



Draft Guidelines on High-Risk AI Classification

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Why These Guidelines Matter

The Commission's draft Guidelines provide practical clarification on when AI systems should be classified as "high-risk" under Article 6 AI Act. The aim is to promote more consistent enforcement and reduce uncertainty for businesses and regulators.



Two Routes to "High-Risk"

AI becomes high-risk either:

- 1) As part of regulated products (Annex I)
- 2) When used in sensitive Annex III use cases such as HR, biometrics or credit scoring



Risk-Based Approach Confirmed

The Guidelines reinforce the AI Act's risk-based philosophy. The Commission stresses that only a limited and targeted category of AI systems should qualify as high-risk. Classification is intended to remain proportionate and sector-specific.



Intended Purpose Is Critical

Classification depends heavily on the provider's intended purpose, technical documentation and product positioning. Marketing materials and usage instructions may also influence the assessment.



Human Oversight Is NOT Enough

Adding human review does not automatically remove high-risk classification. Human oversight is treated as a compliance safeguard — not a way to avoid regulation.



Annex III Focus Areas

The Guidelines provide detailed examples across key sectors including biometrics, employment, education, insurance, migration, law enforcement and access to essential services.



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The “Filter Mechanism”

Certain systems may avoid high-risk classification where they perform only narrow procedural, preparatory or support functions. However, the Commission interprets these exemptions narrowly.



Profiling Remains High-Risk

AI systems involving profiling of natural persons generally cannot benefit from the Article 6(3) exemption. This is particularly relevant for HR, insurance, public sector and financial services use cases.



Complex AI Ecosystems Scrutinised

The Commission warns against attempts to artificially split AI systems to avoid compliance obligations. Interconnected or agentic AI systems may be assessed together as one high-risk system.



Product Safety AI

AI integrated into regulated products — including medical devices, robotics, machinery and automotive systems — may qualify as high-risk where safety functions are involved.



What Happens Next

- **19 May 2026** — Commission launched targeted consultation
- **23 Jun 2026** — Deadline for stakeholder feedback
- **2 Dec 2027** — High-risk rules apply for Annex III sectors
- **2 Aug 2028** — Rules apply for AI in regulated products



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