




# **PROPOSED AI ACT RISK MANAGEMENT SYSTEM**

- Title I: General Provisions
- Title II: Prohibited AI Practices
- Title III: **High-risk systems**
- Title IV: Transparency obligations for certain systems
- Title V: Measures in support of innovation 
- Title VI: Governance
- Title VII: EU database for stand-alone high-risk AI systems
- Title VIII: Post-market monitoring, information sharing, market surveillance
- Title IX: Codes of Conduct
- Title X: Confidentiality and penalties

# Chapter 2

## Requirements for high risk systems



# Chapter 2

## Art. 8

# Compliance with the requirements

1. High-risk AI systems shall comply with the requirements established in this Chapter.
2. **The intended purpose** of the high-risk  system and the **risk management system** referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.

# Chapter 2

## Art. 9

# Risk management system

1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems

## Chapter 2

### Art. 9

# Risk management system

2. The risk management system shall consist of
  - a *continuous iterative process*
  - run throughout the *entire lifecycle* of a high-risk AI system,
  - requiring *regular systematic updating*.
  - It shall comprise the following steps:



# Chapter 2

## Art. 9

# Risk management system

2. *It shall comprise the following steps:*

- a. **identification and analysis** of the **known and foreseeable risks** associated with each high-risk AI system;
- b. **estimation and evaluation** of the risks that may emerge when the high-risk AI system is used in accordance with its **intended purpose** and under conditions of **reasonably foreseeable misuse**;
- c. **evaluation of other possibly arising risks** based on the analysis of data gathered from the **post-market monitoring system** referred to in Article 61;
- d. **adoption of suitable risk management measures** in accordance with the provisions of the following paragraphs.



# Chapter 2

## Art. 9

# Risk management system

3. The risk management measures referred to in paragraph 2, point (d)
  - shall give due consideration to the **effects and possible interactions**
  - resulting from the combined application of the requirements set out in this Chapter 2.
  - They shall take into account **the generally acknowledged state of the art,**
  - including as reflected in relevant harmonised standards or common specifications.



## Chapter 2

### Art. 9

# Risk management system

4. The risk management measures referred to in paragraph 2, point (d)
- shall be such that **any residual risk associated with each hazard**
  - as well as the **overall residual risk of the high-risk AI systems**
  - is judged **acceptable,**
  - provided that the high-risk AI system is **used in accordance with its intended purpose**
  - or under conditions of **reasonably foreseeable misuse.**
  - **Those residual risks shall be communicated to the user.**

# Chapter 2

## Art. 9

# Risk management system

4. In identifying the most appropriate risk management measures, the following shall be ensured:
  - a) **elimination or reduction of risks as far as possible through adequate design and development;**
  - b) where appropriate, implementation of **adequate mitigation and control measures** in relation to risks that cannot be eliminated;
  - c) **provision of adequate information** pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point (b) of this Article, and, where appropriate, training to users.

In eliminating or reducing risks related to the use of the high-risk AI system,

- *due consideration shall be given to the **technical knowledge, experience, education, training***
- *to be expected by the user and*
- *the environment in which the system is intended to be used.*

# Chapter 2

## Art. 9

# Risk management system

5. High-risk AI systems shall be **tested for the purposes** of
  - *identifying the **most appropriate risk management** measures.*
  - *Testing shall ensure that high-risk AI systems **perform consistently***
  - *for their **intended purpose** and*
  - *they are **in compliance** with the requirements set out in this Chapter.*
6. Testing procedures shall be suitable to achieve the intended purpose of the AI system
  - *and do not need to go beyond what is necessary to achieve that purpose.*

# Chapter 2

## Art. 9.7

# Risk management system

7. The **testing of the high-risk AI systems** shall be performed,
- *as appropriate,*
  - *at any point in time throughout the development process, and,*
  - *in any event,*
  - *prior to the placing on the market or the putting into service.*
- Testing shall be **made against preliminarily defined metrics**
- *and probabilistic thresholds*
  - *that are appropriate to the intended purpose of the high-risk AI system.*



# Chapter 2

## Art. 9.8-9

# Risk management system

8. When implementing the risk management system described in paragraphs 1 to 7,
  - *specific consideration shall be given to whether the high-risk AI system*
  - *is likely to be accessed by or have an impact on children.*
9. For **credit institutions** regulated by Directive 2013/36/EU, the aspects described in paragraphs 1 to 8 shall be part of the risk management procedures established by those institutions pursuant to Article 74 of that Directive.



- HumanE-AI-NET

- AI Act: enables, prohibits, restricts
  - *Reasonable?*
  - *Pertinent?*