



# **EC Consultation on High-Risk AI Systems**



### What was the consultation about?

The consultation asked how the AI Act should decide when an AI system is "high-risk". It covered:

- Article 6(1): links to Annex I (product-safety sectors like medical devices).
- Article 6(2): links to Annex III (the list of AI use-cases deemed high-risk).

The EC also asked how to define key terms (e.g. "intended purpose," "substantial modification"), how to interpret "safety components," and how to split responsibilities between providers (who build/supply AI) and deployers (who use AI).



# Why does it matter?

Being classed high-risk triggers extra controls (a Quality management System, data governance, human oversight, testing, documentation, logs, monitoring). For insurers and pension providers, this could affect which actuarial tools and workflows would need those controls and how they would fit with Solvency II, GDPR and DORA.



## What were our key messages?

- Treat traditional actuarial models separately. We noted that GLMs (generalised 4. linear models) and similar actuarial tools are interpretable and professionally overseen, so they should not be classed high-risk by default; only specific deployments that directly determine access, pricing or coverage should trigger high-risk treatment.
- Get the insurance use-cases right in Annex III. We asked for explicit coverage of genuinely high-impact cases (e.g., automated eligibility/terms in life & health, decisions using shared fraud databases, mandatory motor third-party liability), with clear human-in-the-loop safeguards and a distinction between fully automated engines and decision-support tools.
- 3. Proportionality and equivalence. We supported sector-specific guidance and recognition that existing Solvency II / GDPR / DORA controls already deliver many Al-Act outcomes—avoid duplication.

- 4. Provider–deployer roles and documentation. We asked for clear responsibility splits for in-house, vendor and fine-tuned systems; minimum documentation to be shared along the value chain (without forcing IP disclosure); and workable expectations for QMS, logging and incident handling.
- 5. Define intended purpose and change thresholds. Set criteria that prevent underscoping of intended purpose and treat routine recalibrations/data refreshes as non-substantial within a pre-approved model lifecycle plan; re-assessment should be reserved for material changes to method, context or population.
- Keep Article 6(1) to physical safety. We supported a narrow reading of "safety component" so financial-sector analytics aren't misclassified under 6(1), and asked for guidance on borderline cases and overlaps between 6(1) and 6(2).



