

Comments on the Draft Guidelines for High-Risk AI Classification

The draft HRAIS guidelines ignore key AI Omnibus compromises and restrict meaningful feedback. They overextend the AI Act by overriding sectoral safety-component rules and misreading Article 6(1) to include Module A/internal control despite the third-party assessment requirement. The Commission should update the guidelines in a transparent process that includes in-depth industry feedback.

The results of the AI Omnibus are not sufficiently taken into account

The European Commission's draft guidelines for high-risk AI classification contain several highly problematic interpretations of the AI Act that not only extend the scope of application of the high-risk AI requirements, but that also cause significant problems for the workings of the New Legislative Framework as a whole. In addition, the current draft does not sufficiently take into account the final compromises established in the AI Omnibus, such as the addition of the whitelisting of AI applications in Art. 6 (1a) and the transfer of the Machinery Regulation from Annex I Section A to Annex I Section B.

The survey tool limits the ability of stakeholders to provide in-depth comments

The questionnaire provided for this consultation makes a comprehensive review very difficult due to the following structural barriers:

- The 500-character limit per paragraph and 2,500-character limit for missing content are too restrictive for complex analysis.
- Limiting comments to five paragraphs per chapter leaves large sections, such as Chapter III.2.2, mostly uncommented.
- The platform prevents the upload of position papers, thus blocking coherent and comprehensive industry input.

The following section discusses three particularly glaring problems with these guidelines.

1. (33) *The AI Act as the “lex specialis” for the definition of safety component*

- (33): The claim that the AI Act provides an “autonomous” definition of safety components creates legal uncertainty and disrupts the New Legislative Framework (NLF). Sectoral rules, such as those for machinery and lifts, contain more specific and operational definitions, meaning they should prevail under the *lex specialis* principle. It

would lead to a situation where in the same product two separate safety component definitions would apply: one for the AI component and one for the rest of the product.

- Art. 6 (1) establishes a directionality of the interplay between the AI Act and other regulations, by referring to: “*safety component of a product, or the AI system is itself a product, covered by the Union harmonisation legislation*”, i.e. if a product is not covered by the harmonised regulation, it cannot be regulated by the AIA. This was reiterated in the AI Omnibus. Article 2(9) and Recital 64 further show that the AI Act complements existing harmonised rules rather than overriding them.
- Recital 55 AI Act excludes functionally necessary components from high-risk critical infrastructure, establishing Directive 2022/2557 as the upper regulatory limit. To avoid over-regulating e.g. of non-critical machinery, the Machinery Regulation definition must be used to assess safety components.

2. Chapter 2.3: Broadening the scope of Art. 6(1)

- (56) The concept of an “appropriate level of scrutiny” is not defined in the AI Act and conflicts with Decision 768/2008/EC, which requires conformity procedures to be proportionate to risk. Module A therefore cannot qualify as an “equivalent mechanism” or trigger Article 6(1)(b).

(57) Article 6(1)(b) requires a third-party conformity assessment to trigger high-risk classification. Where Module A/internal control applies, this condition is not met.

(58) The concepts of “enhanced regulatory scrutiny” and “equivalent mechanisms” are undefined and conflict with the logic of the NLF and Decision 768/2008/EC.

3. Chapter 3.2: An incomplete assessment (187+38)

- Throughout the three guideline documents recital 55 is quoted five times. In two of these (para. 187 and the footnote of para. 38) it is mentioned that recital 55 excludes the “*components intended to be used solely for cybersecurity purposes from the scope of safety components*”. At the same time, the passage “*but which are not necessary in order for the system to function*” is not mentioned anywhere.
- This added passage obviously leads to a fundamental change in the definition of safety components in the critical infrastructure, by including the caveat of the functional necessity. As such, the current chapter 3.2 is only an incomplete assessment of the regulation. Beyond its relevance for the critical infrastructure applications, this passage also points to the contradiction introduced in para. 33. If the AI Act safety component definition would prevail all other safety component definitions, the caveat of functional necessity would e.g. only apply to machinery in critical infrastructure but not to machinery not used in critical infrastructure. This obvious contradiction can only be resolved by conceding that more specific sectoral definitions of safety components apply for Art. 6(1).