



# SHAPING EUROPE'S DIGITAL FUTURE

## Proposal for a Regulation on Artificial Intelligence

Salvatore SCALZO, CNECT/A2, European Commission  
*"Artificial intelligence Policy Development and  
Coordination"*

# Key regulatory concepts

## Internal market legislation (mainly based on Art. 114 TFEU)

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- ▶ “Classic” internal market rules for the **placing on the market and putting into service of AI systems**
- ▶ Aligned to vast EU acquis on product safety which shall be jointly applied (e.g. AI embedded in products)

Excluded: AI developed used exclusively for military purposes

## Layered risk-based approach



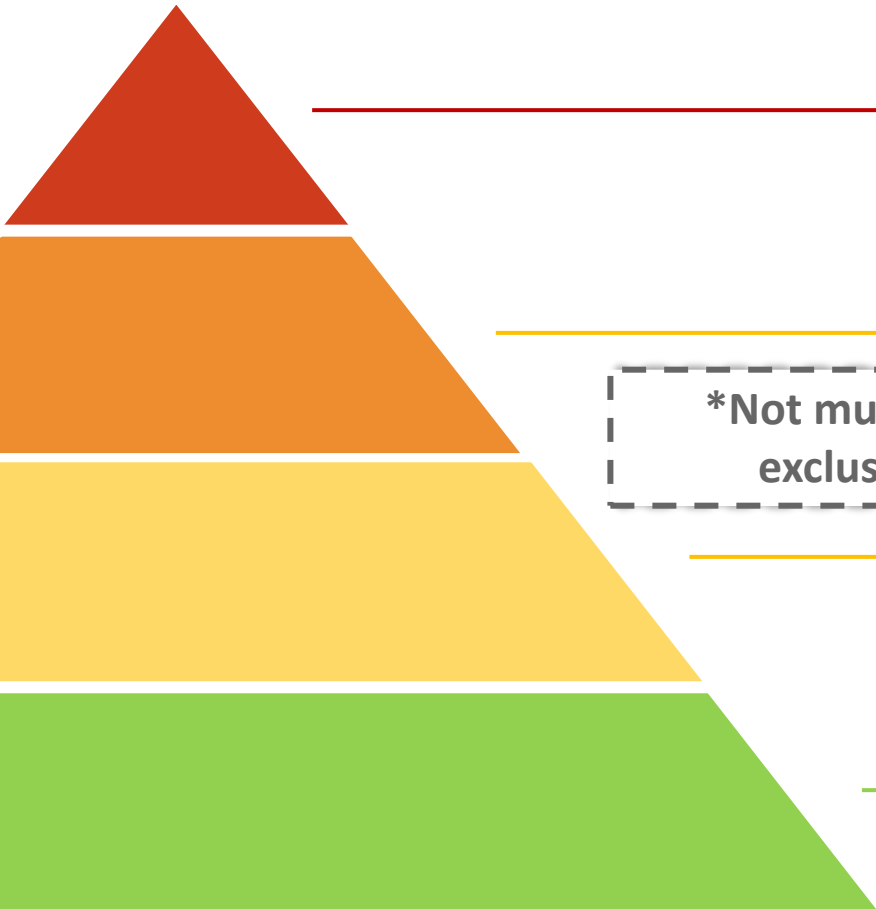
- ▶ No regulation of the technology as such, but of concrete high-risk use cases
- ▶ Covers risks to health, safety and/or fundamental rights

## Level playing field for EU and non-EU players

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- ▶ Independent of origin of producer or user

# A risk-based approach



\*Not mutually exclusive

## Unacceptable risk

e.g. social scoring, remote biometric identification in publicly accessible spaces

**Prohibited**

## High risk

e.g. recruitment, medical devices

**Permitted** subject to compliance with AI requirements and ex-ante conformity assessment

## 'Transparency' risk

'Impersonation' (e.g. chatbots)

**Permitted** but subject to information/transparency obligations

## Minimal or no risk

**Permitted** with no restrictions

# High-risk Artificial Intelligence Systems (Title III, Chapter 1 & Annexes II and III)



## 1 SAFETY COMPONENTS OF REGULATED PRODUCTS

(e.g. medical devices, machinery) which are subject to third-party assessment under the relevant sectorial legislation

## 2 CERTAIN (STAND-ALONE) AI SYSTEMS IN THE FOLLOWING AREAS

- ✓ Biometric identification and categorisation of natural persons
- ✓ Management and operation of critical infrastructure
- ✓ Education and vocational training
- ✓ Employment and workers management, access to self-employment
- ✓ Access to and enjoyment of essential private services and public services and benefits
- ✓ Law enforcement
- ✓ Migration, asylum and border control management
- ✓ Administration of justice and democratic processes

# Requirements for high-risk AI systems (Title III, Chapter 2)



Establish and  
implement **risk  
management  
system**  
&  
in light of the  
**intended  
purpose** of the  
AI system

Use high-quality **training, validation and testing data** (relevant, representative etc.)

Draw up **technical documentation** & set up **logging capabilities** (traceability & auditability)

Ensure appropriate degree of **transparency** and provide users with **information** on capabilities and limitations of the system & how to use it

Ensure **human oversight** (measures built into the system and/or to be implemented by users)

Ensure **robustness, accuracy** and **cybersecurity**



# 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**)

# Harmonised standards in the EU system

Help to advance the **construction of the EU internal market**, while producing an environment which **promotes international trade**

Elaborated following a **request from the EC**

Developed by **European Standardisation Organisations**

**SMEs directly represented** in the European standardization bodies

Agreements in place to **facilitate the use of international standards** within the EU

# Ongoing work on standardisation

**Objective:** To have a large subset of harmonised standards available 3-6 months before the date of application of the future AI Act

## Main activities up to date

- **Mapping research** about relevance of ongoing standardisation activities (JRC report)
- **Strong engagement** with European and international standardisation organisations and direct participation in certain strategic standardisation activities
- **Preparation of first standardisation request** (to be adopted soon)
- **AI chosen as a test-case** to improve the standardisation system: driver for larger mobilisation of stakeholders and experts.



# The governance structure (Titles VI and VII)

## European level

### Artificial Intelligence Board

- ▶ National Supervisory Authorities
- ▶ EDPS
  - ▶ European Commission Secretariat

- ▶ Collect and **share best practices & expertise**
- ▶ contribute to uniform administrative practices in the MS
- ▶ Provide advice, opinions, recommendations on AI issues:
  - ▶ Standards (including harmonized standards) & technical specifications
  - ▶ Preparation of guidance documents

## National level

### National Competent Authorities, incl. National Supervisory Authority

- ▶ Responsible for the application and implementation of the Regulation
  - ▶ Oversight of conformity assessment bodies
  - ▶ Market surveillance activities ex Regulation (EU) 2019/1020

- ▶ **Provisions on establishment of regulatory sandboxes** by Member States

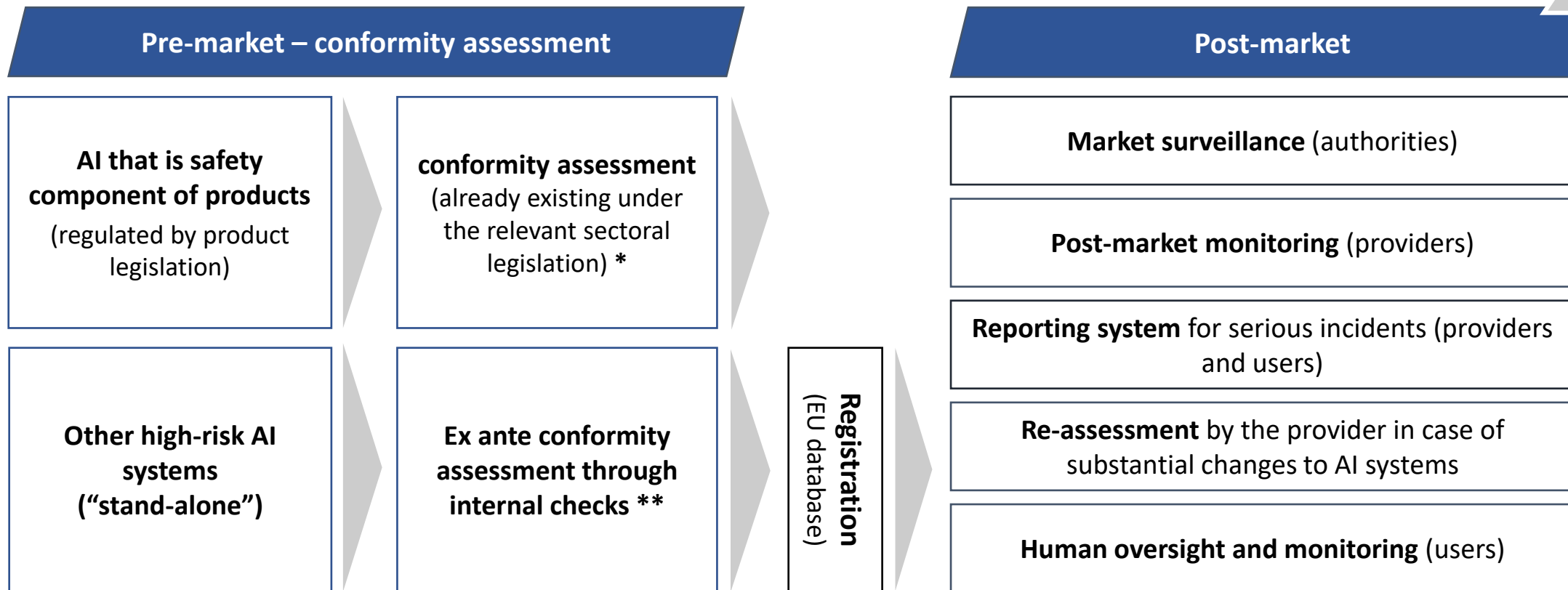


- ▶ National authorities or competent authorities providing or supporting access to data may be associated to the work of the AI Regulatory.

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**Thank you**

# The compliance and enforcement system



\* notified bodies which have been notified under those legal acts shall be entitled to check the conformity, provided that the compliance of those notified bodies with certain requirements (e.g. competence/internal competence on AI) has been assessed in the context of the notification procedure under those legal acts

\*\* Exception remote biometric identification