Council of the European Union
General Secretariat

Interinstitutional files:
2025/0359 (COD)
2025/0360 (COD)

Brussels, 09 December 2025

WK 17004/2025 ADD 1

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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Antici Group (Simplification)
Subject:	Omnibus VII (Digital Omnibus and Digital Omnibus on AI) - compiled comments (ddl 05/12)

Following the meeting of the AGS on 1 December on the Omnibus VII (Digital Omnibus and Digital Omnibus on AI), delegations will find comments as received from: LV.

Questions and Comments for the European Commission on the Digital Omnibus Package for the AI Act

Article 4

- How will the Commission and/or Member States ensure the effective implementation of the Article 4 "shall encourage" approach to AI literacy?

- Are any targeted AI literacy training obligations foreseen?

- Will a minimum baseline for AI literacy "outcomes" (or a common minimum competency standard) be developed to prevent divergent interpretations and fragmentation across Member States?

Article 6 (4) / Annex III

- What will be the minimum criteria or format for this "not high-risk" documentation, where the provider considers that an Annex III system is not high-risk, in order to avoid chaotic Member State supervision?

Article 11 (1)

- What is the legal status of the SME/SMC "simplified manner" under Annex VI (Conformity assessment procedure based on internal control): will it be mandatory for SMEs/SMCs, and will it at the same time constitute a sufficient set of evidence?

Article 72 (3)

- Given that the empowerment to adopt an implementing act establishing a harmonised post-market monitoring plan template is removed, will the Commission's guidelines on the post-market monitoring plan still include a recommended model template and/or a minimum list of required elements to ensure consistent implementation across Member States?

Articles 57 and 58

- Will regulatory sandbox "exit reports" be formally recognised as evidence of compliance under the AI Act?
- Will a single EU – wide standard be established for regulatory sandbox documentation (e.g., testing plans, incident logs, and risk-mitigation evidence) to enable re-use across contexts?
- Whether a horizontal sandbox would qualify as a sandbox under the AI Act in case it is established by a dedicated body - AI agency of the Member state, closely cooperating with national competent authorities to establish such AI sandbox, but not being a national competent authority?

Articles 113 and 99

- What exactly does the phrase "adequate measures … are available" (as used on page 31 of the EU Omnibus document) mean in practice – does it require a full set of standards, or could it be satisfied by a partial set?
- Is a safeguard "safe harbour" logic envisaged where standards are not yet available – i.e., if a provider can document that it has followed the available Commission guidelines or other alternative compliance routes, will enforcement and penalties be applied in a proportionate manner?

AI Act Article 27 + GDPR Article 35

- Does the Commission plan to develop a single combined AI Act + GDPR template – i.e., an integrated approach covering both the DPIA (GDPR Article 35) and the FRIA (AI Act Article 27)?