APPLiA's Feedback on the Draft Commission Guidelines on the Classification of High-Risk AI Systems

APPLiA supports the Commission's objective of ensuring a consistent application of the AI Act, in particular the objective of supporting businesses with guidance documents that support the application and understanding of the classification logic within the AI Act as well as requirements for providers or deployers.

However, the draft guidelines in its current form do not sufficiently resolve key concerns of manufacturers operating under Union harmonisation legislation listed in Annex I AI Act. While several clarifications are helpful, the current text continues to create legal uncertainty for manufacturers that voluntarily introduce AI-enabled safety improvements into already compliant and safe products.

The draft guidelines risk creating a situation where manufacturers are discouraged from developing and deploying additional AI-based safety measures because doing so may trigger high-risk classification and substantial compliance obligations, despite the product remaining safe without the AI functionality.

APPLiA therefore recommends targeted amendments focusing on:

- Correcting the interpretation of the wording "required to undergo third-party conformity assessment" in Article 6, 1 (b)
- Clarifying the interpretation of "safety component" as the key concept for high-risk classification in Article 6, 1 (a)
- Clearly differentiating between critical safety functions and minor, ancillary safety layers that are only installed additionally to already fully compliant products (in line with Annex I legislation).

Document: ANNEX to the Communication – Draft Commission guidelines on the classification of high-risk AI systems under Article 6 of Regulation (EU) 2024/1689 (AI Act) for stakeholder consultation

Guidelines on Annex I of the AI Act

1. Section 2.3 misinterprets the role of conformity assessment under the NLF

Paragraphs 56 - 59

The current wording of the AI Act guidelines and similar wording used in the revision of the Toy Safety Regulation, suggest that that third-party conformity assessment applies "*irrespective of the existing and/or the application of harmonised standards*"

At the same time, self-assessment is portrayed as a mere "**opt-out**" of third-party assessments. APPLiA fundamentally disagrees with these statements. Products falling under AI Act Annex I can only be considered high-risk AI systems **if both conditions set out in Article 6 are met.** An "opt-out" from a particular pathway to ensure conformity with the essential requirements does not exist under the NLF or the Blue Guide. All conformity assessment procedures established under NLF legislation and described in the Blue Guide are on equal footing and do not follow any ranking (or any opt-out logic). The Union harmonisation legislation in Annex I deliberately provides for different conformity assessment modules that can be applied and that a manufacturer can choose from if certain conditions are fulfilled (e.g. availability of harmonised standards). For instance, manufacturers of radio equipment including AI system components may legitimately choose to perform internal production control by demonstrating compliance with the relevant harmonised standards. In this case, the manufacturer is not making use of an "opt-out option" but is following a valid and established compliance route under EU legislation.

The AI Act should avoid situations where the high-risk classification under condition (b) in Article 6, 1 is triggered every single time manufacturers opt for any conformity assessment procedure available under Annex I legislation. The condition in Article 6,1 (b) foresees only products required to undergo third-party conformity assessment (and where the AI system is intended to be used as safety component) to be classified as high-risk.

There are several parts in Chapter 2.3 of the AI Act guidelines on Annex I that might lead to a grave misinterpretation of the original intention of condition (b) in Article 6,1. Such a very broad interpretation of condition (b) might lead to a significant expansion of the scope of products suddenly being interpreted as "high-risk AI systems":

- Paragraph (56) draws from the toy safety regulation a principle of level of scrutiny that is an interpretation that is not founded or justified in the blue guide. Additionally, it implies without justification that a regulation perceived for the special protection needs of children is a precedent for all CE regulations
- Paragraph (57) claiming that self-assessment "does not affect the classification of an AI system as high-risk under Article 6 (1)"
- Paragraph (58) stating that the required regulatory "scrutiny is (only) ensured through the requirements of third-party conformity assessment or equivalent mechanisms"
- Paragraph (59) using wording specifically tailored to the Toy Safety Regulation as a general basis for a far too broad interpretation of mandatory third-party conformity assessment. This paragraph repeatedly uses the concept of "opt-out" which is not known in any NLF legislation listed in Annex I in a misleading manner.

APPLiA hence suggests the deletion or substantial revision of paragraphs 57 to 59, ensuring at the very least that the concept of "opt-out" is further clarified. The condition (b) should not be fulfilled automatically every single time a manufacturer uses certain conformity assessment procedures available, but only be triggered in cases where the use of "third-party" is actually explicitly required by Annex I legislation.

Furthermore, the mere non-listing of a harmonised standard, for example due to delays in listing the standard for purely bureaucratic or formal reasons, should not result in a product with AI-based components being automatically classified as "high-risk". The condition in Article 6,1 b) should not be triggered because of a misinterpretation of the choice of conformity assessment modules in Union harmonisation legislation in Annex I.

This approach is inconsistent with the wording of Article 6(1)(b). The decisive factor must remain whether the relevant product is actually required under the applicable legislation to undergo third-party conformity assessment. The availability of alternative conformity assessment pathways provided by Union harmonisation legislation should not in itself lead to high-risk classification.

APPLiA requests the deletion or substantial revision of paragraphs 57 to 59 (see below)

	The issues	Proposal for clarification
Paragraph 56	The paragraph implies that, when the use of module A is conditioned by the application of a harmonised standard, a higher level of scrutiny is implied. This is an interpretation that cannot be substantiated by the blue guide and neither any CE law (see above). The paragraph may also be misunderstood that the choice of module A is an opt out as such. It must be clarified that the default condition is when the choice of module A exists then a product is not required to undergo 3rd party notification and thus its AI is not high risk.	Reduce 56 to this text: Union harmonisation legislation allows the use of Module A for assessment of conformity of certain products. ***For these products the requirement in Article 6.1 (b) of the AI Act would not be met.*** Delete the rest as it is over interpreting the Toy Directive. The Toy Directive contains language that is specific to its sensitive nature of children being concerned.
Paragraph 57	Claims that self-assessment "does not affect the classification of an AI system as high-risk under Article 6 (1)"	Clarify that the use of Module A, if permitted or foreseen by Annex I legislation, for products falling under Annex I, does not trigger classification as high-risk under Article 6 (1) of the AI Act.
Paragraph 58	States that the required regulatory "scrutiny is (only) ensured through the requirements of third -party conformity assessment or equivalent mechanisms" It also uses the phrase *"mandatory application of harmonized standards,"* which is factually incorrect under the NLF. Standards are always voluntary	- Amend the paragraph to align with the Blue Guide: Remove any wording suggesting that third-party conformity assessment is a baseline "scrutiny" mechanism to which self-assessment is a lesser, secondary alternative. - Remove the "mandatory" wording in relation to the application of harmonised standards"
Paragraph 59	Uses wording specifically tailored to the Toy Safety Regulation as a general basis for a far too broad interpretation of mandatory third-party conformity assessment. This paragraph repeatedly uses the concept of "opt-out" which is not known in any NLF legislation listed in Annex I in a misleading manner.	Delete the "opt-out" phrase. Ensure the text explicitly states that the condition in Article 6(1)(b) is only triggered when third-party conformity assessment is strictly and explicitly mandated by the underlying Annex I legislation, and cannot be triggered by administrative or bureaucratic delays in citation of harmonized standards.

2. The Guidelines do not adequately distinguish between critical safety functions and additional safety layers

Paragraphs 34 - 37

The main concern relates to the treatment of AI systems that provide an additional, only minor layer of safety on top of existing hardware- and software-based safety mechanisms. The draft guidelines interpret the concept of "safety function" much broader than the actual product safety-related legislation listed in Annex I. Under paragraphs 35-37, an AI system may be considered a safety component whenever it contributes to preventing or mitigating safety risks.

However, the guidelines do not distinguish between an AI system that performs a safety-critical function and whose failure would compromise the safety of the product and an AI system that merely provides an additional safety layer while the product remains fully safe and compliant without the AI functionality being added to the product. The high-risk classification in the meaning of Article 6, 1 should better reflect if the AI system has an actual impact to or is able to alter the overall safety composition of the product.

Such a distinction is essential.

Many home appliances already comply with all applicable safety legislation and harmonised standards through established hardware-based safety mechanisms. Manufacturers increasingly add AI functionalities that further improve safety, such as smoke detection, overheating detection, abnormal behaviour monitoring, pattern recognition, predictive maintenance alerts, or enhanced user warnings. In these cases, the AI does not replace the existing safety architecture and is not able to alter it in any way. Rather, it supplements it, increasing the overall product safety.

The guidelines should therefore explicitly state that AI systems providing only an ancillary or supplementary safety function should not be considered safety components where:

- the product remains compliant with all applicable safety requirements without the AI functionality;
- existing safety mechanisms independently ensure product safety; and
- failure of the AI functionality does not create a new safety hazard.

APPLiA requests clarifying that an additional and voluntary safety component added to an already safe product does not automatically classify the AI system as high-risk.

	The issues	Proposal for clarification
Paragraph 34	It states that a system will fulfill the condition of the Art 6,1 (a) if "the system fulfills a 'safety function' or when the system's failure or malfunctioning would endanger the health and safety of persons or property. This does not distinguish between a critical safety component and a voluntary and additional safety component	The text must explicitly clarify that AI systems providing only an ancillary or supplementary safety function should not be considered a safety component. If an additional safety component fails, the product remains safe, according to the Union safety regulation. By changing the "or" condition into an "and", it would exclude such cases.

3. The Interpretation of "Safety Component" Remains Excessively Broad

Paragraphs 31 - 36

The guidelines add the clarification that not all AI systems embedded in regulated products are automatically classified as high-risk. However, the definition of safety component remains excessively broad because it relies on two alternative tests:

- intended safety function; **or**
- **failure or malfunction that endangers health and safety.**

In practice, almost any AI functionality interacting with a product could potentially satisfy the second criterion if interpreted broadly enough. Specifically, the proposed definition still uses "or" rather than "and" when referring to the failure or malfunctioning of the component, and it introduces the word "mitigate" in relation to risk. This is problematic because an additional safety feature, one that goes beyond what is strictly required, would still fall under the high-risk classification, because by definition it mitigates risk.

The examples provided in paragraphs 43 and 49 illustrate this concern.

The guidelines should clarify that:

- a purely theoretical possibility of safety consequences is insufficient;
- failure scenarios must be reasonably foreseeable;
- the assessment should consider the overall safety architecture of the product;
- AI systems should only qualify as safety components where they materially influence the safety outcome of the product.

Without such clarification, manufacturers face substantial uncertainty regarding the boundary between ordinary product software and high-risk AI systems.

Additionally, the safety component definition is not aligned with, differs from and goes beyond definitions in existing NLF legislation in Annex I. The term safety function is not clearly defined, leading to confusion. Both definitions should be harmonised with existing wording in Annex I legislation.

While this definition provides a functional basis for identifying safety-relevant elements within AI systems, it lacks alignment with established safety principles in horizontal product safety legislation such as the Machinery Regulation and other Union Legislations where the term Safety component is not defined. Manufacturers may face inconsistent obligations depending on whether a product is classified as machinery or electrical/radio equipment. We recommend introducing a definition of "safety component" which is applicable across sectors.

APPLiA requests aligning the safety component definition with the existing definition in the NLF legislation in Annex I.

	The issues	**Proposal for clarification**
Paragraph 33	The safety component definition is not aligned with, differs from and goes beyond definitions in existing NLF legislation in Annex I.	Align the safety component definition with the existing one: Article 3 (14): 'safety component' means, **in line with the respective Union harmonisation legislation listed in Annex I**, a component of a product or of a system, **which is independently placed on the market** and which fulfils a safety function for that product or system, ~~**or**~~ **and** the failure or malfunctioning of which endangers the health and safety of persons;

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