



Home Appliance Europe

Bld. Brand Whitlock 114 B-1200 Brussels

hello@applia-europe.eu | www.applia-europe.eu

APPLiA Home Appliance Europe AISBL

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APPLiA's recommendations and amendments proposal for the AI Omnibus



AI Omnibus

Europe's home appliance sector is built on decades of trust, following rigorous safety standards. As we transition into the AI era, the EU's regulatory framework must empower manufacturers to enhance consumer protection, rather than creating a deterrent to safety.

The current New Legislative Framework (NLF), ensures that the European household appliances which are placed on the market are already safe and fully compliant products. However, we are currently facing a legislative paradox within the text and interpretation of the AI Act: if a manufacturer integrates Artificial Intelligence to provide a voluntary, additional layer of safety, they risk being reclassified as "High-Risk".

This classification triggers a cascade of disproportionate administrative and financial burdens that do not reflect the actual risk. By treating voluntary safety enhancements as a liability, we are effectively penalising European innovation and the manufacturers will simply refrain from using the latest technologies to make safer products.

Below we propose targeted improvements to the AI Act to clarify definitions surrounding AI systems, safety components, and high-risk classification conditions. To illustrate the practical implications of these definitions, the Annex provides two hypothetical scenarios involving home appliances where AI is used to improve safety. We demonstrate how these beneficial features could be inadvertently misclassified as 'High-risk' under the existing text.

1. Improve the broad definition of "AI system" (Art. 3 (1))

The definition of "AI system" in its current form is **too broad**. The vague definition entails the risk that simpler software systems that exhibit no adaptiveness after deployment, and which are not able to alter behaviour during use, are included in the scope.

Two elements are especially critical in our view:

a) Autonomy: There is no level or degree of autonomy required or specified. What about systems who do not operate with certain degrees of independence or remain fully in human oversight?

b) Adaptiveness: The wording "*may exhibit adaptiveness*" is too vague. A solid and legally certain definition should enable at least a **differentiation between adaptive / non-adaptive systems**. It should be avoided that "may exhibit" is understood to include every non-adaptive system that through its design and development is prevented from adapting after deployment. If a system does not exhibit any adaptiveness (even though it might be hypothetically feasible) then its risks are very well contained and sufficiently limited during placing on the market by existing safety legislation.



AI Act (EU 2024/1689)

Article 3 (1):

‘AI system’ means a machine-based system that is designed to operate with varying levels of autonomy and 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;

APPLiA proposed amendments

Article 3 (1)

‘AI system’ means a machine-based system that is designed to operate with varying levels of autonomy and that ~~may~~ **exhibits** 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; (1a) **“autonomy” means the ability of the artificial intelligence system to operate, within constraints, without human guidance or intervention.**

2. Need to specify the high-risk classification in Article 6 (1)

It is important to ensure that products already covered by **established product legislation frameworks protecting against safety risks (including AI) under Annexe I are not automatically classified as “high-risk” AI systems**. This concern is particularly relevant if Article 6(1) were to be interpreted such that the choice of a specific conformity assessment module, or a misinterpretation of safety provisions, would lead to an automatic high-risk classification. Classification as high-risk should only be justified when, in light of the product’s intended purpose, the product poses a genuine risk of harm to health and safety or to the fundamental rights of individuals (as explicitly expressed in Recitals 28 and 30).

In particular, there is a need to exclude those cases where the AI functionality only serves a minor or ancillary safety function by adding **another additional safety layer** (i.e. the safety net based on hardware functionalities remains). All cases where the AI system is intended purely as a **supportive measure to an already existing safety net**, i.e. products that are strictly in conformity with all applicable safety legislation and standards, should not be treated the same as applications where the AI fulfills critical safety functions for the respective product. In the cases of non-critical, additional safety functions the product’s safety is fully ensured without the AI system in question.



AI Act (EU 2024/1689)

Article 6 (1):

Irrespective of whether an AI system is placed on the market or put into service independently of the products referred to in points (a) and (b), that AI system shall be considered to be high-risk where both of the following conditions are fulfilled:

(a) the AI system is intended to be used as a safety component of a product, or the AI system is itself a product, covered by the Union harmonisation legislation listed in Annex I;

(b) the product whose safety component pursuant to point (a) is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service of that product pursuant to the Union harmonisation legislation listed in Annex I.

New paragraph

APPLiA proposed amendments

Article 6 (1)

1. Irrespective of whether an AI system is placed on the market or put into service independently of the products referred to in points (a) and (b), that AI system shall be considered to be high-risk where both of the following conditions are fulfilled:

(a) the AI system is intended to be used as a safety component of a product **and the AI functionality has an impact on the safety of the overall system**, or the AI system is itself a product, covered by the Union harmonisation legislation listed in Annex I;

(b) the product whose safety component pursuant to point (a) is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment **related to risks for health and safety or fundamental rights**, with a view to the placing on the market or the putting into service of that product pursuant to the Union harmonisation legislation listed in Annex I.

2. A lack of harmonised standards or part thereof, the references of which have been published in the Official Journal of the European Union, leading to third-party conformity assessment according to the applicable Union harmonisation legislation in Annex I, can in itself not lead to a product or AI system being classified as "high-risk."



Article 6 (3)

By derogation from paragraph 2, an AI system referred to in Annex III shall not be considered to be high-risk when it does not pose a significant risk of harm to the health, safety or fundamental rights of natural persons [...]

Article 6 (3)

By derogation from paragraph 2, an AI system referred to in Annex III shall not be considered to be high-risk **when it is not adaptive after deployment or when its failure or malfunctioning does not endanger the health and safety of persons or property.**

3. Need to clarify the definition of the Safety Component (Article 3(14))

This definition is not aligned with, differs from and goes beyond definitions in existing NLF legislation in Annex I. Moreover, 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.

AI Act (EU 2024/1689)

Article 3 (14):

'safety component' means a component of a product or of an AI system which fulfils a safety function for that product or AI system, or the failure or malfunctioning of which endangers the health and safety of persons or property;

APPLiA proposed amendments

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;

4. Interplay of AI Act with Union harmonisation legislation in Section 1 a of Annex I – Clarify the application of conformity assessment procedures

The current wording of the third subparagraph in Article 43 (3) of the AI Act as well as similar wording used in the ongoing 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. 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 mere non-listing of a harmonised standard, potentially for purely bureaucratic or formal reasons, results in a product with AI-based components being automatically classified as "high-risk" because the second condition is triggered. Equally the condition in Article 6, 1b) should not be triggered because of a misinterpretation of the choice of conformity assessment modules in Union harmonisation legislation in Annex I.

AI Act (EU 2024/1689)

Article 43 (3):

(...)Where Union harmonisation legislation listed in Section A of Annex I provides the product manufacturer with an option to opt out from a third-party conformity assessment, provided that that manufacturer has applied harmonised standards covering all the relevant requirements, that manufacturer may use that option only if it has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering all requirements set out in Section 2 of this Chapter.(...)

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Article 43 (3):

Deletion of the phrase "option to opt out".



ANNEX

Examples of AI high-risk misclassification for home appliances

Below we present two examples where a home appliance is using AI to enhance the safety of a product and risks being misclassified as “High-risk” under the current legislation.

Example 1: The smart pizza oven

The “safety layer” hypothetical scenario

The context: Consider a normal oven. This product is already a safe, fully-functioning product, compliant with all the EU safety standards. The consumer wants to cook a pizza using a conventional program without a time limit. For some reason, the consumer forgets about the pizza and when he or she checks it, the pizza is burned and heavily smoking. There is a very low residual, legally acceptable risk that the smoke damages the oven or changes color of/adds odor to the walls in the kitchen, or that a burnt pizza might be a health risk when mistakenly eaten.

The AI innovation: A manufacturer adds an AI-powered camera inside the oven. This camera recognizes the pizza and can be used to cook it to the ideal point. Additionally it may detect any smoke and depending on further circumstances then shuts the oven off automatically and thus adding an additional layer of safety. Such innovation could be checked in the field under real conditions to estimate its performance and potential.

The issue: Under the current rules, this AI could be labeled as “High-risk” because:

(1) Such a system meets the definition of a safety component with no distinction between a critical safety feature and an additional safety layer.

(2) The product is likely to be a connected appliance and may be required to undergo third party conformity assessment under sectoral law (e.g. under the Radio Equipment Directive, or the future CRA directive). According to the Commission interpretation (see Toy Safety regulation), the home appliances who have the option for the third-party conformity assessment, always fulfill this criteria, even in the case when the manufacturer follows the existing harmonized standards, obtaining the declaration of conformity or does self-assessment.

The absurdity: If the AI camera fails, the oven simply behaves like a normal, safe oven. The product is safer with the AI than without it, yet the regulatory burden for the “safer” oven would be exponentially higher. Companies may refrain from adding new features if they fear either non compliance or unnecessary documentation burden.



Example 2: The non-adaptive hob

The "fixed algorithm" hypothetical scenario

The context: Induction and other ceramic hobs had been using touch sensors on their surface for a long time. For example, for switching on and off and other actions. These sensors must distinguish between a human finger and a spilled drop of water to prevent the stove from turning on accidentally.

The AI innovation: To increase the accuracy of this sensor, engineers use AI (e.g machine learning) during the research and development phase to create a complex algorithm that is more precise to prevent involuntary switching. However, once the product is placed on the market, the algorithm is no longer learning or changing its behaviour, but it becomes a fixed software. At this stage it is not possible to differentiate this AI created algorithm from a one created by human engineers. During conformity assessment it undergoes the same rigorous safety tests and - when passing - is considered a safe appliance.

The issue: Under the current rules, this AI could be labeled as "High-risk" because:

(1) Such a system meets the broad definition of AI (Art 3.1). Here machine learning was used to set-up the algorithm, which allows autonomous inference in use and it influences the environment (switching/off), thus the definition of AI applies.

(2) Such a system meets the definition of a safety component, because an on/ of switch is a safety feature, in analogy to the emergency-off in professional machines.

(3) Such a system may be required to undergo third-party conformity assessment under sectoral law. This condition has the same risk of interpretation as the case above.

The absurdity: This is a standard, non-adaptive piece of software that has been used safely for years. Treating it as high-risk AI adds massive paperwork without adding any actual safety for the consumer.



The solution

To keep European innovation competitive, we need the following clarifications in the AI Omnibus:

1. **Critical safety component vs additional safety layer:** AI should only be "High-Risk" if it is the critical safety component. If it is just an additional safety layer (where the product is safe even if the AI fails), it should not be high-risk.
2. **Definition of AI:** At least when applied to identify high risk AI according to Art 6.1, narrow the definition to ensure that fixed, non-adaptive algorithms (like the hob sensor) are not accidentally caught in the AI net. If a change in the AI definition might be of too wide a consequence, such cases could be added with precision to the other exclusions already existing in Article 6.3.
3. **Self-assessment is not an "opt-out":** Manufacturers should be able to certify their own safe products without being forced into expensive third-party AI audits just because they could have chosen a third party conformity assessment. This method is already an established legal way under the New Legislative framework.

Reference contact

Michał Zakrzewski *Senior Policy Director,*
Digital & Competitiveness
michal.zakrzewski@applia-europe.eu

Reference contact

Iulia Florea *Junior Policy Officer,*
Digital & Competitiveness
iulia.florea@applia-europe.eu