



EU AI Act 2024 1689

Artikel 9

III - 2

Article 9

Risk management system

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

2. The risk management system shall be understood as a continuous iterative process planned and run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic review and updating. It shall comprise the following steps:

(a)

the identification and analysis of the known and the reasonably foreseeable risks that the high-risk AI system can pose to health, safety or fundamental rights when the high-risk AI system is used in accordance with its intended purpose;

(b)

the 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)

the evaluation of other risks possibly arising, based on the analysis of data gathered from the post-market monitoring system referred to in Article 72;

(d)

the adoption of appropriate and targeted risk management measures designed to address the risks identified pursuant to point (a).

3. The risks referred to in this Article shall concern only those which may be reasonably mitigated or eliminated through the development or design of the high-risk AI system, or the provision of adequate technical information.

4. The risk management measures referred to in paragraph 2, point (d), shall give due consideration to the effects and possible interaction resulting from the combined application of

the requirements set out in this Section, with a view to minimising risks more effectively while achieving an appropriate balance in implementing the measures to fulfil those requirements.

5. The risk management measures referred to in paragraph 2, point (d), shall be such that the relevant residual risk associated with each hazard, as well as the overall residual risk of the high-risk AI systems is judged to be acceptable.

In identifying the most appropriate risk management measures, the following shall be ensured:

(a)

elimination or reduction of risks identified and evaluated pursuant to paragraph 2 in as far as technically feasible through adequate design and development of the high-risk AI system;

(b)

where appropriate, implementation of adequate mitigation and control measures addressing risks that cannot be eliminated;

(c)

provision of information required pursuant to Article 13 and, where appropriate, training to deployers.

With a view to 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, the training to be expected by the deployer, and the presumable context in which the system is intended to be used.

6. High-risk AI systems shall be tested for the purpose of identifying the most appropriate and targeted risk management measures. Testing shall ensure that high-risk AI systems perform consistently for their intended purpose and that they are in compliance with the requirements set out in this Section.

7. Testing procedures may include testing in real-world conditions in accordance with Article 60.

8. The testing of high-risk AI systems shall be performed, as appropriate, at any time throughout the development process, and, in any event, prior to their being placed on the market or put into service. Testing shall be carried out against prior defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.

9. When implementing the risk management system as provided for in paragraphs 1 to 7, providers shall give consideration to whether in view of its intended purpose the high-risk AI system is likely to have an adverse impact on persons under the age of 18 and, as appropriate, other vulnerable groups.

10. For providers of high-risk AI systems that are subject to requirements regarding internal risk management processes under other relevant provisions of Union law, the aspects provided in paragraphs 1 to 9 may be part of, or combined with, the risk management procedures established pursuant to that law.



[Verify AI Provenance](#)