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Regulatory/Supervisory Pills | N.90 June 2025



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European Commission

European Commission Launches Public Consultation on High-risk Al Systems

- European Commission's Al The Office has launched a targeted **stakeholder consultation** – until the 18th of July 2025 - to inform forthcoming guidelines on the classification and regulation high-risk AI systems under the AI Act (Regulation (EU) 2024/1689), which entered into force on 1 August 2024. The Al Act adopts a risk-based approach, categorising Al systems by potential risk levels. High-risk systems—governed Αl under Chapter III—will become compliance subject to requirements **starting** 2 August 2026.
- High-risk systems fall into two categories: Article 6(1) covers Al embedded as safety components or Al that constitutes a regulated product with potential adverse impacts on health and safety; Article 6(2) addresses Al systems posing significant risks to health, safety, or fundamental rights, as listed in Annex III.

Exemptions under Article 6(3) allow certain AI systems not to be classified as high-risk when they do not present significant risks.

- Systems classified as high-risk must comply with stringent requirements covering data governance, documentation. transparency, oversight, human robustness, accuracy, and security. Providers must implement quality management systems and conduct conformity assessments, while deployers are tasked with ensuring proper usage, monitoring, and transparency to affected individuals.
- The consultation is structured into **five sections:** Classification under Article 6(1) and Annex Classification under Article 6(2), Annex III, and related exemptions; questions General on high-risk classification; Requirements value chain obligations; Potential amendments to Annex III and prohibited practices in Article 5

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