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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

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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

(1) The Artificial Intelligence Act (the ‘AI Act’)¹, which entered into force on 1 August 2024, lays down harmonised rules for the placing on the market, putting into service, and use of artificial intelligence (‘AI’) in the Union². That regulation aims to promote innovation in and the uptake of AI, while ensuring a high level of protection of health, safety, and fundamental rights in the Union, including democracy and the rule of law. The AI Act follows a risk-based approach, classifying AI systems into different risk categories depending on the risks they pose to health, safety and fundamental rights.

(2) One of those categories is high-risk AI systems, classified as such in accordance with Article 6 AI Act, read in conjunction with Annexes I and III AI Act. Chapter III AI Act imposes a set of

¹ Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689).

² Article 2 AI Act.

requirements and obligations on providers and deployers of high-risk AI systems to ensure that they are trustworthy, safe to use, and respect fundamental rights. The scope of the use cases falling within this high-risk category is limited and proportionate, covering only those AI systems that pose a significant risk of harm to health and safety, or an adverse impact on fundamental rights.

- (3) These Guidelines are issued pursuant to Article 6(5) AI Act. They aim to support providers and deployers of AI systems, as well as competent market surveillance authorities, in assessing whether an AI system should be classified as high-risk, thereby facilitating the uniform application and effective enforcement of Article 6 AI Act. The Guidelines set out the Commission’s interpretation of certain concepts that are relevant for classification purposes and, in accordance with Article 6(5) AI Act, contain practical examples of AI systems that should or should not be classified as high-risk. The examples listed in these Guidelines strive to cover all areas and use cases, but they are not to be considered as exhaustive and may be updated over time. They only aim to clarify which types of AI systems may or may not be classified as high-risk under Article 6 AI Act. The fact that an AI system is listed as an example in these Guidelines does not necessarily mean that its use should automatically be considered to be lawful, since such use would still need to comply with other applicable legislation.
- (4) The scope of these Guidelines is limited only to high-risk classification whether an AI system is high-risk or not. The Guidelines will be complemented in the future with other Commission guidelines aimed to facilitate compliance with the requirements for high-risk AI systems and the obligations for providers and deployers.
- (5) These Guidelines take into account the outcome of a stakeholder consultation and input provided by the Member States in the context of the European Artificial Intelligence Board (‘AI Board’). The draft will be further consulted with the AI Board and published for additional stakeholder feedback before the Guidelines are adopted by the Commission.
- (6) The Guidelines are not binding. Any authoritative interpretation of the AI Act may ultimately only be given by the Court of Justice of the European Union (‘CJEU’).

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

- (7) Under Article 6 AI Act, an AI system shall be considered high-risk in two scenarios. First, if the system is intended to be used as a safety component of a product, or the AI system itself is a product, covered by the Union harmonisation legislation listed in Annex I, and the product whose safety component is the AI system or the AI system itself is required to undergo a third-party conformity assessment, the system will be classified as high-risk pursuant to Article 6(1) AI Act. Second, if the system falls into one of the use cases listed under the areas in Annex III AI Act, it will be classified as high-risk pursuant to Article 6(2) AI Act. Section III below addresses the first category of high-risk AI systems. Section IV below addresses the second category. The following subsections address certain general aspects that apply to the classification of AI systems under both scenarios.

1. The system must be an AI system

- (8) Before a system can be classified as high-risk, it must qualify as an AI system within the meaning of Article 3(1) AI Act. That provision defines an AI system as *‘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.'

- (9) Accordingly, not every software application or automated decision-making system falls within the scope of the AI Act. Only systems that meet the aforementioned definition so qualify. More information on how the Commission interprets the definition of an AI system can be found in the Guidelines on the definition of an artificial intelligence system³, which were adopted pursuant to Article 96(1)(f) AI Act.

2. Intended purpose(s) of the AI system

- (10) The intended purpose of an AI system plays an important role in its classification as high-risk, as well as for assessing compliance with the requirements for high-risk AI systems laid down in Section 2 of Chapter III AI Act⁴. According to Article 3(12) AI Act, the 'intended purpose' of an AI system means *'the use for which that system is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials, and statements, as well as in the technical documentation'*. The intended use must be distinguished from the 'reasonably foreseeable misuse' of an AI system, defined in Article 3(13) AI Act, which is, by definition, a use outside the intended purpose of the system.
- (11) Since the intended purpose of an AI system can entail many different contexts and applications, it is important that providers clearly describe the envisaged use of the system in the information supplied by the provider in the instructions for use, promotional or sales materials, and statements, as well as in the technical documentation. That description should include the functionalities of the AI system, leaving no ambiguity regarding its scope and its intended use. If the system is intended for use in a variety of contexts and application, these should be described to determine whether the system is intended to be used in a manner that could lead to its high-risk classification.
- (12) The manner in which the provider describes the intended use of the system is relevant for systems with multiple purposes, as well as for general-purpose AI systems. If the instructions for use, contractual arrangements, terms of service, usage policy, promotional and sales materials, or the technical documentation present the AI system as broadly applicable across a generality of contexts and functions, and do not consistently limit its application or exclude high-risk uses, the system's intended purpose will be deemed to also encompass high-risk use cases and therefore qualify as high-risk. This will be the case, in particular, where such uses are feasible and reasonably foreseeable given the system's functionalities and capabilities. Furthermore, merely asserting (for example in the terms of service) that high-risk uses are excluded is insufficient to avoid the system from being considered high-risk, where the provider's overall presentation, examples, or product positioning effectively provides for or promotes such uses. Any limitations of use should be clearly, concretely, and coherently described across all materials.
- (13) The assessment whether an AI system is intended to be used for a high-risk use case or not is responsibility of the provider that is supervised by the relevant competent market surveillance authorities. The following sections provide guidelines with illustrative examples to support

³ Commission Guidelines on the definition of an artificial intelligence system established by Regulation (EU) 2024/1689 (AI Act), C(2025) 5053

⁴ Article 8 AI Act.

providers in that self- assessment. In case of doubt, additional questions may be asked to the AI Act service desk and to competent market surveillance authorities.

- (14) Distributors, importers, deployers or other third parties must be mindful of the fact that under Article 25(1) AI Act they may become subject to provider' obligations if they (i) put their name or trademark on a high-risk AI system already placed on the market or put into service⁵; (ii) make a substantial modification to a high-risk AI system that has already been placed on the market or put into service in such a way that it remains a high-risk AI system; (iii) or modify the intended purpose of an AI system, including a general-purpose AI system, which has not been classified as high-risk and has already been placed on the market or put into service in such a way that the AI system concerned becomes a high-risk AI system under Article 6 AI Act⁶.

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

[See separated chapters]

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

- (448) According to Article 113 AI Act, Article 6(2) and the corresponding obligations for high-risk AI systems classified under that provision will apply as from 2 August 2026, whereas Article 6(1) and the corresponding obligations for high-risk AI systems classified under that provision will apply as from 2 August 2027. These dates are now postponed with the AI Omnibus to 2 December 2027 and 2 August 2028 respectively.

- (449) Article 111(2) AI Act provides that that act applies to operators of high-risk AI systems that have been placed on the market or put into service before 2 August 2026 only if, as from that date, those systems are subject to significant changes in their designs. The provision further provides that providers and deployers of high-risk AI systems intended to be used by public authorities shall, in any event, take the necessary steps to comply with the requirements and obligations for high-risk AI systems by 2 August 2030. Article 111(1) AI Act provides a special regime for AI systems that are components of the large-scale IT systems established by the legal acts listed in Annex X AI Act which have been placed on the market or put into service before 2 August 2027. Those systems should be brought into compliance with the high-risk requirements of the AI Act by 31 December 2030.

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

- (450) These Guidelines constitute a first interpretation with practical examples of the classification of AI systems as high-risk pursuant to Article 6 AI Act. The AI Office is available to provide additional

⁵ Without prejudice to contractual arrangements stipulating that the obligations are otherwise allocated.

⁶ Commission is preparing separate Guidelines on the practical application of rules for responsibilities along the AI value chain under Article 25 of the AI Act which will include more detailed explanations about the use cases where the three circumstances under Article 25(1) may apply.

support to operators and authorities on how to understand the classification of high-risk AI systems and to collect further practical use cases on an ongoing basis with input from providers and deployers of AI systems, the AI Board, and other relevant stakeholders. This will be done through, among others, the AI Act Service Desk on the Single Information Platform⁷ and the AI regulatory sandboxes to be established by 2 August 2026.

(451) The AI Act also envisages a mechanism to keep the list of high-risk use cases future-proof and to respond to new and emerging risks and market developments. A specific monitoring instrument to evaluate and review, on an annual basis, high-risk use cases listed in Annex III is envisaged by Article 112(1) AI Act. The Commission is also empowered to adopt a delegated act to amend the list in Annex III AI Act by adding new use cases subject to the conditions in Article 7(1) AI Act. It may also amend or remove high-risk AI use cases where both conditions of Article 7(3) AI Act are fulfilled. The Commission may also adopt a delegated act to amend Article 6(3) AI Act by adding new conditions or modifying the existing conditions for the exceptions laid down in that provision.

⁷ [AI Act Single Information Platform | AI Act Service Desk](#)