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

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

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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 harmonized 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**)

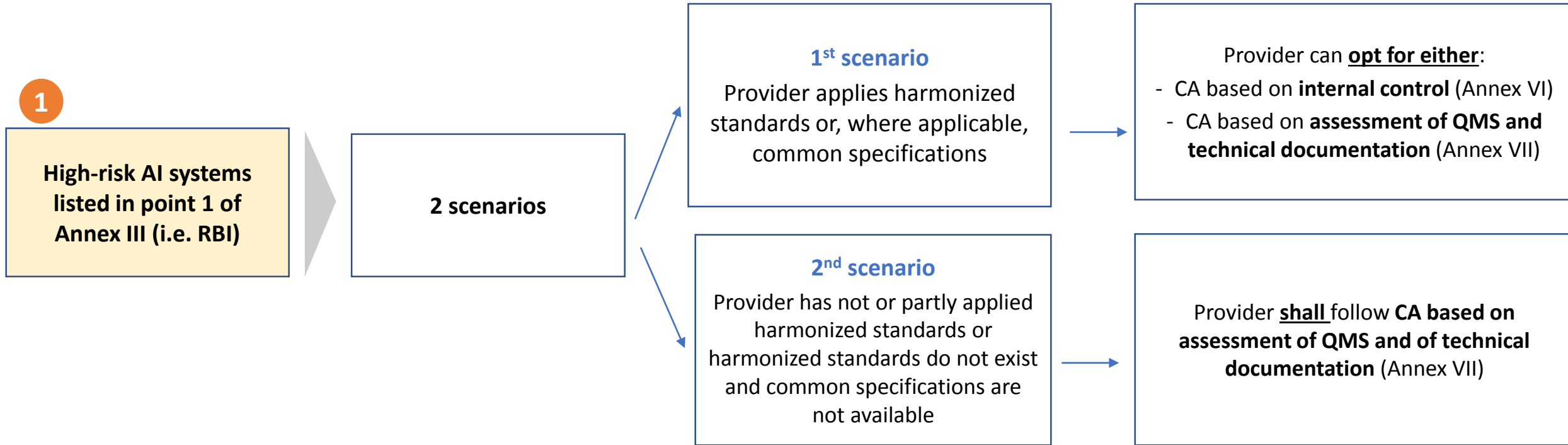
# Presumptions of conformity (Art. 42)

- ▶ **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)

HIGH RISK

Process of verifying conformity of AI system with requirements set in Title II, Chapter 2 prior to the placing on the market or putting into service of that system

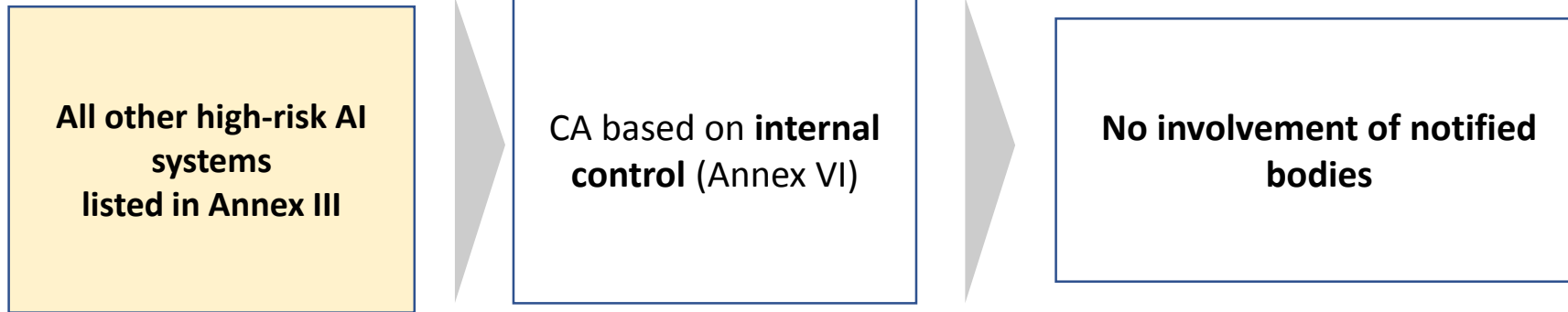


- CA procedure described in **Annex VII** requires the **involvement of a notified body**
- If EU institutions & law enforcement, immigration or asylum authorities are providers, the EDPS & the national data protection authority/national supervisory authority, as applicable, shall act as notified body

# Conformity assessment (CA) - Art. 43(2)

HIGH RISK

2



**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

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



# New conformity assessment (CA) - Art. 43(4)

HIGH RISK

- ▶ **1<sup>st</sup> scenario: when a certificate expires**
- ▶ **2<sup>nd</sup> scenario: substantial modification to the AI system**

*(Art. 3(23)): change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed*

- ▶ Re-assessment necessary, regardless of whether the substantially 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**



# Future-proof & flexible approach



HIGH RISK

- ▶ **Empowerment foreseen for delegated acts** in order to:
  - ▶ **Update conformity assessment procedures** in Annexes VI and VII in light of technical progress
  - ▶ **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. 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. 50 and 51

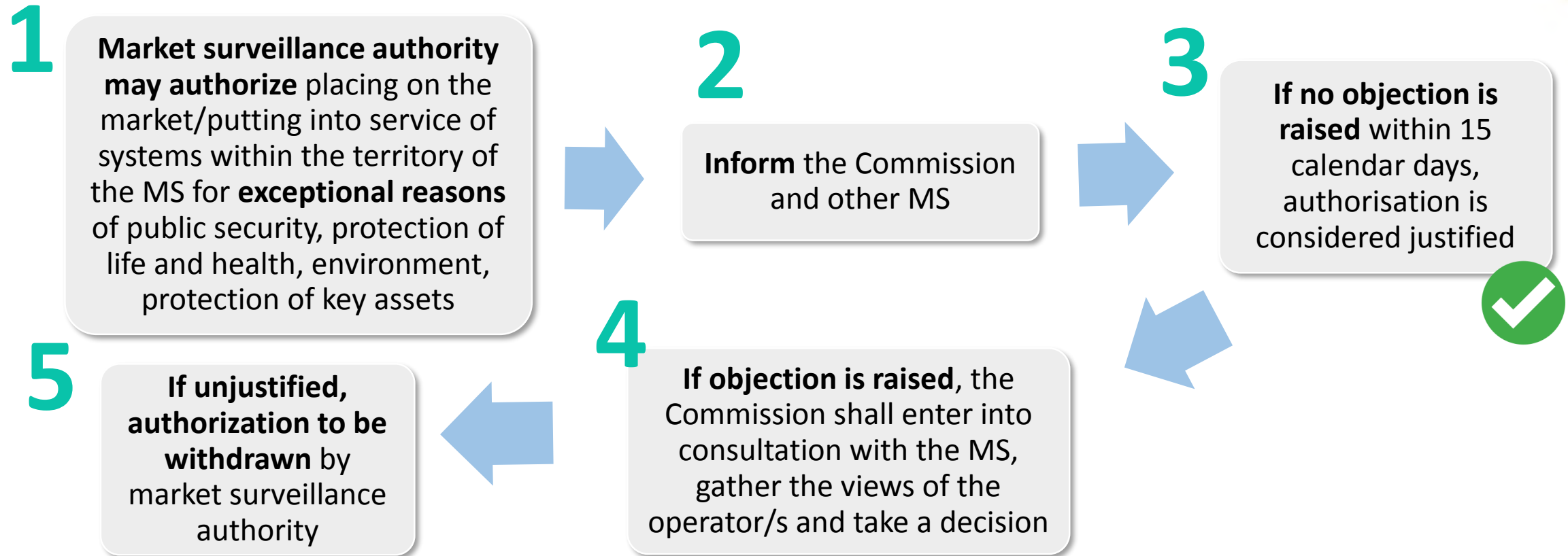
### Retention of documents & registration

- 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

## 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)



## 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