EUROPEAN
COMMISSION

Brussels, XXX
[…](2026) XXX draft

ANNEX

ANNEX

to the

COMMUNICATION FROM THE COMMISSION

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

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

Contents

Disclaimer: These Guidelines are still a draft document. They provide clarifications for the classification of AI systems as high-risk pursuant to Article 6 AI Act and a list of practical examples to assist in such classification. The drafts are published for stakeholder feedback to provide input to the Commission before it adopts a finalised version. The Guidelines are presented in a user friendly manner on the AI Act Single Information Platform that allows users to look and search only the area(s) and use cases of interest to them.

I. Introduction

[see separated chapaters]

II. General principles for classification of high-risk AI systems

[see separated chapters]

III. High-risk classification according to Article 6(1) and Annex I AI Act

(15) Article 6(1) AI Act sets the classification rules for AI systems intended to be used as a safety component of a product or for AI system which are themselves products, covered by the Union harmonisation legislation listed in Annex I AI Act ('regulated products'). This includes Union harmonisation legislation based on the New Legislative Framework (Annex I Section A) and other Union harmonisation legislation (Annex I Section B). This section clarifies how such regulated products are to be classified as high-risk AI systems.

(16) Considering the diversity of AI systems and products covered by the Union harmonisation legislation listed in Annex I AI Act, it is not feasible to provide an exhaustive list of all AI systems that may be classified as high-risk under Article 6(1) AI Act. Accordingly, these Guidelines set out the main elements of the assessment and a horizontal methodology for classification under Article 6(1) AI Act. This methodology applies to all sectors listed in Annex I AI Act. More detailed, sector specific, guidance may be developed, in line with these Guidelines, to provide further clarification on the application of the methodology to sector-specific use cases.

(17) The guidance provided in this section follows the New Legislative Framework ('NLF'), including the guidance provided in the 'Blue Guide'[1], and does not duplicate horizontal issues already addressed by that framework. This guidance should therefore be read in conjunction with the NLF-based legislation and the Blue Guide.

1. The classification rationale

(18) Recital 47 AI Act clarifies the rationale for classifying certain AI systems covered by the Union harmonisation legislation listed in Annex I as high-risk, noting that '*AI systems could have an adverse impact on the health and safety of persons, in particular when such systems operate as safety components of products. Consistent with the objectives of Union harmonisation legislation to facilitate the free movement of products in the internal market and to ensure that only safe and otherwise compliant products find their way into the market, it is important that the safety risks that may be generated by a product as a whole due to its digital components, including AI systems, are duly prevented and mitigated.*'

(19) The main objective of high-risk classification under Article 6(1) AI Act is thus to establish a proportionate, targeted, and safety-based classification mechanism. This mechanism is intended to cover only those AI systems that affect the safety of products already regulated under Union harmonisation legislation, while avoiding unnecessary regulatory burdens for low-risk AI enabled products.

(20) In line with the AI Act's risk-based approach, only AI systems that present significant risks to health, safety, or fundamental rights are classified as high-risk, as explained in Recitals 47 to 51 AI Act. Article 6(1) AI Act operationalises this approach for AI systems covered by Union harmonisation legislation, by linking high-risk classification to risk and the system's safety relevance, as well as to the requirement of third-party conformity assessments.

[1] Commission notice The 'Blue Guide' on the implementation of EU product rules 2022 (Text with EEA relevance) 2022/C 247/01, (OJ C 247, 29.6.2022, pp. 1–152).

(21) Consequently, not all AI systems that are components of regulated products, or that are themselves regulated products, are high-risk AI systems. Only a sub-set of such products qualify as such, namely those that fulfil the classification criteria of Article 6(1) AI Act, and only those products are subject to the high-risk requirements of the AI Act. Consumer products, if they fall into one of the Union harmonisation legislations listed in Annex I AI Act, are not excluded from the scope of Article 6(1) AI Act. Provided all the conditions of Article 6(1) AI Act are fulfilled, both professional and consumer products could be classified as high-risk AI systems. At the same time, many consumer AI systems, such as smart home appliances, will not meet one or more of the cumulative conditions in Article 6(1) AI Act and therefore will not be classified as high-risk, as the analysis below demonstrates.

(22) Article 6(1) AI Act applies irrespective of whether the AI system is embedded within the product or is placed on the market or put into service independently. An AI system supplied, for example, as a software update, an add-on, or a remote service may therefore be classified as high-risk pursuant to Article 6(1) AI Act, provided all the conditions of that provision are met.

2. The main elements for classification as high-risk under Article 6(1) AI Act

2.1. Introduction

(23) Annex I AI Act does not list individual products that should be classified as high-risk, but rather Union harmonisation legislation that regulates the safety aspects of certain products. Whether an AI system falls within the scope of Annex I AI Act as a regulated product itself, or as a safety component of a regulated product, therefore depends on whether the system, or the product of which the system constitutes a safety component, falls within the material scope of one of the legislative acts listed in that annex. Annex I AI Act includes, inter alia, Union harmonisation legislation covering products such as machinery, toys, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, radio equipment, pressure equipment, recreational craft, cableway installations, appliances burning gaseous fuels, medical devices, in vitro diagnostic medical devices, and products in the automotive and aviation sectors. The fact that a product is intended for consumer or household use does not in itself exclude it from the scope of the AI Act.

(24) The list of Union harmonisation legislation in Annex I AI Act is exhaustive. New products may be added or removed from that list, but only through amendments to the scope of the Union harmonisation legislation itself, for example, by expanding or limiting products or product categories covered by the Union harmonisation listed in Annex I (e.g. expanding the material scope of the Machinery Regulation) or by adding new Union harmonisation legislation to Annex I AI Act.

(25) The AI Act addresses risks that AI systems may pose to health, safety and fundamental rights. For the purposes of classification under Article 6(1) the concept of safety component, as defined under Article 3(14) AI Act, may be understood as excluding public interests protected under the Union harmonisation legislation covered in Annex I that go beyond health, safety and fundamental rights, such as risks related to the use of radio spectrum or electromagnetic compatibility.

(26) The classification of an AI system as high-risk under Article 6(1) AI Act is therefore dependent upon and operates in conjunction with existing Union harmonisation legislation. The AI Act, through its Article 6(1), does not in itself extend the scope of Union harmonisation legislation to new or additional products that are not already subject to that legislation. Moreover, as clarified in

Recital 51 AI Act, the AI Act does not determine or change the risk profile of a product, but builds on the sectoral risk classification of regulated products.

(27) Article 6(1) AI Act can be understood as laying down two cumulative conditions that must be satisfied for an AI system to be classified as high-risk pursuant to that provision. First, the AI system must be intended to be used as a safety component of a product, or the AI system itself must be a product, covered by the Union harmonisation legislation listed in Annex I. Second, the product whose safety component is the AI system or the AI system itself is required to undergo a third-party conformity assessment.

(28) This Section of the Guidelines describes the distinction between an AI system that is a component of a product or that is itself a product covered by Union harmonisation legislation. It then describes what it means for a component to be a safety component of a product. Finally, it describes the requirement that the product is required to undergo a 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.

2.2. The AI system is a product itself, or a safety component of a product, covered by the Union harmonisation legislation

(29) Article 6(1) AI Act distinguishes between AI systems that are themselves products covered by Union harmonisation listed in Annex I AI Act and those that are safety components of a product covered by such legislation.

2.2.1. AI systems that are themselves products covered by Union harmonisation legislation

(30) An AI system is the product itself where it is independently placed on the market, has its own intended purpose, and is directly regulated by the Union harmonisation legislation listed in Annex I AI Act. Such systems can include stand-alone AI systems, or AI systems that are embedded in other products. For example, under Regulation (EU) 2023/1230 (the Machinery Regulation)[2], the definition of machinery-related products explicitly includes certain software, which may therefore itself be a regulated product under that Regulation and therefore be classified as high-risk pursuant to Article 6(1) AI Act, provided it is required to undergo a third-party conformity assessment.

2.2.2 Safety components

(31) An AI system is a safety component where it is, or is intended to be, part of a product regulated by the Union harmonisation legislation listed in Annex I AI Act, even if that system is also placed on the market independently of that product. Where the AI system is a safety component of a regulated product, it should be evaluated as part of the product's overall safety assessment under the relevant legislation listed in Annex I AI Act, even if it is also placed on the market independently of that product.

[2] Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC, Text with EEA relevance (OJ L 165, 29.6.2023, pp. 1–102).

(32) Article 3(14) AI Act defines a 'safety component' as *'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'*.

(33) This definition is an autonomous definition of the AI Act that has its own meaning, independent of definitions of 'safety component' included in other Union harmonisation legislation. This definition ensures uniform interpretation of that notion across all sectors covered by the Union harmonisation legislation listed in Annex I. Therefore, in the assessment of whether an AI system is a safety component for the purposes of high-risk classification under Article 6(1) AI Act, only the definition in Article 3(14) AI Act is relevant, not the definition of safety component in any of the legislation listed in Annex I AI Act.

(34) The definition of 'safety component' in Article 3(14) AI Act can be understood to lay down two alternative scenarios under which an AI system may be classified as a safety component. That will be the case, on one hand, where the system fulfils a 'safety function' or, on the other, where the system's failure or malfunctioning would endanger the health and safety of persons or property.

(i) Safety function

(35) Under the first scenario, an AI system constitutes a safety component of a product where it is intended to fulfil a 'safety function'. The safety function must be an intended purpose of the system, which is determined by the provider of the system. Article 3(12) AI Act provides that the provider is specified the intended purpose of the system in the instructions of use, technical documentation, and promotional or sales materials. The mere fact that an AI system is integrated into or operates within a product that is subject to safety regulation does not, in itself, mean that it fulfils a safety function.

(36) Recital 47 clarifies the rationale underlying the concept of a safety function, noting that '*AI systems could have an adverse impact on the health and safety of persons, in particular when such systems operate as safety components of products*'. That recital further clarifies that '*it is important that safety risks that may be generated by a product as a whole due to its digital components, including AI systems, are duly prevented and mitigated*'.

(37) An AI system therefore fulfils a 'safety function' where its intended purpose, as determined by the provider, is to prevent or mitigate risks to health and safety of persons or property.

Safety functions – indicative examples

The AI Act does not provide a list of safety components or safety functions. However, based on the definition of safety component in Article 3(14) AI Act and the clarifications provided in Recitals 47 and 48 AI Act, the concept of 'safety function' may include, in particular, the following preventive or mitigation functionalities:

Preventive functions:

– monitoring and detection of situations which may lead to physical harm or damage to people or property (e.g. AI system detecting abnormal system behaviour);

– monitoring and detection of a need for maintenance or inspections, where failure to perform such actions may lead to physical harm to people or property (e.g. an AI system detecting whether safety-related parts, or parts whose failure may lead to harm to people or property , are worn down and may need replacement or maintenance);

– prevention of physical harm to people or property (e.g. an AI system preventing the system from starting up if abnormal behaviour is detected);

– supervision of another system that performs a safety function (e.g. an AI system that supervises through sensors an operation in real time of a safety component that directly performs the safety function).

Mitigation functions:

– control or limitation of physical harm to people or property (e.g. an AI system controlling specific behaviour or the functioning of a system and adjusting its function accordingly);

– mitigation of consequences of possible physical harm to people or property (e.g. an AI system that triggers action, such as safe stop if dangerous conditions arise);

– control of another system that performs a safety function.

Functions not considered safety functions:
All other AI system functions that are not intended by the provider to prevent and mitigate safety risks do not fall within the notion of 'safety function'. This includes functions related to performance optimisation, service efficiency, automation, comfort, convenience, or quality control operations of non-safety related aspects. By way of example, the following functions are not in themselves safety functions:

– optimisation of product performance (e.g. efficiency or user preference optimisation) where failure would not directly lead to risks to health or safety of persons or property;

– optimisation of service efficiency or service or optimisation of the functioning of a product (e.g. AI systems for billing controls or optimising customers claims processing);

– quality control of non-safety related functions or services (e.g. AI systems for quality-of-service monitoring).

(ii) Failure of malfunctioning endangering health and safety of persons or property

(38) Under the second scenario, an AI system constitutes a safety component of a product where its failure or malfunctioning could endanger the health and safety of persons or property. This scenario ensures that safety relevance is assessed not only based on the intended purpose of the system, but also by reference to the hazards associated with the product and the degree of influence the AI system exercises over those hazards. It captures AI systems that control or influence hazardous processes and that may create or amplify risks in the event of failure or malfunction. Such AI systems could also encompass AI components intended to be used for cybersecurity purposes, when

the failure or malfunctioning of such components could endanger the health and safety of persons or property[3].

(39) Failure or malfunctioning may include incorrect outputs (such as false negatives or false positives), loss of function or availability, performance instability or drift, timing or latency errors, or misclassification leading to hazardous control decisions. The likelihood of failure or malfunctioning must not just be a theoretical possibility, but must lead to endangering persons or property in the product context. Failures or malfunctions can occur because of faults within the product itself (e.g., a programming error) or because of external influences (e.g., unforeseen input data format).

(40) Endangerment of health and safety of persons or property refers to situations in which a person or property is put at risk (as defined in Article 3(2) AI Act) regarding their health and safety. The notion of 'endangerment' means an increase in hazard. Endangerment may occur, for example, where an AI system causes a product to enter or remain in an unsafe state, prevents a protective response, or enables a hazardous operation that the AI Act or sectoral legislation seeks to prevent. The notion of 'endangerment' of health, safety and property does not include reputational harm, purely financial loss, minor service degradation, or inconvenience that does not involve a safety hazard.

(41) Harm to health includes, inter alia, illness or injury, temporary or permanent impairment of a body structure or a body function, and chronic disease. It also encompasses harm to mental health, such as psychological trauma that significantly affects a person's ability to perform ordinary tasks and activities. Harm to property includes, inter alia, loss of or damage to property.

(42) An AI system does not fulfil a safety function where its intended purpose is limited to, for example, efficiency optimisation, performance enhancement, comfort or convenience, automation of user decisions, or quality improvement. However, such a system may nonetheless qualify as a safety component where the consequence of its failure or malfunctioning is relevant for the safety of the product.

(43) By way of illustration, an AI system designed to optimise combustion efficiency in household gas appliances may constitute a safety component. The intended purpose of such an AI system is energy efficiency, which is not a safety function. However, if the product is designed in a way that a failure or malfunction of the AI system could lead to carbon monoxide formation, explosion or fire, the AI system would qualify as a safety component due to its failure-based risk that could endanger health and safety of persons and property. Conversely, an AI system that merely optimises heating schedules based on household habits to reduce energy consumption would not fulfil either a safety function or 'failure or malfunctioning endangering health and safety' criterion where failure would result only in discomfort or higher energy bills. Such a system would therefore not qualify as a safety component of a product.

(44) *Table 1: Summary of the concept of a safety component of a product*

Application of the notion of 'safety component'

[3] Recital 55 AI Act explicitly excludes components intended to be used solely for cybersecurity purposes from the scope of safety components, but does so only in the context of safety components used in critical infrastructure (see Section 3.2).

	'Safety function'	**'Failure or malfunctioning'**
Legal nature	Intent based	Consequences and risk based
Trigger	Focuses on what the AI system is intended to do; the intended purpose must be to prevent or mitigate safety risks	Focuses on the consequences if the AI system fails or malfunctions; such failure or malfunction must endanger health, safety or property
Provider control	High – the provider defines the intended purpose	Lower – the assessment depends on the system's behaviour and risk exposure
Key evidence	Instructions of use, technical documentation, promotional materials	System architecture, failure modes and effects

(45) AI systems that are intended to fulfil a safety function and are therefore considered a safety component within the meaning of Article 3(14) AI Act include, inter alia:

- Machinery: an AI based computer vision system that detects human presence in a robot cell and triggers a safe stop or speed reduction where the intended purpose is to prevent injury;
- ATEX equipment: an AI system that intends to monitor gas concentrations and command shutdown;
- Pressure equipment: an AI system intended to predict runaway pressure and actuate protective measures, such as triggering shutdown linked to safety accessories;
- Rail interoperability: an AI system in a train intended to monitor speed limits and to prevent collisions and derailments.

(46) Even where an AI system is not intended by its provider to fulfil a safety function, it may still qualify as a safety component within the meaning of Article 3(14) AI Act if its failure or malfunctioning would create a safety hazard to health and safety of persons or property. Examples of AI systems that may be classified as safety components based on safety risks related to failure or malfunctioning include:

- Lifts: an AI system managing door closing timing and obstacle detection. Although the provider's intended purpose for such a system may be efficient lift operation, a malfunctioning of the system could cause injury and thus endanger health and safety of persons;
- Vehicles: an AI system for lane assistance. While a provider's intended purpose for such a system may be the enhancement of the user experience, a malfunctioning of such a system, if it steers unexpectedly to cause a collision, could cause injury and thus endangers health and safety of persons and property.
- Agriculture: an AI system targeting the areas of agricultural land for spraying chemicals. While a provider's intended purpose for such a system may be to optimise the use of chemicals, not

adequately accounting for the presence of nearby persons could endanger the health and safety of persons.

(47) AI systems integrated into regulated products covered by the Union's harmonisation legislation listed in Annex I AI Act that are neither intended to fulfil a safety function, nor whose failure or malfunctioning endanger health, safety or property, do not fall within the definition of a safety component. An example of such systems includes:

- Toys: an AI system that recommends music in a connected toy. Such an AI system neither fulfils a safety function, nor would its malfunction endanger health, safety or property.

- Agriculture: an AI system integrated into drone or robot and used for certain agronomic purposes, such as yield forecasting or irrigation optimisation. Such an AI system neither fulfils a safety function, nor would its malfunction endanger health, safety or property[4].

(48) The AI Act does not classify any product in the scope of Article 6(1) automatically as high-risk. Most, but not all[5], AI systems in consumer 'smart' home appliances, such as AI systems in thermostats, washing machines, air purifiers, refrigerators, and televisions, will fall outside the definition of a safety component, since their intended purpose is to ensure comfort, convenience, or optimisation (e.g. energy use, air quality, brightness, sound), and a failure or malfunctioning of the system is unlikely to endanger health and safety of persons or property, but will rather lead to, for example, inconvenience, discomfort, incorrect suggestions and degraded performance.

(49) By way of example, a smart thermostat covered by the Radio Equipment Directive will not constitute a safety component where the system's intended purpose is to enhance user comfort and energy efficiency by learning household routines and optimising temperature settings. Such an AI system is not intended to fulfil a safety function and its failure or malfunctioning would result only in discomfort or higher energy bills, without endangering the health and safety of persons or property. On the contrary, if an intended purpose of a smart thermostat is to fulfil a safety function or where a failure or malfunctioning of a smart thermostat may go beyond mere discomfort or higher energy bills and endanger health and safety then the AI system will constitute a safety component.

2.3. The product is required to undergo a third-party conformity assessment

(50) To be classified as high-risk, the product of which the AI system forms a safety component, or the AI system itself if it is the product, must undergo a third-party conformity assessment. This means that, for classification pursuant to Article 6(1) AI Act, the system must be considered by the Union harmonisation legislation listed in Annex I AI Act as '*of being of complex design or present*[ing]

[4] Where the failure or malfunction of such an AI system could endanger the health and safety of persons or property in the context of the product, it may still qualify as a safety component within the meaning of the AI Act, provided that the other conditions under Article 6(1) are met.

[5] This only applies as long as the AI product does not perform a safety function or its failure or malfunctioning does not endanger the health and safety of persons or property. This may arise, for example, in the case of smart door locks, thermostats or child-lock functions in appliances, depending on the product design and the reasonably foreseeable conditions of use, in particular where children and vulnerable users are concerned.

higher risks of non-compliance for instance'[6], in that it requires public interest protection through a conformity assessment module requiring third-party conformity assessment.

(51) According to the Blue Guide, a '*conformity assessment is the process carried out by the manufacturer of demonstrating whether specified requirements relating to a product have been fulfilled*'[7]. All Union harmonisation legislation listed in Annex I includes provisions specifying the conformity assessment procedures that a manufacturer of a product must follow to demonstrate compliance with legislative requirements, prior to placing the product on the market or putting it into service.

(52) The AI Act does not itself determine the applicable conformity assessment procedures for AI systems deemed high-risk pursuant to Article 6(1) AI Act. Instead, the AI Act relies on the choice of conformity assessment procedures established under the Union harmonisation legislation listed in Annex I AI Act.

(53) Decision 768/2008/EC[8] sets a harmonised structure of conformity assessment modules that applies to all NLF legislation included in Annex I. This structure includes eight main modules for conformity assessment (A to H), including sub-variants and combinations.

(54) For all conformity assessment modules, except module A, the involvement of a notified body is required. Module C does not require the involvement of a notified body, but is always combined with modules that do require notified body involvement. For modules A1 and A2, the involvement of a notified body or accredited in-house body is required, but only in the production phase, not in the design phase. The involvement of a notified body in the design phase is required by module B, which should always be followed by one of the modules covering the production phase, i.e. modules C1, C2, D, E and F, where a notified body is involved on various specific aspects (so called two modules procedure). Involvement of a notified body in both the design and production phases are covered by modules D1, E1, F1, G, H, H1. The Blue Guide, which provides guidance on the conformity assessment modules set by Decision 768/2008/EC, provides the following guidance on the selection of modules for conformity assessment by the Union legislature: '[t]*he complexity of the modules selected should be proportional to the risk (impact on public interest, health, safety, environment) of the product, its design complexity, the nature of its production (large series vs small series, custom-made, simple vs complex production mechanism etc.)* '[9].

[6] Commission notice The 'Blue Guide' on the implementation of EU product rules 2022, Text with EEA relevance, 2022/C 247/01, (OJ C 247, 29.6.2022, pp. 1–152), Section 5.9.; See also Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, Article 4, 'Conformity assessment procedures' that sets criteria for the legislator for choosing among the conformity assessment modules. One of the criteria, set in Article 4(1)(b) includes 'the nature of the risks entailed by the product and the extent to which conformity assessment corresponds to the type and degree of risk".

[7] Commission notice The 'Blue Guide' on the implementation of EU product rules 2022, Text with EEA relevance, 2022/C 247/01, (OJ C 247, 29.6.2022, pp. 1–152), Section 5.1.

[8] Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, Text with EEA relevance, (OJ L 218, , pp. 82–128).

[9] Commission notice The 'Blue Guide' on the implementation of EU product rules 2022, Text with EEA relevance, 2022/C 247/01, (OJ C 247, 29.6.2022, pp. 1–152), Section 5.1.9.

(55) According to the Blue Guide, module A is intended for products '*of low complexity (simple design and production mechanism) that present a low risk for the public interest*'[10].

(56) Union harmonisation legislation allows the use of Module A for assessment of conformity of certain products[11]. However, in some cases use of Module A is conditioned on the application of harmonised standards, such as in the Regulation (EU) 2025/2509[12] ('the Toys Safety Regulation'), the Machinery Regulation, or the Radio Equipment Regulation. In these cases the use of module A for certain products or certain aspects is allowed, but only where the manufacturer applies harmonised standards published in the Official Journal that cover all relevant health and safety requirements. The mandatory application of such harmonised standards as a condition for the application of Module A, for certain products, ensures that those products are subject to an appropriate level of scrutiny and that internal control alone is not relied upon where additional safeguards of public interest are necessary.

(57) The fact that the Union harmonisation legislation may allow a manufacturer to rely on internal control based on harmonised standards, as one procedural option, does not affect the classification of an AI system as high-risk under Article 6(1) AI Act. The choice of conformity assessment module provides manufacturers with procedural flexibility for demonstrating compliance, but it does not confer discretion on the manufacturer to determine the risk classification of an AI system for the purposes of the AI Act.

(58) In line with the legislative intent of the AI Act, the decisive factor for the classification of an AI system as high-risk under Article 6(1) AI Act is that the product, according to the Union harmonised legislation listed in Annex I AI Act, is subject to enhanced regulatory scrutiny before it can be lawfully placed on the market or put into service in the Union, due to its potential impact on public interests, such as health, safety and the environment. Such scrutiny is ensured through the requirement of a third-party conformity assessment or equivalent mechanisms, including internal control subject to mandatory application of harmonised standards published in the Official Journal. As emphasised in the Blue Guide, the 'protection of the public interest' should be a key consideration for the conformity assessment[13] and the selection of applicable conformity assessment modules by the Union legislature.

(59) This classification logic for the purpose of the AI Act is expressly confirmed by the Union legislature in the Toys Safety Regulation, which explains in its Recital 15 that '[i]*n accordance with Regulation (EU) 2024/1689, toys with AI systems as safety components that require a third-*

[10] Commission notice The 'Blue Guide' on the implementation of EU product rules 2022, Text with EEA relevance, (OJ C 247, 29.6.2022, pp. 1–152), Section 5.1.9.

[11] For example, under Article 3(1) (a) of the Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC Text with EEA relevance (OJ L 153, 22.5.2014, pp. 62–106), for aspect of safety the manufacturer can use Module A without mandatory use of harmonised standards or mandatory involvement of a notified body.

[12] Regulation (EU) 2025/2509 of the European Parliament and of the Council of 26 November 2025 on the safety of toys and repealing Directive 2009/48/EC, Text with EEA relevanc, (PE/50/2025/INIT, OJ L, 2025/2509, 12.12.2025).

[13] Commission notice The 'Blue Guide' on the implementation of EU product rules 2022, Text with EEA relevance, 2022/C 247/01, (OJ C 247, 29.6.2022, pp. 1–152), Section 5.1.1: '*Conformity assessment must not be confused with market surveillance, which consists of controls by the national market surveillance authorities after the product has been placed on the market. However, both techniques are complementary and equally necessary to ensure the protection of the public interests at stake and the smooth functioning of the internal market.*'

party conformity assessment are classified as high-risk AI systems. The choice by the manufacturer of the conformity assessment procedures for such toys, if it is possible to opt out of a third-party conformity assessment where harmonised standards have been applied, should not affect the classification as a high-risk AI system in accordance with Article 6(1) of that Regulation.' On this basis, AI systems that are intended to be used as safety components or are themselves products covered by the Toys Safety Regulation, in accordance with Article 26(2) and Article 26(3) of that regulation, are classified as high-risk pursuant to Article 6(1) AI Act. Similarly, AI systems that are intended to be used as safety components of products or that are themselves products covered by Annex I of the Machinery Regulation, in accordance with Article 25(2) and Article 25(3) of that regulation, are classified as high-risk pursuant to Article 6(1) AI Act.

3. Mechanisms for minimisation of compliance burden for economic operators

(60) AI systems classified as high-risk under Article 6(1) AI Act as regards products covered by the Union harmonisation legislation listed in Section A of Annex I are subject to the requirements for high-risk systems listed in Section 2 of Chapter III AI Act. In contrast, for AI systems classified as high-risk AI systems under Article 6(1) AI Act as regards products covered by the Union harmonisation legislation listed in Section B of Annex I, only Article 6(1), Articles 102 to 109, and Article 112 AI Act apply[14].

(61) Moreover, to reduce the compliance burden for economic operators of AI systems classified as high-risk under Article 6(1) AI Act, Article 8(2) AI Act on the interplay with the sectoral legislation, Article 9(10) AI Act on risk management, and Article 17(3) AI Act on quality management allow economic operators to add, when necessary and appropriate, an assessment of AI-specific risks into already existing risk and quality management systems. Article 40 AI Act further requires consistency of AI Act harmonised standards with standards developed under the Union harmonisation legislation listed in Annex I AI Act.

(62) Such mechanisms provided in the AI Act enable economic operators to comply with the requirements of the AI Act and Union harmonisation legislation within a single compliance framework, thereby avoiding any possible duplication of compliance efforts while ensuring a high level of protection of health, safety and fundamental rights of AI systems covered by Article 6(1) AI Act.

IV. High-risk classification according to Article 6(2) and Annex III AI Act

[see separated chapters]

V. Entry into application of the rules for high-risk AI systems

[see separated chapters]

VI. Review and update of the high-risk use cases and the Commission guidelines

[see separated chapters]

[14] Article 2(2) AI Act.