



The EU AI Act enabler for **TRUST and INNOVATION**



Dr. Tatjana Evas, DG CNECT, European Commission, Tatjana.evas@ec.europa.eu
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1. European Approach on AI

Enable the EU
to become a
world-class AI
hub, while
ensuring that AI
is trustworthy

- **Commission: Regulation of AI – staged approach**
- **3 sets of legislative initiatives: AIA, revision of liability rules, revision of safety legislation**

**AI
Package
04/2021**



- **Communication: “Fostering a European approach to AI”**
- **Coordinated Plan on AI 2021 review**
- **Proposal for the Artificial Intelligence Act**
- **Horizon Europe/ Digital Europe Programme Funding, e.g. EuroHPC**



2. EU Artificial Intelligence Act

Main Reasons for the proposed regulation

Complexity—○ Opacity
Unpredictability—○
Autonomy—○ Data

—○ Safety
—○ Fundamental rights
and values

**Solid framework
of EU legislation**
already in place at
EU and national
level

HOWEVER



Certain
specific features of AI
can make application
and enforcement of the
existing rules more
challenging and generate
**risks to safety and
fundamental rights**

The
Commission's
**proposal for a
regulatory
framework on AI**



A tailored horizontal
regulatory response needed



3. AI Act Fundamentals

Key objective:

**TRUST &
INNOVATION**

**First PRODUCT SAFETY
Comprehensive
LEGISLATION on AI**

1. SAFETY FIRST: uniform safety rules for AI in the EU market

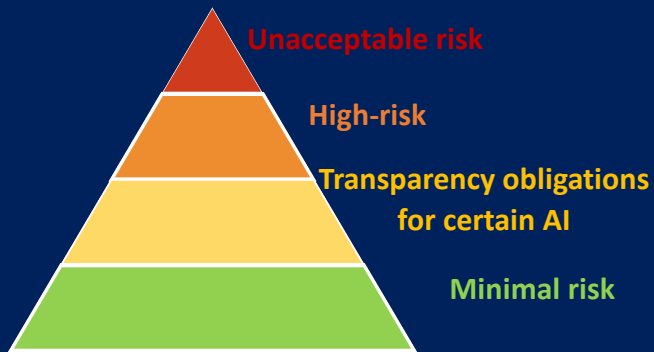
- ▶ “Two main objectives:
 - ▶ address **risks to health, safety and fundamental rights**
 - ▶ **create a single market for trustworthy AI in EU**

2. NO OVERREGULATION: Innovation-friendly and agile

- ▶ Supports innovation e.g. through **regulatory sandboxes**
- ▶ Provide **legal certainty** to operators and stimulate **trust** in the market

3. RISK-BASED:

- ▶ **Focus on use cases/application of technology not AI technology itself**
- ▶ **No overregulation:** designed to intervene only where strictly needed



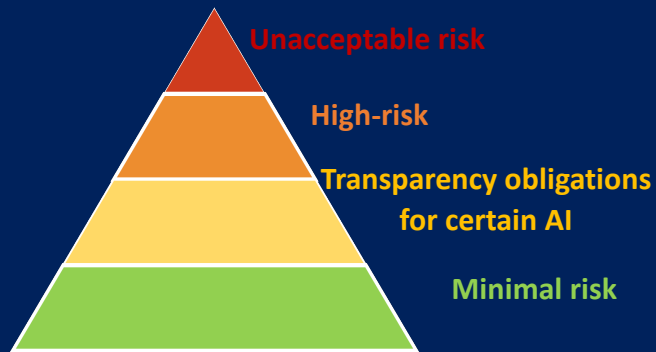


4. AI Act Fundamentals

Key objective:

**TRUST &
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**First PRODUCT SAFETY
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4. FUTURE-PROOF

- ▶ In-build legislative flexibility
- ▶ Standards is a key driver

5. EQUALITY: Creates a level playing field for EU and non-EU players

- ▶ Applicable independent of origin of producer or user

5. COMPLEMENTARITY

- ▶ Based on well established and functioning EU system of conformity assessment/ market surveillance



5. AI Act: Main Operational Elements

risks to health, safety and
fundamental rights

New Legislative Framework (NLF)
Product Safety Legislation +



Sets

Mandatory Requirements
for high-risk AI system
before they can be used



Provides for

Presumption of conformity
if AI high risk AI system is
in compliance with
harmonized standards



1. **risk management system** for AI systems *[Art. 9 AI Act]*
2. **governance and quality of datasets** used to build AI systems *[Art. 10 Data and data governance]*
3. **record keeping** - built-in logging capabilities in AI systems *[Art. 11 Technical documentation and Art. 12 record-keeping]*
4. **transparency and information** to the users of AI systems *[Art. 13 Transparency and provisions of information to users]*
5. **human oversight** of AI systems *[Art. 14 Human oversight]*
6. **accuracy** specifications for AI systems *[Art. 15 Accuracy, robustness and cybersecurity]*
7. **robustness** specifications for AI systems *[Art. 15 Accuracy, robustness and cybersecurity]*
8. **cybersecurity** specifications for AI systems *[Art. 15 Accuracy, robustness and cybersecurity]*
9. **quality management system** for providers of AI system *[Art. 17]*
10. **conformity assessment** for AI systems *[Art. 19 + Art. 43 Conformity Assessment]*



6. The EU AI Act: main elements of the legal text

1. Defines of the AI system

2. Defines what AI use cases and under what conditions (different level of risks) can be put on the market or used in EU or banned from the EU. Requirements are for the system!

3. For High-risk AI systems

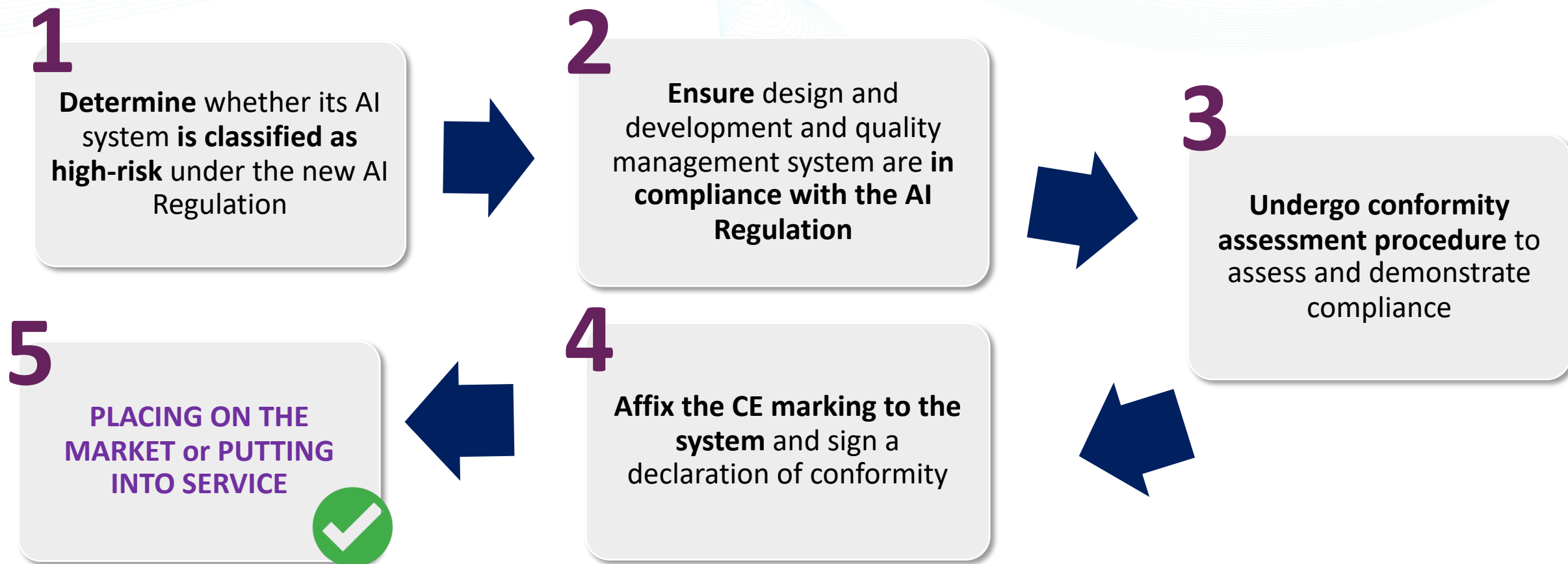
- Sets key requirements (+ special rules for remote biometric identification systems)
- Spells out obligations for providers and users
- Defines relevant bodies and applicable processes **before** the AI system can be put on the market (e.g. standards, notifying authority, notified body, conformity assessment, certificates and registration)
- Defines supervision and market surveillance mechanisms **after** AI system is put on the market
- Sets governance mechanism



7. Operational Steps for compliance with the AI Act

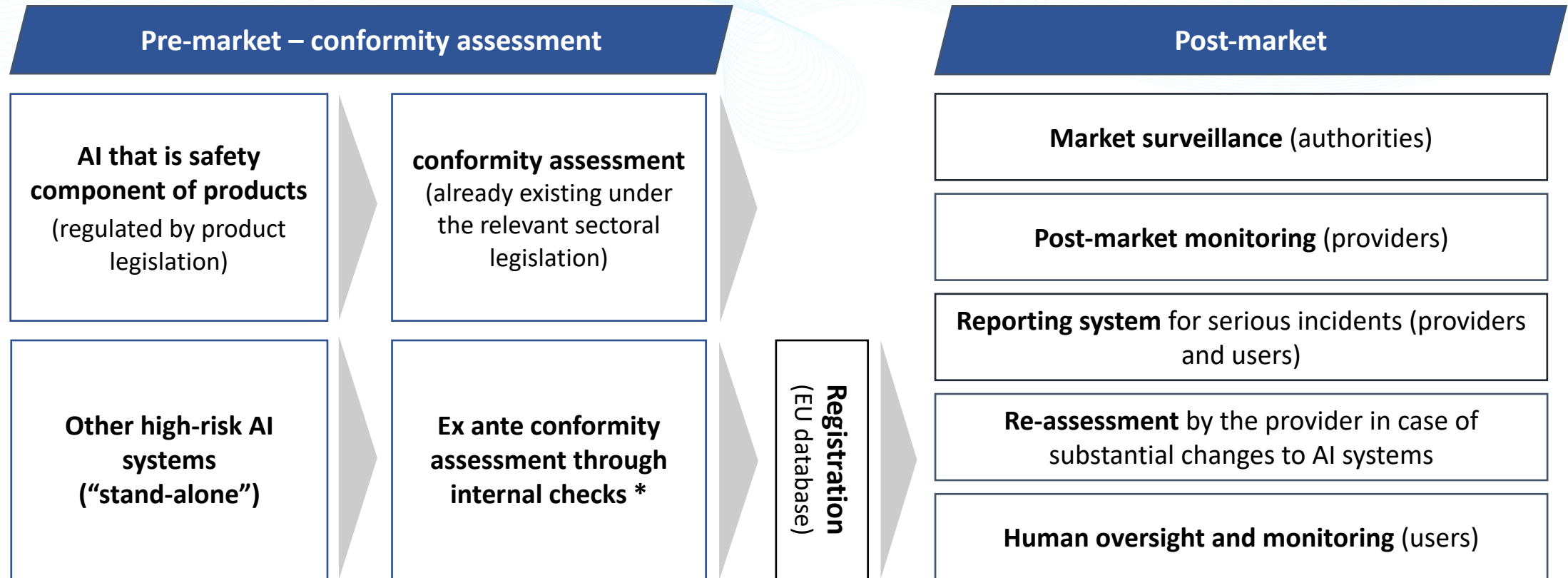
CE marking = indication that product complies with requirements of applicable Union legislation

In order to affix a CE marking, **provider** shall undertake **the following steps**:





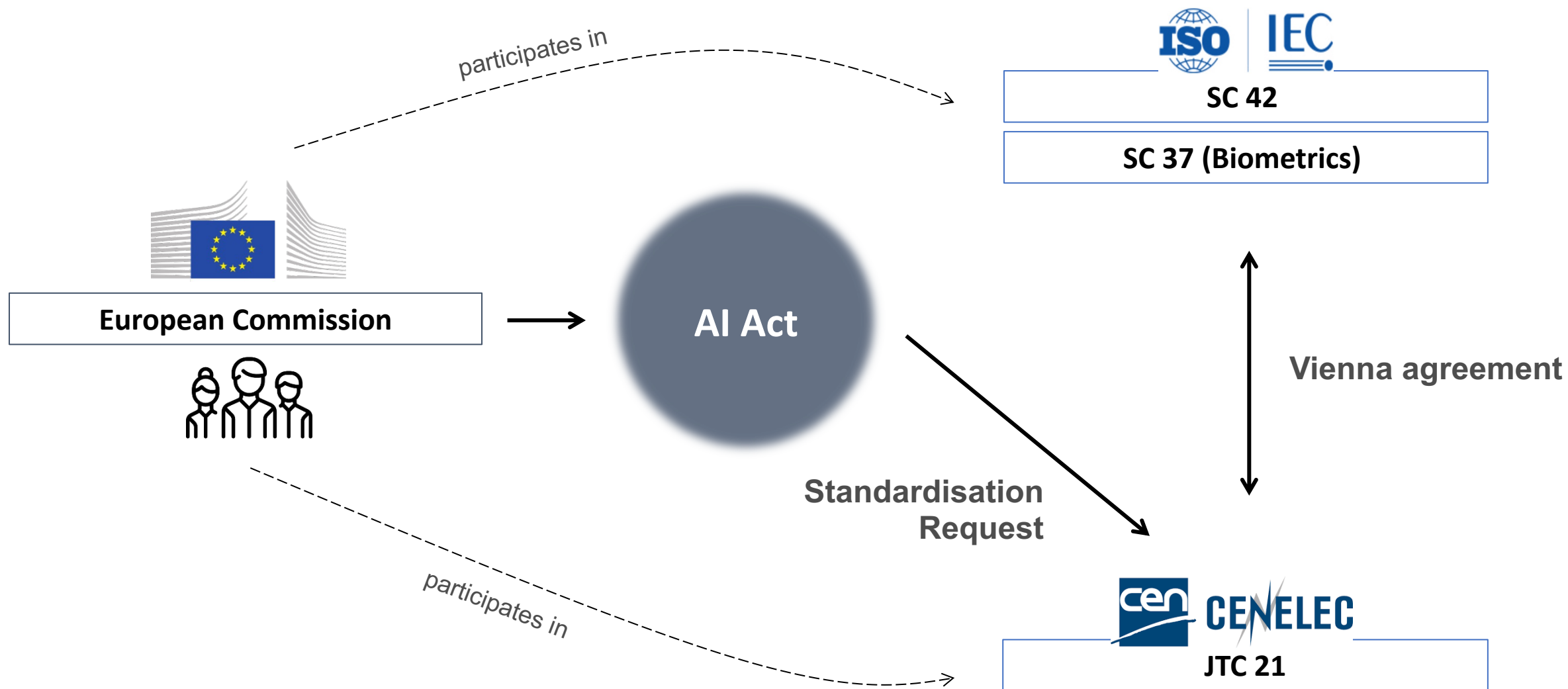
8. Compliance and enforcement system



Standardisation request(s) – key elements

- **Timeline:** deliverables by **30 April 2025**
- **Representation and participation** of relevant stakeholders, including **SMEs**, and **societal stakeholders**
- **Fundamental rights** to be taken into account (relevant expertise needed)
- Leveraging on the existing knowledge and ongoing **efforts at the EU and international levels**, however without any prejudice to the **full alignment of standards with EU values** (as stated in the TUE Art. 3)

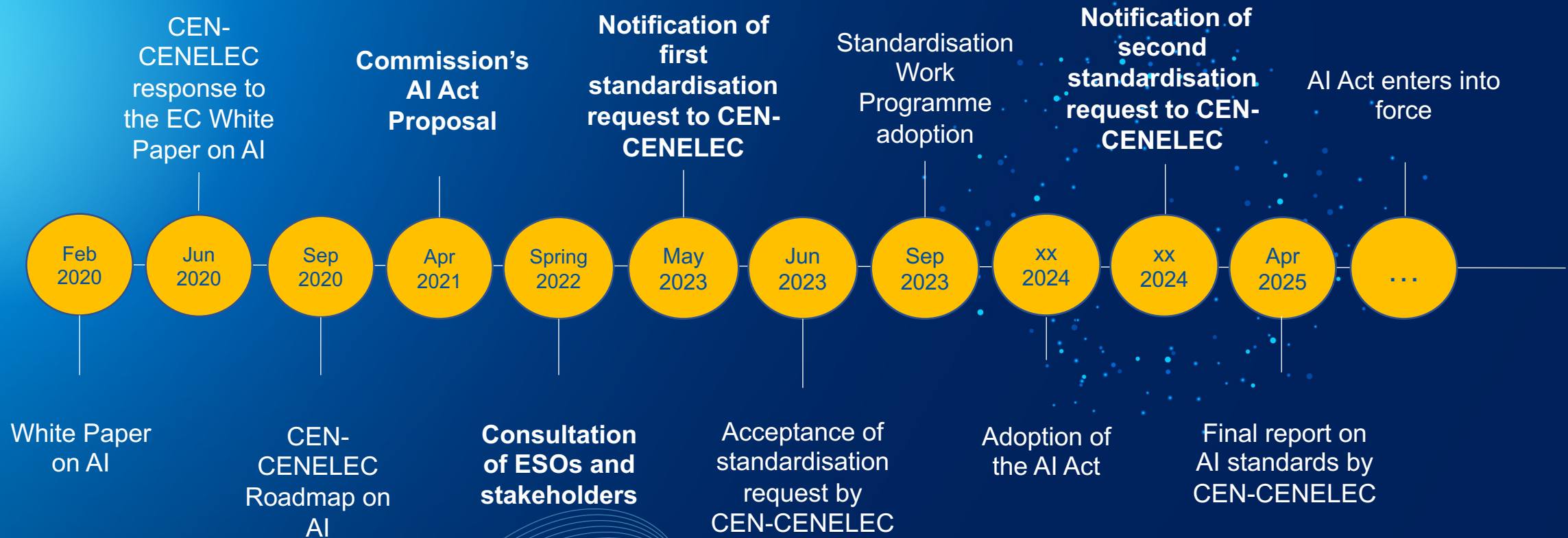
Distribution of work



Commission's involvement at SC42 level

- **We very much value SC42's standardisation activities** (AI technologies are global -> global interoperability -> reduce costs for companies).
- EU AI Act is first the world's first horizontal and legal binding AI product safety legislation. International companies operating on the European market will have to comply with the AI Act. As a result, **the closer international standards are to the requirements of the AI Act, the more beneficial it is for companies** (fewer adaptations costs).
- For this reason, **the Commission is closely following and contributes to the work of both JTC21 and SC42. Our core mission is to ensure that the requirements of the AI Act are fully understood!**

AI Standardisation timeline





References

Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts [COM/2021/206 final](#)

Commission Implementing Decision of 22.5.2023 on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation in support of Union policy on artificial intelligence, C(2023)3215 – [Standardisation request M/593](#)

European Commission in November 2023 launched an [AI Pact webpage](#) explaining the (high-level) concept of the AI Pact, calling on interested companies to [express their interest](#), and providing a [dedicated space on the AI Alliance platform](#) for “frontrunners” to share their best practices.

TRUST



EXCELLENCE
& TRUST

Thank you!

