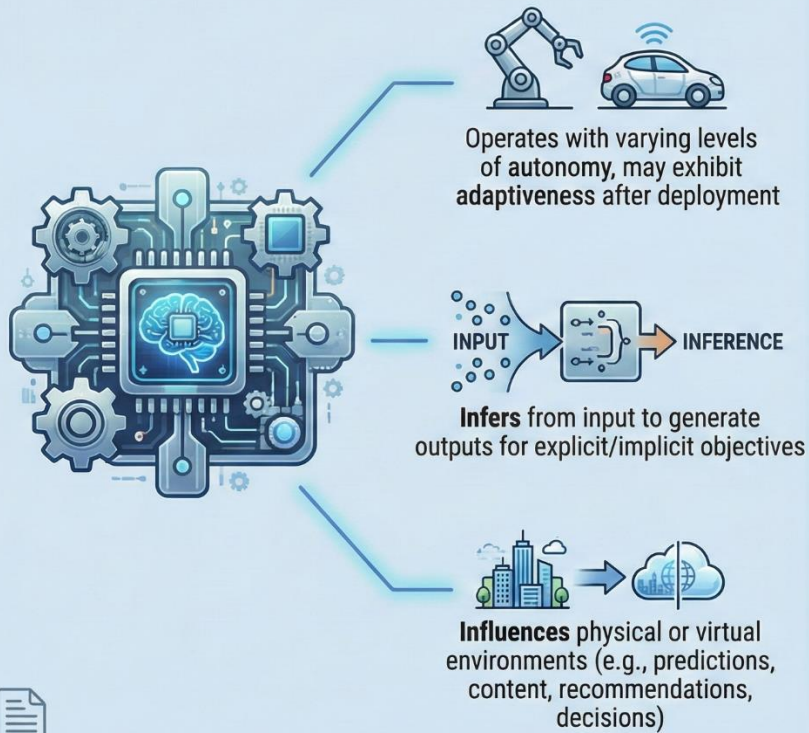


# What is the AIA's Material Scope: AI Systems vs AI Models

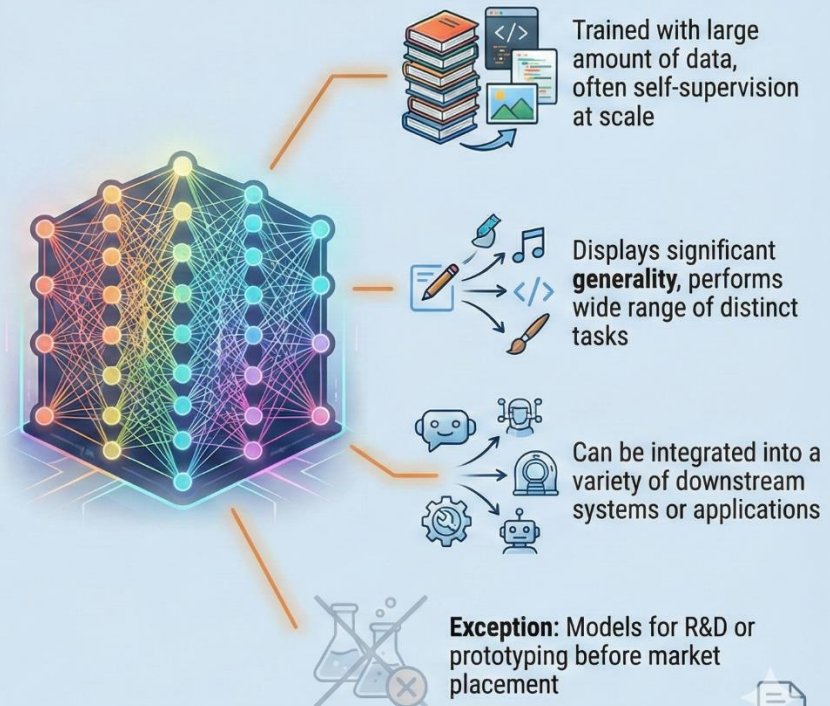
- AI System: «means a machine-based system that is designed to operate with varying levels of **autonomy** and that **may exhibit adaptiveness** after deployment, and that, for explicit or implicit objectives, **infers**, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments» (Article 3(1))
- GPAI Model: «means an AI model, including where such an AI model is trained with a large amount of data using self-supervision at scale, that displays significant generality and is capable of competently performing a wide range of distinct tasks regardless of the way the model is placed on the market and that can be integrated into a variety of downstream systems or applications, except AI models that are used for research, development or prototyping activities before they are placed on the market» (Article 3(63))

# AI Systems vs AI Models

## AI SYSTEM (Article 3(1))



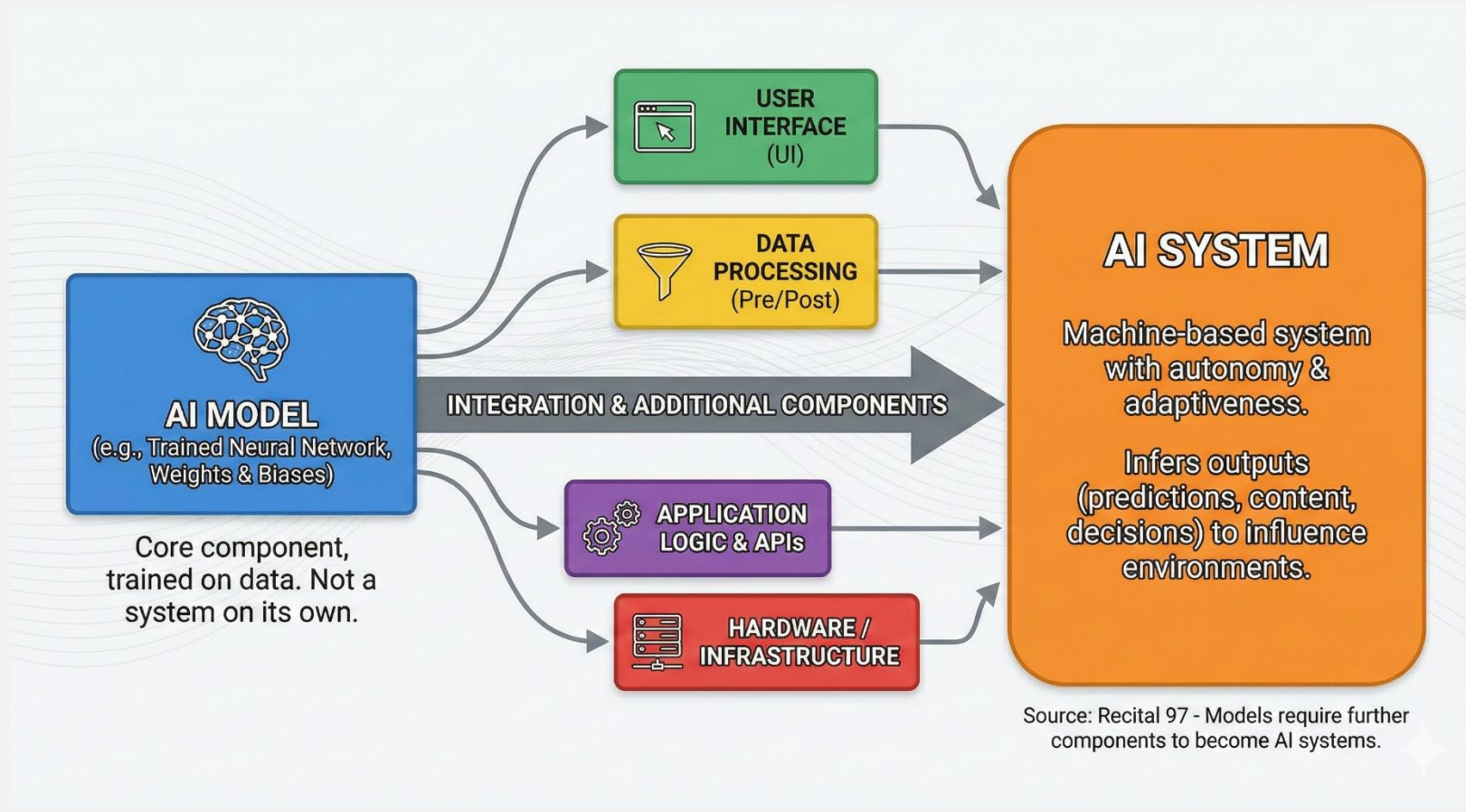
## GENERAL-PURPOSE AI MODEL (GPAI) (Article 3(63))



# AI Systems vs AI Models

- «...the definition [of AI system] should be based on key characteristics of AI systems that distinguish it from simpler traditional software systems or programming approaches and should not cover systems that are based on the rules defined solely by natural persons to automatically execute operations.»
- «Although AI models are essential components of AI systems, they do not constitute AI systems on their own. AI models require the addition of further components, such as for example a user interface, to become AI systems. AI models are typically integrated into and form part of AI systems. » (Recital 97)

# AI Systems vs AI Models



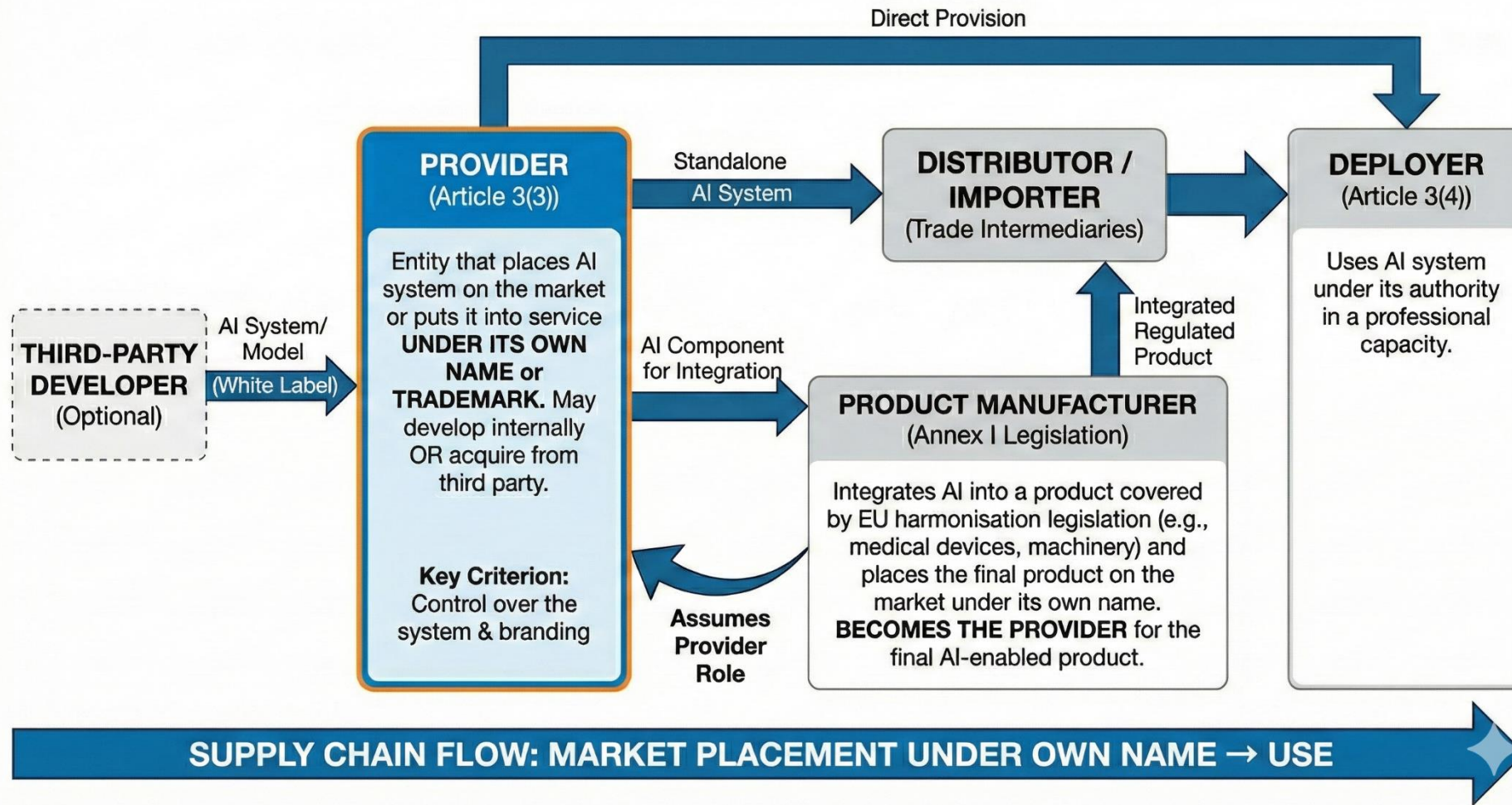
# What is the AIA's Material Scope: Market Focus

- Two main actions:
  - Placing on the market: «*the first making available of an AI system or a general-purpose AI model on the Union market*» (Article 3(9))
    - Making available on the market: «*the supply of an AI system or a general-purpose AI model for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge*» (Article 3(10))
  - Putting into service: «*the supply of an AI system for first use directly to the deployer or for own use in the Union for its intended purpose*» (Article 3(11))
- AIA does not apply to non-marketed AI!

# What is the AIA's Personal Scope: Operators

- Provider: 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 (Article 3(3))
- 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 (Article 3(5))
- Product manufacturer: means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under that person's name or trademark (GPSR)
- Deployer: 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 (Article 3(4))
- 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 (Article 3(7))
- 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 (Article 3(6))

# Operators



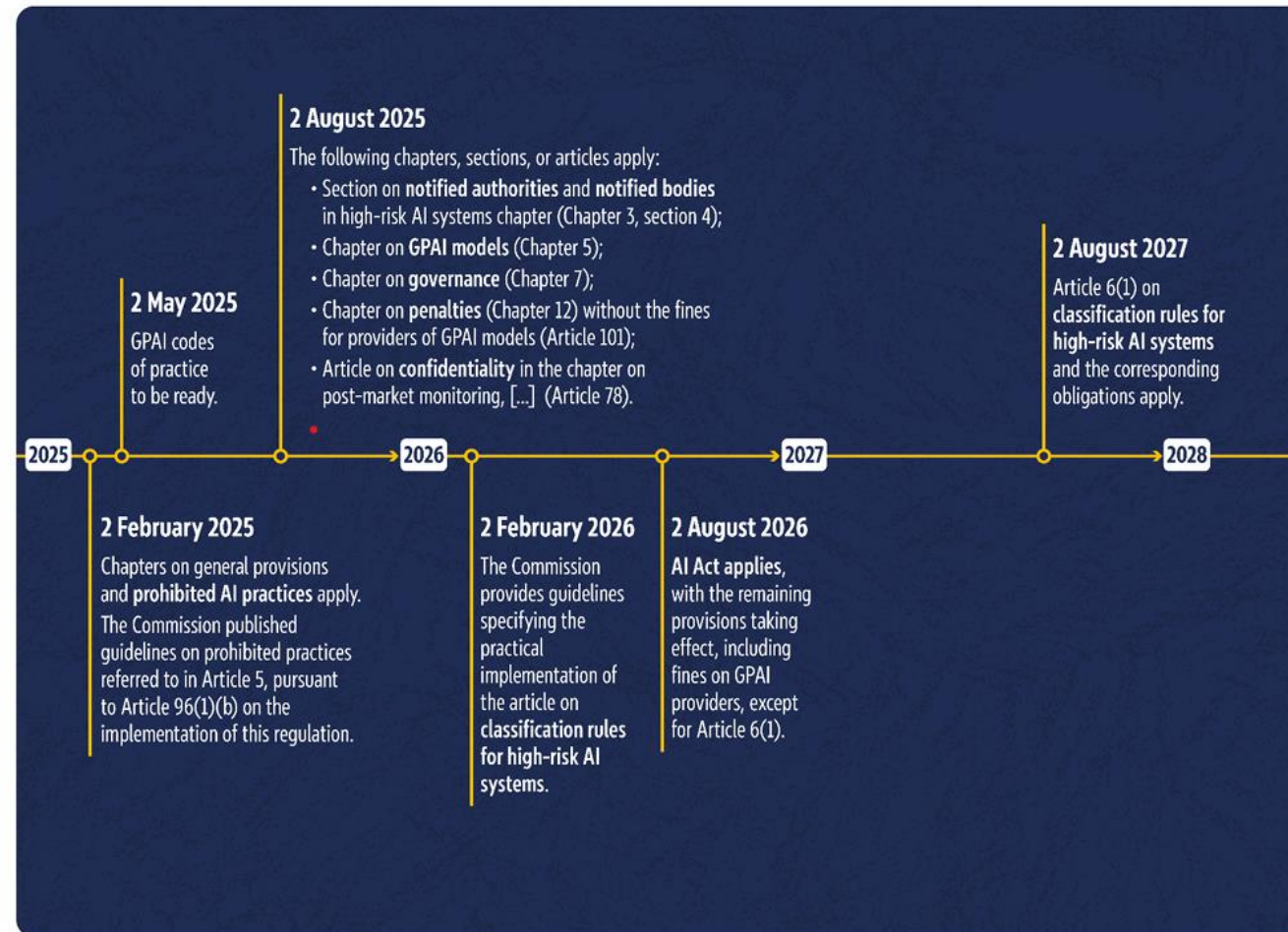
# What is the AIA's Territorial Scope

- Provider: 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 (Article 3(3))
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# What is the AIA's Temporal Scope

- Provider: 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 (Article 3(3))
- 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 (Article 3(5))
- Product manufacturer: means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under that person's name or trademark (GPSR)
- Deployer: 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 (Article 3(4))
- 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 (Article 3(7))
- 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 (Article 3(6))

# AI Act Implementation Timeline (Current Text)



EPRS | European Parliamentary Research Service

Author: Tristan Marcelin with Lucille Killmayer, Members' Research Service  
PE 772.906 – June 2025

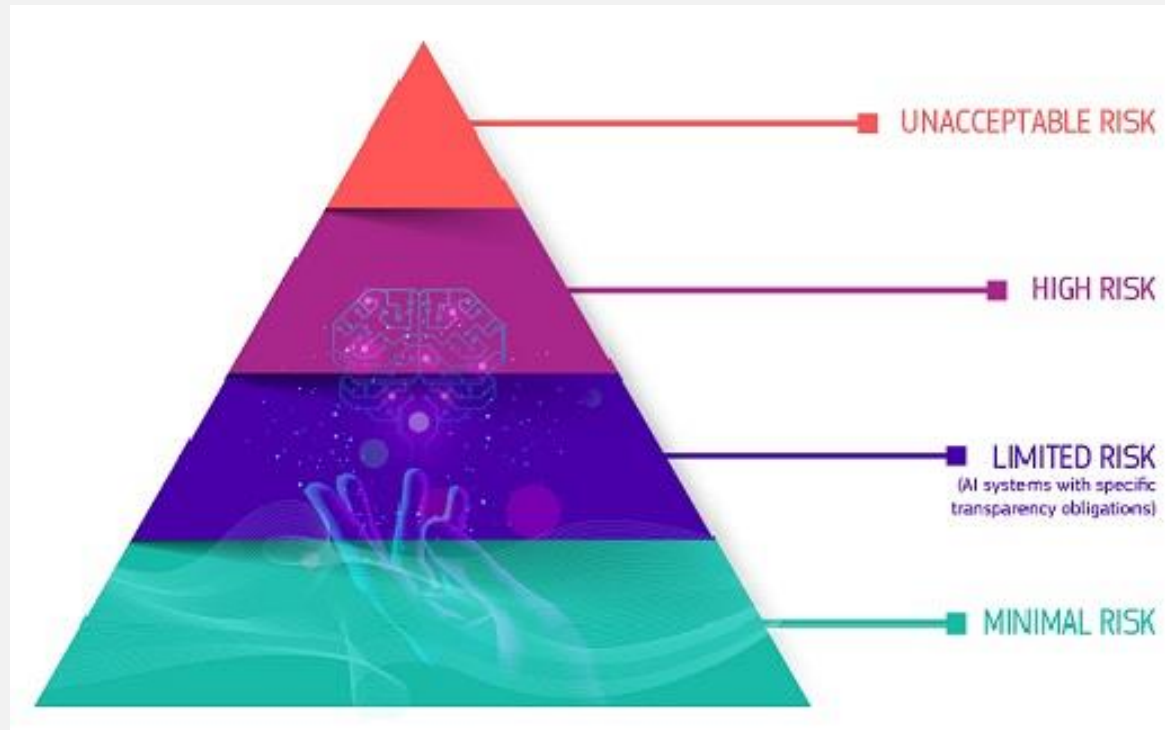


# The Obligations & Requirements under the AI Act

# The Classification

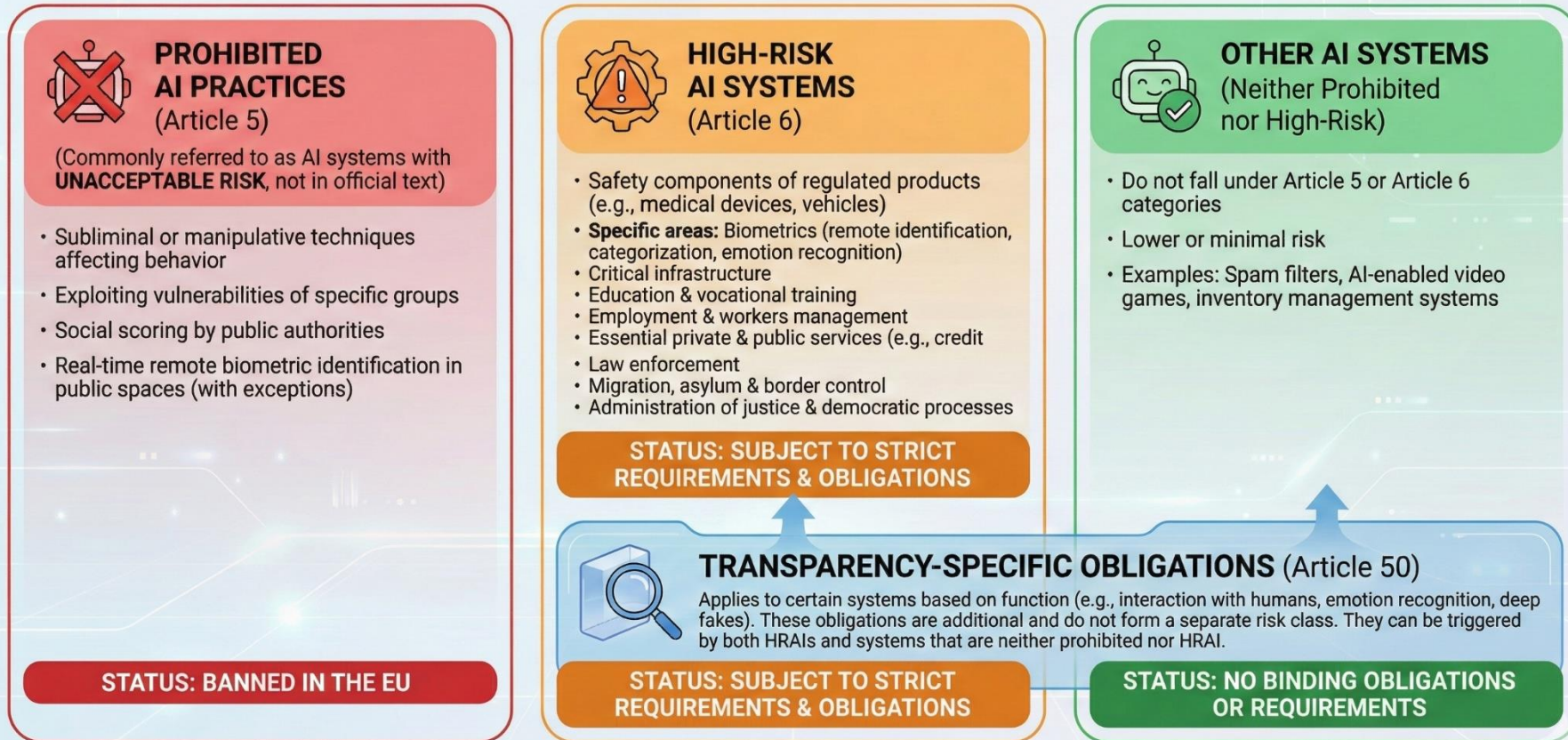
- If the scope assessment concludes that AIA indeed applies to a given system or GPAI model, then a classification must be conducted.
- In principle, AIA treats AI systems and GPAI models separately under different risk-classifications.

# The Classification: AI Systems



# Classification: AI Systems

## CLASSIFICATION OF AI SYSTEMS UNDER THE EU AI ACT



\*Note: The three main groups (Prohibited, High-Risk, Other) are exclusive to each other. A single AI system can only belong to one of these groups.

# Prohibited AI Practices

## PROHIBITED AI PRACTICES UNDER THE AI ACT (ARTICLE 5)

### MANIPULATION & VULNERABILITY EXPLOITATION

#### SUBLIMINAL & MANIPULATIVE TECHNIQUES (Art. 5(1)(a))



Deploying subliminal techniques or purposefully manipulative/deceptive techniques to distort behavior and impair informed decision-making, causing significant harm.

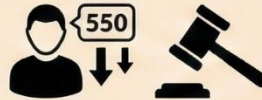
#### EXPLOITATION OF VULNERABILITIES (Art. 5(1)(b))



Exploiting vulnerabilities due to age, disability, or social/economic situation to materially distort behavior and cause significant harm.

### SOCIAL SCORING & PREDICTIVE POLICING

#### SOCIAL SCORING (Art. 5(1)(c))



Evaluating or classifying persons over time based on social behavior or personality for detrimental or unfavorable treatment in unrelated contexts or disproportionately.

#### PREDICTIVE POLICING (Art. 5(1)(d))



Assessing risk of committing criminal offenses based solely on profiling or assessing personality traits and characteristics. **Exception:** Supporting human assessment based on objective facts.

### BIOMETRICS & SURVEILLANCE

#### BIOMETRIC CATEGORIZATION (Art. 5(1)(g))



Categorizing natural persons based on biometric data to deduce sensitive attributes (race, politics, religion, etc.). **Exception:** Lawful labeling/filtering in law enforcement.

#### EMOTION RECOGNITION (Art. 5(1)(f))



Inferring emotions in workplaces and education institutions. **Exception:** Medical or safety reasons.

#### UNTARGETED FACIAL SCRAPING (Art. 5(1)(e))



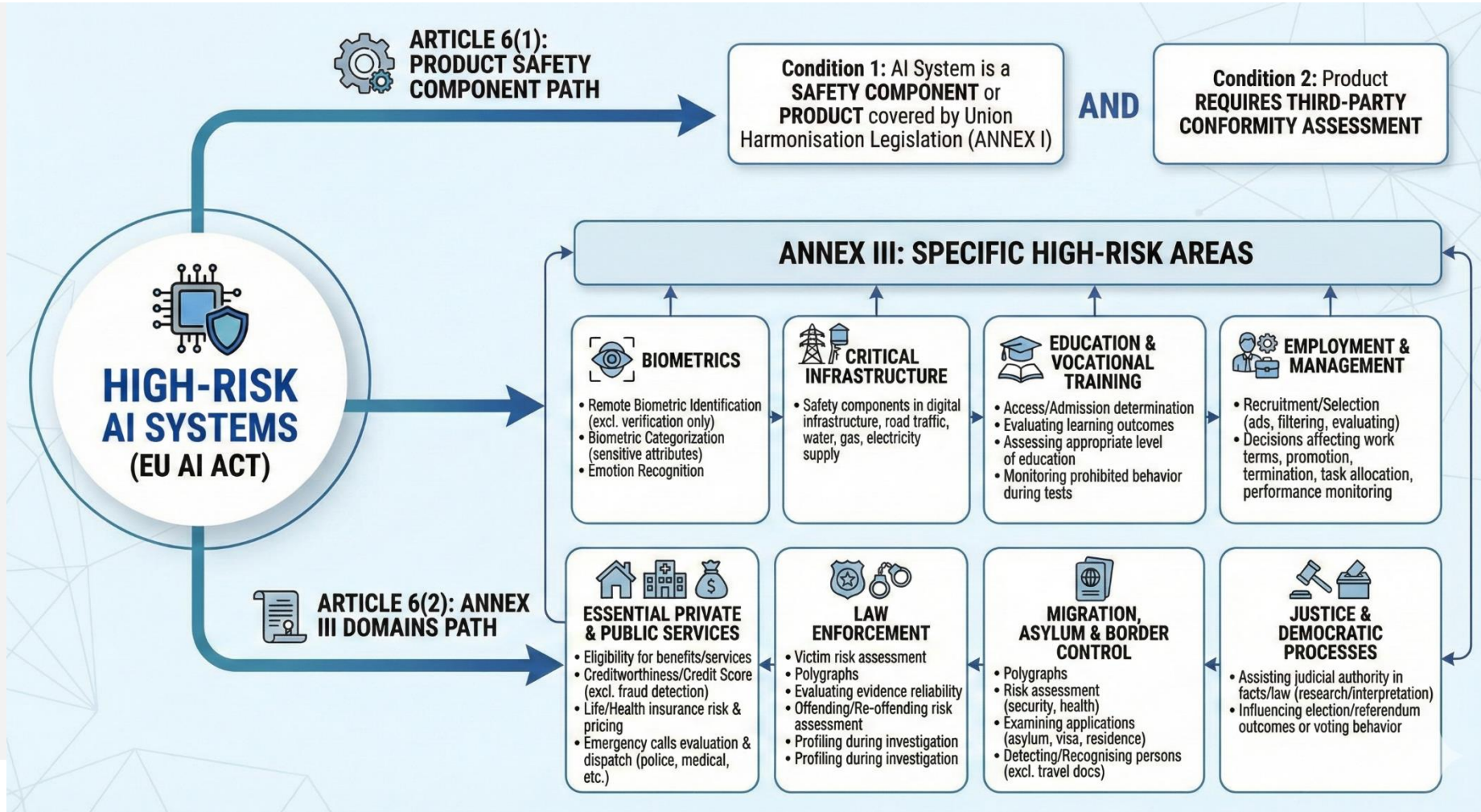
Creating or expanding facial recognition databases through untargeted scraping of facial images from the internet or CCTV footage.

#### REAL-TIME REMOTE BIOMETRIC IDENTIFICATION (Art. 5(1)(h))



Real-time remote biometric identification in publicly accessible spaces for law enforcement. Strictly limited exceptions apply (victims, threats, serious crimes) with procedural safeguards (prior authorization, FRIA, etc.).

# High Risk AI Systems



# Technical Requirements for HRAIS

## EU AI Act: Technical Requirements for High-Risk AI Systems (Articles 8-15)

### RISK MANAGEMENT SYSTEM (Art. 9)

- Continuous, iterative process & lifecycle review.
- Identify & analyze risks to health, safety, fundamental rights.
- Estimate & evaluate foreseeable risks & misuse.
- Adopt mitigation measures (design, controls, information).
- Testing & post-market data integration.
- Consider vulnerable groups (e.g., minors).

### ACCURACY, ROBUSTNESS & CYBERSECURITY (Art. 15)

- Achieve & maintain appropriate levels throughout lifecycle.
- **Accuracy:** Declared metrics, benchmarks.
- **Robustness:** Resilient to errors, faults, feedback loops (technical redundancy).
- **Cybersecurity:** Resilient to attacks (data poisoning, model evasion, flaws).

### HUMAN OVERSIGHT (Art. 14)

- Designed for effective natural person oversight.
- Prevent/minimise risks, even with other measures.
- **Measures:** Built-in or deployer-implemented.
- **Enable:** Understanding, monitoring anomalies, avoiding automation bias, intervening/stopping system.

### GENERAL COMPLIANCE (Art. 8)

- Comply with all requirements & state of the art.
- Integrate with existing Union harmonization legislation.
- Avoid duplication & minimize burden.

### DATA GOVERNANCE (Art. 10)

- High-quality training, validation, testing data.
- Relevance, representativeness, error-free, complete.
- Appropriate data management practices (design, collection, cleaning).
- Bias detection & mitigation measures (incl. limited special data use).
- Address data gaps & shortcomings.

### TECHNICAL DOCUMENTATION (Art. 11)

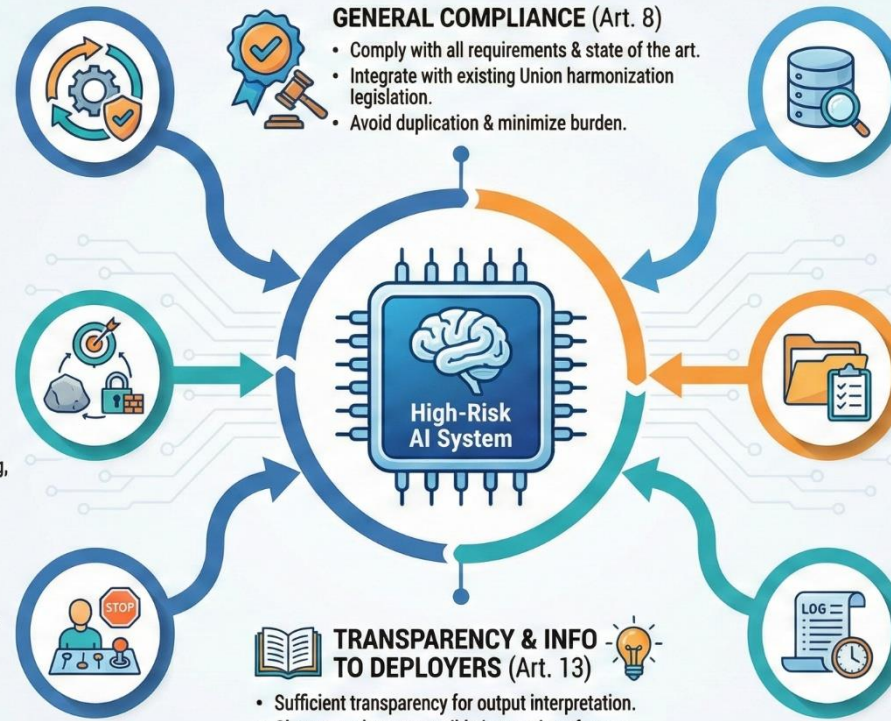
- Drawn up before market entry & kept up-to-date.
- Demonstrates compliance & provides necessary info for authorities/notified bodies.
- Comprehensive details (Annex IV elements) or simplified for SMEs.
- Integration with Union harmonisation legislation docs.

### RECORD-KEEPING (LOGS) (Art. 12)

- Automatic recording of events over system lifetime.
- Traceability appropriate to intended purpose.
- Log situations presenting risk/modification, post-market monitoring.
- Capture period of use, input data, match results, human verification.

### TRANSPARENCY & INFO TO DEPLOYERS (Art. 13)

- Sufficient transparency for output interpretation.
- Clear, complete, accessible instructions for use.
- Includes: Identity, characteristics, capabilities, limitations, human oversight measures, maintenance needs.
- Information on data specifications & changes.



# Obligations of the Providers of HRAIS

## EU AI Act: Obligations of Providers of High-Risk AI Systems

### ENSURE & DEMONSTRATE COMPLIANCE (Art. 16, 43, 47, 48, 49)

- Ensure compliance with Section 2 requirements.
- Undergo conformity assessment procedure.
- Draw up EU declaration of conformity.
- Affix CE marking.
- Comply with registration obligations.
- Demonstrate conformity upon reasoned request.

### DOCUMENTATION & LOGS (Art. 18, 19)

- Keep for 10 years after market placement (at disposal of authorities):
  - Technical documentation
  - QMS documentation
  - Changes approved by notified bodies
  - Decisions of notified bodies
  - EU declaration of conformity
- Keep automatically generated logs (under control) for appropriate period (at least 6 months).

### CORRECTIVE ACTIONS & DUTY OF INFORMATION (Art. 20)

- Immediately take corrective actions for non-conformity (bring to conformity, withdraw, disable, recall).
- Inform distributors, deployers, authorised representatives, importers.
- Immediately investigate & inform market surveillance authorities & notified bodies if system presents a risk (Art. 79(1)).

\*Specific obligations may apply for financial institutions under relevant Union financial services law (Art. 17(4), 18(3), 19(2)).

### QUALITY & RISK MANAGEMENT (Art. 9, 17)

- Establish & maintain a Quality Management System (QMS) (Art. 17).
  - QMS includes: Regulatory compliance strategy
  - Design & development procedures
  - Examination/test/validation
  - Data management
  - Risk management system (Art. 9)
  - Post-market monitoring
  - Serious incident reporting
  - Communication handling
  - Resource management
  - Accountability framework
- Implementation proportionate to provider's size.

### TRANSPARENCY & COMMUNICATION (Art. 16, Directives)

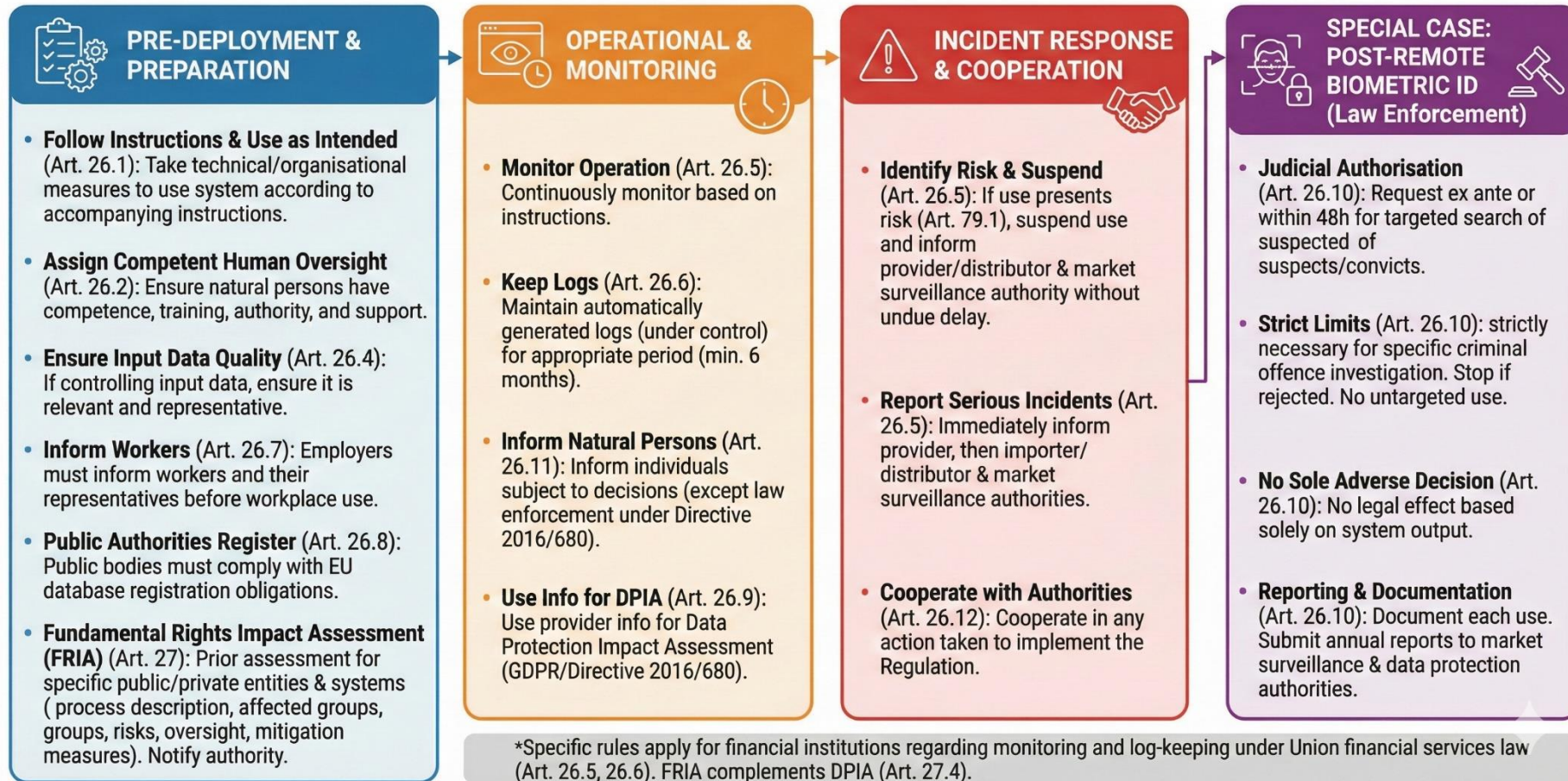
- Indicate provider name, trade name/mark, contact address on system/packaging/docs.
- Ensure accessibility compliance (Directives (EU) 2016/2102 & 2019/882).
- Provide information & cooperate with competent authorities.

### COOPERATION WITH AUTHORITIES (Art. 21)

- Provide necessary information & documentation to demonstrate conformity upon reasoned request.
- Provide access to automatically generated logs upon reasoned request.
- All provided information treated with confidentiality.

# Obligations of the Deployers of HRAIS

## AI Act: Obligations of Deployers of High-Risk AI Systems (Articles 26 & 27)



# Obligations of Other Operators

## AI Act Obligations: Authorised Representatives, Importers, & Distributors of High-Risk AI Systems


**AUTHORISED REPRESENTATIVE**  
 (Art. 22)
 

Appointed by non-EU Provider via Written Mandate

**Key Obligations**



-  **Verify Compliance Docs**  
Verify EU Declaration of Conformity, Technical Documentation, & Conformity Assessment.
-  **Keep Records (10 Yrs)**  
Keep Provider contact, EU Decl. of Conformity, Tech Docs, Certificates available to authorities.
-  **Provide Info & Logs**  
Provide necessary info, docs, & access to generated logs to competent authorities upon request.
-  **Cooperate with Authorities**  
Cooperate in actions to reduce/mitigate risks.
-  **Handle Registration**  
Comply with registration obligations or verify Provider's registration info.
-  **Terminate Mandate**  
Terminate if Provider acts contrary to obligations; inform authorities & notified body.


**IMPORTER**  
 (Art. 23)
 

Places AI System on Union Market






**Key Obligations**

-  **Pre-Market Verification**  
Ensure conformity assessment done, Technical Docs drawn up, CE marking & EU Decl. of Conformity present, Authorised Rep appointed.
-  **Block Non-Compliant Systems**  
Do not place on market if reasons to believe it's not in conformity, falsified, or presents a risk. Inform Provider, Auth. Rep, & Authorities.
-  **Indicate Contact Details**  
Indicate name, registered trade name/mark, & contact address on system/packaging/docs.
-  **Ensure Compliant Storage/Transport**  
Conditions must not jeopardise compliance while under responsibility.
-  **Keep Records (10 Yrs)**  
Keep Certificates, Instructions for Use, & EU Decl. of Conformity.
-  **Provide Info & Cooperate**  
Provide info/docs to authorities in understood language; cooperate to mitigate risks.


**DISTRIBUTOR**  
 (Art. 24)
 

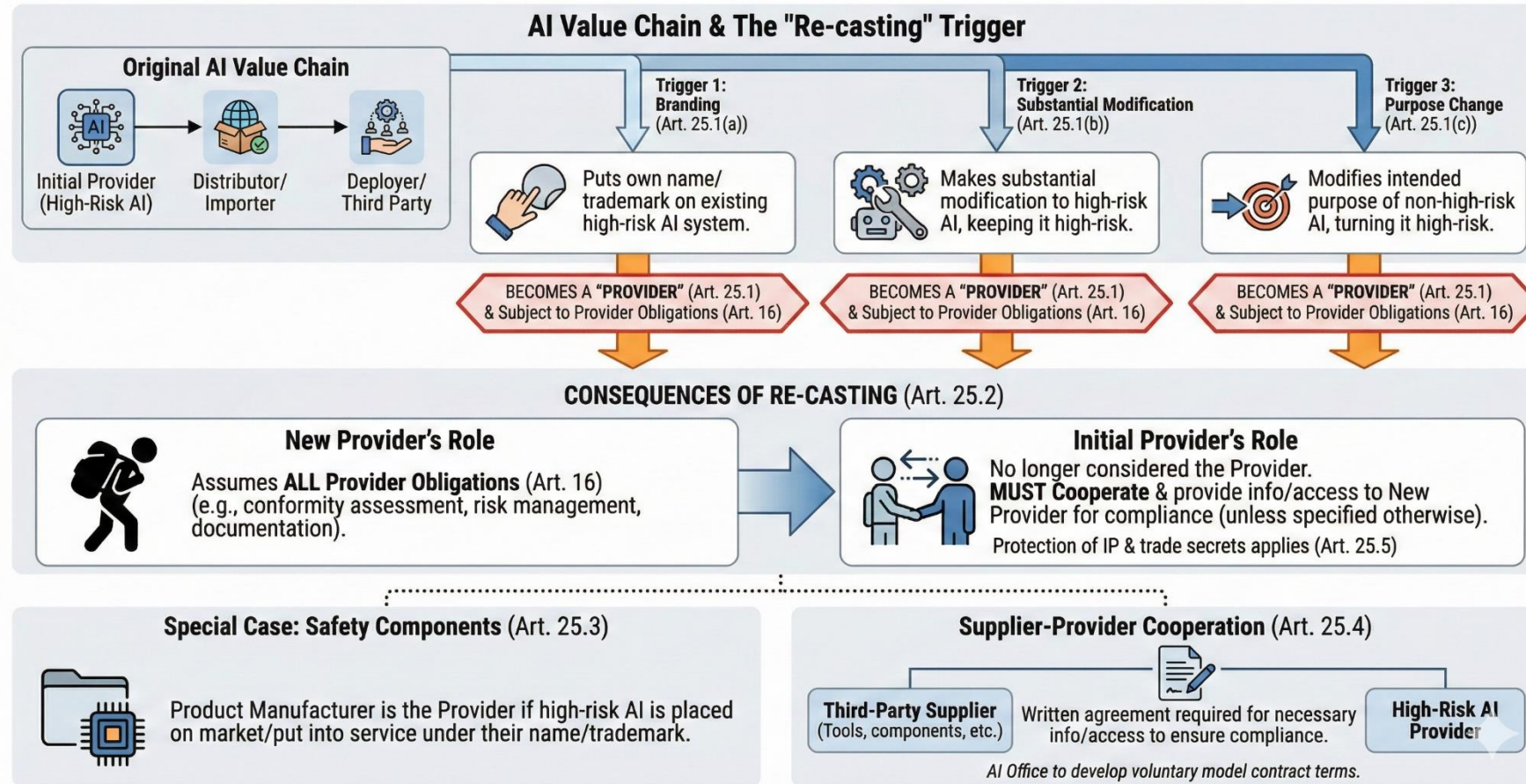
Makes AI System Available on Market

**Key Obligations**

-  **Verification Checks**  
Verify required CE marking, EU Decl. of Conformity, Instructions for Use, & Provider/Importer info.
-  **Block & Correct Non-Compliance**  
Do not make available if not in conformity. Take corrective actions (bring to conformity, withdraw, recall) if already made available. Inform Provider/Importer.
-  **Report Risks**  
Immediately inform Provider/Importer & Authorities if system presents a risk, detailing non-compliance & actions taken.
-  **Ensure Compliant Storage/Transport**  
Conditions must not jeopardise compliance while under responsibility.
-  **Provide Info & Cooperate**  
Provide info/docs demonstrating conformity actions; cooperate with authorities to mitigate risks.

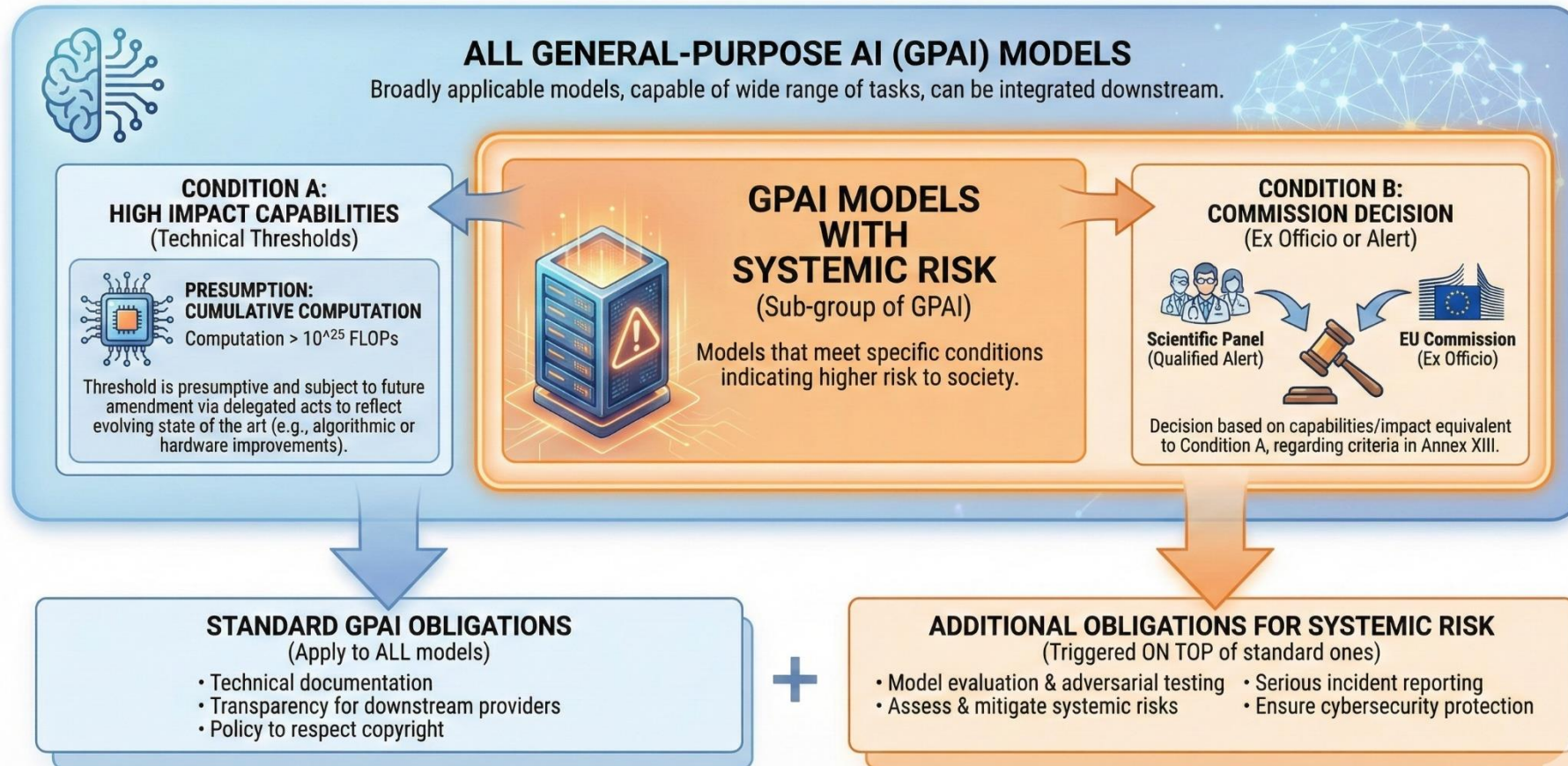
# Obligations Along the Value Chain and Operator-Casting

## AI Act Operator Casting Provision (Article 25): Responsibilities along the AI Value Chain



# Classification: GPAI Models

## CLASSIFICATION & OBLIGATIONS OF GENERAL-PURPOSE AI (GPAI) MODELS (EU AI ACT)



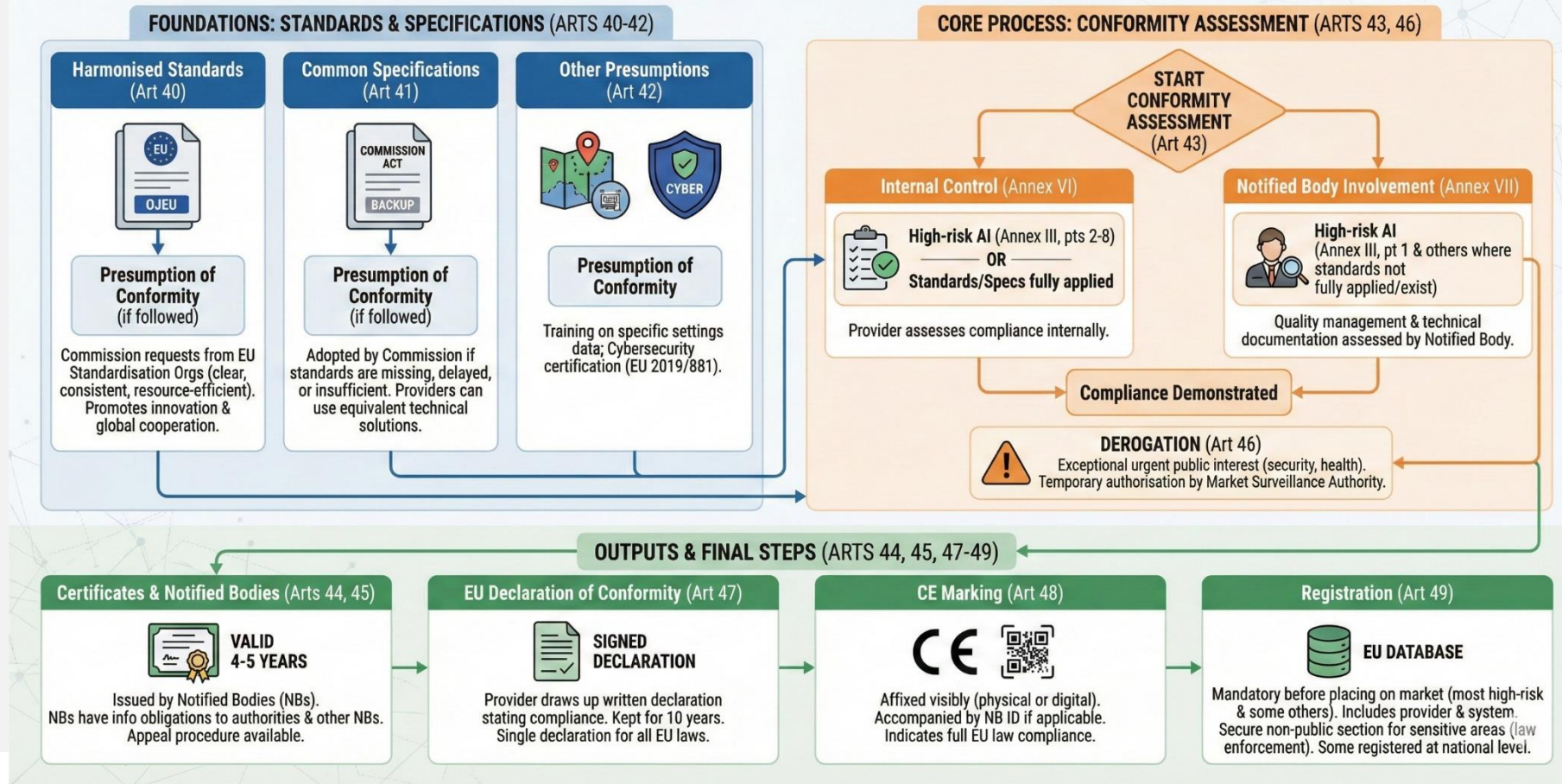
Note: GPAI Models and GPAI Models with Systemic Risk are NOT exclusive. A model classified as having systemic risk is also a GPAI model and must comply with both sets of obligations.

# Enforcement and Governance



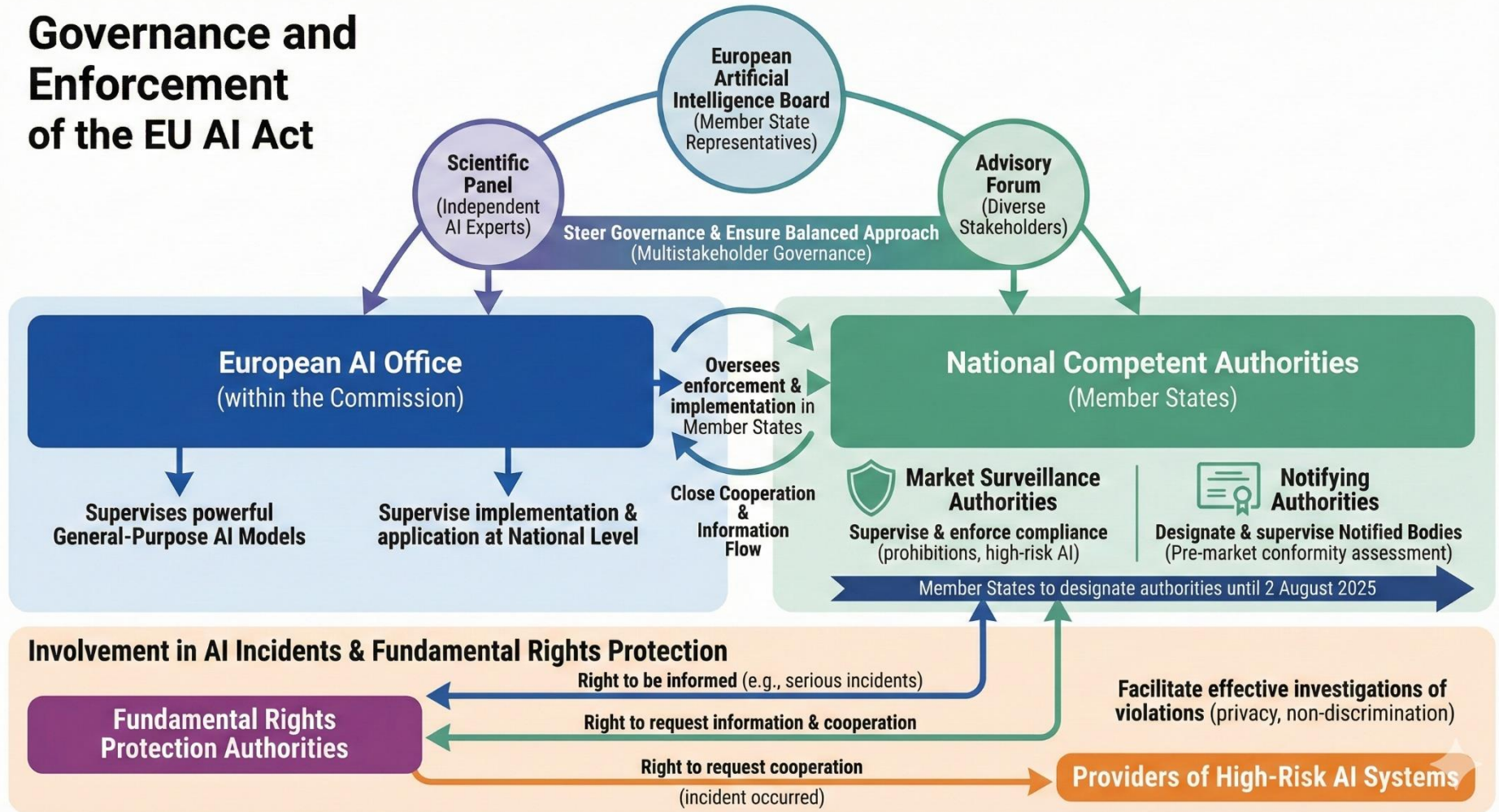
# Enforcement of the AI Act: Conformity Assessment

## AI Act Section 5: Standards, Conformity, Certificates, and Registration Process Flow



# AI Act Governance and Enforcement

## Governance and Enforcement of the EU AI Act



# Digital Omnibus Package and Expected Changes



# Digital Omnibus on AI Regulation Proposal



Brussels, 19.11.2025  
COM(2025) 836 final  
2025/0359 (COD)

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI)**

{SWD(2025) 836 final}

(Text with EEA relevance)



# Key Takeaways from the Omnibus

- This is a proposal to amend a regulation. So in order to get adopted, it has to go through the ordinary legislative procedure (OLP) of the EU just like the Act itself has done.
- OLP requires the agreement of the EU co-legislators, the Parliament and the Council. So it can be a long process, which makes it uncertain whether the omnibus will be adopted in time, before the application date of the current text, 2 August 2026

# Standard table slide

Title	Title	Title	Title	Title
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3	Lorem ipsum dolor sit amet	123,456,789	Lorem ipsum dolor sit amet	Lorem ipsum dolor sit amet
4	Lorem ipsum dolor sit amet	123,456,789	Lorem ipsum dolor sit amet	Lorem ipsum dolor sit amet
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# Thank You!

**BSC AIF Market  
Research Survey**

**Social Media**



[aifactory@tubitak.gov.tr](mailto:aifactory@tubitak.gov.tr)

[bsc-ie@bsc.es](mailto:bsc-ie@bsc.es)



**Web Page**



**BSC AI Factory Partners**

**Affiliated entities**

This project has received funding from the European High-Performance Computing Joint Undertaking (JU) under grant agreement No 101234399 and Spain, Portugal, Romania and Türkiye. The JU receives support from the European Union's Horizon Europe Programme.

