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WORKING PAPER

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From: General Secretariat of the Council
To: Working Party on Telecommunications and Information Society

Subject: Artificial Intelligence Act
- PowerPoint Presentation : Articles 40-51

Delegations will find in annex the PowerPoint Presentation on Artificial Intelligence Act (Articles 40-51) made by the Commission at the Telecommunications and Information Society Working Party on 12 October 2021.
Artt. 40-51
STANDARDS, CONFORMITY ASSESSMENT, CERTIFICATES, REGISTRATION
Standards and common specifications (Artt. 40-41)

- **Harmonised standards** whose references are published in the OJ of the EU provide a presumption of conformity with the requirements of Ch. 2 (Artt. 9-15)

- **Common specifications** may be adopted by the Commission (via implementing act) where
  - harmonised standards do not exist, or
  - relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns

  - Involvement of sectorial expert groups or bodies to be ensured

  - Providers to justify when they do not comply with common specifications (i.e. they have adopted equivalent solutions)
Presumptions of conformity (Art. 42)

► **Compliance with Article 10(4) presumed** for high-risk AI systems that have been trained and tested on data concerning the specific geographical, behavioural and functional setting within which they are intended to be used

► Rationale: reinforces the need for due consideration of the specific European setting or context within which the AI system is to be used (to the extent required by the intended purpose)

► **Compliance with the cybersecurity requirements in Article 15 presumed** for systems certified under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 (Cybersecurity Act)

► Rationale: appropriate linkage with cybersecurity legislation and avoid any possible duplication of obligations/procedures for providers

► First use of possibility foreseen in Art. 54(3) Cybersecurity Act
Conformity assessment (CA) - Art. 43(1)

1st scenario
Provider applies harmonized standards or, where applicable, common specifications

Provider can opt for either:
- CA based on internal control (Annex VI)
- CA based on assessment of QMS and technical documentation (Annex VII)

2nd scenario
Provider has not or partly applied harmonized standards or harmonized standards do not exist and common specifications are not available

Provider shall follow CA based on assessment of QMS and of technical documentation (Annex VII)

- CA procedure described in Annex VII requires the involvement of a notified body
- If EU institutions & law enforcement, immigration or asylum authorities are providers, the EDPS & the national data protection authority/national supervisory authority, as applicable, shall act as notified body
For credit institutions regulated by Directive 2013/36/EU as providers, CA carried out as part of the procedure referred to in Articles 97 to 101 of that Directive.
Conformity assessment (CA) - Art. 43(3)

High-risk AI systems for which the AIA applies together with one of the NLF legislations listed in Annex II, Section A

Requirements of AI Act to be checked as part of existing conformity assessment under those legislations

Involvement of notified bodies designated under those legislations (provided they meet requirements of AI Act for notified bodies – Art. 33)

• Special cases with certain Union harmonisation legislation (e.g. toys): certain products may be exempted (opt-out) from third-party assessment if harmonised standards are in place and applied by the manufacturer
  
  • AI-based safety components of those products would be high-risk under AIA
  
  • As long as applied harmonised standards cover also AI requirements, opt-out prerogative in sectorial law may be used for the AI system-part
1st scenario: when a certificate expires

2nd scenario: substantial modification to the AI system

Re-assessment necessary, regardless of whether the substantually modified system is intended to be further distributed or continues to be used by the current user.

For AI systems which continue to learn after being placed on the market or put into service: any changes which have been pre-determined by the provider (and addressed through appropriate design/control measures) and documented at the moment of the initial conformity assessment shall not constitute a substantial modification.
Empowerment foreseen for delegated acts in order to:

1. Update conformity assessment procedures in Annexes VI and VII in light of technical progress

2. Adapt the conformity assessment procedure of self-certified standalone AI systems (Annex III, points 2 to 8) so as to make them subject to Annex VII or parts thereof (i.e. third-party assessment)
**Artt. 44-51**

**Art. 44**

**Certificates**
- To be issued in accordance with Annex VII
- Cannot exceed 5-year validity
- Can be suspended/withdrawn by notified bodies, when the system is no longer compliant

**Art. 50 and 51**

**Retention of documents & registration**
- Provider shall keep for a period of 10 years at the disposal of competent authorities: technical documentation; documentation on quality management system and on changes approved by notified bodies; decision and other documents issued by notified bodies; declaration of conformity
- Standalone AI systems (Annex III) shall be registered prior to placing on the market or putting into service

**Art. 45**

**Appeals against notified bodies**
- MS to ensure that appeal procedure against decisions of notified bodies is available to relevant parties

**Art. 48 and 49**

**Declaration of conformity & CE marking**
- Declaration of conformity: drawn-up and kept-up to date by provider – who assumes responsibility for compliance with requirements – and contains elements listed in Annex V
- CE marking: affixed on the AI system or, if not applicable, on the packaging or accompanying documentation

**Art. 46**

**Information obligations of notified bodies**
- **Vis-a-vis notifying authorities:** QMS approvals and certificates issued, refused, restricted, suspended or withdrawn; circumstances affecting notification; requests received from market surveillance authorities; upon request, info on conformity assessment activities
- **Vis-à-vis other notified bodies:** QMS approvals or certificates refused, withdrawn, suspended or otherwise restricted; upon request, QMS approvals and certificates issued
Derogation from CA procedure (Art. 47)

1. **Market surveillance authority may authorize** placing on the market/putting into service of systems within the territory of the MS for **exceptional reasons** of public security, protection of life and health, environment, protection of key assets.

2. **Inform** the Commission and other MS.

3. **If no objection is raised** within 15 calendar days, authorisation is considered justified.

4. **If objection is raised**, the Commission shall enter into consultation with the MS, gather the views of the operator/s and take a decision.

5. **If unjustified, authorization to be withdrawn** by market surveillance authority.

**Additional considerations:**
- Authorizations shall be **for a limited period of time** until the conformity assessment procedures are carried out.
- Authorizations are issued only if the market surveillance authority concludes that the high-risk AI system complies with the requirements of Title II, Chapter II.
- For Article 6(1) systems for which AIA applies jointly with Medical Devices legislation, the derogation procedure set therein is the applicable one.