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# Risk assessment analysis of AI systems

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## EU Artificial Intelligence Act (Reg. 2024/1689)

Establishes harmonised rules on AI systems on a risk-based approach.

Title I. General Provisions (Art. 1–4): Defines scope, key terms, and promotes AI literacy.

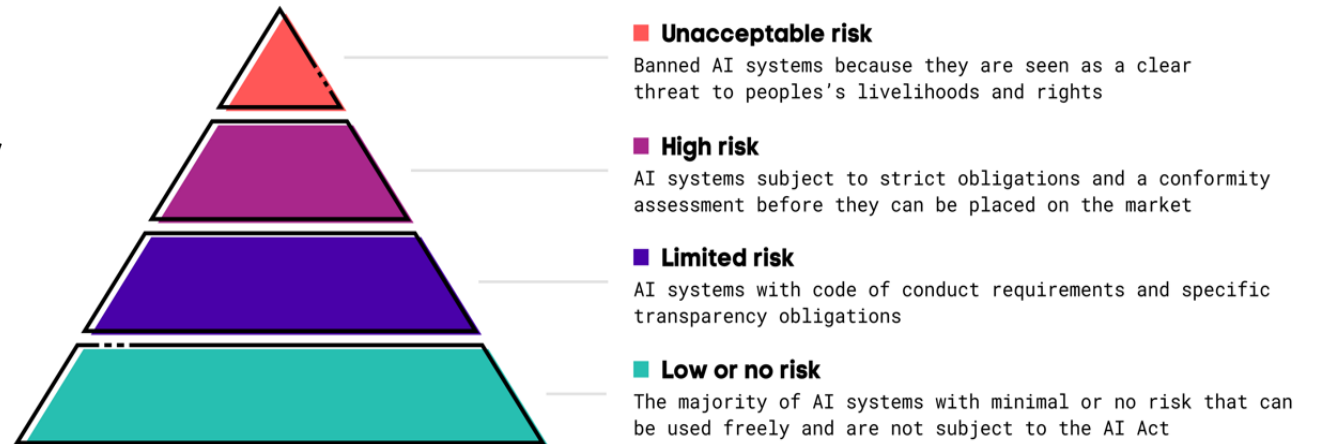
Title II. Prohibited Practices (Art. 5): Bans AI that exploits vulnerabilities, enables social scoring, or biometric ID in public.

Title III. High-Risk AI (Art. 6–43):

Requirements include:

- Risk management, data governance, documentation, transparency, human oversight, accuracy, cybersecurity,...
- Also covers provider obligations and conformity assessment.

Title IV. Transparency (Art. 50–52): AI must inform users when interacting with humans, using biometrics, or generating content.



## Purpose

Help organisations determine whether their AI systems may fall under the **High-Risk** category of the **EU AI Act** and support early preparation for compliance, <https://citcomtef.eu/services/ai-act-risk-level-evaluation>

## Scope

Applies to industrial automation, energy and utilities, critical infrastructure, mobility, agrifood, healthcare, and public-sector AI.  
Focus on classification triggers described in Articles 5 and 6, Annex I and Annex III.

## What does the service provide

- A structured methodology that translates AI Act requirements into a practical assessment, supported by relevant international and sectoral standards.
- Initial screening of model type, use case, deployment domain, risk indicators, testing approaches, and role-based obligations.
- Early insights into classification outcomes, compliance gaps, and readiness for conformity assessment.
- A foundation for informed decision-making and strategic planning for AI-based products and services.

## Service foundations

### Two-Path High-Risk Assessment Logic

#### Article 6 (High-Risk AI Systems)

##### Path A – Product-Based (Art. 6(1)(a)(b))

*“AI systems that are safety components of products, or which are themselves products, covered by the Union harmonization legislation listed in Annex I, and that are subject to a third-party conformity assessment under that legislation.”*

##### Path B – Use-Based (Art. 6(2))

*“AI systems that are intended to be used in any of the areas listed in Annex III.”*

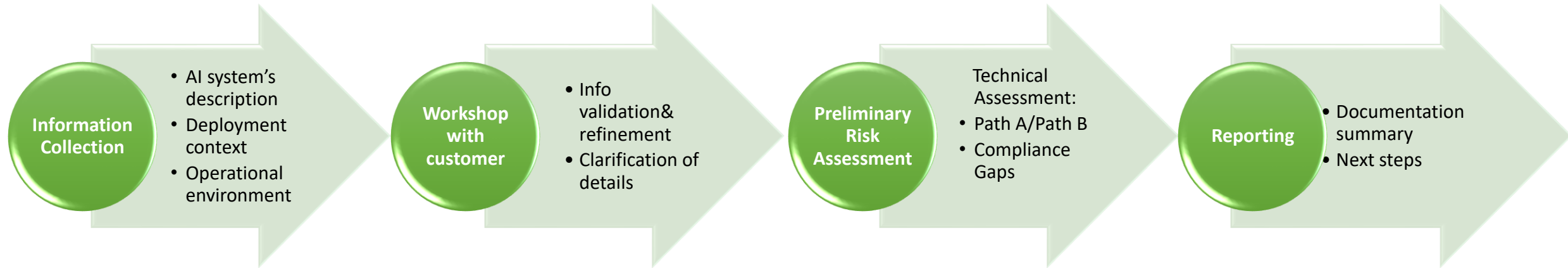
### Standards & Reference Frameworks

**Interim:** ISO/IEC 23894, ISO/IEC 42001, ISO 12100,

**AI Act:** prEN 18286 (emerging harmonized standard)

**Complementary:** NIST AI RMF, JRC AI Watch

## Process Flow



### Tools and Inputs:

- ❖ Assessment Questionnaire (system purpose, context of use, technical design, deployment patterns, and potential regulatory triggers)
- ❖ Screening Matrix (Article 5) (prohibited use)
- ❖ Legal Mapping Template (Article 6) (high-risk identification)
- ❖ Compliance Gap Table (missing elements as RM, fundamental rights assessment, oversight mechanisms, etc)
- ❖ Actor-Role Identification Template (Provider, Deployer, Importer, or Distributor, etc)

### Deliverables:

- ❖ Preliminary Risk Classification Report summarising outcomes, rationale, regulatory references, and contextual considerations.
- ❖ Validated Questionnaire and Evidence Record including clarifications and assumptions.
- ❖ Compliance Gap Table highlighting missing or partial measures required under the EU AI Act.
- ❖ Optional Testing and Compliance Roadmap presenting further recommendations.

## Visual Quality Inspection (Manufacturing)

Deep-learning defect detection (approve/reject).

Deployment via PLCs, robotic integration, semi-automated or automated modes.

Results:

**Path A may apply if the AI acts as a safety function under Machinery Regulation (EU) 2023/1230.**

**Path B applies only in specific critical-infrastructure contexts.**

**For now: Minimal-Risk (Article 52 transparency obligations)**

<https://citcomtef.eu/news/gimic-first-to-undergo-rises-new-ai-risk-assessment-service>

## District-Heating Forecasting (Energy Infrastructure)

Forecasts heat demand, indoor temperature, and distribution delays.

Integrated with SCADA and PLCs (operator-in-the-loop).

Results:

**Path B applies: Confirmed High-Risk under Annex III.2 (critical infrastructure).**

**Path A may apply if future versions execute autonomous control functions.**

### Gimic first to undergo RISE's new AI risk assessment service



Fri, 24. Oct. 2025

By Marie Elmquist

The company Gimic develops AI-based systems for automated quality control in the manufacturing industry and is the first to undergo RISE's new Risk Assessment Analysis Service for evaluating systems in relation to the EU AI Act. The service has been developed within the framework of CITCom AI TEF.

"We received a clear report showing where we stand today and what steps we need to take going forward," says Anders Cederlund, Project Manager at Gimic.

#### Supporting decision-making and strategic planning

The goal of the service is to support decision-making and strategic planning for AI-based products and services, focusing on analysis and compliance with the AI Act and other AI-related regulations.

#### AI as the final puzzle piece

Gimic develops AI-based systems for automated quality control in industrial production. Instead of an operator manually inspecting, for example, a gear to identify defects, cameras and AI models are used.

"We see our technology as the final puzzle piece in fully automated factories. Today, almost the entire production flow is automated, but the final inspection is often still manual. With our solution, the process can become fully automated."

1

## Limited Information Visibility and Documentation

Providers often hesitate to share technical or deployment details, even under NDA.

Deployment information is frequently incomplete or undocumented, making classifications conditional and dependent on actual use cases.

2

## Uncertainty in Applying Article 6 (Path A / Path B)

Determining whether AI is a **safety component** under the Machinery Regulation (Path A) or falls within **critical-infrastructure domains** under Annex III (Path B) remains difficult.

Ambiguous Annex III wording complicates borderline cases, especially for industrial control systems.

3

## Strong Dependence on Deployment Context

Classification outcomes rely more on **where and how** the AI system is used than on its core function.

Technical integration into robotics or control systems can elevate risk under **Article 6(2)**.

4

## Lack of Harmonised Standards and Compliance Pathways

Harmonised AI Act standards are not yet available and providers struggle to demonstrate compliance (e.g., robustness, accuracy, cybersecurity).

Interim reliance on **ISO 23894**, **ISO 42001**, **IEC 62443** offers procedural support, and the forthcoming **prEN 18286** will be central for conformity.

5

## Questionnaire and Methodology Practicalities

Designing universally applicable questions is challenging; many items cannot be answered with simple yes/no choices.

The structured, stepwise process (screening → classification → obligations mapping) improves traceability but requires time and customer engagement.

6

## Customer Awareness, Expectations, and Sensitivity

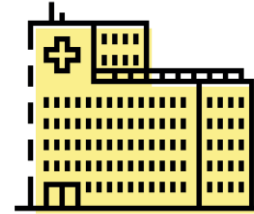
Many organisations remain unaware of the AI Act and underestimate their likelihood of falling into the High-Risk category.

Customers expect not only classification results but also practical guidance on compliance.

Risk classification reports can be sensitive, especially in critical sectors, requiring attention to confidentiality and contractual arrangements.

- ❖ CitCom TEF continues to develop the Risk Classification Analysis Service, extending it into new application sectors.
- ❖ The service will be adapted to upcoming harmonised standards, new secondary legislation, and related EU directives.
- ❖ Expansion to other TEFs (Health, AgriFood) is planned, requiring additional work on identifying and integrating sector-specific standards.
- ❖ The full report on Risk Classification has been prepared at CitCom.
- ❖ A scientific article on the challenges of risk classification for industrial and ICS-related AI systems is under development.

## ❖ TEFs at RISE



Health



AgriFood



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CitCom<sup>AI</sup>

Please, reach out to us for any further details concerning the service!