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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI) - Preparation for the trilogue

I. INTRODUCTION

1. On 19 November 2025 the Commission put forward a proposal for the Digital Omnibus on AI, as one of the two proposals constituting the Omnibus VII package, with the aim to simplify and clarify some of the provisions of the AI Act. One of the proposed changes is the postponement of the application of some of the provisions on high-risk AI systems, which are currently due to enter into application on 2 August 2026. For this reason, it is important that the proposal is agreed between the co-legislators well in advance of this date.

2. On 13 March 2026, the Permanent Representatives Committee agreed on a negotiating mandate for the Presidency (doc. 7322/26), with a view to reaching an agreement at first reading with the European Parliament on that basis. On 26 March 2026, shortly after the vote in the European Parliament, the co-legislators and the Commission held the first political trilogue on the AI Omnibus, during which all three institutions outlined their priorities for the negotiations and the technical level was given a broad mandate to work on the entire proposal.

Between 26 March and 17 April 2026, numerous interinstitutional technical meetings were held, during which the Presidency was able to reach agreement with the European Parliament on most elements of the proposal.

3. On 22 April 2026, the Permanent Representatives Committee agreed on a revised negotiating mandate for the second trilogue on the Digital Omnibus on AI, granting the Presidency flexibilities and indicating red lines on the outstanding issues.

4. On 28 April 2026, the second political trilogue was held, during which the co-legislators were not able to find agreement on the outstanding elements of the text. The European Parliament proposed to postpone the negotiations and hold another trilogue.

II. POLITICAL ISSUES FOR POTENTIAL AGREEMENT DURING THE THIRD TRILOGUE

5. At the **third trilogue on 6 May 2026**, which will be hosted by the Council, the following **five topics** are going to be re-discussed:

- new prohibitions in Article 5 concerning AI systems generating non-consensual intimate content or child sexual abuse material;
- the European Parliament's proposal to transfer all or some sectoral laws from Section A to Section B of Annex I to the AI Act and changes concerning safety components in Article 6;
- division of competences between the AI Office and national competent authorities with regard to AI systems based on general-purpose AI models where that model and that system are developed by the same provider (Article 75 and Articles 75a-75e of the Council mandate);
- the 6-month transitional period for providers who need to retroactively include technical transparency solutions in their generative AI systems; and
- the deadline for the Member States to establish an AI regulatory sandbox at national level.

On 22 April 2026, the Presidency obtained flexibilities from the Permanent Representatives Committee with regard to these five topics. However, **concerning the first two items, the Presidency would like to ask for additional flexibilities and clarification of preferences of the delegations in order to be able to establish acceptable landing zones for the third trilogue**. The questions are presented in points 6 and 7 below.

6. *[Article 5 of the AI Act – new prohibitions in Article 5 concerning AI systems generating non-consensual intimate content or child sexual abuse material]*

With regard to **the new prohibitions in Article 5**, the co-legislators had a preliminary agreement on a new version of the proposed compromise text, which can be found **Part I of the Annex to this note**. There is one outstanding question, which is the definition of intimate parts in **Recital 6b**. The main difference between this revised version and the one that was approved by Coreper on 22 April 2026 is that first, the text no longer excludes conduct covered by other criminal law directives from the scope of the use prohibition, thereby responding to a concern raised by the European Parliament and increasing legal certainty. The recitals clarify that in case of overlap, the *ne bis in idem* principle must be respected. Second, the operative part no longer provides that only increasing the level of nudity is covered by the nudification ban, because the European Parliament argued that the recitals sufficiently covered this. Finally, various technical changes and minor clarifications have been made, including as regards exceptions for medical emergencies.

Question 1: Concerning the revised compromise text with the new prohibitions in Article 5, delegations are requested to indicate whether they would be flexible to accept the revised wording as negotiated by the Presidency with the European Parliament, subject to further minor changes to be agreed during the third trilogue.

7. *[Annex I and Article 6 of the AI Act]*

With reference **to the European Parliament's proposal to transfer all or some sectoral laws from Section A to Section B of Annex I and the proposed changes concerning safety components in Article 6**, the Presidency duly noted during the meeting of the Permanent Representatives Committee on 22 April 2026 that there was near unanimous opposition in the Council to the European Parliament's demand to transfer all or some sectoral laws from Section A to Section B of Annex I of the AI Act. The Presidency also noted the flexibilities granted by the Permanent Representatives Committee to address the European Parliament's concerns with regard to potential duplication of requirements between sectoral legislation and the AI Act. Based on this, and in the spirit of compromise, during the second trilogue the Presidency translated these flexibilities into a very generous, **enhanced compromise package** for the European Parliament. The package consists of **six elements**:

- a mechanism that allows to resolve situations in which sectoral law has similar AI-specific requirements to the AI Act, by limiting the AI Act's application in those specific cases, with implementing acts determining when the conditions are fulfilled;

- removing possible duplication in the practical application of high-risk requirements through Commission guidelines that explain how procedures under the AI Act and under sectoral law can be combined to avoid duplications;

- a clarification that the risk management system does not need to cover risks which are not affected by an AI system;

- removing possible duplication of conformity assessment through a clarification that manufacturers of AI-enabled products keep their choice of conformity assessment procedure, in particular by relying on harmonised standards as a path to conformity;

- amending Article 40 to introduce some targeted amendments to bridge the standards mandate and expand CEN/CENELEC's work to establish how and when the AI Act requirements are needed to complement sectoral legislation, with integrated testing procedures; and

- limiting the scope of high-risk AI systems in products through a revision of the definition of 'safety component' and making additional related clarifications in Article 6, to clearly reduce the number of AI systems that are regulated as high-risk.

The relevant text proposals for these six elements and further explanations can be found in Part II of the Annex to this note.

The Presidency considers that **this package of six compromise proposals addresses all the concerns raised by the European Parliament with regard to Annex I and the issue of safety components**. However, despite a brief moment during the second trilogue when it seemed that the European Parliament was on the verge of accepting this very generous compromise package, ultimately it informed the Council that it was not sufficient. For this reason, the Presidency wishes to explore further options ahead of the third trilogue, based on the following question:

Question 2: Delegations are requested to indicate whether they can accept the Presidency's enhanced compromise proposal described above, and if yes, which option from the list below they would be flexible to support in order to make a further step towards the European Parliament on this topic, if needed:

Option A: Presidency enhanced compromise package as presented in **Part II of the Annex to this note** and no additional modifications.

Option B: Presidency enhanced compromise package as presented in **Part II of the Annex to this note**, together with **further limited amendments in Article 2** to provide additional reassurance to the European Parliament on the issue of potential duplications of requirements between sectoral legislation and the AI Act. The amendments would include **a deadline of 2 August 2027, by which the Commission would be required to adopt the implementing acts**. Moreover, **Article 17 of the AI Act (Quality Management System) would be added to the list of elements that the implementing acts would need to cover**. The proposed wording of Article 2 with these additional amendments for Option B can be found in **Part III of the Annex to this note**.

Option C: Presidency enhanced compromise package as presented in **Part II of the Annex to this note**, together with **the two additional elements from Option B**, as well as **further modifications in Article 2**. The **additional modifications would extend the range of elements that the implementing acts would be required to cover from Articles 9-15 (requirements high-risk AI systems), to include also Articles 17-25 (obligations for providers of high-risk AI systems and for other actors in the AI value chain)**. The proposed wording of Article 2 with these additional amendments for Option C can be found in **Part IV of the Annex to this note**.

Option D: Transfer of **the Machinery Regulation from Section A to Section B of Annex I** of the AI Act.

III. CONCLUSION

8. In light of the above, and with a view to obtaining further guidance for trilogue negotiations on the AI Omnibus on 6 May 2026, the Permanent Representatives Committee is invited to:

   – **indicate its flexibility with regard to Questions 1 and 2 presented in section II above**.

ANNEX

- **Part I**: Revised compromise proposal on amendments in Article 5 and the related recitals
- **Part II**: Six elements of the enhanced compromise package proposed to the European Parliament to address its concerns with regard to Annex I and Article 6 (safety components)
- **Part III**: Additional modifications in Article 2 proposed under Option B for Question 2
- **Part IV**: Additional modifications in Article 2 proposed under Option C for Question 2

Part I

Revised compromise proposal on amendments in Article 5 and the related recitals

The following points are added to paragraph 1, first subparagraph:

'(ba) the placing on the market, the putting into service or the use of an AI system that generates or manipulates realistic images, videos, audio or similar material of an identifiable natural person's intimate parts, or of an identifiable natural person engaged in sexually explicit activities, without that person's freely-given, specific, informed, unambiguous and explicit consent for that generation or manipulation;

(bb) the placing on the market, the putting into service or the use of an AI system that generates or manipulates material or performance within the meaning of Article 2, points (c) and (e), of Directive 2011/93/EU, save where a 'without right' defence applies under national law;

The following paragraph is inserted:

'1a. For the purposes of paragraph 1, first subparagraph, points (ba) and (bb):

(a) the placing on the market or putting into service of an AI system that generates or manipulates the material or performance referred to in points (ba) or (bb) above is only prohibited where:

(i) that generation or manipulation is the intended purpose of the AI system; or
(ii) the system's design, training, architecture, capabilities or user-facing functionalities make that generation or manipulation a reasonably foreseeable reproducible outcome, without requiring significant technical modification, and the system does not have reasonable and adequate technical safety measures and other safeguards to reliably prevent that generation or manipulation, taking into account reasonably foreseeable misuse, and to correct observed or reported misuse.

(b) the use of an AI system that generates or manipulates the material or performance referred to in points (ab) and (bb) above is only prohibited where the deployer uses the system for the purpose of generating or manipulating such material or performance.

Recitals

(6a) Article 5 of Regulation (EU) 2024/1689 prohibits certain practices of AI systems that are particularly harmful and abusive, contradict certain Union values and violate certain fundamental rights. Article 5 is to be kept under review, as notably shown by Article 112(1) of that Regulation. In light of technological and societal developments since the adoption of that Regulation, including the deployment and widespread use of AI systems generating non-consensual intimate images, videos, audio and similar material ('non-consensual intimate material') and child sexual abuse material, it is necessary to amend that list.

Non-consensual intimate material constitutes sexual violence and abuse against individuals, especially women. AI systems that generate or manipulate such material pose a severe risk to health, safety and fundamental rights, including victims' human dignity, personal autonomy, integrity and private life, with potentially serious lasting psychological and other harms and abuse at scale. The proliferation of such technologies, often described as 'nudification' applications, has created an urgent need for explicit regulatory prohibition. Child sexual abuse material, including wholly or partially synthetic material, constitutes a grave threat to the safety and fundamental rights of children. AI systems generating, or manipulating such material pose a grave risk to human dignity and the rights of the child, and risk normalising, amplifying and perpetuating sexual violence against children. Accordingly, an amendment to Article 5 of Regulation (EU) 2024/1689 is necessary both to protect women, children, other individuals and society from seriously harmful practices, thereby pursuing the objectives of that Regulation itself, and to bring clarity to providers and deployers as to the scope of their obligations, thereby addressing implementation challenges.

(6b) It is necessary to define clearly the scope of the prohibition, including in particular the extent of providers' and deployers' obligations. This prohibition should not prevent providers from developing technical capabilities of AI systems to generate or manipulate images, videos, audio or similar material. The prohibition should be limited to AI systems that generate or manipulate non-consensual intimate material or child sexual abuse material in two cases concerning providers. First, it should cover systems intended to generate or manipulate such material. Second, it should cover systems where such generation, or manipulation is a reasonably foreseeable and reproducible outcome and there are no reasonable and adequate technical safety measures and other safeguards in place, taking into account reasonable foreseeable misuse to reliably prevent, and where necessary correct, that outcome and correct observed or reported misuse, including circumvention of such measures. Technical measures and other safeguards to prevent the generation of such material could include data cleaning, refusal training, prompts safe design and output controls, runtime prompt guardrails, content classification and filtering mechanisms, usage restrictions, abuse detection mechanisms, and notice and action mechanisms. Such preventive measures should be reasonable for the specific AI system, and are considered adequate if they align with the state of the art and demonstrably prevent or sufficiently reduce in each specific case [as feasible] the likelihood of generating or manipulating such material, taking into account known and reasonably foreseeable misuse, including reasonably foreseeable circumvention of the preventive measures without significant technical modification. For providers retaining effective control over the provision of AI systems, for instance through a platform or a web interface, that could include following and reporting methods for misuse cases in full compliance with EU data protection law. In cases of observed or reported circumvention of the preventive measures or other safeguards, adequate corrective measures must also be taken to the extent that such measures are reasonable, taking into account the specific AI system, including its release and distribution strategy (such as open-source releases). The use of an AI system should be prohibited only where the deployer uses an AI system for the purpose of generating or manipulating non-consensual intimate material or child sexual abuse material. This also includes cases when a deployer uses for such purposes lawful AI systems not intended to generate or manipulate such material, AI systems placed on the market or put into service that lack reasonable and adequate preventive measures or when the deployer circumvents the preventive measures mentioned above. Conversely, the prohibition does not cover the use of an AI system for other lawful purposes, such as the generation of material other than non-consensual intimate material or child sexual abuse material, even in cases where the AI system lacks reasonable and adequate safeguards [such that the provider has breached the prohibition] [that should have been put in place by the provider].

Concerning the prohibition regarding non-consensual intimate material, where an AI system is intended for generation or manipulation of material falling under this prohibition, those measures and other safeguards should include means appropriate for the distribution of the system aimed at enabling the reliable collection and demonstration of consent of the depicted person to such generation or manipulation, in compliance with Regulation (EU) 2016/679. The prohibition regarding non-consensual intimate material should be limited to realistic depictions of [all/whole or part of any] visible intimate parts [(namely the genitals, pubic area, anus, [fully exposed] buttocks or [fully exposed] female breasts, regardless of sexual intent or context)] or of sexually explicit activity. This includes intimate parts that are visible through wet or otherwise transparent clothing. This 'realism' refers to the depiction of the person's face, voice or their body in a credible real-life manner, regardless of the realism of the context of that depiction and of whether it fully corresponds to the actual voice or appearance of the depicted person. Conversely, it excludes cartoonish or physically impossible depictions of a person's body. The prohibition of non-consensual intimate material does not affect the generation or manipulation of other forms of nude material, such as material that does not depict identifiable natural persons, realistic partially nude depictions where intimate parts are not revealed and sexually explicit activities are not depicted, non-realistic artistic nude works, and satirical works that do not realistically depict identifiable natural persons engaged in sexually explicit activity or depict their intimate parts. It also does not cover generative AI applications where intimate parts are not exposed or, if exposed, this is subject to the freely given, specific, informed, unambiguous and explicit consent of the depicted person (for example try-on applications, medical anatomical simulations or mammograms). This prohibition does not preclude the exceptional use of an AI system for medical purposes, in accordance with the Charter and applicable medical law and standards, where this is strictly necessary for medical treatment and diagnosis purposes by healthcare professionals and the person concerned is incapable of consent (for instance in an emergency situation). Finally, the prohibition on 'manipulating' non-consensual intimate material should exclude cases where pre-existing intimate material is manipulated in a way that does not increase the degree of its intimacy, for instance the mere enhancement of an existing image depicting intimate parts or video depicting sexually explicit activities. Conversely, any manipulation of material, including material that already depicts intimate parts or sexually explicit activity, that increases the level of intimacy falls within this prohibition.

The prohibition on child sexual abuse material should not prevent the placing on the market, putting into service or use of an AI system where a 'without right' defence applies under national law, as referred to in Article 5(1) of Directive 2011/93/EU. This includes activities carried out under domestic legal powers, such as the legitimate generation, or manipulation of child sexual abuse material by the authorities in order to conduct criminal proceedings or to prevent, detect or investigate crime, [as well as red-teaming and evaluations of AI systems for the purpose of assessing their compliance with the prohibition laid down in this Regulation].

(6c) These prohibitions constitute justified interferences with the freedom of expression and information and the freedom to conduct a business. They pursue weighty objectives of general interest and protect the rights and freedoms of others, including under Articles 1, 3(1), 4, 7, 8, 21, 23 and 24 of the Charter of Fundamental Rights. They are closely tailored, including by being limited to realistic depictions of identifiable natural persons as regards non-consensual intimate material; impose an obligation of means rather than ends on providers with regard to the implementation of reasonable and adequate safety technical measures and other safeguards; exclude generation or manipulation with the person's consent in the case of intimate material; and are aligned with existing Union law, including Directive (EU) 2011/93/EU and Directive (EU) 2024/1385. The interference respects the essence of Articles 11 and 16 of the Charter, is prescribed by law, and is proportionate.

(6d) The conduct covered by these prohibitions may also violate other law, including criminal law. The prohibitions do not preclude prosecution under that law. However, insofar as an infringement of the prohibitions may result in the imposition of penalties of a criminal nature, which may be laid down pursuant to Article 99(1) of Regulation (EU) 2024/1689, and to the extent that the same conduct is sanctioned under criminal law, including criminal law falling within the scope of Directive 2011/93/EU and Directive (EU) 2024/1385, Member States are required to ensure respect for the ne bis in idem principle in accordance with the Charter of Fundamental Rights.

Part II

Six elements of the enhanced compromise package proposed to the European Parliament to address its concerns with regard to Annex I and Article 6 (safety components)

To address the concerns of the European Parliament with regard to Annex I of the AI Act and the interplay between sectoral legislation and the high-risk rules of the AI Act, as well as with the issue of safety components in Article 6, the Presidency has proposed **an enhanced compromise package consisting of the following six elements**:

1. **Addition of a mechanism in Article 2 that allows to resolve situations in which sectoral law has similar AI-specific requirements to the AI Act, by limiting the AI Act's application in those specific cases through implementing acts.**

   ***Legal drafting**:*

   In Article 2, the following paragraph 13 is added:

   "13. For high-risk AI systems referred to in Article 6(1), the application of specific requirements or obligations laid down in Articles 9-15 of this Regulation may be limited, where and to the extent that:

   (a) Union harmonisation legislation listed in Section A of Annex I lays down requirements or obligations providing for an equivalent or higher level of protection of health, safety or fundamental rights as the requirement or obligation concerned; and

   (b) such limitation does not reduce the overall level of protection provided for by this Regulation.

   The Commission is empowered to adopt implementing acts in accordance with Article 98(2) to specify the high-risk AI systems concerned, the requirements or obligations that may be limited, the conditions under which such limitation applies, and the scope of the limitation."

   ***Explanatory recital**:*

   (3a) Regulation (EU) 2024/1689 lays down horizontal rules for AI systems in order to ensure a consistent and high level of protection of public interests as regards health, safety and fundamental rights. For high-risk AI systems referred to in Article 6(1), that Regulation applies in conjunction with the Union harmonisation legislation listed in Section A of Annex I. In certain cases, the Union harmonisation legislation may lay down requirements that achieve the same or a higher level of protection of the relevant public interests as specific requirements or obligations laid down in Regulation (EU) 2024/1689. Where this is the case, it should be possible to limit the application of specific requirements or obligations laid down in Regulation (EU) 2024/1689 in order to facilitate compliance, minimise administrative burden and duplications, while preserving the level of protection ensured by that Regulation.

Such limitation should be possible where, and to the extent that, the Union harmonisation legislation listed in Section A of Annex I lays down requirements providing for an equivalent level of protection of health, safety or fundamental rights as the requirement or obligation concerned. The Commission should be empowered to adopt implementing acts to identify such cases, specifying the products concerned, the requirements or obligations that may be limited, and the conditions and scope of any limitation, ensuring that the level of protection provided by Regulation (EU) 2024/1689 is not reduced.

Explanation:
This mechanism would offer a simple, risk-based and future proof possibility to address situations where overlaps can emerge in practice between requirements of the AI Act and of product law, while preserving the architecture of the AI Act and its horizontal application. Rather than changing how the AI Act applies to all AI systems in products, which is what the move from Annex I Section A to Section B would imply, this approach allows targeted clarification for specific requirements under sectoral law that should take precedent because they overlap with the AI Act's high-risk requirements. This approach will achieve the same result, i.e. avoiding possible duplication, however with a less disruptive mechanism, allowing to preserve the benefits of the horizontal approach, provide legal certainty for market players, avoid delay in application of the AI Act and avoid further delays in the availability of harmonised standards.

2. **Inclusion of a requirement for the Commission to issue guidelines that explain how procedures under the AI Act and under sectoral law can be combined to avoid duplication (in Article 96). The Presidency is also proposing to set a deadline for these guidelines.**

Legal drafting:
Article 96 is amended as follows:

in paragraph 1, the following point (g) is added:

"(g) the practical implementation of Articles 8(2), 9(10), and 17(3) in line with the principle of complementarity and proportionality, with a view to ensuring consistency, avoiding duplication and minimising additional burdens when complying with the requirements of this Regulation and the requirements of the Union harmonisation legislation listed in Section A of Annex I. These guidelines shall be published at the latest on **1 August 2027**.";

Explanatory recital:

(19a) The requirements for high-risk AI systems laid down in Regulation (EU) 2024/1689 address specific risks inherent to AI systems, including bias, unpredictable model behaviour, poor robustness or accuracy, vulnerabilities to attacks by third parties, lack of transparency of AI system. By addressing AI specific risks, that Regulation complements the requirements laid down in Union harmonisation legislation listed in its Annex I, without duplicating them. Regulation (EU) 2024/1689 provides mechanisms for economic operators to minimise the compliance burden. In particular, Articles 8(2) on the interplay with the sectoral legislation, 9(10) on risk management and 17(3) on quality management allow economic operators to integrate, when necessary and appropriate, an assessment of AI specific risks into existing risk and quality management systems. Article 40 further requires the Commission to specify that

AI Act harmonised standards must be consistent with standards developed under the Union harmonisation legislation listed in Annex I. The Commission should provide guidelines to assist economic operators of high-risk AI systems covered in Annex I in complying with this Regulation, including by providing guidance on application of Articles 8(2), 9(10) and 17(3) as mechanisms to minimise the compliance burden, in line with principles of complementary and proportionality. These guidelines should be published at the latest on 1 August 2027.

Explanation:
Building on the Council mandate, this proposal would require the Commission to provide guidance on how procedures can be combined under the AI Act and sectoral law. The AI Act already has a number of provisions that allow re-using documentation and integrating procedures, as well as risk management and quality management. However, the uncertainty on how these provisions are implemented prevents companies from relying on them, and guidelines should help to fill this gap. To offer even more predictability to companies, the Presidency is proposing to fix a deadline for the Commission to provide these guidelines.

3. A clarification in Article 9 that the risk management does not need to cover risks which are not affected by an AI system.

Legal drafting:
In Article 9, a new point 3a is added:

"3a. A risk that is manifestly not posed by the intended purpose of the AI system does not need to be identified for the purposes of paragraph 2.";

Explanatory recital:

The risk management system should remain targeted to the risks that are meaningfully linked to the intended purpose of the high-risk AI system. In order to avoid unnecessary compliance and documentation burdens related to remote or purely hypothetical risks, it should therefore be clarified in Article 9 of Regulation (EU) 2024/1689 that the obligation does not extend to risks that are manifestly not posed by the AI system. This may be the case, for example, where a high-risk AI system serving as a safety component of machinery does not, in view of its intended purpose, meaningfully affect certain or most fundamental rights. This is a non-exhaustive clarification and does not in any way imply *a contrario* that Article 9(2), point (a), requires the identification of risks other than those that are known and reasonably foreseeable. This clarification is without prejudice to the obligations under this Regulation concerning risks arising under conditions of reasonably foreseeable misuse and risks identified through post-market monitoring.

Explanation:
A key concern that has been voiced is that the scope of the risk management for AI systems, which are safety components of products, would always require an assessment of all fundamental rights covered by the Charter and therefore lead to a heavy procedure. However, the intention of the AI Act on this is set out in Article 9(1)(a): only known and reasonably foreseeable risks to health, safety or fundamental rights need to be assessed. This is not sufficiently clear and the Presidency is proposing to add a clarification in Article 9 that risk management does not need to cover risks which are not affected by an AI system – for example, fundamental rights impact might not be relevant for machinery.

4. **Removal of a possible duplication of conformity assessment by clarifying in Article 43 that manufacturers of AI-enabled products keep their choice of conformity assessment procedure, in particular by relying on harmonised standards as a path to conformity.**

Legal drafting:

In Article 43(3), the third subparagraph is replaced by the following:

"Where Union harmonisation legislation listed in Section A of Annex I provides the product manufacturer with an option **to rely on a conformity assessment not involving a third-party,** ~~to opt out from a third-party conformity assessment~~, provided that that manufacturer has applied harmonised standards **to show the compliance** 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. **The classification of a product as a high-risk AI system under Article 6(1) does not affect the choice of the conformity assessment procedure provided to the manufacturers of products covered by Union harmonisation legislation listed in Section A of Annex I, including, where applicable, an option to rely on harmonised standards. The manufacturers of such products are not obligated to choose a conformity assessment procedure involving third-party conformity assessment only because the product includes a high-risk AI system as a safety component, if this is not required by the Union harmonisation legislation.";**

Explanatory recital:

(8a) In accordance with Article 6(1) of Regulation (EU) 2024/1689, AI systems are classified as high-risk where an AI system that is a component of a product covered by Union harmonisation legislation listed in Section A of Annex I to that Regulation is a safety component and that product requires a third-party conformity assessment. The requirement that such product must require a third-party conformity assessment, however, does not affect the choice of the manufacturer regarding the conformity assessment procedure for such product. Where Union harmonisation legislation listed in Section A of Annex I allows to choose a conformity assessment procedure based on harmonised standards amongst alternative conformity assessment procedures, this possibility remains applicable also to products in which a high-risk AI system is embedded. Article 6(1) of Regulation (EU) 2024/1689 should not be understood to require products in which a high-risk AI system is embedded automatically to undergo a third-party conformity assessment involving a notified body. Where this possibility is provided under Union harmonisation legislation, the provider of the product in which a high-risk AI system is embedded could continue to rely on harmonised standards to comply with the requirements of the Union harmonisation legislation and Regulation (EU) 2024/1689 as a conformity assessment procedure."

Explanation:
This proposal aims to clarify that the AI Act in Article 6 does not impact the choice of conformity assessment procedure under Article 43(3). For example, manufacturers that currently rely on harmonised standards to prove the conformity of a machine with the Machinery Regulation can continue to do so, even if that machine has a high-risk AI system component. The question whether a third-party conformity assessment is required is only relevant for the high-risk classification, it does not mean that this procedure needs to be followed if the product law in question offers alternative routes.

5. Proposal to add additional amendments in Article 40 to bridge standards mandate and expand CEN/CENELEC's work to establish how and when the AI Act requirements are needed to complement sectoral legislation, with integrated testing procedures.

Legal drafting

Article 40 (new sub-para in paragraph 2)

The Commission shall request, in accordance with the Regulation (EU) No 1025/2012 and without undue delay, the European standardisation organisations to develop standardisation deliverables, including, as appropriate, harmonised standards, to facilitate the joint compliance and presumption of conformity with the requirements or obligations set out in Chapter III, Sections 2 and 3, and the relevant requirements and obligations laid down in the Union harmonisation legislation listed in Annex I.

Explanatory recital

(xx) In order to enhance competitiveness and innovation, it is essential to support economic operators that are required to comply simultaneously with the requirements or obligations set out in Chapter III, Sections 2 and 3, and with relevant requirements and obligations laid down in the Union harmonisation legislation listed in Annex I. To support and simplify the regulatory compliance pathways of such economic operators, the Commission should request, without undue delay, the European standardisation organisations, to develop standardisation deliverables, including, where appropriate, harmonised standards. Those standardisation deliverables should be based on the harmonised standards published in the Official Journal that give presumption of conformity with the requirements or obligations of this Regulation as well as any relevant harmonised standards published in the Official Journal that give presumption of conformity with the relevant requirements or obligations under the Union harmonisation legislation listed in Annex I. Such standardisation deliverables should help reduce legal uncertainty, avoid unnecessary duplication of conformity assessment activities, testing, documentation and reporting obligations, and lower compliance costs, in particular for small and medium-sized enterprises and start-ups. Timely development of such deliverables is essential in order to provide economic operators with practical and reliable technical solutions, strengthen legal certainty and facilitate the placing on the market, putting into service and use of AI systems in accordance with this Regulation and the Union harmonisation legislation listed in Annex I.

6. **Agreement to amend Article 6 on safety components but based on text that does not allow for any circumvention of the requirement to classify high-risk AI systems as non-high risk.**

The proposed amendment in Article 6 would read as follows:

New paragraphs 6(1a), 6(1b), 6(1c) and 6(1d) are added:

1a. For the purposes of this Regulation including paragraph 1 of this Article, AI systems that are solely used for non-safety related aspects of user assistance, performance optimisation, service efficiency, automation or convenience or quality control shall not qualify as safety components.

1b. AI systems whose failure or malfunctioning would endanger health and safety shall qualify as safety components notwithstanding paragraph 1a.

1c. A product that is required to undergo a third-party conformity assessment solely due to risks other than risks to health and safety of persons or cybersecurity, such as risks relating to distribution of radio spectrum or electromagnetic interference that do not affect health, safety or cybersecurity, shall not be considered as fulfilling the condition in paragraph 1, point (b).

1d. For the purposes of classification under paragraph 1, only the definition of safety component set out in Article 3, point (14) of this Regulation shall be taken into account.

The amendments in Article 6 would be in addition to changes in Article 3(14) to revise the definition of safety component:

Article 3(14) definition of a safety component

(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; for the purposes of this definition, a component fulfils a safety function where its intended purpose is to prevent or mitigate risks to health and safety of persons or property;

***Explanatory recital**:*

(4a) The notion of 'safety component' is decisive for the classification of certain AI systems as high-risk according to Regulation (EU) 2024/1689. Thus, it should be targeted to capture only AI systems which could have an adverse impact on the health and safety of persons or property, in line with the risk-based approach of Regulation (EU) 2024/1689. The definition set out in Article 3(14) of Regulation (EU) 2024/1689 does not provide the necessary clarity to allow providers of AI systems to determine whether an AI system qualifies as a safety component and, as a result, risks leading to a disproportionate scope. It is therefore necessary to amend that definition. First, It is necessary to provide clarity on the concept of safety function. **The safety function must be an intended purpose of the system, which is determined by the provider of the system**.

~~An AI system 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.~~ In particular, this does not include AI systems which are intended to solely fulfil functions related to user assistance, performance optimisation, service efficiency, automation, convenience, or quality control operations of non-safety related aspects. **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**.

Part III

Additional modifications in Article 2 proposed under Option B for Question 2

***Legal drafting**:*

In Article 2, the following paragraph 13 is added:

"13. For high-risk AI systems referred to in Article 6(1), the application of specific requirements or obligations laid down in Articles 9-15 **and 17** of this Regulation may be limited, where and to the extent that:

(a) Union harmonisation legislation listed in Section A of Annex I lays down requirements or obligations providing for an equivalent or higher level of protection of health, safety or fundamental rights as the requirement or obligation concerned; and

(b) such limitation does not reduce the overall level of protection provided for by this Regulation.

By 2 August 2027 the Commission **shall** adopt implementing acts in accordance with Article 98(2) to specify the high-risk AI systems concerned, the requirements or obligations that may be limited, the conditions under which such limitation applies, and the scope of the limitation."

Part IV

Additional modifications in Article 2 proposed under Option C for Question 2

***Legal drafting**:*

In Article 2, the following paragraph 13 is added:

"13. For high-risk AI systems referred to in Article 6(1), the application of specific requirements or obligations laid down in Articles 9-15 **and 17-25** of this Regulation may be limited, where and to the extent that:

(a) Union harmonisation legislation listed in Section A of Annex I lays down requirements or obligations providing for an equivalent or higher level of protection of health, safety or fundamental rights as the requirement or obligation concerned; and

(b) such limitation does not reduce the overall level of protection provided for by this Regulation.

By 2 August 2027 the Commission **shall** adopt implementing acts in accordance with Article 98(2) to specify the high-risk AI systems concerned, the requirements or obligations that may be limited, the conditions under which such limitation applies, and the scope of the limitation."