

**.AGORIA**

# Why do we need the AI Act?



“AI is complex to understand”

“AI is used to automate human tasks”



“AI uses a lot of data, which can be biased”

“AI can have a big impact on our society”



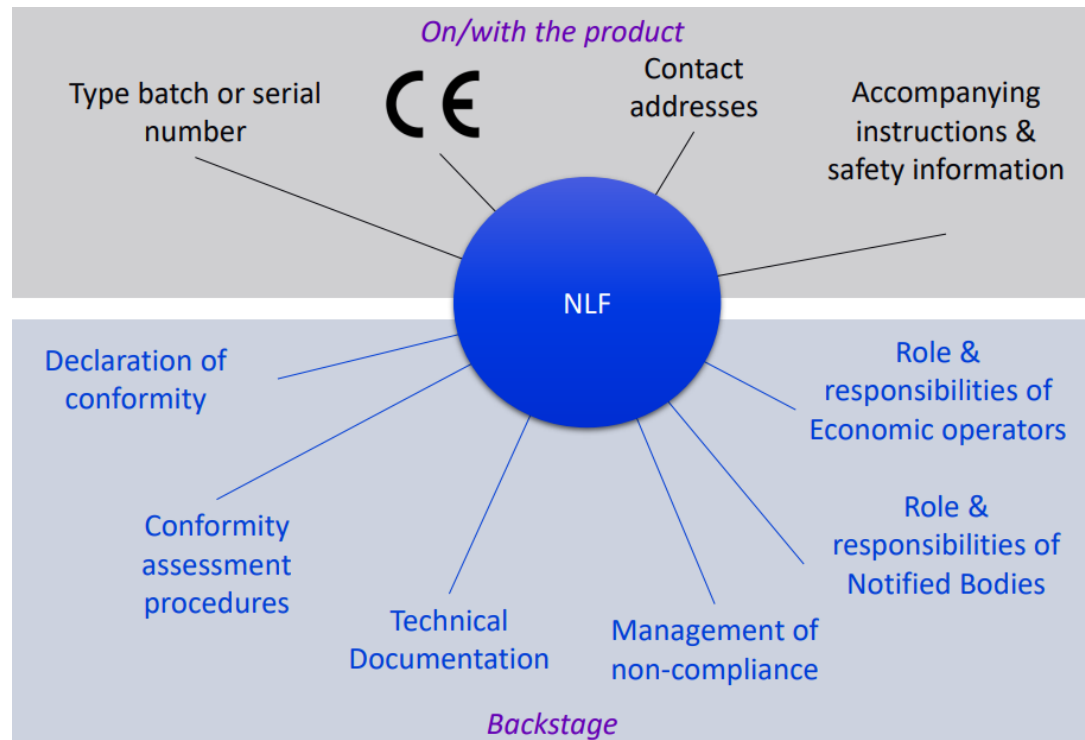
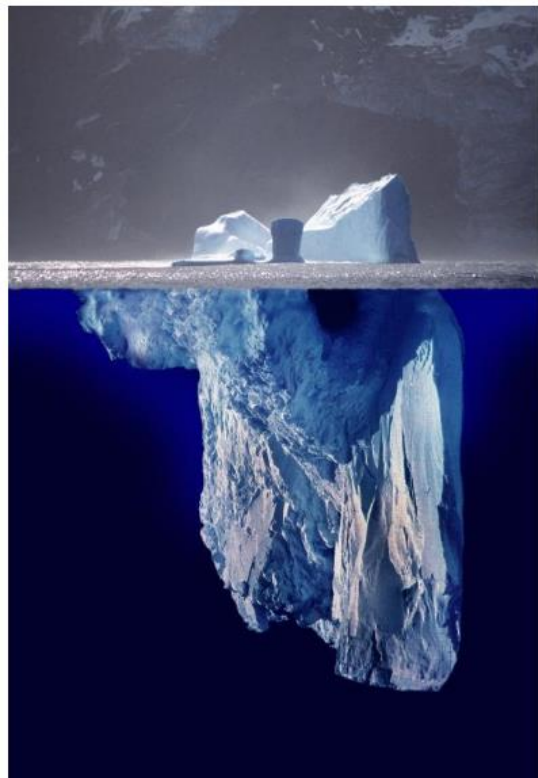
# How will AI be regulated?



CE



# The New Legislative Framework (“NLF”)



# NLF Product legislation

- Toy Safety - Directive 2009/48/EU
- Transportable pressure equipment - Directive 2010/35/EU
- Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU
- Ecodesign requirements for energy-related products (Directive 2009/125/EC and all implementing Regulations)
- Construction products - Regulation (EU) No 305/2011
- Pyrotechnic Articles - Directive 2013/29/EU
- Recreational craft and personal watercraft - Directive 2013/53/EU
- Civil Explosives - Directive 2014/28/EU
- Simple Pressure Vessels - Directive 2014/29/EU
- Electromagnetic Compatibility - Directive 2014/30/EU
- Medical devices - Regulation (EU) 2017/745
- In vitro diagnostic medical devices - Regulation (EU) 2017/746
- Drones - Commission Delegated Regulation (EU) 2019/945 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems
- Machinery – Regulation (EU) 2023/1230
- ....

# “Essential Requirements” vs “Standards”

## Essential Requirement

- Compulsory;
- High-level requirement.



## Standard

- Voluntary;
- Detailed specification and limits;
- When cited in Official Journal\*, provide “presumption of conformity” with Essential requirements.



\*\*



\*\*\*

World Class Standards

# Declaration of conformity

- Common structure for all EU directives aligned with the NLF
- Declaration of Conformity with relevant legislation
- Shall be translated into language(s) requested by member states into which product is intended to be distributed
- One single declaration covering all relevant legislations



## EU Declaration of Conformity

In accordance with of European Parliament and Council Decision No 768/2008/EC Annex III

### 1. Product model / product:

Product Plastic extrusion line  
Model/type Line 1

### 2. Manufacturer

Name ABC Extrusions PLC  
Address 123 Polymer Road, Manchester, M12 3AB, UK  
*Authorised Representative*  
Name Authorised Rep Compliance Ltd.  
Address Ground Floor, 71 Lower Baggot Street, Dublin, D02 P593, Ireland

3. This declaration is issued under the sole responsibility of the manufacturer.

### 4. Object of the declaration:

Product PVC extrusion line  
Installed at DEF Extrusions GmbH, Berlin Germany.

5. The object of the declaration described above is in conformity with the relevant UK Statutory Instruments (and their amendments):

2006/42/EC Machinery Directive

6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:

Reference & Date	Title
EN 1114-1:2011	Plastics and rubber machines. Extruders and extrusion lines. Safety requirements for extruders
EN 1114-3:2019	Plastics and rubber machines – Extruders and extrusion lines – Part 3: Safety requirements for haul-offs
EN 61000-6-2: 2019	Electromagnetic compatibility (EMC). Generic standards. Immunity for industrial environments
EN 61000-6-4: 2019	Electromagnetic compatibility (EMC). Generic standards. Emission standard for industrial environments

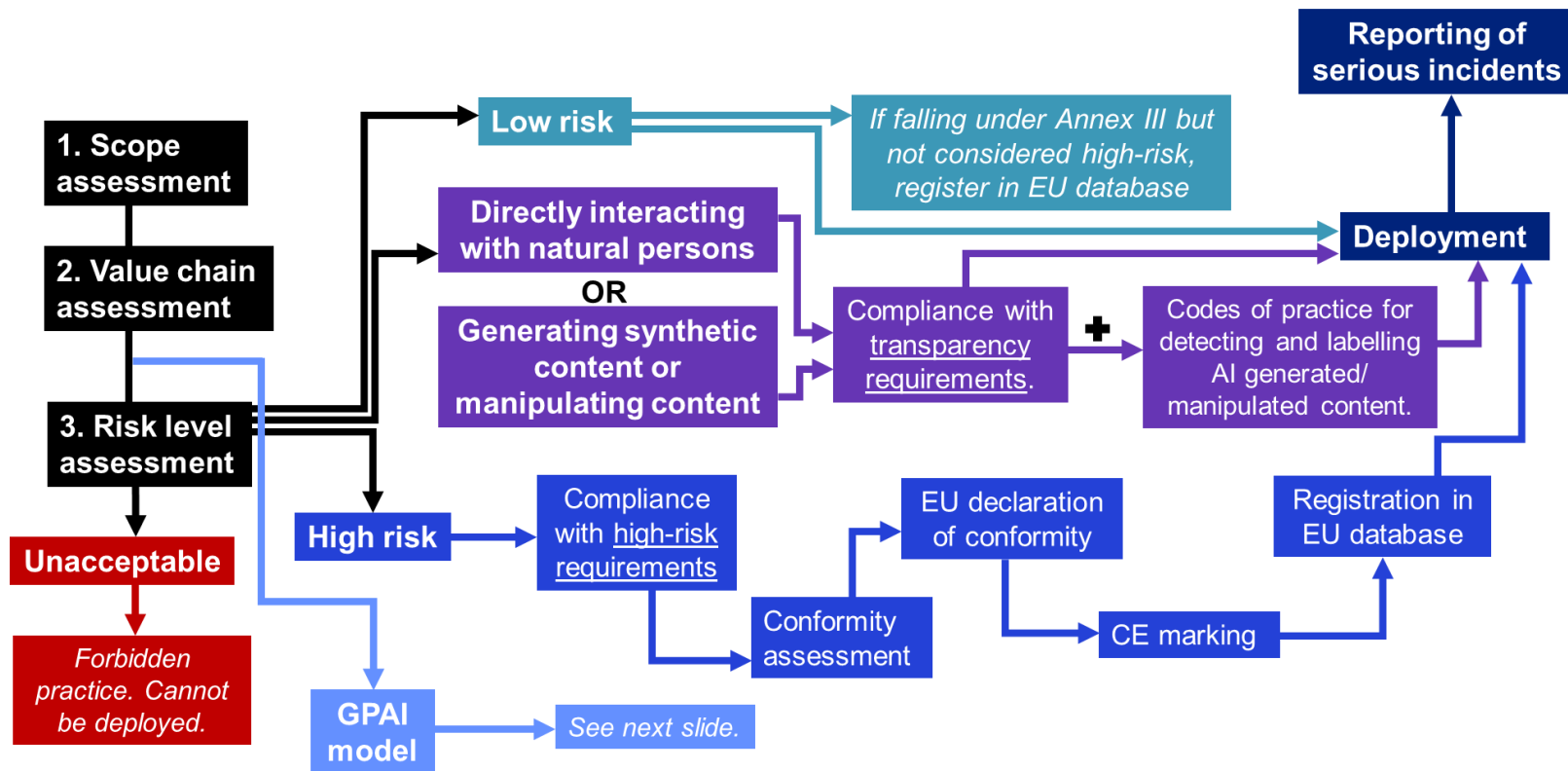
7. The manufacturer applied the procedure for assessment of conformity with internal checks on manufacture. A conformity assessment body was not involved

### 8. Additional information:

The technical documentation for the machinery is available from the authorised representative at the address above.

Signed for and on behalf of: ABC Extrusions PLC  
Place of issue: Manchester  
Date of issue: 8 November 2021  
Name: D. Jones  
Function: Managing Director,

# AI Act Compliance cycle





# Case study

- **Case: AI Tools for Proactive HR Risk Management**

- **Background:**

PeopleFirst Corp., a multinational HR services provider headquartered in Belgium, is deploying an AI-powered platform to enhance workplace safety and employee well-being across its client organizations. The system, developed by TalentGuard AI and powered by a GenAI model from DeepSeek, uses machine learning to monitor real-time employee feedback, absenteeism trends, and incident reports.

# Step 1 : Scope assessment

# Scope assessment

What makes a  
software an AI system?  
*Art. 3(1)*



A **machine-based** system



Designed to operate with **varying levels of autonomy**,



That **may exhibit adaptiveness** after deployment



And that, for **explicit or implicit objectives**,

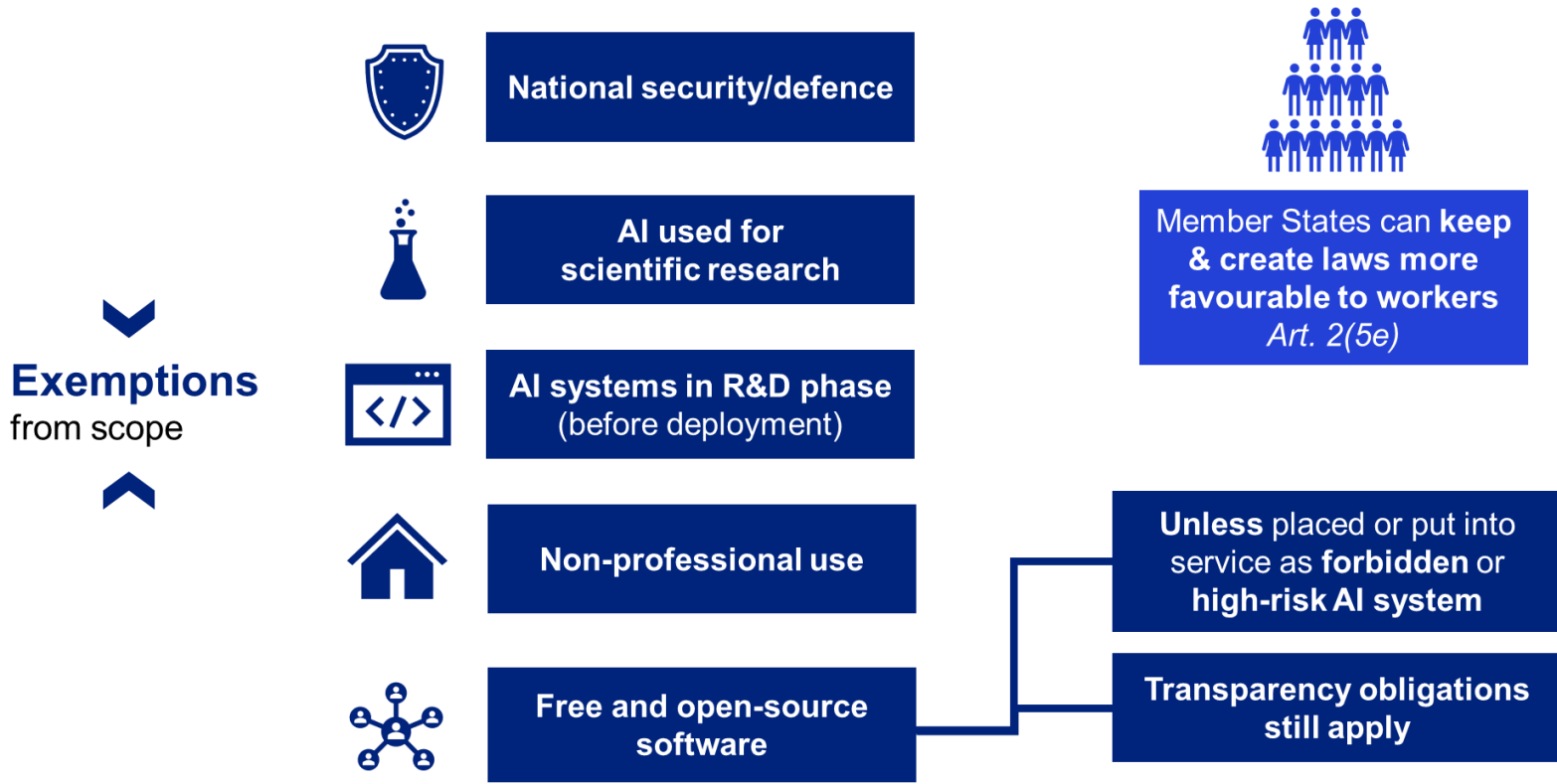


**Infers**, from the input it receives, how to generate outputs,  
such as predictions, content, recommendations or decisions



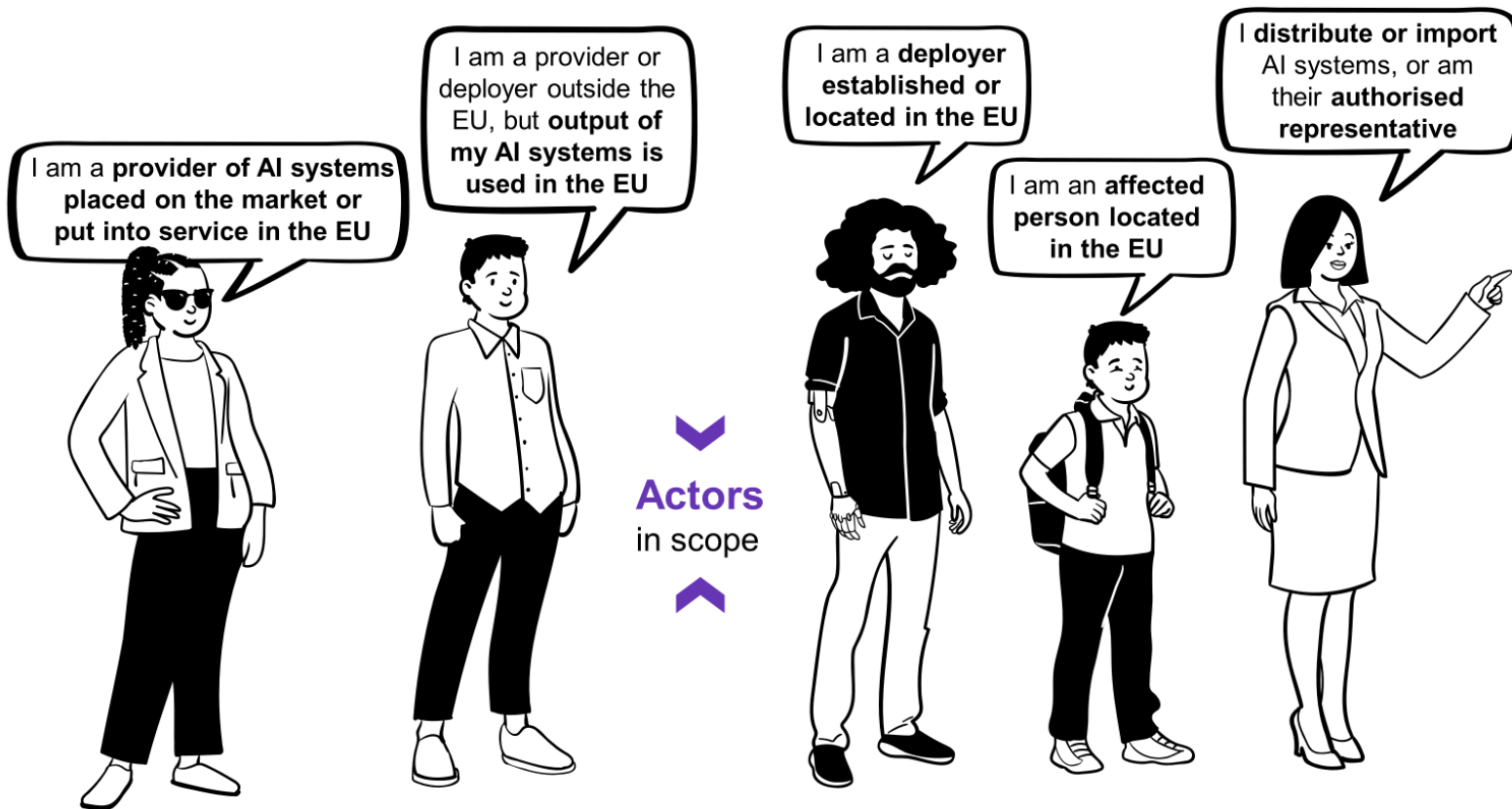
That can **influence physical or virtual environments**.

# Scope assessment



# Step 2 : Role assessment

## Step 2 : Role assessment



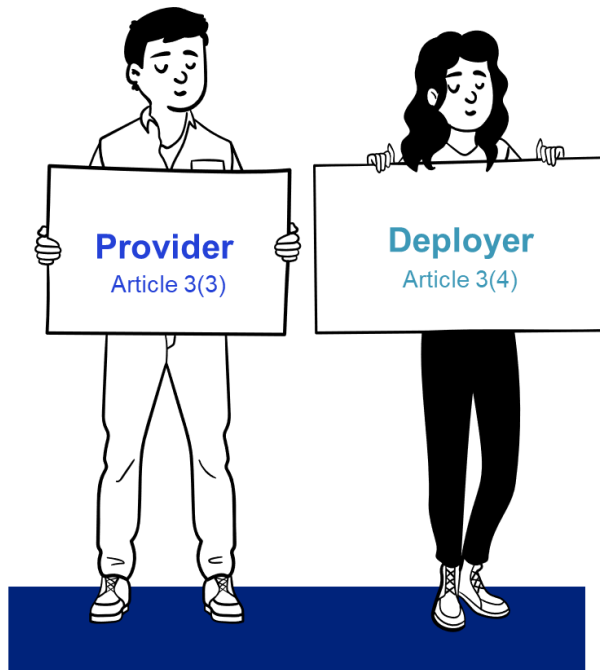
## Step 2 : Role assessment

A person, company or organisation...

That **develops** an AI system or GPAI model

Or has them developed and **places them on the market**

Or **puts the AI system into service** under its own name or trademark.



A person, company or organisation...

That **uses an AI system under its authority.**

# Case study

- **Case: AI Tools for Proactive HR Risk Management**

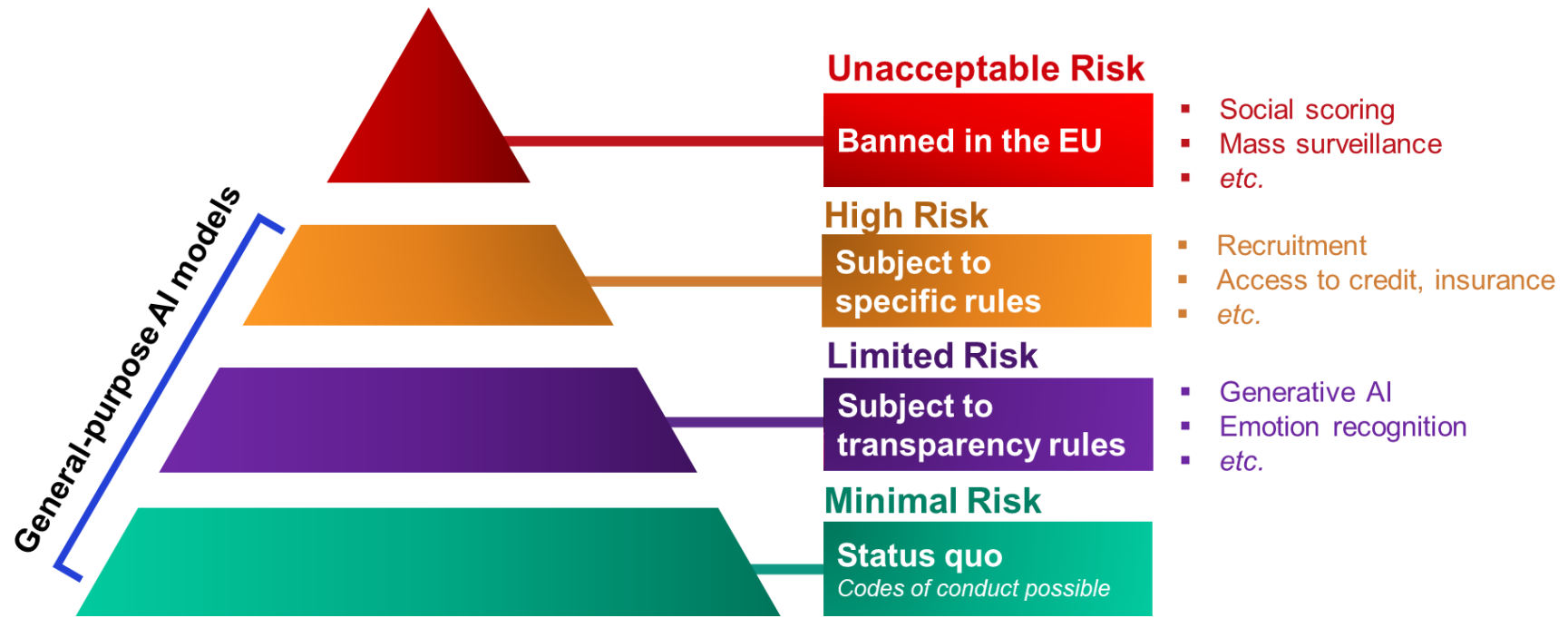
- **Background:**

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# Step 3 : Risk assessment

# The AI Act's risk-based approach



# AI Act - Scope - Unacceptable Risk

Manipulation	Exploitation	Biometric categorisation	Social scoring	Predictive policing	Untargeted scraping of footage	Emotion recognition
Subliminal techniques to distort a person's behaviour that may cause physical or mental harm.	Exploiting vulnerabilities of specific groups of persons due to age, disabilities, socioeconomic situation, to distort behaviour that may cause harm.	Categorising individually natural persons to infer their race, political opinions, trade union membership, religious beliefs, or sexual orientation.	Evaluation of persons based on their social behaviour, leading to detrimental treatment: <ul style="list-style-type: none"> <li>- Unrelated to data collection context.</li> <li>- Unjustified.</li> <li>- Disproportionate</li> </ul>	Making assessment of a natural person to assess or predict the risk of committing a criminal offence based on profiling or personality traits.	Creating or expanding facial recognition databases through untargeted scraping of facial images from the internet or CCTV footage.	Inferring emotions in workplace and education institutions, <u>unless it is for medical or safety reasons.</u>

 **All these AI use cases are banned**  
*Except certain exemptions*



*Continued on next slide*

# AI Act - Scope - Unacceptable Risk

## Mass surveillance

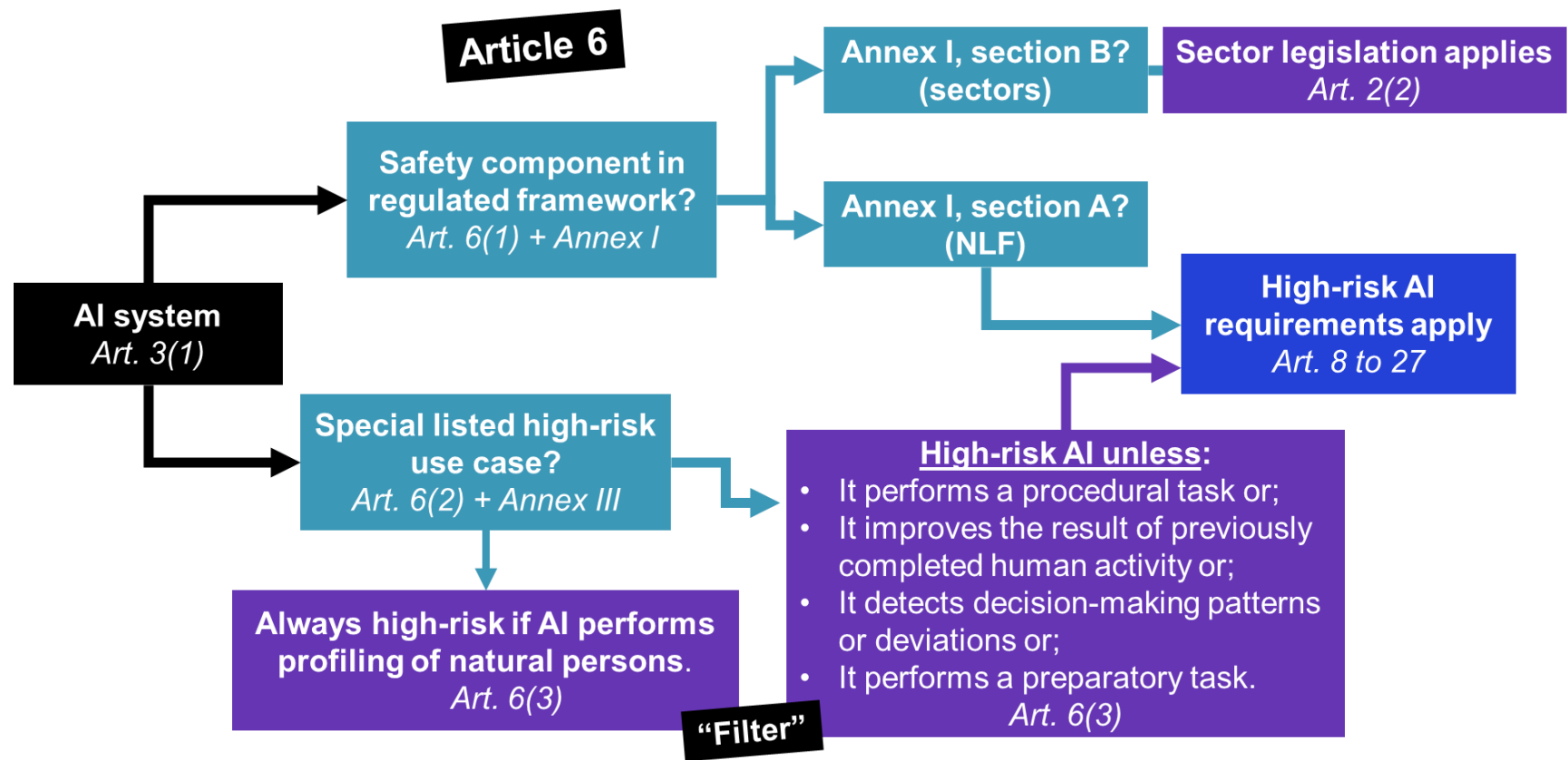
Real-time remote biometric identification in publicly accessible spaces, for law enforcement uses



## Member States can bypass biometric ID ban:

- Based on national law provisions – Art. 5(5).
- Or via exceptions listed in Art. 5(1)(h) (counterterrorism, finding missing children, etc.) and Annex II.
- Subject to prior authorisation granted by judicial or independent administrative authority – Art. 5(3).

# AI Act - Scope - High Risk



# AI Act - Scope - High Risk

## 8 categories of intended use of AI

1. Biometrics.
2. Critical infrastructure.
3. Education (admission, selection and evaluation).
4. Employment (HR/recruitment processes).
5. Essential services (access to social benefit, credit or insurance, emergency first response).
6. Law enforcement.
7. Migration, asylum & border control.
8. Justice and democratic processes.

**Annex III**

+ see "filter" in previous slide

## AI as safety component to products under New Legislative Framework

*Including:*

- Machinery Regulation.
- Radio Equipment Directive.
- Toys Safety Directive.
- Medical Devices Regulation.
- In-Vitro Diagnostics Regulation.

**Annex I  
Section A**

# Case study

- **Case: AI Tools for Proactive HR Risk Management**

- **Background:**

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## Emotion recognition

Inferring emotions in workplace and education institutions, unless it is for medical or safety reasons.

## 8 categories of intended use of AI

1. Biometrics.
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8. Justice and democratic processes.

**Annex III**

# AI Act - Requirements for High-Risk AI



**Risk management system – art. 9**



**Data governance – art. 10**



**Technical documentation – art. 11**



**Record keeping – art. 12**



**Transparency – art. 13**



**Human oversight – art. 14**

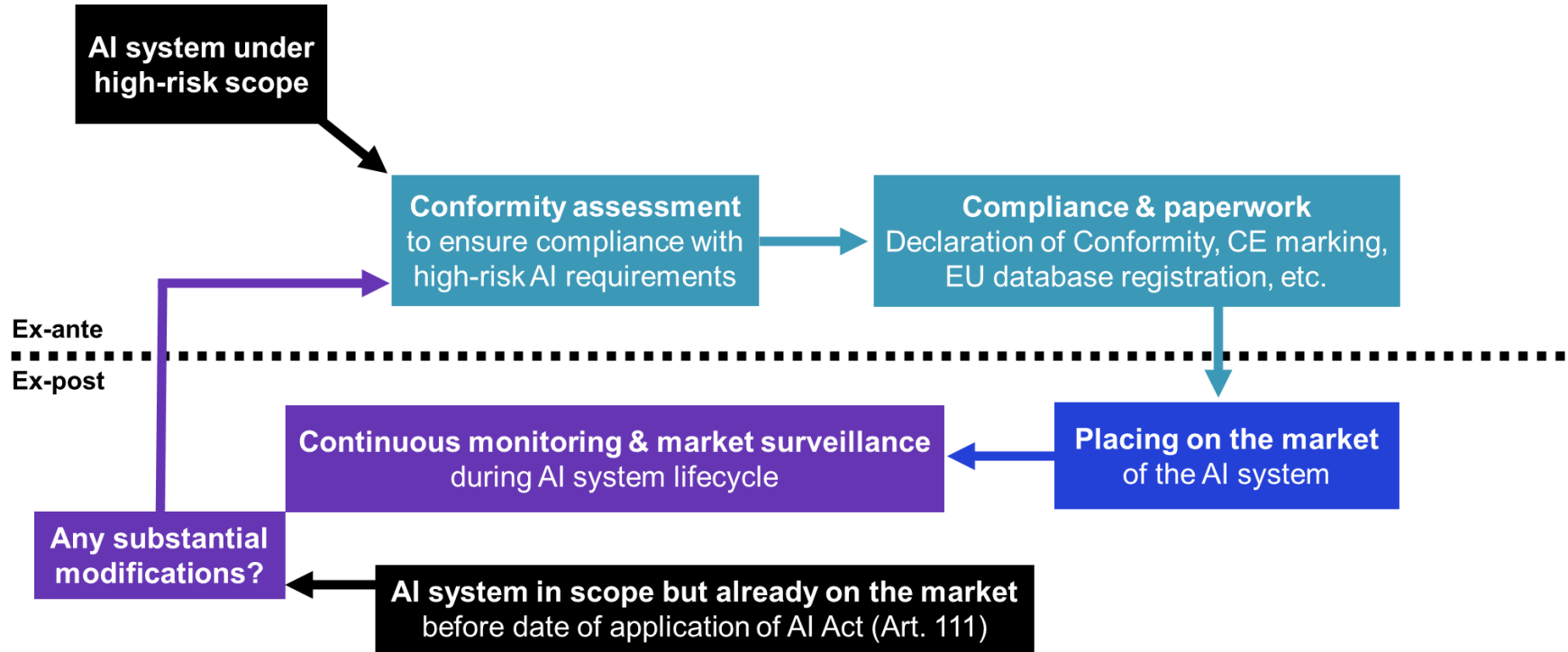


**Robustness, accuracy & cybersecurity – art. 15**



# Step 4 : Compliance cycle

# AI Act - Putting on the market and compliance



# Obligations for high-risk providers & deployers

Providers

Deployers

Conformity assessments

Share necessary info and provide technical access to deployers

Inform & cooperate with competent authorities

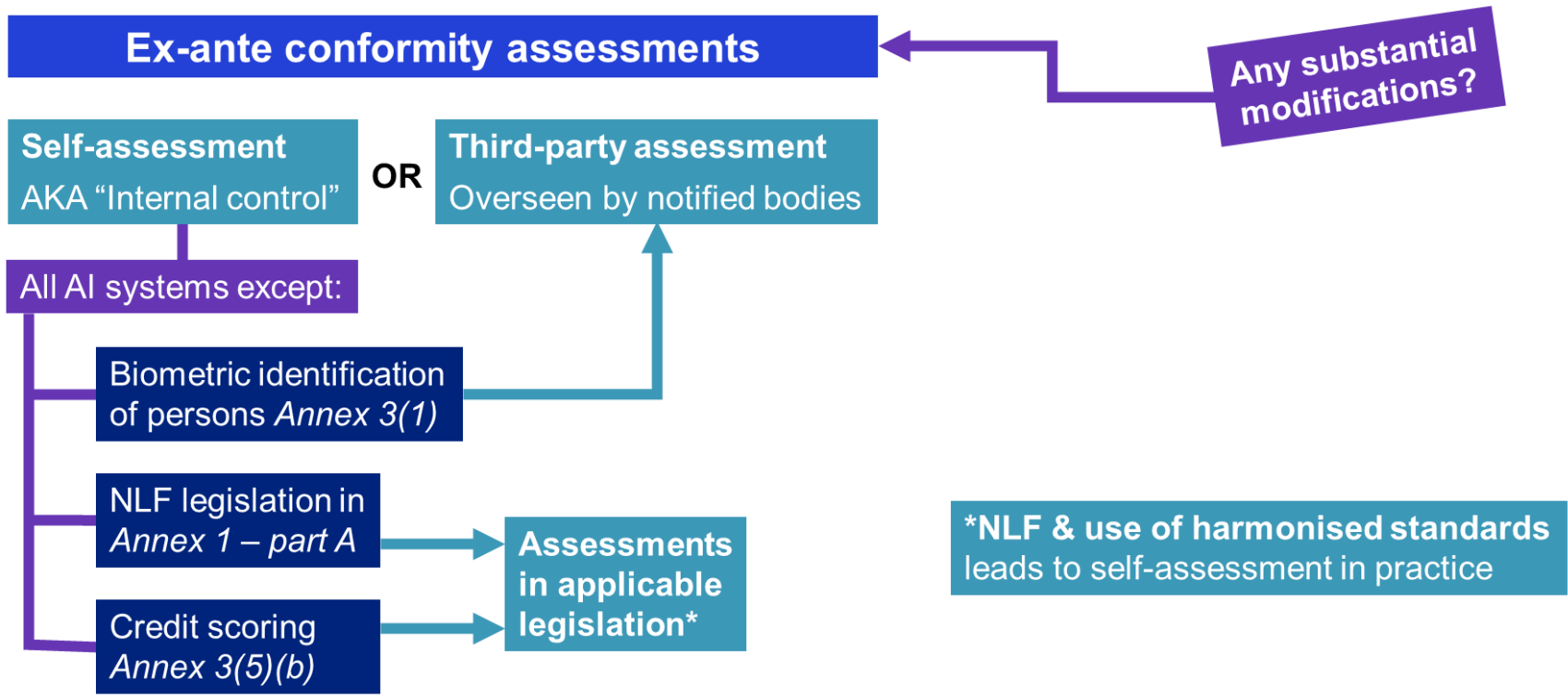
Develop a quality management system

Develop post-market monitoring systems

Report serious incidents & malfunctioning

Feed relevant input, monitor operations & keep logs

# Proving conformity



**\*NLF & use of harmonised standards**  
leads to self-assessment in practice

# Transparency obligations

## Providers:



### Interaction with AI

Inform people in  
direct contact  
with AI



### Generative AI

Ensure **outputs** are  
**marked & detectable**  
**as AI-generated or**  
**manipulated**  
via machine-readable means

## Deployers:



**Emotion recognition**  
+ Biometric categorisation

**Inform affected people**  
& process personal data  
according to GDPR.



**AI-generated or**  
**manipulated content**  
(incl. deep fakes)

Disclose that content is  
artificially generated or  
manipulated.



Transparency rules can add up to high-risk rules  
*Both risk categories are not mutually exclusive*

# Penalties & enforcement

AI Act rules	Maximum penalties
Prohibited AI practices	35.000.000 EUR or 7 % of its total worldwide annual turnover
<ul style="list-style-type: none"> <li>High-risk AI: obligations for providers, authorised representatives, importers, distributors, deployers</li> <li>Requirements and obligations of notified bodies</li> <li>Transparency obligations for providers and deployers (interaction with AI, generative AI)</li> </ul>	15.000.000 EUR or 3 % of its total worldwide annual turnover
Incorrect, incomplete or misleading information in reply to authorities	7.500.000 EUR or 1 % of its total worldwide annual turnover

## AI Literacy - Article 4

- **Providers and deployers of AI systems shall take measures to ensure, to their best extent, a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems** on their behalf, taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used.
- Applicable from 31 Jan 2025
- Regardless of the 'risk'



# AI Literacy

An implementation guide

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# AI Act Timeline

12/07/2024	Publication in Official Journal
01/08/2024	Entry into force
02/02/2025	General Provisions (Title I) apply
02/02/2025	Prohibited AI Systems (Title II) apply
02/08/2025	Application date for main articles – General purpose AI , Governance
02/08/2026	Application for High-Risk AI Systems - Digital applications (Annex III)
02/08/2027	Application for High-Risk AI Systems – Safety components of products (Annex I a)

# Thank you

For your attention



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