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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Antici Group (Simplification)
Subject:	(Digital Omnibus on AI) - MS comments on the second Presidency compromise text - deadline 26 Feb. 2026

Following the written consultation launched on 18 Feb. 2026 on the second Presidency compromise text, delegations will find below comments from the Member States: : AT, BE, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT, LV, MT, NL, PL, PT, SE, SI and SK

Digital Omnibus on AI Deadline: ***26 February 2026***

From: AT, BE, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT, LV, MT, NL, PL, PT, SE, SI, SK **Updated: 03/03/2026 11:17**

Guidelines to be followed

Please kindly provide your contributions in the table below.

Drafting suggestions: you may use '**track changes**'* or formatting (for example **bold-underline** for additions and ~~strike-through~~ for deletions, **where necessary, in a different colour**). *Track changes can only be connected once the cursor is placed in editable areas (Drafting or Comments columns).

To make it feasible to consolidate all contributions, the structure of the table must not be changed, so **no rows can be added or deleted.**

New provisions may only be added in any of the **'existing cells'.**

Name of document: please add the **two initials** of your delegation's country followed by a space (to the MS Word document name), followed by any optional text, for example, for Austria: **AT comments on … .docx**

Thank you for your cooperation!

Second presidency compromise text	Drafting suggestions and Comments
General Comments	BE (Comments): **Belgium supports the objective pursued by the Spanish proposal to include a new prohibited AI system (Article 5 of the AI Act). This is an important issue that requires action, notably to ensure adequate ex-ante protection in this area. However, this objective should not justify delaying the planned progress of the Digital Omnibus. We will also pay close attention to the outcome of the Council Legal Service's analysis regarding the inclusion of this proposal.** DE (Comments): Please note that the following views are preliminary as we are still examining the proposal. We reserve the right to make further comments.

Second presidency compromise text	Drafting suggestions and Comments
	Germany submitted a position paper on 23.10.2025 and written comments on 16 January to which we refer. Taking into consideration the first compromise proposal by the Presidency we hereby like to submit our first views DK (Comments): Firstly, we would like to express gratitude to the Presidency for effective negotiations with the appropriate pace and focus on simplification. Overall, we are positive towards the 2nd compromise proposal. Especially, we agree with the decision to propose definitive deadlines for the application of high-risk requirements. A targeted extension of deadlines should remain the main objective of the omnibus. However, we believe it to be an omission that relevant guidance is postponed, especially on high-risk requirements, with the rest of the rules. Therefore, we believe they should be available at least 6 months before entry into application of these rules. We have inserted a proposal below. EE (Comments): Dear Sir or Madam, We thank the Presidency for the opportunity to submit written comments on AI Omnibus articles. We appreciate the possibility to contribute to the ongoing discussion and to present our preliminary yet non-exhaustive views on the matter. We are currently working on a clearly defined mandate that will guide our position in the AI omnibus negotiations. Please note that these are our initial

Second presidency compromise text	Drafting suggestions and Comments
	thoughts on the topics, and **our submission is made under a parliamentary scrutiny reservation.** FI (Comments): **From the overall perspective of the AI Act, any issues that could further complicate and delay the legislative process—such as adding new prohibited practices—reduce predictability and push the adoption of the AI Omnibus amendments ever closer to the start of August 2026. Finland does not support that.** Companies and other stakeholders, including the public sector, must have sufficient advance notice of the entry into force of the requirements well before August 2026. IE (Comments): Prohibitions • Ireland supports using the Digital Omnibus on AI to incorporate a new prohibition within Article 5 to prohibit AI systems that enable the generation of child sexual abuse material and nonconsensual intimate content of people. We would caveat this by saying careful and appropriate drafting is needed to avoid any unintended consequences and to ensure the legislative drafting meets the objective. Timelines • Fixed predictable timeline extensions are preferred, and Ireland considers this approach essential to provide legal certainty for all stakeholders.

Second presidency compromise text	Drafting suggestions and Comments
	• Ireland also suggests that further consideration be given to the DE suggestion to extend the deadline under Art. 113 (b) for determining national supervisory structures or a standstill period before initiating infringement proceedings. • Ireland requests that if the August 2027 deadline is considered unfeasible for the banking sector, engagement and consultation is needed. • Definition Financial Institution - IE notes a separate definition of Financial Institution for the purposes of the AI Act is required. This definition could consist of a list of applicable regulations, similar to Annex I for products. SI (Comments): Slovenia supports Spain's efforts to prohibit the generation of malicious content. However, it warns that care must be taken to avoid duplication with existing EU legal acts that already regulate this issue.
Proposal for a	
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	

Second presidency compromise text	Drafting suggestions and Comments
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)	
(Text with EEA relevance)	
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,	
Having regard to the proposal from the European Commission,	
After transmission of the draft legislative act to the national parliaments,	
Having regard to the opinion of the European Economic and Social Committee[1],	
Having regard to the opinion of the Committee of the Regions[2],	

1 OJ C , , p. .

2 OJ C , , p. .

Second presidency compromise text	Drafting suggestions and Comments
Acting in accordance with the ordinary legislative procedure,	
Whereas:	
(1) Regulation (EU) 2024/1689 of the European Parliament and of the Council[3] lays down harmonised rules on artificial intelligence (AI) and aims to improve the functioning of the internal market, to promote the uptake of human-centric and trustworthy artificial intelligence, while ensuring a high level of protection of health, safety and fundamental rights, and supporting innovation. Regulation (EU) 2024/1689 entered into force on 1 August 2024. Its provisions enter into application in a staggered manner, with all rules entering into application by 2 August 2027. 3 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, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).	
(2) The experience gathered in implementing the parts of Regulation (EU) 2024/1689 that have already entered into application can inform the implementation of those parts that are yet to apply. In this context, the delayed preparation of standards, which should provide technical solutions for providers of high-risk AI systems to ensure compliance with their obligations under that regulation, and the delayed establishment of the governance and the conformity assessment frameworks at national level result in a compliance burden that is heavier than expected. In addition, consultations of stakeholders have revealed the need for additional measures that facilitate and provide	

Second presidency compromise text	Drafting suggestions and Comments
clarification on the implementation and compliance, without reducing the level of protection for health, safety and fundamental rights from AI-related risks that the rules of Regulation (EU) 2024/1689 seek to achieve.	
(3) Consequently, targeted amendments to Regulation (EU) 2024/1689 are necessary to address certain implementation challenges, with a view to the effective **and simple** application of the relevant rules.	EE (Comments): Please point out the challenges. Although the purpose of the recitals is to make the provisions clearer, this point is still difficult to understand for someone who has not worked with the implementation of the AI Regulation.
(4) Enterprises outgrowing the micro, small and medium-sized enterprises ('SME') definition – the 'small mid-cap enterprises' ('SMCs') – play a vital role in the Union's economy. Compared to SMEs, SMCs tend to demonstrate a higher pace of growth, and level of innovation and digitisation. Nevertheless, they face challenges similar to SMEs in relation to administrative burden, leading to a need for proportionality in the implementation of Regulation (EU) 2024/1689 and for targeted support. To enable the smooth transition of enterprises from SMEs into SMCs, it is important to address in a coherent manner the effect that regulation may have on their activity once those enterprises outgrow the segment of SMEs and are faced with rules that apply to large enterprises. Regulation (EU) 2024/1689 provides for several measures for small-scale providers, which should be extended to SMCs. In order to clarify the treatment of SMEs and SMCs in Regulation (EU) 2024/1689, it is necessary to introduce definitions for SMEs and SMCs, which should correspond to the definition set out in the Annex to Commission Recommendation 2003/361/EC[4] and Annex to Commission Recommendation 2025/3500/EC[5]. 4 Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, pp. 36–41, ELI: http://data.europa.eu/eli/reco/2003/361/oj).	

Second presidency compromise text	Drafting suggestions and Comments
5 Commission Recommendation (EU) 2025/1099 of 21 May 2025 on the definition of small mid-cap enterprises (OJ L, 2025/1099, 28.5.2025, ELI: http://data.europa.eu/eli/reco/2025/1099/oj).	
(5) Article 4 of Regulation (EU) 2024/1689 currently imposes an obligation on all providers and deployers of AI systems to ensure AI literacy of their staff. AI literacy development starting from education and training and continuing in a lifelong learning manner is crucial to equip providers, deployers and other affected persons with the necessary notions to make informed decisions regarding AI systems deployment. However, experience shared by stakeholders reveals that a one-size-fits-all solution is not suitable for all types of providers and deployers in relation to the promotion of AI literacy, rendering such a horizontal obligation ineffective in achieving the objective pursued by this provision. Moreover, data indicate that imposing such an obligation creates an additional compliance burden, particularly for smaller enterprises, whereas AI literacy should be a strategic priority, regardless of regulatory obligations and potential sanctions. In light of that, Article 4 of Regulation (EU) 2024/1689 should be amended to require the Member States and the Commission, without prejudice to their respective competences, to individually, collectively and in cooperation with relevant stakeholders encourage providers and deployers to provide a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, including through offering training opportunities, providing informational resources, and allowing exchange of good practices and other non-legally binding initiatives. **European competence frameworks, for example the Digital Competence Framework for Citizens (DigComp), Digital Competence Framework for Educators (DigCompEdu) and the Digital Competence Framework for Organisations (DigCompO), should be taken into account in the encouragement under this article.** The European Artificial Intelligence	EE (Drafting suggestions): (5) Article 4 of Regulation (EU) 2024/1689 currently imposes an obligation on all providers and deployers of AI systems to ensure AI literacy of their staff. AI literacy development starting from education and training and continuing in a lifelong learning manner is crucial to equip providers, deployers and other affected persons with the necessary notions to make informed decisions regarding AI systems deployment. However, experience shared by stakeholders reveals that a one-size-fits-all solution is not suitable for all types of providers and deployers in relation to the promotion of AI literacy, rendering such a horizontal obligation ineffective in achieving the objective pursued by this provision. Moreover, data indicate that imposing such an obligation creates an additional compliance burden, particularly for smaller enterprises, whereas AI literacy should be a strategic priority, regardless of regulatory obligations and potential sanctions. **In light of that, Article 4 of Regulation (EU) 2024/1689 should be amended to adding Member States and Commission the possibility to individually, collectively and in cooperation with relevant stakeholders to support providers and deployers, with a particular focus on SMEs, in taking appropriate measure in developing AI literacy skills, such as**~~require the Member States and the Commission, without prejudice to their respective competences, encourage providers and deployers to provide a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, including through offering~~ training opportunities, providing informational resources, and allowing exchange of

Second presidency compromise text	Drafting suggestions and Comments
Board ('Board') **should support the Commission and Member States in the promotion of AI literacy by adopting recommendations setting out common objectives to be achieved in order to meet their obligation and** will ensure recurrent exchange between the Commission and Member States on the topic, while the Apply AI Alliance will allow discussion with the wider community. This amendment is without prejudice to the broader measures taken by the Commission and the Member States to promote AI literacy and competences for the wider population, including learners, students, and citizens at different ages and in particular through education and training systems. **Moreover, this encouragement complements ~~in no way affects~~ the obligations that providers and deployers have under other provisions to ensure adequate training and competence, both as specifically required by certain provisions (such as Article 26(2) of Regulation 2024/1689) and as may be required to fulfil other obligations, such as risk management obligations (Article 9 of the same Regulation) ~~such as Article 26(2) to ensure the necessary competence, training and authority of relevant persons~~.**	good practices and other non-legally binding initiatives. European competence frameworks, for example the Digital Competence Framework for Citizens (DigComp), Digital Competence Framework for Educators (DigCompEdu) and the Digital Competence Framework for Organisations (DigCompO), should be taken into account in the encouragement under this article. The European Artificial Intelligence Board ('Board') should support the Commission and Member States in the promotion of AI literacy by adopting recommendations setting out common objectives to be achieved in order to meet their obligation and will ensure recurrent exchange between the Commission and Member States on the topic, while the Apply AI Alliance will allow discussion with the wider community. This amendment is without prejudice to the broader measures taken by the Commission and the Member States to promote AI literacy and competences for the wider population, including learners, students, and citizens at different ages and in particular through education and training systems. Moreover, this encouragement complements the obligations that providers and deployers have under other provisions to ensure adequate training and competence, both as specifically required by certain provisions (such as Article 26(2) of Regulation 2024/1689) and as may be required to fulfil other obligations, such as risk management obligations (Article 9 of the same Regulation). EE (Comments): The development of AI literacy is necessary for competitiveness. The development of digital skills, including AI literacy, is relevant for all roles. Therefore, instead of shifting this obligation to the Member States and the Commission, we suggest considering ways in which the Member States and the Commission could support providers and deployers. They can take into account differences, especially SMEs. The solution does not have to be one-size-fits-all.

Second presidency compromise text	Drafting suggestions and Comments
	Please also refer to the comment and amendment under the new Article 4a. IE (Comments): Guidance would be helpful in relation to the implications for Member States and MSAs as regards changes to responsibility and standards around AI literacy.
(6) Bias detection and correction constitute a substantial public interest because they protect natural persons from biases' adverse effects, including discrimination. ~~Discrimination might result from the bias in AI models and AI systems other than high-risk AI systems for which of~~ **For that reason,** Regulation (EU) 2024/1689 ~~already~~ provides a legal basis authorising the **providers of high-risk AI systems to process** ~~the processing of~~ special categories of personal data ~~under Article 9(2), point (g), of Regulation (EU) 2016/679 of the European Parliament and of the Council[6].~~**in certain exceptional cases and subject to strict safeguards. This legal basis is linked to those providers' obligation to establish practices concerning the detection, prevention and mitigation of biases likely to affect the health and safety of persons, have a negative impact on fundamental rights or lead to discrimination prohibited under Union law.** ~~Given that discrimination~~ **Nevertheless, biases likely to have those effects** might **also** result from ~~those other AI systems and models~~ **the actions of the deployers of high-risk AI systems. Furthermore, such biases could also arise in the case of other AI systems or models. In each of those further cases, a substantial public interest exists to permit, exceptionally and where strictly necessary, the processing of special category personal data for the purposes of bias detection and correction. I**~~i~~t is therefore ~~appropriate that~~ **necessary to extend the legal basis established under** Regulation (EU) 2024/1689 **so that it also applies to the** ~~in providing for a legal basis for the processing of special categories of personal data also by~~ providers and	FI (Comments): We can support this proposal. SE (Drafting suggestions): **Furthermore, such biases could also arise in the case of other AI systems or models. In each of those further cases, a substantial public interest exists to permit, exceptionally and where ~~strictly~~ necessary, the processing of special category personal data for the purposes of bias detection and correction.** SE (Comments): See comment following SE proposed changes in art. 1(5).

Second presidency compromise text	Drafting suggestions and Comments
deployers of other AI systems and AI models~~, as well as deployers of high-risk AI systems. The~~ **That** legal basis ~~is established in~~ **should be subject to the same limitations, conditions and safeguards as apply under the existing Article 10(5), thereby ensuring** compliance with Article 9(2), point (g) of Regulation (EU) 2016/679 Article 10(2), point (g) of Regulation (EU) 2018/1725 of the European Parliament and of the Council[7] and Article 10, point (a) of Directive (EU) 2016/680 of the European Parliament and of the Council[8]**.** ~~provides a legal basis allowsing, where necessary for the purpose of the detection and removal of bias, the processing of special categories of personal data by providers and deployers of all AI systems and models, subject to appropriate safeguards that complement Regulations (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU) 2016/680, as applicable.~~ **Whilst the same conditions apply, it is likely that the exceptional circumstances justifying reliance on this new legal basis will arise less frequently in practice, notably given that AI systems that are not high-risk pose lower risks to health, safety and fundamental rights. Furthermore, to enable providers of high-risk AI systems to lawfully undertake bias detection and mitigation activities in preparation for compliance with the high-risk requirements, including Article 10(2), points (f) and (g), of Regulation (EU) 2024/1689, the legal basis established by Article 4a should apply from entry into application of this Regulation.**	

6 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/679/oj).

7 Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision

Second presidency compromise text	Drafting suggestions and Comments
No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: http://data.europa.eu/eli/reg/2018/1725/oj). 8 Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, pp. 89–131, ELI: http://data.europa.eu/eli/dir/2016/680/oj).	
(7) In order to ensure consistency, avoid duplication and minimise administrative burdens in relation to the procedure for designating notified bodies under Regulation (EU) 2024/1689, while maintaining the same level of scrutiny, a single application and a single assessment procedure should be available for new conformity assessment bodies and notified bodies which are designated under the Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689, such as under Regulations (EU) 2017/745[9] and (EU) 2017/746[10] of the European Parliament and of the Council, where such a procedure is established under that Union harmonisation legislation. The single application and assessment procedure aims at facilitating, supporting and expediting the designation procedure under Regulation (EU) 2024/1689, while ensuring compliance with the requirements applicable to notified bodies under that Regulation and the Union harmonisation legislation listed in Section A of Annex I thereto. **Moreover, it should be clarified that a conformity assessment body that is designated under more than one Union harmonisation legislation listed in Section A of Annex I should have to apply only once to be designated under this Regulation.** 9 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC)	IE (Comments): The availability of *a "single application and a single assessment procedure" to "new conformity assessment bodies and notified bodies"* appears limited to circumstances where *"such a procedure is established under that Union harmonisation legislation"*. No such procedure is provided under the RED. If there is no existing "single application and single assessment procedure" in RED, can it still be established at sectoral level? The "single application and a single assessment" is stated "to ensure consistency, avoid duplication and minimise administrative burdens". However, in the absence of this proposed streamlined application are existing RED notifying authorities (together with NBs & CABs), not left with the same obstacles. This approach does not appear to be a solution for all stakeholders. **"Moreover, it should be clarified that a conformity assessment body that is designated under more than one Union harmonisation legislation listed**

Second presidency compromise text	Drafting suggestions and Comments
No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj). 10 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176, ELI: http://data.europa.eu/eli/reg/2017/746/oj).	**in Section A of Annex I should have to apply only once to be designated under this Regulation."** This amendment is not clear on the divergence between designation v notification. If a CAB is designated under RED, it is thereafter 'notified' (by the NA) to the Commission and the other Member States to become a 'notified body'.
(8) With a view to ensuring the smooth application and consistency of Regulation (EU) 2024/1689, amendments should be made to it. A technical correction to Article 43(3), first subparagraph, of Regulation (EU) 2024/1689 should be added to align the conformity assessment requirements with the requirements of providers of high-risk AI systems in Article 16 of that Regulation. Moreover, it should be clarified that where a provider of a high-risk AI system is subject to the conformity assessment procedure under Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689, and the conformity assessment extends to compliance of the quality management system of that Regulation and of such Union harmonisation legislation, the provider should be able to include aspects related to quality management systems under that Regulation as part of the quality management systems under such Union harmonisation legislation, in line with Article 17(3) of Regulation (EU) 2024/1689. Article 43(3), second subparagraph, should be amended to clarify that notified bodies which have been notified under the Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689 and which aim to assess high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I to that Regulation, should apply for the designation as a notified body under that Regulation within 18 months from [the entry into application of this Regulation]. This amendment is without prejudice to Article 28 of Regulation (EU) 2024/1689. Moreover, Regulation (EU) 2024/1689 should be amended to clarify that where a high-risk AI system is both covered by the	IE (Comments): Suggest inclusion of text to acknowledge and address uncertainty related to other obligations and responsibilites (apart from relating to CAPs) in scenarios of where "a high-risk AI system is both covered by the Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689 and falls within one of the use-cases listed in Annex III", e.g. who is the appropriate MSA (MSAs with responsibility for Annex I or III or both), which obligations is a provider subject to (Annex I or III or both) etc

Second presidency compromise text	Drafting suggestions and Comments
Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689 and falls within one of the use-cases listed in Annex III to that Regulation, the provider should follow the relevant conformity assessment procedure as required under that relevant harmonisation legislation.	
(9) To streamline compliance and reduce the associated costs, **the registration of** ~~providers of AI systems should not be required to register~~ AI systems referred to in Article 6(3) of Regulation (EU) 2024/1689 in the EU database pursuant to Article 49(2) of that Regulation **should be simplified by streamlining the required content in Section B of Annex VIII to that Regulation**. **While it remains crucial for effective market surveillance and public accountability that such AI systems are registered in the EU database,** ~~Given that such systems are not considered high-risk under certain conditions where they do not pose significant risk of harm to the health, safety or fundamental rights of persons, imposing~~ **the** registration requirements ~~would constitute a disproportionate compliance burden~~**should be simplified and made more proportionate. This simplification will strike a better balance without undermining the protection laid down by Regulation 2024/1689. Such systems are not considered high-risk under certain conditions where they do not pose significant risk of harm to the health, safety or fundamental rights of persons.** ~~Nevertheless,~~ **Furthermore, a** provider **applying** ~~who considers that an AI system falls under~~ Article 6(3) remains obligated to document its assessment before that system is placed on the market or put into service. This assessment may be requested by national competent authorities.	AT (Comments): AT: It is not clear what "under certain conditions" refers to. IE (Comments): IE welcomes the reversal of the proposal to remove the requirement to register exempt high-risk AI systems and are accepting of a more streamlined registration process. IE also notes that, per Council Legal Services (CLS) in the AGS meeting discussing the compromise proposal, providers who consider than an Annex 3 system is not high-risk would still register but would not register their explanation on why, nor the MS in which the system is deployed/placed on market etc. Knowing whether the system was deployed in a given MS is important information that needs to appear on the register. SE (Drafting suggestions): (9) To streamline compliance and reduce the associated costs, ~~**the registration of**~~ providers of AI systems should not be required to register AI systems referred to in Article 6(3) of Regulation (EU) 2024/1689 in the EU

Second presidency compromise text	Drafting suggestions and Comments
	database ~~pursuant to Article 49(2) of that~~ **Regulation** ~~**should be simplified by streamlining the required content in Section B of Annex VIII to that Regulation. While it remains crucial for effective market surveillance and public accountability that such AI systems are registered in the EU database.**~~ **Given that such systems are not considered high-risk under certain conditions where they do not pose significant risk of harm to the health, safety or fundamental rights of persons, imposing the** registration requirements **would constitute a disproportionate compliance burden** ~~**should be simplified and made more proportionate. This simplification will strike a better balance without undermining the protection laid down by Regulation 2024/1689. Such systems are not considered high-risk under certain conditions where they do not pose significant risk of harm to the health, safety or fundamental rights of persons.**~~ ~~Nevertheless,~~ **Furthermore, a** provider ~~**applying**~~ **who considers that an AI system falls under** Article 6(3) ~~remains~~ **should neither be** obligated to document its assessment before that system is placed on the market or put into service. **Such obligation is not proportionate to the risk that the AI-systems falling under article 6(3) poses.** ~~This assessment may be requested by national competent authorities.~~ SE (Comments): See comment under art. 1(10).
(10) Articles 57, 58 and 60 of Regulation (EU) 2024/1689 should be amended to strengthen further cooperation at Union level of AI regulatory sandboxes, foster clarity and consistency in the governance of AI regulatory sandboxes, and to extend the scope of real-world testing outside AI regulatory sandboxes to high-risk AI systems covered by the Union harmonisation legislation listed in Annex I to that Regulation. In particular, to allow procedural simplification, where applicable, in the projects supervised in the AI regulatory sandboxes that include also real-world testing, the real-world	

Second presidency compromise text	Drafting suggestions and Comments
testing plan should be integrated in the sandbox plan agreed by the providers or prospective providers and the competent authority in a single document. In addition, it is appropriate to provide for the possibility of the AI Office to establish an AI regulatory sandbox at Union level for AI systems that are covered by Article 75(1) of Regulation (EU) 2024/1689. **To ensure coherence, legal certainty and an efficient allocation of supervisory responsibilities between Union and national levels, the scope of the Union-level AI regulatory sandbox should be clearly defined in order to avoid any overlapping with national AI regulatory sandboxes established pursuant to that Regulation.** By leveraging these infrastructures and facilitating cross-border collaboration, coordination would be better streamlined and resources optimally utilised.	
(11) To foster innovation, it is also appropriate to extend the scope of real-world testing outside AI regulatory sandboxes in Article 60 of Regulation (EU) 2024/1689, currently applicable to high-risk AI systems listed in Annex III to that Regulation, and allow providers and prospective providers of high-risk AI systems covered by the Union harmonisation legislation listed in Annex I to that Regulation to also test such systems in real-world conditions. This is without prejudice to other Union or national law on the testing in real-world conditions of high-risk AI systems related to products covered by that Union harmonisation legislation. ~~To address the specific situation of high-risk AI systems covered the Union harmonisation legislation listed in Section B of Annex I to that Regulation, it is necessary to allow the conclusion of voluntary agreements between the Commission and Member States to enable testing of such high-risk AI systems in real-world conditions.~~	
(11a) It is also appropriate to ensure that real-world testing of high-risk AI systems covered by the Union harmonisation legislation listed in Section B of Annex I to that Regulation is possible. The situation of those systems is specific, in that they are subject to the requirements and procedures of the relevant sectoral legislation and are, for most purposes,	EE (Drafting suggestions): (11a) It is also appropriate to ensure that real-world testing of high-risk AI systems covered by the Union harmonisation legislation listed in Section B

Second presidency compromise text	Drafting suggestions and Comments
not directly subject to Regulation (EU) 2024/1689. Those sectoral acts will, in due course, incorporate requirements corresponding to the requirements laid down by Articles 8-15 of that Regulation. It is therefore not possible to lay down in that Regulation an exhaustive regime regulating real-world testing, as regards those specific requirements, under each of those acts. However, it is appropriate to ensure that Member States can allow such testing. To that end, the essential elements of those testing regimes should be laid down, and Member States who choose to allow such testing should lay down the detailed rules regarding those regimes. First, those regimes should comply with the sectoral legislation, including any provisions regarding testing. However, in the event that this sectoral legislation does not (yet) enable testing as regards the high-risk AI system component, such testing should be made possible. This conflict rule is strictly limited to the extent necessary to enable testing of the requirements that correspond to Articles 8-15 of Regulation 2024/1689. If those corresponding rules have yet to be adopted, that testing should take Articles 8-15 of Regulation 2024/1689 itself as the benchmark. Second, and particularly given the risks that could be posed by real-world testing of high-risk AI systems that are safety components of or constitute products subject to that sectoral legislation, those regimes should comply with certain essential elements. Third, the detailed implementation and procedures should be laid down by the Member States, acting alone or jointly, and be subject to review by the Commission.	of Annex I to that Regulation is possible. The situation of those systems is specific, in that they are subject to the requirements and procedures of the relevant sectoral legislation and are, for most purposes, not directly subject to Regulation (EU) 2024/1689. Those sectoral acts will, in due course, incorporate requirements corresponding to the requirements laid down by Articles 8-15 of that Regulation. It is therefore not possible to lay down in that Regulation an exhaustive regime regulating real-world testing, as regards those specific requirements, under each of those acts. However, it is appropriate to ensure that Member States can allow such testing. To that end, the essential elements of those testing regimes should be laid down, and Member States who choose to allow such testing should lay down the detailed rules regarding those regimes. First, those regimes should comply with the sectoral legislation, including any provisions regarding testing. However, in the event that this sectoral legislation does not ~~(yet)~~ **enable** testing as regards the high-risk AI system component, such testing should be made possible. This conflict rule is strictly limited to the extent necessary to enable testing of the requirements that correspond to Articles 8-15 of Regulation 2024/1689. If those corresponding rules have yet to be adopted, that testing should take Articles 8-15 of Regulation 2024/1689 itself as the benchmark. Second, and particularly given the risks that could be posed by real-world testing of high-risk AI systems that are safety components of or constitute products subject to that sectoral legislation, those regimes should comply with certain essential elements. Third, the detailed implementation and procedures should be laid down by the Member States, acting alone or jointly~~, and be subject to review by the Commission~~.
(12) Article 63 of Regulation (EU) 2024/1689 offers microenterprises who are providers of high-risk AI systems the possibility to benefit from a simplified way to comply with the obligation to establish a quality management system. With a view to facilitating compliance for more innovators, that possibility should be extended to all SMEs, including start-ups.	

Second presidency compromise text	Drafting suggestions and Comments
(13) Article 69 of Regulation (EU) 2024/1689 should be amended to simplify the fee structure of the scientific panel. If Member States call upon the panel's expertise, the fees they may be required to pay the experts should be equivalent to the remuneration the Commission is obliged to pay in similar circumstances. ~~Furthermore, to reduce the procedural complexity, Member States should be able to consult the experts of the scientific panel directly, without involvement of the Commission.~~	
(14) In order to strengthen the governance system for AI systems based on general-purpose AI models, it is necessary to clarify the role of the AI Office in monitoring and supervising compliance of such AI systems with Regulation (EU) 2024/1689, while excluding AI systems related to products covered by the Union harmonisation legislation listed in Annex I to that Regulation **and excluding AI systems referred to in point (2) of Annex III to that Regulation**. While sectoral authorities continue to remain responsible for the supervision of AI systems related to products covered by that Union harmonisation legislation, Article 75(1) Regulation (EU) 2024/1689 should be modified to bring all AI systems based on general-purpose AI models developed by the same provider within the scope of the AI Office's supervision. This does not include AI systems placed on the market, put into service or used by Union institutions, bodies, offices or agencies, which are under the supervision of the European Data Protection Supervisor pursuant to Article 74(9) of Regulation (EU) 2024/1689. To ensure effective supervision for those AI systems in accordance with the tasks and responsibilities assigned to market surveillance authorities under Regulation (EU) 2024/1689, the AI Office should be empowered to take the appropriate measures and decisions to adequately exercise its powers provided for in that Section and Regulation (EU) 2019/1020 of the European Parliament and of the Council[11]. Article 14 of Regulation (EU) 2019/1020 should apply mutatis mutandis. Furthermore, to ensure effective enforcement, ~~the~~ **rules should be laid down regarding the cooperation with** authorities involved in the application of Regulation	IE (Comments): Rather than the EU AI Office having responsibility, ComReg understands that Annex I MSAs (together with the MSA for point (2) of Annex III) will now be responsible for supervision and enforcement, where an system is based on a general-purpose AI model and that model and that system are developed by the same provider. This sentence in recital 14, is reiterating the exemption in the preceding sentence i.e. "*while excluding AI systems related to products covered by the Union harmonisation legislation listed in Annex I to that Regulation*". However, there is no reiteration of the exemption of "AI systems referred to in point (2) of Annex III". Therefore, should the highlighted text be replaced with "Subject to the above exemptions" to cover both Annex I & point (2) of Annex III?

Second presidency compromise text	Drafting suggestions and Comments
(EU) 2024/1689 ~~should cooperate actively~~**and assistance of those authorities to the AI Office** in the exercise of those powers, **as well as the assistance of the police or equivalent enforcement authority** ~~in particular where enforcement actions need to be taken in the territory of a Member State~~. 11 Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1, ELI: http://data.europa.eu/eli/reg/2019/1020/oj).	
(15) Considering the existing supervisory and enforcement system under Regulation (EU) 2022/2065 of the European Parliament and of the Council[12], it is appropriate to grant the Commission the powers of a competent market surveillance authority under Regulation (EU) 2024/1689 where an AI system qualifies as a very large online platform or a very large online search engine within the meaning of Regulation (EU) 2022/2065, or where it is embedded in such a platform or search engine. This should contribute to ensuring that the exercise of the Commission's supervision and enforcement powers under Regulation (EU) 2024/1689 and Regulation (EU) 2022/2065, as well as those applicable to general-purpose AI models integrated into such platforms or search engines, are carried out in a coherent manner. In the case of AI systems embedded in or qualifying as a very large online platform or search engine, the first point of entry for the assessment of the AI systems are the risk assessment, mitigating measures and audit obligations prescribed by Articles 34, 35 and 37 of Regulation (EU) 2022/2065, without prejudice to the AI Office's powers to investigate and enforce *ex post* non-compliance with the rules of this Regulation. In the context of the analysis of this risk assessment, mitigating measures and audits, the Commission services responsible for the enforcement of Regulation (EU) 2022/2065 may seek the opinion of the AI Office on the outcome of a potential earlier or parallel risk assessment carried out under this Regulation and the applicability of prohibitions under this	

Second presidency compromise text	Drafting suggestions and Comments
Regulation. In addition, the AI Office and the competent national authorities under (EU) 2024/1689 should coordinate their enforcement efforts with the authorities competent for the supervision and enforcement of Regulation (EU) 2022/2065, including the Commission, in order to ensure that the principles of loyal cooperation, proportionality and non bis in idem are respected, while information obtained under the respective other Regulation would be used for the purposes of supervision and enforcement of the other only provided the undertaking agrees. In particular, those authorities should exchange views regularly and take into account, in their respective areas of competence, any fines and penalties imposed on the same provider for the same conduct through a final decision in proceedings relating to an infringement of other Union or national rules, so as to ensure that the overall fines and penalties imposed are proportionate and correspond to the seriousness of the infringements committed. 12 Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) (OJ L 277, 27.10.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/2065/oj).	
(16) To further operationalise the AI Office's supervision and enforcement set out in Article 75(1) of Regulation (EU) 2024/1689, it is necessary to further define the ~~which of the~~**enforcement** powers ~~listed in Article 14 of Regulation (EU) 2019/1020 should be~~ conferred upon the AI Office. ~~The Commission should~~**It is** therefore ~~be empowered~~**appropriate** to ~~adopt implementing acts to specify those~~ **set out provisions regarding the exercise of the AI Office's** powers **of investigation and enforcement as well in respect of AI systems supervised by the AI Office**, including **as regards judicial authorisation and fundamental rights as well as** the ability to impose penalties, such as fines or other administrative sanctions, in accordance with the conditions and ceilings referred to in Article 99, and	EE (Drafting suggestions): (16) To further operationalise the AI Office's supervision and enforcement set out in Article 75(1) of Regulation (EU) 2024/1689, it is necessary to further define the which of theenforcement powers listed in Article 14 of Regulation (EU) 2019/1020 should be conferred upon the AI Office. The Commission shouldIt is therefore be empoweredappropriate to adopt implementing acts to specify those set out provisions regarding the exercise of the AI Office's powers of investigation and enforcement as well in respect of AI systems supervised by the AI Office, including as regards

Second presidency compromise text	Drafting suggestions and Comments
applicable procedures. **Moreover, the Commission should be empowered to adopt implementing acts to further specify those powers. The implementing acts should also lay down the modalities of collaboration and consultation with the authorities involved in the application of that Regulation, including on the exchange of information~~.~~, especially where national authorities require information from the AI Office to effectively fulfil their tasks under that Regulation and vice versa.** This should ensure that the AI Office has the necessary tools to effectively monitor and supervise compliance with Regulation (EU) 2024/1689.	judicial authorisation and fundamental rights as well as the ability to impose penalties, such as fines or other administrative sanctions, in accordance with the conditions and ceilings referred to in Article 99, and applicable procedures. ~~**Moreover, the Commission should be empowered to adopt implementing acts to further specify those powers.**~~ The implementing acts should also lay down the modalities of collaboration and consultation with the authorities involved in the application of that Regulation, including on the exchange of information, especially where national authorities require information from the AI Office to effectively fulfil their tasks under that Regulation and vice versa. This should ensure that the AI Office has the necessary tools to effectively monitor and supervise compliance with Regulation (EU) 2024/1689. EE (Comments): Under Article 290 of TFEU, the Commission may adopt delegated acts only to supplement or amend non-essential elements of a legislative act. Essential elements must be decided by the EU legislator. Rules on investigative powers, enforcement measures, judicial authorisation, fundamental rights, and penalties are generally essential elements. Therefore, their scope and limits must be clearly defined in the basic act itself. The Commission cannot use delegated or implementing acts to expand or redefine those powers. It may only specify technical or procedural details within the limits already set by the legislator. The suggested amendment that the Commission should be empowerd to adopt immplementing act to further specify those power, is beyond what is compatible with Article 290 of TFEU.

Second presidency compromise text	Drafting suggestions and Comments
(17) Additionally, it is essential to ensure that effective procedural safeguards apply to providers of AI systems subject to monitoring and supervision by the AI Office. To that end, the procedural rights provided for in Article 18 of Regulation (EU) 2019/1020 should apply mutatis mutandis to providers of AI systems, without prejudice to more specific procedural rights provided for in Regulation (EU) 2024/1689.	
(18) To enable access to Union market for AI systems which are under the supervision by the AI Office pursuant to Article 75 of Regulation (EU) 2024/1689 and subject to third party conformity assessment, the Commission should be enabled to carry out pre-market conformity assessments of those systems.	
(19) Article 77 and related provisions of Regulation (EU) 2024/1689 constitute an important governance mechanism, as they aim to enable authorities or bodies responsible for enforcing or supervising Union law intended to protect fundamental rights to fulfil their mandate under specific conditions and to foster cooperation with market surveillance authorities responsible for the supervision and enforcement of that Regulation. It is necessary to clarify the scope of such cooperation, as well as to clarify which public authorities or bodies benefit from it. With a view to reinforcing the cooperation, it should be clarified that requests to access information and documentation should be made to the competent market surveillance authority, which should respond to such requests, and that the involved authorities or bodies should have a mutual obligation to cooperate. **It should be clarified that these provisions are without prejudice to the competences, tasks, powers and independence of the relevant national public authorities or bodies under their mandates. In particular, these provisions do not limit any powers that those authorities and bodies have to request information pursuant to other Union or national law. Accordingly, those authorities and bodies retain any power they have to**	

Second presidency compromise text	Drafting suggestions and Comments
directly request information from operators pursuant to their mandate or other law.	
(20) To allow sufficient time for providers of generative AI systems subject to the marking obligations laid down in Article 50(2) of Regulation (EU) 2024/1689 to adapt their practices within a reasonable time without disrupting the market, it is appropriate to introduce a transitional period of 6 months for providers who have already placed their systems on the market before the 2 August 2026.	PL (Drafting suggestions): ~~To allow sufficient time for providers of generative AI systems subject to the marking obligations laid down in Article 50(2) of Regulation (EU) 2024/1689 to adapt their practices within a reasonable time without disrupting the market, it is appropriate to introduce a transitional period of 6 months for providers who have already placed their systems on the market before the 2 August 2026.~~ PL (Comments): Poland does not support extending the implementation period for labeling requirements for synthetic content generated by AI. The priority should be to ensure users' rights to information and transparency as quickly as possible, given the dynamic development of generative AI and its impact on social relations. Consequently, we do not support an additional six-month grace period for systems introduced to the market before August 2, 2026.
(21) To provide sufficient time for providers of high-risk AI systems and to clarify applicable rules to the AI systems already placed on the market or put into service before the entry into application of relevant provisions of the Regulation (EU) 2024/1689, it is appropriate to clarify the application of a grace period provided in Article 111(2) of that Regulation. The grace period, for the purpose of Article 111(2), should apply to a type and model of AI systems already placed in the market. This means that if at least one individual unit of the high-risk AI system has been lawfully placed on the market or put into service before the date specified in Article 111(2), other individual units of the same type and model of high-risk AI system are subject to the grace	

Second presidency compromise text	Drafting suggestions and Comments
period provided in Article 111(2) and thus may continue to be placed on the market, made available or put into service on the Union market without any additional obligations, requirements or the need for additional certification, as long as the design of that high-risk AI system remains unchanged. For the purposes of application of the grace period provided in Article 111(2), the decisive factor is the date on which the first unit of that type and model of high-risk AI system was placed on the market or put into service on the Union market for the first time. Any significant change to the design of that AI system after the date specified in Article 111(2) should trigger the obligation of the provider to comply fully with all relevant provisions of this Regulation applicable to high-risk AI systems, including the conformity assessment requirements.	
(22) Article 113 of Regulation (EU) 2024/1689 establishes the dates of entry into force and application of that Regulation, notably that the general date of application is 2 August 2026. For the obligations related to high-risk AI systems laid down in Sections 1, 2 and 3 of Chapter III of Regulation (EU) 2024/1689, the delayed availability of standards, common specifications, and alternative guidance and the delayed establishment of national competent authorities lead to challenges that jeopardise those obligation's effective entry into application and that risk to significantly increase implementation costs in a way that does not justify maintaining their initial date of application, namely 2 August 2026. ~~Building on experience~~ **Against this background**, it is appropriate to **align the implementation timeline and set the date for the application of Sections 1, 2 and 3 of Chapter III to 2 December 2027 for AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and to 2 August 2028 for AI systems classified as high-risk pursuant to Article 6(1) and Annex I** ~~put in place a mechanism that links the entry into application to the availability of measures in support of compliance with Chapter III, which may include harmonised standards, common specifications, and Commission guidelines. This should be confirmed by the Commission by decision, following which the rules obligations for high-risk~~	EE (Drafting suggestions): (22) Article 113 of Regulation (EU) 2024/1689 establishes the dates of entry into force and application of that Regulation, notably that the general date of application is 2 August 2026. For the obligations related to high-risk AI systems laid down in Sections 1, 2 and 3 of Chapter III of Regulation (EU) 2024/1689, the delayed availability of standards, common specifications, and alternative guidance and the delayed establishment of national competent authorities lead to challenges that jeopardise those obligation's effective entry into application and that risk to significantly increase implementation costs in a way that does not justify maintaining their initial date of application, namely 2 August 2026. Building on experience Against this background, it is appropriate to align the implementation timeline and set the date for the application of Sections 1, 2 and 3 of Chapter III to 2 December 2027 for AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and to 2 August 2028 for AI systems classified as high-risk pursuant to Article 6(1) and Annex I put in place a mechanism that links the entry into application to the availability of

Second presidency compromise text	Drafting suggestions and Comments
~~AI systems should apply after 6 months as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and after 12 months as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to Regulation (EU) 2024/1689. However, this flexibility should only be extended until 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and until 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to that Regulation, by which dates those rules should enter into application in any case~~. The distinction between the entry into application of the rules as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and Article 6(1) and Annex I to that Regulation is consistent with the difference between the initial dates of application envisaged in Regulation (EU) 2024/1689 and aims to provide the necessary time for adaptation and implementation of the corresponding obligations. **The timely availability of support instruments, including guidance, relevant standards, common specifications and codes of practice is important in order to facilitate compliance and reduce the risk of divergent interpretation and uneven application of the rules across Member States.**	measures in support of compliance with Chapter III, which may include harmonised standards, common specifications, and Commission guidelines. This should be confirmed by the Commission by decision, following which the rules obligations for high-risk AI systems should apply after 6 months as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and after 12 months as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to Regulation (EU) 2024/1689. However, this flexibility should only be extended until 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and until 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to that Regulation, by which dates those rules should enter into application in any case. The distinction between the entry into application of the rules as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and Article 6(1) and Annex I to that Regulation is consistent with the difference between the initial dates of application envisaged in Regulation (EU) 2024/1689 and aims to provide the necessary time for adaptation and implementation of the corresponding obligations. The timely availability of support instruments, including guidance, relevant standards, common specifications and codes of practice is **essential**~~important~~ in order to facilitate compliance and reduce the risk of divergent interpretation and uneven application of the rules across Member States. IT (Drafting suggestions): Article 113 of Regulation (EU) 2024/1689 establishes the dates of entry into force and application of that Regulation, notably that the general date of application is 2 August 2026. For the obligations related to high-risk AI systems laid down in Sections 1, 2 and 3 of Chapter III of Regulation (EU) 2024/1689, the delayed availability of standards, common specifications, and alternative guidance and the delayed establishment of national competent authorities lead to challenges that jeopardise those obligation's

Second presidency compromise text	Drafting suggestions and Comments
	effective entry into application and that risk to significantly increase implementation costs in a way that does not justify maintaining their initial date of application, namely 2 August 2026. ~~Building on experience~~ **Against this background**, it is appropriate to **align the implementation timeline and set the date for the application of Sections 1, 2 and 3 of Chapter III to 2 December 2027 for AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and to 2 August 2028 for AI systems classified as high-risk pursuant to Article 6(1) and Annex I** ~~put in place a mechanism that links the entry into application to the availability of measures in support of compliance with Chapter III, which may include harmonised standards, common specifications, and Commission guidelines. This should be confirmed by the Commission by decision, following which the rules obligations for high-risk AI systems should apply after 6 months as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and after 12 months as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to Regulation (EU) 2024/1689. However, this flexibility should only be extended until 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and until 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to that Regulation, by which dates those rules should enter into application in any case~~. The distinction between the entry into application of the rules as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and Article 6(1) and Annex I to that Regulation is consistent with the difference between the initial dates of application envisaged in Regulation (EU) 2024/1689 and aims to provide the necessary time for adaptation and implementation of the corresponding obligations. **Moreover, in order to ensure legal certainty and predictability for operators, as well as to enable competent authorities to provide consistent and meaningful regulatory guidance to sandbox participants, it is necessary to postpone the application of the rules set out in Chapter VI on the establishment and operation of regulatory sandboxes to 2**

Second presidency compromise text	Drafting suggestions and Comments
	December 2027. Such postponement is justified both with regard to high-risk systems, as the absence of relevant standards and guidelines would prevent the effective performance of sandbox-related tasks, and with regard to other systems, since the implementing act has not yet entered into force and sandboxes could otherwise be established in a manner not fully aligned with the requirements that will subsequently apply. **The timely availability of support instruments, including guidance, relevant standards, common specifications and codes of practice is important in order to facilitate compliance and reduce the risk of divergent interpretation and uneven application of the rules across Member States.**
(23) In light of the objective to reduce implementation challenges for citizens, businesses and public administrations, it is essential that harmonised conditions for the implementation of certain rules are adopted only where strictly necessary. For that purpose, it is appropriate to remove certain empowerments bestowed on the Commission to adopt such harmonised conditions by means of implementing acts in cases where those conditions are not met. Regulation (EU) 2024/1689 should therefore be amended to remove the empowerments conferred on the Commission in Article 50(7), Article 56(6), and Article 72(3) thereof to adopt implementing acts. The removal of the empowerment to adopt a harmonised template for a post-market monitoring plan in Article 72(3) of Regulation (EU) 2024/1689 has as an additional benefit that it will offer more flexibility for providers of high-risk AI systems to put in place a system for post-market monitoring that is tailored to their organisation. At the same time, recognising the need to offer clarity how providers of high-risk AI systems are required to comply, the Commission should be required to publish guidance.	FR (Drafting suggestions): ~~(23) In light of the objective to reduce implementation challenges for citizens, businesses and public administrations, it is essential that harmonised conditions for the implementation of certain rules are adopted only where strictly necessary. For that purpose, it is appropriate to remove certain empowerments bestowed on the Commission to adopt such harmonised conditions by means of implementing acts in cases where those conditions are not met. Regulation (EU) 2024/1689 should therefore be amended to remove the empowerments conferred on the Commission in Article 50(7), Article 56(6), and Article 72(3) thereof to adopt implementing acts. The removal of the empowerment to adopt a harmonised template for a post-market monitoring plan in Article 72(3) of Regulation (EU) 2024/1689 has as an additional benefit that it will offer more flexibility for providers of high-risk AI systems to put in place a system for post-market monitoring that is tailored to their organisation. At the same time, recognising the need~~

Second presidency compromise text	Drafting suggestions and Comments
	~~to offer clarity how providers of high-risk AI systems are required to comply, the Commission should be required to publish guidance.~~ FR (Comments): DELETION. We believe that implementing acts allow Member States to be directly involved, via the comitology process, in decisions for which they bear most of the operational and budgetary consequences. Finally, this choice is consistent with the objective of simplification. Greater involvement of Member States at an early stage reduces the risk of divergent interpretations, implementation difficulties, and subsequent revisions. It promotes consistent, predictable, and robust application of the AI Act, to the benefit of both authorities and economic actors.
(24) Conformity assessment of high-risk AI systems under Regulation (EU) 2024/1689 may require involvement of conformity assessment bodies. Only conformity assessment bodies that have been designated under that Regulation may carry out conformity assessments and only for the activities related to the categories and types of AI systems concerned. To enable the specification of the scope of the designation of conformity assessment bodies notified under Article 30 of Regulation (EU) 2024/1689, it is necessary to draw up a list of codes, categories, and corresponding types of AI systems. The list of codes should take into account whether the AI system is a component of a product or itself a product covered by the Union harmonisation legislation listed in Annex I (referred to as 'AIP codes', for AI systems covered by product legislation) or a system referred in Annex III of Regulation (EU) 2024/1689, which currently concerns only biometric AI systems referred to in point (1) of Annex III (referred to as 'AIB codes', for biometric AI systems). Both AIP codes and AIB codes are vertical codes. The AIP codes are reference codes to provide a link to the Union harmonisation	

Second presidency compromise text	Drafting suggestions and Comments
legislation listed in Section A of Annex I of Regulation (EU) 2024/1689. The AIB codes are new codes specific to Regulation (EU) 2024/1689 to identify biometric AI systems referred in paragraph 1 of Annex III of that Regulation. The list of codes should also take into account specific types and underlying technologies of AI systems (referred to as 'AIH codes', for horizontal AI system codes). The AIH codes are new AI technology-specific codes and can be applied in conjunction with AIP or AIB vertical codes. The AIH codes cover AI systems' underlying types and technologies. The list of codes, including three categories, should provide for a multi-dimensional typology of AI systems which ensures that conformity assessment bodies designated as notified bodies are fully competent for the AI systems they are required to assess.	
	FR (Drafting suggestions): Addition : **(24a) To achieve an appropriate level of cybersecurity, an AI system should resist attempts by unauthorised third parties to alter its use, outputs, or performance by exploiting vulnerabilities specific to AI as well as all other vulnerabilities in the system by applying horizontal conventional cybersecurity measures, as specified in Annex I, part 1 under Regulation 2024/2847 if relevant, in addition to cybersecurity requirements specific to AI.** FR (Comments): The legal and operational articulation between the AI Act and the CRA must be clarified to ensure that AI system should apply horizontal cybersecuirty requirements in addition to cybersecurity requirements specific to AI. The current wording implies that measures from the AI Act are equivalent to CRA horizontal cybersecurity measures. However, French authorities believe that AI Act measures are not sufficient and the CRA should apply in

Second presidency compromise text	Drafting suggestions and Comments
	addition to them. The CRA must apply as an horizontal cyersecurity framework for all products with digital elements.
(25) Regulation (EU) 2018/1139 of the European Parliament and the Council[13] lays down common rules in the field of civil aviation. Article 108 of Regulation (EU) 2024/1689 sets out amendments to Regulation (EU) 2018/1139 to ensure that the Commission takes into account, on the basis of the technical and regulatory specificities of the civil aviation sector, and without interfering with existing governance, conformity assessment and enforcement mechanisms and authorities established therein, the mandatory requirements for high-risk AI systems laid down in Regulation (EU) 2024/1689 when adopting any relevant delegated or implementing acts on the basis of that act. A technical correction extending specific articles of Regulation (EU) 2018/1139 is necessary to ensure that those mandatory requirements for high-risk AI systems laid down in Regulation (EU) 2024/1689 are fully covered when adopting relevant delegated or implementing acts on the basis of Regulation (EU) 2018/1139. 13 Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91(OJ L 212, 22.8.2018, pp. 1–122, ELI: http://data.europa.eu/eli/reg/2018/1139/oj).	
(26) In order to ensure legal certainty as soon as possible, with a view to the imminent general application of Regulation (EU) 2024/1689, this Regulation should enter into force as a matter of urgency**.**	

Second presidency compromise text	Drafting suggestions and Comments
(27) The European Data Protection Supervisor and the European Data Protection Board were consulted in accordance with Article 42(1) and (2) of Regulation (EU) 2018/1725 and delivered their joint opinion on 20 January 2026,	
HAVE ADOPTED THIS REGULATION:	
	FR (Drafting suggestions): **Addition to AIA recitals :** **(35) In recital 171, after the second sentence, the following sentence is added:** **Such an explanation should enable affected persons to understand the procedural logic of the decision, including the respective roles of automated processing and human intervention, and should not be interpreted as requiring to explain the internal functioning of the AI system.** **(36) In recital 139, after the sentence "To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the AI regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes" is added the following sentence:** **AI regulatory sandboxes should allow broad and equal access to facilitate participation by providers, while allowing Member States to prioritise sectors where regulatory learning and risk mitigation are mpost needed, as well as for reasons of regulatory capacity or expertise.**

Second presidency compromise text	Drafting suggestions and Comments
	(37) In recital 168, after the words "including by laying down effective, proportional and dissuasive penalties," are added the words "which can be administrative fines,". FR (Comments): (35) The current wording is ambiguious and could be interpreted as imposing requirements in the range of 'explanable AI'. Such a reading would put disproportionate constrains on providers without benefits for the concerned individuals. The proposed clarification protects innovation while guaranteeing an effective right to information. (36) The current wording creates an uncertainty when it comes to the expected format of the sandboxes. A clarification would allow to preserve th room for maneuvre of Member States, allowing them to prioritize certain sectors and guarentying an implementation adapted to their capabilities and national priorities. (37) The lack of reference to some obligations of the AI Act in article 99, which sets the above limits of financial sanctions for some breaches, risks leading to an interpretation on the fact that breach to obligations not strictly mentionned in article 99 are not financially punishable. This creates an uncertainty for Member States, which are required to make these obligations

Second presidency compromise text	Drafting suggestions and Comments
	effective and enforceable, and may lead to less effective compliance by operation. It is therefore preferable to clarity the Member States's room for maneuver by explicitly allowing them to provide for financial penalties for breaches not explicitly mentionned in article 99.
Article 1	
Amendments to Regulation (EU) 2024/1689	
Regulation (EU) 2024/1689 is amended as follows:	
(1) in Article 1(2), point (g) is replaced by the following:	
'(g) measures to support innovation, with a particular focus on small mid-cap enterprises (SMCs) and small and medium-sized enterprises (SMEs), including start-ups.';	
(2) in Article 2, paragraph 2 is replaced by the following:	
'2. For AI systems classified as high-risk AI systems in accordance with Article 6(1) related to products covered by the Union harmonisation legislation listed in Section B of Annex I, only Article 6(1), Article 60a, Articles 102 to ~~109 and Articles 111 and~~ 112 shall apply. Article**s** 57 **to 59** shall apply only in so far as the requirements for high-risk AI systems under this Regulation have been integrated in that Union harmonisation legislation.;	
	DE (Drafting suggestions): Research exemption

Second presidency compromise text	Drafting suggestions and Comments
	We ask for the following clarifications: Clarification of the research exemption in Article 2(6): "This Regulation does not apply to AI systems or AI models, including their output, put into service for the ~~sole~~ purpose of scientific research and development." Clarification of the interplay of the research exemptions for open-source models: Researchers open-sourcing their general-purpose AI models must not constitute a "placing on the market Clarification of the research exemption in Article 2(8): "This Regulation does not apply to any research, testing or development activity regarding AI systems or AI models prior to their being placed on the market or put into service, including testing under real world conditions. Such activities shall be conducted in accordance with applicable Union law. ~~Testing in real world conditions shall not be covered by that exclusion."~~
(3) in Article 3, the following points (14a) and (14b) are inserted:	
'(14a) micro, small and medium-sized enterprise ('SME') means a micro, small or medium-sized enterprise as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC;	
(14b) small mid-cap enterprise ('SMC') means a small mid-cap enterprise as defined in point (2) of the Annex to Commission Recommendation (EU) 2025/1099';	
	DE (Drafting suggestions):

Second presidency compromise text	Drafting suggestions and Comments
	In Article 3, point (34) is replaced by: "'biometric data' means data referred to in Article 4(14) of Regulation (EU) 2016/679 DE (Comments): Harmonization of terminology and risk class categories across legal acts Discrepancies can be seen, for example, in the definitions of safety components and substantial modifications between the AI Act and the Machinery Regulation. Therefore the suggest further harmonization and clarification within the AI Act. We suggest that Art. 3 (34) (biometric data) should refer to Article 4 (14) of Regulation 2016/679 (GDPR).
(4) Article 4 is replaced by the following:	
'*Article 4*	
AI literacy	DE (Comments): AI literacy The legal obligation for providers and deployers of AI systems in Article 4 AI Act has caused too many uncertainties among businesses which must be resolved. A recital highlighting the importance of AI literacy and – as far as businesses are concerned - the general duties of company management with regard to the selection and deployment of employees should be included.

Second presidency compromise text	Drafting suggestions and Comments
	We also ask for practice-oriented guidelines for companies as well as instructive and free online training courses provided by the AI Service Desk should be provided. ES (Comments): **No objections are raised to this proposal.** SK (Comments): In the area of AI literacy, we welcome the clarification that, despite the shift of the general AI literacy obligations to the Member States and the Commission, providers and deployers of high-risk AI systems remain responsible for ensuring appropriate training and competences related to AI. At the same time, we recommend introducing clear, measurable and verifiable objectives in a non-binding manner, allowing sufficient flexibility in implementation while ensuring transparency, accountability and the effective achievement of AI literacy goals.
'**1.** The Commission and Member States shall encourage providers and deployers of AI systems to take measures **within their respective roles and responsibilities** to ensure a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, level of education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used. ~~**European competence frameworks shall be taken into account in the encouragement under this article.**~~	EE (Drafting suggestions): ~~The Commission and Member States shall encourage~~ **The** providers and deployers of AI systems ~~to~~ **shall** take measures to ensure a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, level of education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI

Second presidency compromise text	Drafting suggestions and Comments
	systems are to be used. **The Commission and Member States encourage providers and deployers to take necessary measures.** EE (Comments): We consider the development of digital and AI-related skills to be a key policy priority, essential for fostering innovation, competitiveness, and inclusive participation in the digital transformation driven by artificial intelligence. We therefore welcome the direction of travel towards a more coordinated, public-policy-driven approach to AI literacy at Union and Member State level. However, we do not support the shifting of responsibilities from providers and deployers. They also have their part in raising AI literacy levels. AI literacy should be understood as a horizontal, long-term capability, embedded in education systems, public administration, and lifelong learning frameworkswhere individual providers or deployers also have an important role to play. At the same time, we note that AI literacy encompasses different levels of knowledge and skills depending on the target group, ranging from general awareness for citizens to more advanced competencies for public officials, regulators, and professionals working with or overseeing AI systems. Any future approach should therefore allow sufficient flexibility for Member States to tailor measures to national contexts and existing institutional arrangements. PL (Comments): Poland supports the goal of increasing the level of AI literacy skills, but points out that achieving this goal should not rely solely on incentives directed at market entities. Poland believes that the European Commission should take a more active, supportive role by developing common guidelines and best practices, providing training materials, and providing appropriate financial instruments, particularly for SMEs and public administration. Effectively raising the level of AI literacy in the EU requires coordinated

Second presidency compromise text	Drafting suggestions and Comments
	and systemic support at the EU level to ensure coherent actions and equal conditions for competence development across all Member States. PT (Comments): Leaving implementation entirely to Member States may result in divergent literacy standards. The Commission shall adopt guidance, in cooperation with the AI Board, specifying common principles and minimum elements for AI literacy measures across the Union. Futhermore, the revised Article 4 lacks clarity on supervision and enforcement. Portugal suggests that Member States shall ensure that the promotion of AI literacy is reflected, where appropriate, in the supervisory activities of competent authorities designated under Article 70. SE (Drafting suggestions): The Commission and Member States shall encourage providers and deployers of AI systems to take measures within their ~~respective roles and responsibilities~~ existing structures and resources to ensure a sufficient level of AI literacy of their staff and other persons… SE (Comments): Budget neutrality should be specified. SI (Comments): Slovenia agrees that the Commission and the Member States should play an active role in encouraging and supporting the adoption of AI literacy measures by providers and deployers for their employees. However, such supportive actions should not substitute for clear and binding obligations for providers and deployers.

Second presidency compromise text	Drafting suggestions and Comments
1a. In addition to paragraph 1, providers and deployers of high-risk AI systems are subject to specific obligations regarding training and competence under Articles 17(1) point (m) and 26(2).	AT (Drafting suggestions): 1a. In addition to paragraph 1, providers and deployers of high-risk AI systems ~~are subject to specific obligations regarding under~~ **shall ensure adequate** training and competence **of their staff and other persons dealing with the design, operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used, when meeting the legal obligations set out in** Articles 1**6** ~~7(1) point (m)~~ and 26~~(2)~~. AT (Comments): AT: Competence requirements are indeed already included in Art 17(1) b-d, f, g, j, l-m as well as Art 26 (1) and (2) but it would be preferable to link the obligation more generally to the obligations of providers and deployers of high-risk AI systems. The important aspect of the current formulation of Art 4 is indeed the specification of how AI literacy is relevant to meeting obligations of providers and deployers, which should be retained with minimum changes. BE (Comments): New paragraph 1a clarifies the requirements related to AI knowledge for providers and deployers already in place in the AI Act. We support the clarifications made in this Article but insist again on the importance of ensuring **a shared responsibility**. EE

Second presidency compromise text	Drafting suggestions and Comments
	(Comments): Thank you for the clarity in this section. IT (Drafting suggestions): In addition to paragraph 1, providers and deployers of high-risk AI systems ~~are~~ **remain** subject to specific obligations regarding training and competence, **including the specific obligations provided under Articles 9 and 26(2).** ~~under Articles 17(1) point (m) and 26(2).~~ IT (Comments): We suggest aligning the wording of the paragraph with the revised version of the recital, removing the reference to Article 17 and referring more generally, by way of example, to the applicable provisions. SI (Drafting suggestions): **In addition to paragraph 1, providers and deployers of AI systems shall ensure, to their best extent, a sufficient level of AI literacy of their staff. Providers and deployers of high-risk AI systems are subject to specific obligations regarding training and competence under Articles 17(1) point (m) and 26(2).** SI (Comments): In order to develop, deploy and use AI systems in a responsible, ethical and legally compliant manner, it is essential to establish stronger and more precise requirements on AI literacy for providers and deployers of all AI systems. Employees and other persons dealing with the operation and use of AI systems should have basic knowledge about how artificial intelligence systems work and limitations of their use, as well as about their potential

Second presidency compromise text	Drafting suggestions and Comments
	impact on human rights, and the broader societal context of their use. This will contribute to responsible use of AI systems and minimise risks associated with it, and at the same time ensure a consistent and effective level of AI literacy across the entire value chain. Slovenia therefore recommends maintaining the obligation for providers and deployers of AI systems to take measures to ensure that their staff and other relevant persons have sufficient level of AI literacy
2. The Board shall adopt recommendations, taking into account European competence frameworks, to support the Commission and Member States in the promotion of AI literacy required by paragraph 1, including by setting out non-binding common objectives.’;	EE (Comments): EU Academy (https://academy.europa.eu/) could develop AI training materials that can be used by Member States and companies to support the implementation of the AI Regulation and development of AI literacy.
(5) the following Article 4a is inserted in Chapter I:	
‘*Article 4a*	IE (Comments): While the proposed amendments to limit the processing of special categories of personal data for bias detection and mitigation to a standard of “strict necessity” are in line with the Joint Opinion, the proviso added to the recital “*it is likely that the exceptional circumstances justifying reliance on this new legal basis will arise less frequently in practice, notably given that AI systems that are not high-risk pose lower risks to health, safety and fundamental rights*” does not, per advice in the recent EDPB/S Joint Opinion*, provide adequate guidance as to what those exceptional circumstances are. Examples or guidance are particularly important where there is processing of special category data in non-high-risk AI systems (or AI models). Here it is a question of how that the standard of “strict necessity” be met in those circumstances?

Second presidency compromise text	Drafting suggestions and Comments
	* Recommendation that the AI Omnibus provide, "*by way of a recital, more detailed justifications for the envisaged extension of the scope of the exception by indicating specific examples of non-high-risk AI systems or models that could adversely affect individuals based on protected characteristics that would warrant processing of special categories of data to counter such bias.*" [pt. 14, p.8, EDPB/S JO on the AI Omnibus] PL (Comments): The proposed provisions concerning the processing of special categories of personal data in AI systems (Article 4a) may benefit from further clarification regarding additional privacy safeguards and clearly defined limits. It would be worth considering such refinements to ensure regulatory coherence and an appropriate level of protection of EU citizens' right to privacy. Poland takes a similar approach with regard to the amendments to Article 10 resulting from the introduction of Article 4a. In the relationship between this provision and the personal data protection framework, it is important that the proposed solutions remain transparent, proportionate, and practically workable, while respecting the competences of national data protection authorities. At the same time, it is important to ensure an adequate level of security and confidentiality for special categories of data used, among other purposes, to identify and mitigate bias or in system training processes, including in cases of cross-border processing. Efforts in this area could be carried out in a coordinated and consultative manner, involving relevant national bodies as well as EU institutions and agencies, within their respective mandates. With regard to high-risk systems and areas such as law enforcement, security (including cybersecurity), border protection, and migration management, it may be appropriate to consider adequate security measures, taking into account the potential consequences of possible data breaches.

Second presidency compromise text	Drafting suggestions and Comments
Processing of special categories of personal data for bias detection and mitigation	DE (Comments): Our examination regarding the new article 4a (processing of special categories of personal data for bias detection and mitiga-tion) is ongoing, that also includes possible effects of article 4a in general and its interplay with other legal bases for data pro-cessing for AI training. PT (Comments): The proposal extends the possibility of processing special categories of data for the detection and correction of biases, provided that the criteria of strict necessity is observed, and that technical and organizational measures are observed to ensure the appropriate safeguards. While the proposal requires safeguard measures, we understand it introduces uncertainty when leaving open the concrete and clear definition of what should be deemed an appropriate organizational or technical measure and how compliance with such definition can be demonstrated to supervisory authorities. This terminological and conceptual ambiguity represents a risk, as it may increase the chances of a practical result where bias is reinforced instead of being corrected. Therefore, we woul appreciate the following clarifications: 1) whether the Commission is considering developing harmonized guidelines regarding the requirements for assessing the criteria of strict necessity, as a decision-making tool and a way to reduce regulatory uncertainty; 2) whether the Commission is considering developing concrete guidelines and mechanisms to clarify how appropriate organizational and technical measure can be documented and how compliance with such definition can be demonstrated to supervisory authorities.]

Second presidency compromise text	Drafting suggestions and Comments
1. To the extent **strictly** necessary to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the ~~safeguards~~ **provisions** set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:	EE (Comments): We will submit additional comments on this article in the beginning of next week. We need to analyse this provision with our data protection team. NL (Comments): The Netherlands welcomes the amendments for recital 6 that now clarifies the scope and that it should be understood as limited to the detection, prevention and mitigation of biases that are likely to affect the health and safety of persons, have a negative impact on fundamental rights or lead to discrimination prohibited under Union law – as also expressed in the Joint Opinion EDPB -EDPS 1/2026. We also welcome the amendment to art. 4a that now adds 'strict' necessity. We still have some concerns, in particular regarding the right to data protection, that the adjustments to the AI Act are not sufficiently clear. In line with the Joint Opinion EDPB-EDPS 1/2026, the Netherlands would welcome, by way of a recital, a more detailed justification for the envisaged extension of the scope of the exception under art. 4a. SE (Drafting suggestions): 1. To the extent ~~**strictly**~~ necessary to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards **provisions** set out in Regulations (EU) 2016/679 and (EU)

Second presidency compromise text	Drafting suggestions and Comments
	2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur: SE (Comments): In order to enable the responsible design of AI systems, it must be possible to process special categories of personal data. SE therefore welcomes the proposal to broaden the legal basis. It should also be emphasised that several safeguards already apply to the processing of such data, which is why SE considers the change from "strictly necessary" to "necessary" to be a well-justified adjustment. SE also notes that risks to fundamental rights may result in greater harm to individuals if bias in an AI system is not detected and corrected. Provided that the term "strictly" is removed, the relationship with the Law Enforcement Directive (LED) needs to be clarified. Under the LED (Article 10), the processing of special categories of personal data is permitted only where it is "strictly necessary". It should be clarified that the processing of such personal data for the purpose of identifying bias is permissible where the requirement of "necessary" under the AI Act is fulfilled. In such cases, the higher threshold of "strictly necessary" under the LED should not apply.
	PL (Drafting suggestions): Additional point (aa): aa) the processing is clearly defined, transparent, proportionate and limited to what is strictly necessary with regard to its purpose, scope and duration;
(a) the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;	

Second presidency compromise text	Drafting suggestions and Comments
(b) the special categories of personal data are subject to technical limitations on the re-use of the personal data, and state-of-the-art security and privacy-preserving measures, including pseudonymisation;	
(c) the special categories of personal data are subject to measures to ensure that the personal data processed are secured, protected, subject to suitable safeguards, including strict controls and documentation of the access, to avoid misuse and ensure that only authorised persons have access to those personal data with appropriate confidentiality obligations;	
(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties;	
(e) the special categories of personal data are deleted once the bias has been corrected or the personal data has reached the end of its retention period, whichever comes first;	PL (Drafting suggestions): (e) the special categories of personal data are deleted once the bias has been corrected, **once the data are no longer necessary for the stated purpose,** or **once** the personal data has reached the end of its retention period, whichever comes first;
(f) the records of processing activities pursuant to Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680 include the reasons why the processing of special categories of personal data was necessary to detect and correct biases, and why that objective could not be achieved by processing other data.	PL (Drafting suggestions): (f) the records of processing activities pursuant to Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680 include the reasons why, including the **assessment demonstrating the necessity and proportionality,** processing of special categories of personal data was necessary to detect and correct biases, and **explaining** why that objective could not be achieved by processing other data or implementing **other means**.

Second presidency compromise text	Drafting suggestions and Comments
2. ~~Paragraph 1 may apply to p~~**P**roviders and deployers of other AI systems and models and deployers of high-risk AI systems ~~where necessary and proportionate if the processing occurs for the purposes set out therein and provided that the conditions set out under the safeguards set out in this paragraph.;~~ **may exceptionally process special categories of personal data to the extent that:**	BE (Comments): We would like to thank the Presidency for the clarifications of this paragraph. Given the potential impact of this provision on the fundamental rights of the individuals concerned, we would like to insist on the need to ensure that such extension is limited to what is strictly necessary, clearly defined and accompanied by adequate safeguards. In order to achieve these conditions, we ask for the following additional safeguards. First, as recommended by the EDPS/EDPB in its joint opinion, a detailed justification for this extension by indicating specific examples of non-high-risk AI systems or models that could adversely affect individuals based on protected characteristics that would warrant processing of special categories of data to counter such bias should be included in the recital. Secondly, the concept of "strict necessity" as mentioned in Article 4.2 deserves to be further clarified in the recital by specifying that this refers in particular to the priority use of other technical solutions to detect and correct biases. FR (Drafting suggestions): ~~2. Paragraph 1 may apply to pProviders and deployers of other AI systems and models and deployers of high-risk AI systems where necessary and proportionate if the processing occurs for the purposes set out therein and provided that the conditions set out under the safeguards set out in this paragraph.; may exceptionally process special categories of personal data to the extent that:~~ FR (Comments): DELETION

Second presidency compromise text	Drafting suggestions and Comments
	By limiting the exceptional processing of special categories of personal data only to cases where biases are "likely to affect health and safety" or have a "negative impact on fundamental rights," the text effectively prevents proactive bias mitigation for a wide range of AI applications. Bias detection and correction should be encouraged as a baseline best practice for all AI systems to prevent discriminatory outcomes before they escalate into high-level risks. Restricting this legal basis to "exceptional" and extreme scenarios undermines the overarching objective of promoting human-centric and reliable AI across the Union. We therefore request the removal of these additions to maintain a framework that facilitates, rather than penalizes, proactive efforts to eliminate algorithmic bias.
(a) processing is strictly necessary to ensure bias detection and correction in view of possible biases that are likely to affect the health and safety of persons, have a negative impact on fundamental rights or lead to discrimination prohibited under Union law, especially where data outputs influence inputs for future operations; and	FR (Drafting suggestions): ~~(a) processing is strictly necessary to ensure bias detection and correction in view of possible biases that are likely to affect the health and safety of persons, have a negative impact on fundamental rights or lead to discrimination prohibited under Union law, especially where data outputs influence inputs for future operations; and~~ FR (Comments): DELETION SE (Drafting suggestions):

Second presidency compromise text	Drafting suggestions and Comments
	(a) processing is ~~strictly~~ necessary to ensure bias detection and correction in view of possible biases that are likely to affect the health and safety of persons, have a negative impact on fundamental rights or lead to discrimination prohibited under Union law, especially where data outputs influence inputs for future operations; and
(b) all of the conditions and safeguards set out in paragraph 1 are applied.	FR (Drafting suggestions): ~~(b) all of the conditions and safeguards set out in paragraph 1 are applied.~~ FR (Comments): DELETION
This paragraph does not create any obligation to conduct such bias detection and correction.	FR (Drafting suggestions): ~~This paragraph does not create any obligation to conduct such bias detection and correction~~.
	AT (Drafting suggestions): **3. Regulation (EU) 2019/1020 does not apply to the supervision and enforcement of this provision. Member States shall designate one or more competent authorities to supervise or enforce this prohibition according to the framework provided in Regulation (EU) 2016/679.** AT (Comments):

Second presidency compromise text	Drafting suggestions and Comments
	AT: As we have stressed repeatedly, including a legal basis for processing (personal) data within a product safety law is incompatible with the enforement practices for the New Legislative Framework. Please note that enforcement based on the Market Surveillance Regulation 1020/2019 will mean that customs authorities conduct randomised checks for products to which this provision is applicable (i.e., all AI models and systems – which is potentially all software, and therefore also all products containing software), and that at least one competent authority will need to take proactive (in addition to reactive) measures to enforce it – which may entail on-site inspections for any provider or deployer of any AI model or AI system. If this provision is enforced using the NLF, this consitutes regulatory overreach. If it is not enforced, it opens any provider or deployer up to liability, as the likelihood of civil proceedings increases if market surveillance authorities are unable to conduct their tasks. As this is not a provision that can reasonably be enforced through the NLF, we strongly oppose including the enforcement of this provision within the oversight framework of the AI Act. We are open to any other options for structuring regulatory oversight as long as a carve-out from the NLF is ensured. ES (Drafting suggestions): **In article 5 (1) a new point (i) should be added**: ‘(i) the placing on the market, the putting into service or the use of an AI system that generates, manipulates or alters realistic images, audio or video content depicting identifiable natural persons in intimate, sexual or otherwise private contexts without their explicit consent, with the objective, or the effect, of creating the false appearance that such person engaged in or was present in such contexts, thereby causing or being reasonably likely to cause that person significant harm, including harm to their dignity, reputation, psychological well-being or safety.’

Second presidency compromise text	Drafting suggestions and Comments
	ES (Comments): **The proposal remains in place. Red line** Following the proliferation and mass dissemination of non-consensual intimate content generated by 'Grok' AI system in December 2024, Spain deems it necessary to incorporate a new prohibition within Article 5 to the proposed Omnibus Regulation. FR (Drafting suggestions): Addition of a new provision: **(5b) in Article 5, the following paragraphs are added:** **(i) the placing on the market, the putting into service or the use of AI systems designed to generate or alter sexually explicit content without consent;** **(j) the placing on the market, the putting into service or the use of AI systems designed to generate child sexual abuse material.** FR (Comments): An analysis of the applicable European legal framework shows its inadequacy when it comes to preventing and punishing the generation of child pornography content. This practice if not explicitly prohibited in the AI Act or other instruments, in particular the DSA which prohibits its dissemination on major platforms. It could therefore be appropriate to request, through the Omnibus, the addition of a new prohibited practive allowing for the direct punichment of such uses. Criminal law mechanisms essentially intervene ex post and do not allow for the upstream prevention of the put into market of AI systems designed to

Second presidency compromise text	Drafting suggestions and Comments
	produce this type of content. A targeted prohibition included in Article 5 would constitue a proportionate and consistent lever to fill this gap, aligning ex ante framework for AI with the fundamental requirements of protecting human dignity and children.
(6) ~~in Article 6(4), paragraph 4 is replaced by the following:~~	FI (Comments): This is a general comment and call for attention about the challenges of the interplay of sectoral product safety legislation and AIA. There's been discussion whether Annex I Part A should remain a strictly horizontal NLF- based framework or be revised to allow more sector- specific flexibility. E.g. Orgalim has proposed **moving the entire Section A of the Annex I to Section B** in order to simplify the regulatory framework and prevent legislative overlap. Moving these instruments under the more flexible logic of Part B, or alternatively revising Part A to better accommodate justified sectoral differences, could reduce unnecessary administrative load while still preserving essential safety requirements. On the other hand, this would represent a shift from the emphasis on horizontal regulation, and therefore requires discussion. When it comes to the coordination between the AI Act and MDR/IVDR, it would be clearer to **include the essential requirements of the AI Act directly in the MD/IVD Regulations** instead of a separate implementing act (e.g. Article 10 on manufacturer's obligations and Annex I, General Safety and performance requirements) and to use implementing acts only for smaller technical and other details where necessary. However, if a separate implementing act were considered a suitable way of laying down these requirements, it should be implemented as quickly as possible so that manufacturers do not become unaware of the applicable requirements.

Second presidency compromise text	Drafting suggestions and Comments
	The Commission has proposed moving the Medical Devices and in-vitro diagnostics regulations from Section A to B of AIA Annex I (COM(2025) 1023 final), which **Finland supports**. FR (Drafting suggestions): **(6) in Article 6(4), paragraph 4 is replaced by the following:** IT (Comments): We appreciate the maintenance of the registration obligation under Art. 6.4 and Art. 49.2. However, we do not agree with the new proposal to delete the information set out in Annex VIII point 7 and 9. In particular, "the brief summary of the reasons why an AI system is classified as not high-risk under the procedure outlined in Article 6(3)" (point 7, Annex VIII), is of crucial importance for the MSAs. The information provided in point 6 alone is insufficient for a preliminary evaluation of the rationale behind the application of the filters specified in Article 6.3 of the AI Act and to determine whether to activate the procedure under Article 80 of the AI Act, as well as to establish the priority for doing so. Additionally, the information in point 9 indicating "any Member States in which the AI system has been placed on the market, put into service, or made available in the Union," is also important for assessing the relevance of the AI systems and the potential cross-border issues that may arise. We could be open only to the deletion of the information under point 9 for AI systems that are considered not high-risk, not for all the AI systems.
~~'4. A provider who considers that an AI system referred to in Annex III is not high-risk shall document its assessment before that system is placed on the~~	DE (Drafting suggestions):

Second presidency compromise text	Drafting suggestions and Comments
~~market or put into service. Upon request of national competent authorities, the provider shall provide the documentation of the assessment.';~~	4. A provider who considers that an AI system referred to in Annex III is not high-risk shall document its assessment before that system is placed on the market or put into service**. Such provider shall be subject to the registration obligation set out in Article 49(2).** Upon request of national competent authorities, the provider shall provide the documentation of the assessment. **An easily accessible guidance shall be provided at the database.** DE (Comments): The obligation to register AI systems covered by the exemption under Article 6(3) in the EU database should be maintained. Registration currently constitutes a key instrument for ensuring a minimum level of transparency for the competent market surveillance authorities regarding the use of such systems and for enabling effective supervision. Without registration in the database, MSAs have no clear picture which AI systems are currently in use which potentially are high-risk. It is also questionable whether the change in this obligation effectively lightens the bureaucratic burden, given that regardless of registration in the database the provider continues to be obliged to fulfill an assessment and present it upon request to the competent national authority. It seems to us that registration in the database will usually be a relatively small effort compared to the assessment which must be conducted anyway. We are also currently exploring the potential use of AI for the benefit of an effective and efficient market surveillance which illustrates the benefits of having a database. Nonetheless we see potential of improvement for of Art. 6 (4): The registration procedure should be designed to offer structured and easily understandable guidance to users who want to register an AI system. EE (Comments):

Second presidency compromise text	Drafting suggestions and Comments
	Extend with concrete light-touch safeguards: In principle we agree with removing the obligation to register AI systems used in high-risk areas where the provider has credibly concluded, under Article 6(3), that the system is not high-risk, including cases where the AI is used only for narrow, procedural, or preparatory tasks. However, the current safeguards in the AI Act are not sufficient on their own to prevent overly broad or strategic use of Article 6(3) to avoid compliance obligations. Additional, light-touch safeguards would be needed to ensure consistent interpretation, accountability, and enforceability across Member States. For instance, simplified registration could be used, where only the application and brief description are provided. FR (Drafting suggestions): **'4. A provider who considers that an AI system referred to in Annex III is not high-risk shall document its assessment before that system is placed on the market or put into service. Upon request of national competent authorities, the provider shall provide the documentation of the assessment.';** FR (Comments): France calls for a return to the Commission's initial proposal regarding Article 1(6). The current wording imposes a systematic documentation requirement on providers for all Annex III systems they deem not to be 'high-risk.' This creates a significant and unnecessary administrative burden that contradicts the very essence of the Omnibus initiative. The original intent of this measure was to introduce meaningful simplification: when a system does not pose significant risks, it is

Second presidency compromise text	Drafting suggestions and Comments
	disproportionate to weigh down the market entry process with ex-ante documentation that effectively acts as a compliance burden. Reverting to the initial proposal ensures a high level of protection while providing concrete relief for companies, particularly SMEs and startups. Regulation must remain risk-based; imposing excessive reporting requirements on systems that have been found to pose no threat to safety or fundamental rights stifles innovation.
	DE (Drafting suggestions): Integration of a lex specialis rule by adding a new paragraph 2a in Article 8: **The requirements of Chapter III, Sections 2 and 3, or Chapter IX, Sections 1, 2 and 3, are deemed to be fulfilled as long as these requirements or obligations are addressed in specific provisions with the same objective in the Union harmonisation legislation listed in Annex I, Section A, and the applicable requirements or obligations therein are met by the provider. The respective conformity assessment shall be carried out as part of the procedures laid out under Union harmonisation legislation listed in Annex I, Section A.** Insert new article 9 para 11: **The obligation to carry out risk management measures referred to in paragraph 2 (a) does not apply with regard to risks to fundamental rights that are obviously not directly affected by the intended purpose of the AI system or that are already addressed in the Union harmonisation legislation listed in Annex I, Section A.** DE (Comments):

Second presidency compromise text	Drafting suggestions and Comments
	Our proposal for a lex specialis rule to simplify the interplay, e.g. with the MDR/IVDR has not been taken into account yet. We stress again the importance of that rule for the interplay of differ-ent legislative acts. The AI Act is intended to set fundamental rules for AI systems. These rules are often basic or very general. There are product sectors (e.g. Medical devices) which are already or – in the near future – will be subject to more specific rules & requirements (compared with the AI Act rules) relating to AI-based products. It is critical that **companies applying both horizontal requirements of the AI Act as well as sectoral requirements of Union harmonisation legislation can clearly discern applicable requirements**. It is essential that we provide clarity and avoid unnecessary bureaucracy for our companies. We are currently examining the implications for industrial companies due to recent questions arising from the industry that relate to legal uncertainties. Therefore, a ***lex specialis* rule** is **necessary** to avoid that for the same product multiple rules & requirements are applicable, even where these rules & requirements only differ slightly contextually (e.g. two slightly differing quality management systems). This is why Germany requests to include a *lex specialis* rule by adding a new paragraph 2a in article 8. Moreover, to ensure that **companies are not bogged down by obligations that do not concern risks actually related to their AI systems in practice or that in effect lead to a duplification of efforts**, we propose amendments to the Fundamental Rights Risk Assessment (article 9) and the Quality Management System (art. 17 below). ES (Drafting suggestions): **Article 8, new paragraph 2a**

Second presidency compromise text	Drafting suggestions and Comments
	"Without prejudice to the preceding paragraph, the requirements of Chapter III, Sections 2 and 3 shall also be deemed to be fulfilled where those requirements and obligations are included in the Union harmonisation legislation listed in Annex I, Section A at least at the same level of detail as they are described in this Regulation." ES (Comments): **Spain supports the requests by Germany related to ensure material coherence between the AI Act and Sectoral Legislation (lex specialis rule).** **In the drafting proposal, it must be ensured that, where requirements are incorporated into sectoral legislation, they are only considered fulfilled when they provide the same level of detail as in the AI Regulation.** FR (Drafting suggestions): **Addition:** (6a) In Article 7, paragraph 1 is replaced by the following: 1. **Taking utmost account of the opinion of the Board,** the Commission is empowered to adopt delegated acts in accordance with Article 97 to amend Annex III by adding or modifying use-cases of high-risk AI systems here both of the following conditions are fulfilled: (a) the AI systems are inteded to be used in any of the areas listed in Annexe III; (b) the AI systems pose a risk of harm to health and safety, or an adverse impact on fundamental rights, and that risk is equivalent to, or greater than,

Second presidency compromise text	Drafting suggestions and Comments
	the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III. FR (Comments): The list of high-risk AI systems in Annex III is the cornerstone of the AI Act's scope; any modification to it carries profound implications. Adding or modifying use-cases is a highly sensitive exercise, as it directly affects the level of protection for citizens' fundamental rights, health, and safety, while simultaneously creating substantial compliance obligations and economic costs for the industry. Furthermore, such changes have a direct and significant impact on national regulatory authorities, who are responsible for oversight and enforcement. Given these high stakes, it is essential that the Commission's power to adopt delegated acts be balanced by the technical and operational expertise of the Member States. Requiring the Commission to take **'utmost account of the opinion of the Board'** ensures that any update to Annex III is grounded in the field experience of national regulators and reflects a coordinated Union-wide approach to emerging risks.
(7) Article 10 is amended as follows:	
(a) paragraph 1 is replaced by the following:	
'1. High-risk AI systems which make use of techniques involving the training of AI models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2, 3 and 4 of this Article and in Article 4a(1) whenever such data sets are used.';	
(b) paragraph 5 is deleted;	

Second presidency compromise text	Drafting suggestions and Comments
(c) paragraph 6 is replaced by the following:	
'6. For the development of high-risk AI systems not using techniques involving the training of AI models, paragraphs 2, 3 and 4 of this Article and Article 4a(1) shall apply only to the testing data sets.';	
(8) in Article 11(1), the second subparagraph is replaced by the following:	DE (Comments): See comment Art. 63 IE (Comments): The RED does not provide for submitting simplified technical documentation? This presents difficulties if the an AI provider (e.g is an SME) and is following the RED CAP. Clarification required on 'simplified technical documentation form' and what this entails
'That technical documentation shall be drawn up in such a way as to demonstrate that the high-risk AI system complies with the requirements set out in this Section and to provide national competent authorities and notified bodies with the necessary information in a clear and comprehensive form to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV. SMCs and SMEs, including start-ups, may provide the elements of the technical documentation specified in Annex IV in a simplified manner. To that end, the Commission shall establish a simplified technical documentation form targeted at the needs of SMCs and SMEs, including start-ups. Where an SMC or SME, including a start-up, opts to provide the information required in Annex IV in a simplified	DE (Comments): See comment Art. 63 SE (Drafting suggestions): …To that end, the Commission shall**, within existing tools and resources,** establish a simplified technical documentation form… SE

Second presidency compromise text	Drafting suggestions and Comments
manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment.'; 	(Comments): Budget neutrality should be specified.
	DE (Drafting suggestions): Insert new paragraph 6 in Art. 15 AI Act: **"6. For providers that are financial institutions subject to requirements regarding digital operational resilience under Union financial services law, the obligations set out in paragraphs 1, 3, 4 and 5 shall be deemed to be fulfilled by complying with the rules on digital operational resilience pursuant to the relevant Union financial services law."** Insert the following text at the end of Art. 26 (5): **"For providers that are financial institutions subject to requirements regarding digital operational resilience under Union financial services law, the obligation to report serious incidents to the relevant market surveillance authorities shall be deemed to be fulfilled by complying with the rules on digital operational resilience pursuant to the relevant Union financial services law."** DE (Comments): **Better alignment with existing sectoral legislation** Further regulatory privileges should be considered in areas already governed by sector-specific legislation, following the example of provisions such as Art. 17 (4) or 18 (3) and 19 (2). This approach is very effective in reducing double requirements under multiple legal acts. We propose to identify further examples where the AI Act can make reference to existing sectoral regulation. In particular, there are several EU legal acts which include a extensive and comprehensive framework for cyber risks.

Second presidency compromise text	Drafting suggestions and Comments
	For instance, there is significant overlap between the cybersecurity requirements of the AI Act (Art. 15) and other EU cybersecurity legislation such as the DORA regulation directive. A new paragraph (6) should be added to Art. 15 AIA stating that the cybersecurity requirements under the AI Act are automatically met if the provider complies with sector-specific cybersecurity requirements under DORA. The same applies to risk management requirements under the AI Act (Art. 9) and the respective obligations under DORA. A further example is incident reporting. Deployers of high-risk AI systems must report serious security incidents to the MSA (Art. 26 (5) AIA). However, most companies must already report serious ICT incidents under sectoral laws such as DORA. In particular, it should be clarified in Art. 26 (5) AIA that financial companies have fulfilled their reporting obligation under Art. 26 AIA if they have submitted an incident report in accordance with DORA. ES (Drafting suggestions): **Article 15** ES (Comments): Spain supports the comments of Germany related to avoid overlap between cybersecurity requirements of AI AC and other cybersecurity legislation, p**rovided that the cybersecurity requirements laid down in other specific legislation include at least the same level of detail as Article 15 of the AI Regulation and that the cybersecurity measures are specifically focused on AI systems rather than on traditional software.**
(9) in Article 17, paragraph 2 is replaced by the following:	DE (Comments):

Second presidency compromise text	Drafting suggestions and Comments
	See comment Art. 63
'2. The implementation of the aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation, in particular, if the provider is an SMC or an SME, including a start-up. Providers shall, in any event, respect the degree of rigour and the level of protection required to ensure the compliance of their high-risk AI systems with this Regulation.';	
	DE (Drafting suggestions): **For providers of AI systems according to article 6 paragraph 1 of this Regulation that are subject to the EU Machinery Regulation (EU) 2023/1230, the obligation to put in place a quality management system, with the exception of paragraph 1, points (g), (h) and (i) of this Article, shall be deemed to be fulfilled by complying with the conformity assessment procedure according to Annex IX of Regulation (EU) 2023/1230.** DE (Comments): Moreover, to ensure that **companies are not bogged down by obligations that do not concern risks actually related to their AI systems in practice or that in effect lead to a duplification of efforts**, we propose amendments to the Fundamental Rights Risk Assessment (article 9 see above) and the Quality Management System (article 17).
(10) ~~in~~ Article 28 the following paragraph~~s 8~~ **are**~~is~~ added:	ES (Comments): We support Germany's proposal to give preference to the use of single designation procedures. SE

Second presidency compromise text	Drafting suggestions and Comments
	(Comments): There are already large queues for, and lack of competence at, other notifying bodies, for example during MDR. The current model risks creating bottlenecks in the AI Act as well.
'8. Notifying authorities designated under this Regulation responsible for AI systems covered by the Union harmonisation legislation listed in Section A of Annex I shall ~~be established, organised and operated in such a way that~~ ensures that the conformity assessment body that applies for designation both under this Regulation and the Union harmonisation legislation listed in Section A of Annex I shall be provided with the possibility to submit a single application and undergo a single assessment procedure to be designated under this Regulation and Union harmonisation legislation listed in Section A of Annex I, where the relevant Union harmonisation legislation provides for such single application and single assessment procedure. **To that end, notifying authorities designated under this Regulation and under any other Union harmonisation legislation listed in Section A of Annex I shall cooperate in their assessments.**	DE (Drafting suggestions): '8. Notifying authorities designated under this Regulation responsible for AI systems covered by the Union harmonisation legislation listed in Section A of Annex I shall **be established, organised and operated in such a way that** ensures that the conformity assessment body that applies for designation both under this Regulation and the Union harmonisation legislation listed in Section A of Annex I shall be provided with the possibility to submit a single application and undergo a single assessment procedure to be designated under this Regulation and Union harmonisation legislation listed in Section A of Annex I, ~~where the relevant Union harmonisation legislation provides for such single application and single assessment procedure.~~ ~~To that end, notifying authorities designated under this Regulation and under any other Union harmonisation legislation listed in Section A of Annex I shall cooperate in their assessments.~~ DE (Comments): To make sure that the objective of a single application procedure is reached by the Omnibus proposal, in Art. 1 (10) the following deletions concerning Article 28 para 8 are needed. IE (Comments):

Second presidency compromise text	Drafting suggestions and Comments
	IE supports this subject to clarification from the Commisison on what qualifies as a single application and single assessment procedure to ensure existing framework in Ireland complies SE (Drafting suggestions): 8. Notifying authorities designated under this Regulation responsible for AI systems covered by the Union harmonisation legislation listed in Section A of Annex I shall ~~be established, organised and operated in such a way that~~ ensure~~s~~ that the conformity assessment body that applies for designation both under this Regulation and the Union harmonisation legislation listed in Section A of Annex I shall be provided with the possibility to submit a single application and undergo a single assessment procedure to be designated under this Regulation and Union harmonisation legislation listed in Section A of Annex I~~, where the relevant Union harmonisation legislation provides for such single application and single assessment procedure~~. **To that end, notifying authorities designated under this Regulation and under any other Union harmonisation legislation listed in Section A of Annex I shall cooperate in their assessments.** SE (Comments): Current national notifying authorities propose these changes to facilitate the designation of notified bodies under both the AI Act and sector specific legislation.
The single application and single assessment procedure referred to in this paragraph shall also be made available to notified bodies already designated under the Union harmonisation legislation listed in Section A of	DE (Drafting suggestions):

Second presidency compromise text	Drafting suggestions and Comments
Annex I, when those notified bodies apply for designation under this Regulation, provided that the relevant Union harmonisation legislation provides for such a procedure.	The single application and single assessment procedure referred to in this paragraph shall also be made available to notified bodies already designated under the Union harmonisation legislation listed in Section A of Annex I, when those notified bodies apply for designation under this Regulation~~, provided that the relevant Union harmonisation legislation provides for such a procedure.~~ SE (Drafting suggestions): The single application and single assessment procedure referred to in this paragraph shall also be made available to notified bodies already designated under the Union harmonisation legislation listed in Section A of Annex I, when those notified bodies apply for designation under this Regulation~~, provided that the relevant Union harmonisation legislation provides for such a procedure~~.
A conformity assessment body that is designated under more than one Union harmonisation legislation listed in Section A of Annex I shall have to apply only once to be designated under this Regulation. A designation under this Regulation shall be applicable for all Union harmonisation legislation listed in Section A of Annex I for which the conformity assessment body is designated.	BE (Drafting suggestions): ~~**A conformity assessment body that is designated under more than one Union harmonisation legislation listed in Section A of Annex I shall have to apply only once to be designated under this Regulation. A designation under this Regulation shall be applicable for all Union harmonisation legislation listed in Section A of Annex I for which the conformity assessment body is designated.**~~ BE (Comments): This paragraph is problematic because it seems to assume that if a notified body is already competent under several Union harmonisation legislations listed in Annex I, A, and wishes to become competent for the AI Act in

Second presidency compromise text	Drafting suggestions and Comments
	relation to these legislations, it should be able to do it without having to approach all the relevant sectoral notifying authorities individually, which would each, for their part, ultimately establish the notified body's "AI" scope (i.e., the aggregation of AI sub-scopes into the sectoral scopes). According to our interpretation, this implies the existence of a coordinating/central notifying authority making sure the 'single procedure' is carried out, which will not be the case for all Member States. It refers to the idea of a single procedure for all Union harmonisation legislations together with the AI Act ("all in one"), which is not feasible in practice. DE (Drafting suggestions): ~~A conformity assessment body that is designated under more than one Union harmonisation legislation listed in Section A of Annex I shall have to apply only once to be designated under this Regulation. A designation under this Regulation shall be applicable for all Union harmonisation legislation listed in Section A of Annex I for which the conformity assessment body is designated.~~ IE (Comments): How will this 'apply once' work if the designation/notification relates to differing conformity assessment procedures or modules and the product or products for which that body claims to be competent. For example, if this applies in the RED context, a national NB in respect of Machinery and RED (both are Union harmonisation legislation listed in Section A of Annex I) may be notified in respect of different procedures/modules (e.g. module B under RED and EC type-examination under the Machinery Directive), can the same NB still apply once only for designation/notification under the AI Act?

Second presidency compromise text	Drafting suggestions and Comments
The single application and single assessment procedure shall avoid any unnecessary duplications, build on the existing procedures for designation under the Union harmonisation legislation listed in Section A of Annex I and ensure compliance with the requirements both relating to notified bodies under this Regulation and the relevant Union harmonisation legislation.’;	
‘9. A notifying authority that has been designated under the Union harmonisation legislation listed in Section A of Annex I is also the notifying authority for the application of the single application and single assessment procedure referred to in paragraph 8, unless the Member State designates another notifying authority for this Regulation.’;	BE (Comments): We see some contradictions with Article 29, §2. Indeed, in the case that the “AI Act notifying authority” manages the application, then the application would be submitted to the “AI Act notifying authority” and not to the *‘the notifying authority designated in accordance with that Union harmonisation legislation.’* We propose to keep this paragraph (which can be reworded in simple terms), and to therefore delete the contradicting §2 of Article 29. IE (Comments): This appears to prescribe the same NA in union harmonisation legislation for the purposes of the application of the single application and single assessment procedure pursuant to the AI Act (unless the MS designates otherwise)? If there is no single application and single assessment procedure under the union harmonisation legislation, the NAs can then still be different authorities?
(11) in Article 29, paragraph 4 is replaced by the following:	
‘4. For notified bodies which are designated under any other Union harmonisation legislation, all documents and certificates linked to those	

Second presidency compromise text	Drafting suggestions and Comments
designations may be used to support and expedite their designation procedure under this Regulation, as appropriate.	
Notified bodies, which are designated under any of the Union harmonisation legislation listed in Section A of Annex I and which apply for the single assessment referred to in Article 28(8), shall submit the single application for assessment to the notifying authority designated in accordance with that Union harmonisation legislation.	
The notified body shall update the documentation referred to in paragraphs 2 and 3 of this Article whenever relevant changes occur, in order to enable the authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements laid down in Article 31.’;	
(12) in Article 30, paragraph 2 is replaced by the following:	DE (Drafting suggestions): ~~(12) in Article 30, paragraph 2 is replaced by the following~~ DE (Comments): Furthermore, we ask for the deletion of Article 30 para 2 and Annex XIV establishing the NANDO codes, because the majority of the fully harmonized product regulations use a different procedure for determining NANDO codes, namely determining the NANDO codes outside the relevant regulation.
‘2. Notifying authorities shall notify the Commission and the other Member States, based on the list of codes, categories, and corresponding types of AI systems referred to in Annex XIV, and using the electronic notification tool developed and managed by the Commission, of each conformity assessment body referred to in paragraph 1.	DE (Drafting suggestions): ~~2. Notifying authorities shall notify the Commission and the other Member States, based on the list of codes, categories, and corresponding types of AI~~

Second presidency compromise text	Drafting suggestions and Comments
	~~systems referred to in Annex XIV, and using the electronic notification tool developed and managed by the Commission, of each conformity assessment body referred to in paragraph 1.~~ FR (Drafting suggestions): 2. Notifying authorities shall notify the Commission and the other Member States, based on the list of codes, categories, and corresponding types of AI systems referred to in Annex XIV, and using the electronic notification tool developed and managed by the Commission, of each conformity assessment body referred to in paragraph 1. **Where applicable, cross-referencing to other implementing acts in force allows for a more accurate and simplified notification.** FR (Comments): In order to facilitate the designation under the IDA of bodies already notified under the MDR/IVDR according to software codes, a simplification of the codes in Annex XIV is proposed. This simplification is necessary for a sector subject to a detailed NANDO code granularity.
The Commission is empowered to adopt delegated acts in accordance with Article 97 to amend Annex XIV, in the light of technical progress, advances in knowledge or new scientific evidence by adding to the list of codes, categories, and corresponding types of AI systems a new code, a category or a type of AI system, withdrawing an existing code, category or a type of AI system from that list or moving a code or type of AI system from one category to another.'; DE (Drafting suggestions): ~~The Commission is empowered to adopt delegated acts in accordance with Article 97 to amend Annex XIV, in the light of technical progress, advances in knowledge or new scientific evidence by adding to the list of codes, categories, and corresponding types of AI systems a new code, a category or a type of AI system, withdrawing an existing code, category or a type of AI system from that list or moving a code or type of AI system from one category to another~~.';

Second presidency compromise text	Drafting suggestions and Comments
	FR (Drafting suggestions): The Commission is empowered to adopt delegated acts in accordance with Article 97 to amend Annex XIV, in the light of technical progress, advances in knowledge or new scientific evidence**, taking utmost account of the opinion of the Board,** by adding to the list of codes, categories, and corresponding types of AI systems a new code, a category or a type of AI system, withdrawing an existing code, category or a type of AI system from that list or moving a code or type of AI system from one category to another.'; FR (Comments): The classification of AI systems under Annex XIV carries significant operational weight for both notifying authorities and notified bodies. Any unilateral modification to these codes could disrupt existing notification procedures and create legal uncertainty for national oversight. Therefore, it is essential that the Board is formally consulted to ensure these updates remain aligned with the operational constraints of Member States and the technical reality of the field.
	FR (Drafting suggestions): **Addition**: (13) in Article 43, paragraph 1, after the words "with the requirements set out in Section 2", the following words are added: "and in Article 4a". FR (Comments): Chapter I is not covered by article 43, implying that harmonised standards would not provide presumption of conformity otherwise.

Second presidency compromise text	Drafting suggestions and Comments
(13) in Article 43, paragraph 3 is replaced by the following:	
'For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider of the system shall follow the relevant conformity assessment procedure as required under the relevant Union harmonisation legislation. The requirements set out in Section 2 of this Chapter shall apply to those high-risk AI systems and shall be part of that assessment. Assessment of the quality management system set out in Article 17 and Annex VII shall also apply.	ES (Drafting suggestions): <u>Drafting suggestion 1 (reinstauration of the original wording):</u> For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider of the system shall follow the relevant conformity assessment procedure as required under the relevant Union harmonisation legislation. The requirements set out in Section 2 of this Chapter shall apply to those high-risk AI systems and shall be part of that assessment. P**oints 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of** Annex VII shall also apply. <u>Drafting suggestion 2 (limited to quality system assessment):</u> For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider of the system shall follow the relevant conformity assessment procedure as required under the relevant Union harmonisation legislation. The requirements set out in Section 2 of this Chapter shall apply to those high-risk AI systems and shall be part of that assessment. Assessment of the quality management system set out in Article 17 shall also apply, **as well as points 3 and 5 of Annex VII.** <u>Drafting suggestion 3:</u> For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider of the system shall follow the relevant conformity assessment procedure as required under the relevant Union harmonisation legislation. The requirements set out in Section 2 of

Second presidency compromise text	Drafting suggestions and Comments
	this Chapter shall apply to those high-risk AI systems and shall be part of that assessment. Assessment of the quality management system set out in Article 17 shall also apply, **as well as points 3, 4.3, 4.4., 4.5, the fifth paragraph of point 4.6 and 5 of Annex VII shall also apply.** ES (Comments): **This does not constitute a red line, but it would be highly desirable.** The wording of the proposal gives rise to the interpretation that the application of the entirety of Annex VII is being extended. If the proposal is intended to be limited to the quality system aspects of Annex VII, the wording should be revised. **To that end, it is proposed to reinstate the wording of the original Regulation text (drafting suggestion 1), or to make explicit reference to the specific points related to quality system assessment of Annex VII (drafting suggestion 2).**
For the purposes of that conformity assessment, notified bodies which have been notified under the Union harmonisation legislation listed in Section A of Annex I shall have the power to assess the conformity of high-risk AI systems with the requirements set out in Section 2, provided that the compliance of those notified bodies with the requirements laid down in Article 31(4), (5), (10) and (11) has been assessed in the context of the notification procedure under the relevant Union harmonisation legislation **and as is evidenced through the assessment as part of the existing notification**. Without prejudice to Article 28, such notified bodies which have been notified under the Union harmonisation legislation in Section A of Annex I, shall apply for	DE (Drafting suggestions): For the purposes of that conformity assessment, notified bodies which have been notified under the Union harmonisation legislation listed in Section A of Annex I shall have the power to assess the conformity of high-risk AI systems with the requirements set out in Section 2, provided that the compliance of those notified bodies with the requirements laid down in Article 31(4), (5), (10) and (11) has been assessed in the context of the notification procedure under the relevant Union harmonisation legislation. ~~Without prejudice to Article 28, such notified bodies which have been~~

Second presidency compromise text	Drafting suggestions and Comments
designation in accordance with Section 4 at the latest [18 months from the entry into application of this Regulation].	~~notified under the Union harmonisation legislation in Section A of Annex I, shall apply for designation in accordance with Section 4 at the latest [18 months from the entry into application of this Regulation/.~~ DE (Comments): We also question the deadline of Art. 1 (13) para 2 of 18 months. What happens if there are new bodies that are willing to apply after the 18 month timeline? Art. 43 (3) of the AI Act does not describe any interim / transitional phase why we ask for the deletion of the limitation by a deadline in Article 43 para 3 sub-para 2: ES (Comments): **No objections are raised to this proposal.**
Where Union harmonisation legislation listed in Section A of Annex I provides the product manufacturer with an option to opt out from a third-party conformity assessment, provided that that manufacturer has applied harmonised standards covering all the relevant requirements, that manufacturer may use that option only if it has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering all requirements set out in Section 2 of this Chapter.	IE (Comments): According to the Commission "EU AI Act Compliance Checker": "*Third-party conformity assessment* *Is your product, or the product in which your AI system is intended to be used as a safety component is required to undergo a third-party conformity assessment under the sectoral law? Note that this also includes products for which you can opt-out of a third-party conformity assessment when harmonised standards are fully applied*". As such, it appears on the basis of the '*EU AI Act Compliance Checker'*, the use of the opt out option is still considered a "*procedural mechanism*" that does not affect the qualification of a radio equipment device as a HRAI system.

Second presidency compromise text	Drafting suggestions and Comments
	However, aside from the reference in the "EU AI Act Compliance Checker", no other clarification is provided in either the AI Act or Omnibus as to whether the use of the opt out option is still considered a "*procedural mechanism*". ComReg previously highlighted to the EU AI Office, the impact this has on the market sizing of RED products classed as high-risk. Many operators seek to rely on harmonised standards to 'opt out' from third party conformity assessment. Suggest to inlcude clarification in the Omnibus as to whether the use of the opt out option is still considered a "*procedural mechanism*" that does not affect the qualification of a radio equipment device as a HRAI system
Where a high-risk AI system is both covered by the Union harmonisation legislation listed in Section A of Annex I and it falls within one of the categories listed in Annex III, the provider of the system shall follow the relevant conformity assessment procedure as required under the relevant Union harmonisation legislation listed in Section A of Annex I.';	IE (Comments): See ComReg submission to EU AI Office on 24.12.25 where we made the below point. This section acknowledges that a HRAI system can be covered in both Annex I and Annex III. However, aside from specifying the appropriate CAP to be followed, the AI Act (or Omnibus) does not provide any clarity as to whether operators can avoid duplication of obligations between Annex I and Annex III. Leads to uncertainty for appropriate competent authorities also.
(14) ~~in Article 49, paragraph 2 is deleted;~~	FR (Drafting suggestions): (14) in Article 49, paragraph 2 is deleted; FR

Second presidency compromise text	Drafting suggestions and Comments
	(Comments): France calls for a return to the Commission's initial proposal regarding Article 1(14). The current wording imposes a systematic documentation requirement on providers for all Annex III systems they deem not to be 'high-risk.' This creates a significant and unnecessary administrative burden that contradicts the very essence of the Omnibus initiative. The original intent of this measure was to introduce meaningful simplification: when a system does not pose significant risks, it is disproportionate to weigh down the market entry process with ex-ante documentation that effectively acts as a compliance burden. Reverting to the initial proposal ensures a high level of protection while providing concrete relief for companies, particularly SMEs and startups. Regulation must remain risk-based; imposing excessive reporting requirements on systems that have been found to pose no threat to safety or fundamental rights stifles innovation. SE (Drafting suggestions): in Article 49, paragraph 2 is deleted; SE (Comments): SE proposes reverting to the original Commission proposal in Article 1(14) regarding the removal of Article 49(2). SE further considers that it would be preferable to entirely remove the documentation requirement for AI systems that, following an assessment pursuant to Article 6(3) of the AI Act, have been determined not to qualify as high-risk systems.

Second presidency compromise text	Drafting suggestions and Comments
(15) in Article 50, paragraph 7 is replaced by the following:	
'7. The AI Office shall encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the obligations regarding the detection, marking and labelling of artificially generated or manipulated content. The Commission **and the Board** may assess whether adherence to those codes of practice is adequate to ensure compliance with the obligation laid down in paragraph 2 **of this Article**, in accordance with the procedure laid down in Article 56(6), ~~first subparagraph~~. If it deems the code is not adequate, the Commission may adopt an implementing act specifying common rules for the implementation of those obligations in accordance with the examination procedure laid down in Article 98(2).';	EE (Drafting suggestions): '7. The AI Office shall encourage and facilitate the drawing up of codes of practice at Union level **by the stakeholders** to facilitate the effective implementation of the obligations regarding the detection, marking and labelling of artificially generated or manipulated content. The Commission, **including the AI Board,** may assess whether adherence to those codes of practice is adequate to ensure compliance with the obligation laid down in paragraph 2 of this Article, in accordance with the procedure laid down in Article 56(6)~~, first subparagraph~~. If it deems the code **of practice** is not adequate, the Commission may adopt an implementing act specifying common rules for the implementation of those obligations in accordance with the examination procedure laid down in Article 98(2).'; EE (Comments): If the Commission is not responsible for drawing up the codes, then who is? AI Board is part of the Commission structure, therefore emphasising the Board separately from the Commission will give a wrong impression. FR (Drafting suggestions): '7. The AI Office shall encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the obligations regarding the detection, marking and labelling of artificially generated or manipulated content. The Commission may **adopt implementing acts to approve those codes of practice** ~~**and the Board** may assess whether adherence to those codes of practice is adequate to ensure~~

Second presidency compromise text	Drafting suggestions and Comments
	~~compliance with the obligation laid down in paragraph 2~~ **~~of this Article~~**, in accordance with the procedure laid down in Article 56(6), ~~first subparagraph~~. If it deems the code is not adequate, the Commission may adopt an implementing act specifying common rules for the implementation of those obligations in accordance with the examination procedure laid down in Article 98(2).'; FR (Comments): France expresses a strong reservation regarding the proposed removal of the explicit approval of codes of practice through implementing acts. These codes of practice will be a cornerstone of the technical response to information manipulation, a top strategic priority for EU Governments with significant impact on public discourse and democratic resilience. The involvement of the AI Board does not offer the same level of legal certainty and institutional oversight as the comitology process. The adoption of implementing acts is the only mechanism that guarantees Member States' effective control over measures with such far-reaching consequences. Forfeiting this procedure in favor of a mere assessment of 'adequacy' by the Board would bypass the necessary scrutiny of national experts.
	DE (Comments): **Clarification of important definitions / concepts** Further clarification of important definitions/concepts in the legal text of the AI Act, for example that an entity does not become a provider of an AI model merely by making it available to other entities within the same corporate group (in the definition of "provider" in Article 3(3) or "placing on the market" in Article 3(9) AI Act). It must be ensured, however, that the

Second presidency compromise text	Drafting suggestions and Comments
	obligations for providers are fulfilled once an AI model is placed on the market (i.e. outside of the corporate group). A clear definition of when a company becomes a provider should be established (e.g. in Article 53 AI Act). A clear definition of when a company becomes a provider should be established with-in the AI Act. This definition should clarify, that a company purchasing and fine-tuning a gpAI model (or having it fine-tuned) and subsequently using it in AI systems becomes a provider of the AI model, if the training compute used for the modification is greater than a third of the training compute of the original model. The question whether a company purchasing and fine-tuning a gpAI model is a provider of the AI model is without prejudice to applicable/existing copyright law. FR (Drafting suggestions): **Addition:** **(15a) in Article 51, the second paragraph is replace by the following:** **2. A general-purpose AI model shall be presumed to have high impact capabilities pursuant to paragraph 1, point (a), when the cumulative amount of computation used for its training measured in floating point operations is greater than 10^26.** FR (Comments): The current threshold does not reflect the current state of the art. Maintaining it would lead to imposing heavy obligations on models that do no present a proven systemic risk. Raising the threshold would allow to target more effectively models whose computing power justifies increased vigilance, while preserving innovation.

Second presidency compromise text	Drafting suggestions and Comments
(16) in Article 56~~(6)~~, **paragraph 6**~~the first subparagraph~~ is replaced by the following:	FR (Drafting suggestions): ~~(16) in Article 56(6), paragraph 6the first subparagraph is replaced by the following:~~ FR (Comments): DELETION
'6. The Commission and the Board shall regularly monitor and evaluate the achievement of the objectives of the codes of practice by the participants and their contribution to the proper application of this Regulation. The Commission, taking utmost account of the opinion of the Board, shall assess whether the codes of practice cover the obligations provided for in Articles 53 and 55, and shall regularly monitor and evaluate the achievement of their objectives. The Commission shall publish its assessment of the adequacy of the codes of practice.';	FR (Drafting suggestions): ~~6. The Commission and the Board shall regularly monitor and evaluate the achievement of the objectives of the codes of practice by the participants and their contribution to the proper application of this Regulation. The Commission, taking utmost account of the opinion of the Board, shall assess whether the codes of practice cover the obligations provided for in Articles 53 and 55, and shall regularly monitor and evaluate the achievement of their objectives. The Commission shall publish its assessment of the adequacy of the codes of practice.'~~ FR (Comments): DELETION France expresses a strong reservation regarding the proposed removal of the explicit approval of codes of practice through implementing acts. These codes of practice will be a cornerstone of AI society, with large impact in various fields.

Second presidency compromise text	Drafting suggestions and Comments
	The involvement of the AI Board does not offer the same level of legal certainty and institutional oversight as the comitology process. The adoption of implementing acts is the only mechanism that guarantees Member States' effective control over measures with such far-reaching consequences. Forfeiting this procedure in favor of a mere assessment of 'adequacy' by the Board would bypass the necessary scrutiny of national experts.
(17) Article 57 is amended as follows:	ES (Comments): **No objections are raised to this proposal.** HU (Drafting suggestions): paragraph 1. is amended as follows: 1. Member States shall ensure that their competent authorities establish at least one AI regulatory sandbox at national level, which shall be operational by **2 December 2027.**. That sandbox may also be established jointly with the competent authorities of other Member States. The Commission may provide technical support, advice and tools for the establishment and operation of AI regulatory sandboxes. HU (Comments): MS obligation on establising AI Regilatory sandboxes aligned to the (first) application date of High Risk AI Systems (see our comments to Art. 113 for detailed justification) IE (Comments):

Second presidency compromise text	Drafting suggestions and Comments
	Where regulatory sandboxes involve the processing of personal data, has there been clarification of the interaction between the AI Office and data protection authorities? The proposal does provide for a role for the EDPS but this only applies in certain (specified) circumstances. IE also notes the new proposals in relation to "real-world testing" (in other words, testing outside of the regulatory sandbox). In relation to "real-world testing", while it appears that safeguards are set out in the operative provision (Article 1(20)), there does not appear to be any (or sufficient) reference to safeguards in the recitals. Testing in "real-world" conditions would (obviously) give rise to different considerations and require additional safeguards in place than regulatory sandboxes. In this respect clarity would be welcome as to how the implementing acts per AI Act Article 58(1) will consider how data protection matters which may arise will be handled?
(-a) paragraph 3 is replaced by:	
'3. The European Data Protection Supervisor may also establish an AI regulatory sandbox for Union institutions, bodies, offices and agencies. For this purpose references to national competent authorities in this Chapter shall be construed as references to the European Data Protection Supervisor .'	PT (Comments): Portugal requests clarification regarding the provision stating that the European Data Protection Supervisor may establish an AI regulatory sandbox. In particular, it would be important to clarify whether the substitution of national competent authorities by the EDPS is intended to apply exclusively in relation to the supervision of Union institutions, bodies, offices and agencies acting as providers or deployers of AI systems, and whether the EDPS would exercise the full range of powers attributed to national competent authorities under this Chapter or only those strictly necessary for the operation of the sandbox. Further clarification would also be welcome on how this mandate interacts with the competences of the EDPS under Regulation (EU) 2018/1725 and

Second presidency compromise text	Drafting suggestions and Comments
	how coordination with the AI Intelligence Board would be ensured. Greater clarification in this respect would enhance legal certainty and preserve institutional coherence within the Union supervisory framework.
(a) the following paragraph ~~3a~~ is inserted:	
'**3a.** The AI Office may also establish an AI regulatory sandbox at Union level for AI systems covered by Article 75(1)**. For this purpose references to national competent authorities in this Chapter shall be construed as references to the AI Office~~, and may exercise the roles and tasks of national competent authorities in accordance with this Chapter~~**. Such an AI regulatory sandbox shall be implemented in close cooperation with relevant competent authorities, in particular when **compliance with** Union legislation other than this Regulation is supervised in the AI regulatory sandbox, and shall provide priority access to **SMCs and** SMEs**, including start-ups**.';	SE (Drafting suggestions): […] and shall provide priority access to SMCs and SMEs, including start-ups, **and shall do so within existing resources and without additional budgetary implications.** SE (Comments): Budget neutrality needs to be specified.
3b. The establishment of a Union level AI regulatory sandbox by the AI Office shall be without prejudice to the competences of Member States to establish and supervise AI regulatory sandboxes for AI systems under their supervision.';	IT (Drafting suggestions): **The establishment of a Union level AI regulatory sandbox by the AI Office shall be without prejudice to the competences of Member States to establish and supervise AI regulatory sandboxes for AI systems under their supervision.';** **It being understood that testing of AI systems under Article 75 shall be performed only after the EU sandbox becomes operational.** PT (Comments): Portugal requests clarification regarding the governance implications of the provision stating that the establishment of a Union-level AI regulatory

Second presidency compromise text	Drafting suggestions and Comments
	sandbox by the AI Office shall be without prejudice to the competences of Member States to establish and supervise AI regulatory sandboxes for AI systems under their supervision. In particular, Portugal asks for further clarification of supervisory responsibilities between the AI Office and national competent authorities, especially in cases involving cross-border AI systems or providers operating in multiple Member States. Clarification would also be welcome on whether participation in a Union-level sandbox may affect or pre-empt national supervisory powers, and how consistency of outcomes, supervisory approaches and risk mitigation measures will be ensured across the Union. Greater detail on these governance aspects would enhance legal certainty and help avoid overlaps, regulatory fragmentation or conflicting supervisory decisions. SK (Comments): We support the proposal of clarification concerning the competences of the Member States with regard to the establishment of AI regulatory sandboxes for AI systems under their supervision.
(b) paragraph 5 is replaced by the following:	
'5. AI regulatory sandboxes established under this Article shall provide for a controlled environment that fosters innovation and facilitates the development, training, testing and validation of innovative AI systems for a limited time before their being placed on the market or put into service pursuant to a specific sandbox plan agreed between the providers or prospective providers and the competent authority, ensuring that appropriate safeguards are in place. Such sandboxes may include testing in real world conditions supervised therein. When applicable, the sandbox plan shall incorporate in a single document the real-world testing plan.';	SE (Drafting suggestions): …When applicable, the sandbox plan shall incorporate in a single document the real-world testing plan, **ensuring that appropriate safeguards are in place, and without requiring the establishment of new administrative structures or additional budgetary resources.** SE (Comments):

Second presidency compromise text	Drafting suggestions and Comments
	Budget neutrality needs to be specified.
(c) paragraph 9, point (e) is replaced by the following:	
‘(e) facilitating and accelerating access to the Union market for AI systems, in particular when provided by SMCs and SMEs, including start-ups.’;	
(d) ~~paragraph 13 is replaced by the following:~~	
~~’13. The AI regulatory sandboxes shall be designed and implemented in such a way that they facilitate cross-border cooperation between national competent authorities.’;~~	DK (Comments): We are still supportive of the Presidency’s removal of the requirement for Member States on cross-border cooperation between sandboxes as we believe that this should remain voluntary and limited to areas of added-value for the participating Member States and providers.
(e) paragraph 14 is replaced by the following:	
’14. National competent authorities**, the EDPS and the AI Office** shall coordinate their activities and cooperate within the framework of the Board. They ~~shall~~ **may** support the joint establishment and operation of AI regulatory sandboxes, including in different sectors.’;	DE (Comments): Regarding the proposal of cross-border cooperation, we see no need to stipulate an obligation by law EE (Drafting suggestions): **Where appropriate,** national competent authorities, the EDPS and the AI Office shall coordinate their activities and cooperate within the framework of the Board. They may support the joint establishment and operation of AI regulatory sandboxes, including in different sectors.” EE

Second presidency compromise text	Drafting suggestions and Comments
	(Comments): Please clarify what is meant here with the framework of the Board.
(18) Article 58, paragraph 1, is replaced by the following:	
'1. In order to avoid fragmentation across the Union, the Commission shall adopt implementing acts specifying the detailed arrangements for the establishment, development, implementation, operation, governance, and supervision of the AI regulatory sandboxes. The implementing acts shall include common principles on the following issues:	SE (Drafting suggestions): In order to avoid fragmentation across the Union, the Commission shall**,** **where necessary and within existing resources,** adopt implementing acts specifying the detailed arrangements for the establishment, development, implementation, operation, governance, and supervision of the AI regulatory sandboxes. SE (Comments): Budget neutrality specified.
(a) eligibility and selection criteria for participation in the AI regulatory sandbox;	
(b) procedures for the application, participation, monitoring, exiting from and termination of the AI regulatory sandbox, including the sandbox plan and the exit report;	
(c) the terms and conditions applicable to the participants;	
(d) the detailed rules applicable to the governance of AI regulatory sandboxes covered under Article 57, including as regards ~~the exercise of the tasks of the competent authorities and~~ the coordination and cooperation at national and **Union**~~EU~~ level.';	

Second presidency compromise text	Drafting suggestions and Comments
(19) Article 60 is amended as follows:	
(a) in paragraph 1, the first subparagraph is replaced by the following:	
'Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of high-risk AI systems listed in Annex III or covered by Union harmonisation legislation listed in Section A of Annex I, in accordance with this Article and the real-world testing plan referred to in this Article, without prejudice to the prohibitions under Article 5.';	SE (Drafting suggestions): … without prejudice to the prohibitions under Article 5**, and with all costs related to such testing borne by the providers or prospective providers.** SE (Comments): SE is supportive of the extension of the scope for real-world testing, provided that sufficient flexibility is maintained to allow for adaptations based on national circumstances. SE also considers it important that clear guidlines are established for each project, comparable to those applicable to regulatory sandboxes, and that the relevant national authorities are duly involved in the development and implementation of such guidlines.
(b) paragraph 2 is replaced by the following:	
'2. Providers or prospective providers may conduct testing of high-risk AI systems referred to in Annex III or covered by Union harmonisation legislation listed in Section A of Annex I in real world conditions at any time before the placing on the market or the putting into service of the AI system on their own or in partnership with one or more deployers or prospective deployers.';	DE (Drafting suggestions): 6. In accordance with Article ~~75~~**74**, Member States shall confer on their market surveillance authorities the powers of requiring providers and prospective providers to provide information, of carrying out unannounced remote or on-site inspections, and of performing checks on the conduct of the testing in real world conditions and the related high-risk AI systems. Market surveillance

Second presidency compromise text	Drafting suggestions and Comments
	authorities shall use those powers to ensure the safe development of testing in real world conditions. DE (Comments): Presumably incorrect reference to Article 75: Article 60(6) states "In accordance with Article 75, Member States shall confer on their market surveillance authorities the powers of requiring providers and prospective providers to provide information, of carrying out…". However, Article 75 concerns "Mutual assistance, market surveillance and control of general-purpose AI systems". It would seem more logical to refer to Article 74, which gives the market surveillance authority the necessary powers w.r.t. Article 60(6) (including the power to request information and documentation from providers or get remote access, see Article 74(12)). SE (Drafting suggestions): on their own or in partnership with one or more deployers or prospective deployers**, and with all costs related to such testing borne by the providers or prospective providers.** SE (Comments): Budget neutrality specified.
(20) the following Article 60a is inserted:	
'*Article 60a*	

Second presidency compromise text	Drafting suggestions and Comments
Testing of high-risk AI systems covered by Union harmonisation legislation listed in Section B of Annex I in real-world conditions outside AI regulatory sandboxes	
1. Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of AI enabled products covered by Union harmonisation legislation listed in Section B of Annex I, **with a view to ensuring those systems' conformity with the sectoral provisions that correspond to Articles 9 to 15 of this Regulation,** in accordance with this Article and ~~a voluntary real-world testing agreement, without prejudice to the prohibitions under~~ **with the national frameworks implementing this** Article ~~5.~~.	DE (Comments): In general, we support the extension of real world testing to Annex I but we also see some questions regarding the different scope of application of the AI Act of Annex IA und Annex IB and the interplay with sectorial legislation. ES (Comments): **No objections are raised to this proposal.** MT (Drafting suggestions): Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of AI enabled products covered by Union harmonisation legislation listed in Section B of Annex I, **with a view to ensuring those systems' conformity with the sectoral provisions that correspond to Articles ~~9~~ 8 to 15 of this Regulation,** in accordance with this Article and ~~a voluntary real-world testing agreement, without prejudice to the prohibitions under~~ **with the national frameworks implementing this** Article ~~5.~~. MT (Comments):

Second presidency compromise text	Drafting suggestions and Comments
	To ensure legal coherence and accurately reflect the intent of the compromise, it is proposed to align the wording of Article 60a with Recital 11a by referring to compliance with Articles 8–15 of the AI Act, rather than Articles 9–15 alone. While Article 8 partially addresses systems listed in Annex I, Section A, it also plays an overarching role by establishing that high-risk AI systems must comply with the requirements laid down in Section 2 as a whole, taking into account their intended purpose and the state of the art, and by explicitly linking compliance to the risk management system under Article 9. The inclusion of Article 8 in Recital 11a confirms the legislator's intention to subject real-world testing of high-risk AI systems under Annex I, Section B to the full compliance framework of Section 2. Aligning the operative provision accordingly avoids interpretative ambiguity and ensures consistency between the Recital and the binding text.
~~2. The voluntary real-world testing agreement referred to in paragraph 1 shall be concluded in writing between interested Member States and the Commission. It shall set the requirements for the testing of those AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex I in real-world conditions.~~	
2a. ~~Member States **that are party to the voluntary real-world testing agreement**, the Commission,~~ **Member States which choose to permit testing as referred to in paragraph 1 shall, individually or jointly, implement this Article by laying down frameworks for real-world testing. These frameworks shall lay down the detailed conditions under which that testing may take place, as well as the requirements, governance and accountability arrangements necessary for that implementation.**	
Member States shall notify the Commission of any draft framework measures in good time before their adoption. The Commission may	

Second presidency compromise text	Drafting suggestions and Comments
decide, by means of implementing acts, whether the draft framework measures are appropriate in light of the applicable Union law. In the absence of a Commission decision within two months of their notification, the draft framework shall be considered approved.	
3. Member States that have adopted framework measures shall ensure that the relevant market surveillance authorities and public authorities responsible for the management and operation of infrastructure and products covered by Union harmonisation legislation listed in Section B of Annex I ~~shall~~ cooperate closely with each other and in good faith, and ~~shall~~ remove any practical obstacles, including on procedural rules providing access to physical public infrastructure, where this is necessary, to successfully implement ~~the voluntary real-world testing agreement~~ **those framework measures** and test AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex I.	
4. ~~The signatories of the voluntary real-world testing agreement, shall specify conditions of the testing in real world conditions and establish governance and accountability arrangements and detailed~~ **Testing as referred to in the first paragraph, as well as the national measures implementing this Article, shall respect the following essential** elements ~~of the~~**:**	
(a) Articles 60(2), (3), (4)(d)-(j) and (5)-(9) apply, save that any reference to market surveillance authorities shall be read as a reference to the national competent authority or appropriate authority;	
(b) A real-world testing plan ~~for AI systems covered by~~ **shall be agreed between the provider or prospective provider and the national competent authority or appropriate authority;**	PT (Comments): Portugal requests clarification regarding the requirement in which authority is to be considered the "appropriate authority" in situations where multiple

Second presidency compromise text	Drafting suggestions and Comments
	authorities may have sectoral or functional competence, and how this provision interacts with the designation of competent authorities.
(c) Both the design of the framework and the individual real-world testing plans shall ensure that any risk of harm to health, safety or fundamental rights of natural persons is minimised.	
4a. Applicable Union and national law, including the Union harmonisation legislation listed in Section B of Annex I**, shall apply in full to the testing referred to in paragraph 1. In particular, that testing shall comply with any applicable provisions of that legislation regarding the performance of tests. However, in case of a conflict between that Union harmonisation legislation and the requirements laid down in this Article, this Article shall prevail to the extent necessary to enable the testing referred to in paragraph 1.**	
~~5. Article 60(2), (5) and (9) shall apply.';~~	
(21) Article 63(1) is replaced by the following:	DE (Comments): We welcome the extension of the scope of application of Article 63(1) AI Act to SME and start-ups. We are currently reviewing the other provisions more closely. E.g. Art. 17 para 2 in its actual version already foresees a proportionality of the obligation corresponding to the provider's size. We therefore have to see whether there is an added value by explicitly mentioning SMEs. We are generally open to extend some of the regulatory privileges for SMEs also to SMCs. However, we still need to assess if the extension to SMCs is appropriate for each of the provisions.

Second presidency compromise text	Drafting suggestions and Comments
'1. SMEs, including start-ups, may comply with certain elements of the quality management system required by Article 17 in a simplified manner**, provided that they do not have partner enterprises or linked enterprises within the meaning of Recommendation 2003/361/EC**. For that purpose, the Commission shall develop guidelines on the elements of the quality management system which may be complied with in a simplified manner considering the needs of SMEs, without affecting the level of protection or the need for compliance with the requirements in respect of high-risk AI systems.';	ES (Comments): **No objections are raised to this proposal.**
(22) Article 69 is amended as follows:	
(a) paragraph 2 is replaced by the following:	
'2. The Member States may be required to pay fees for the advice and support provided by the experts at a rate equivalent to the remuneration fees applicable to the Commission pursuant to the implementing act referred to in Article 68(1).';	
(b) ~~paragraph 3 is deleted.~~	
(23) in Article 70, paragraph 8 is replaced by the following:	
'8. National competent authorities may provide guidance and advice on the implementation of this Regulation, in particular to SMCs and SMEs, including start-ups, taking into account the guidance and advice of the Board and the Commission, as appropriate. Whenever national competent authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union law, the national competent authorities under that Union law shall be consulted, as appropriate.';	IT (Drafting suggestions): 8. National competent authorities may provide guidance ~~and advice~~ on the implementation of this Regulation, in particular to SMCs and SMEs, including start-ups, taking into account the guidance and advice of the Board and the Commission, as appropriate. Whenever national competent authorities intend to provide guidance and advice with regard to an AI

Second presidency compromise text	Drafting suggestions and Comments
	system in areas covered by other Union law, the national competent authorities under that Union law shall be consulted, as appropriate.'; IT (Comments): We propose to remove the authority to provide "advice" on implementing the AI Act, due to the unclear nature of this new responsibility and its potential legal implications.
(24) in Article 72, paragraph 3 is replaced by the following:	
'3. The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt guidance on the post-market monitoring plan **by 2 December 2027**.';	AT (Drafting suggestions): 3. The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt guidance on the post-market monitoring plan by 2 December 2027 **after taking into utmost account the opinion of the AI Board, and shall update that guidance when necessary or at the request of the AI Board**. AT (Comments): AT: The market surveillance authorities must be involved in setting out the criteria for post-market monitoring if this guidance should provide any value to providers. As the comparative advantage of guidance in relation to an implementing act is its flexibility for future adaptation, the AI Board should be able to request updates in order to align the guidance with the state of the art. DK (Drafting suggestions):

Second presidency compromise text	Drafting suggestions and Comments
	'3. The post-market monitoring system shall be based on a post-market monitoring plan. The post market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt guidance on the post market monitoring plan **by 2 June 2027.**'; DK (Comments): In our opinion, relevant guidance should be available at least 6 months before the entry into application as foreseen in the original Act. Therefore, we find it necessary to amend 1(24) so that the guidance on the post-market monitoring plan are to be finalised by 2 June 2027. ES (Comments): **No objections are raised to this proposal.** FR (Drafting suggestions): '3. The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission, **taking utmost account of the opinion of the Board,** shall adopt guidance on the post-market monitoring plan **by 2 December 2027**.' FR (Comments): The AI Board should be closely involved in the review of the guidelines, as post-market monitoring requirements could impose significant operational burdens, particularly on SMEs and startups. In the interest of administrative simplification, the guidelines must ensure that compliance requirements remain proportionate to their actual safety benefits. MT

Second presidency compromise text	Drafting suggestions and Comments
	(Drafting suggestions): 3. The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt guidance on the post-market monitoring plan by 2 ~~December~~**June** 2027.'; MT (Comments): The deadline for the guidance document on the post-market monitoring plan aligns with the date specified in the current compromise text under Article 1(31) for the implementation of requirements for AI systems classified as high-risk, as per Article 6(2) and Annex III. Given that post-market monitoring is a mandatory requirement for high-risk AI systems, the plan's requirement will become effective simultaneously with the guidance document's deadline on how to prepare it. This scenario might lead to operators lacking sufficient legal certainty or adequate time to establish their post-market monitoring systems properly, potentially resulting in non-compliance with the Regulation. Therefore, we propose amending the deadline for the post-market monitoring plan from 2 December 2027 to **2 June 2027**. This change would give providers time to set up their post-market monitoring systems in accordance with the Regulation. This proposal also aligns with the current AI Act's deadline of 2 February 2026, which is six months prior to the date when high-risk requirements are currently set to apply (2 August 2026). SI (Drafting suggestions):

Second presidency compromise text	Drafting suggestions and Comments
	The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt guidance on the post-market monitoring plan **by 2 ~~December~~ June 2027** SI (Comments): We suggest shortening the deadline for the Commission to adopt guidance on the post-market monitoring plan, so that the relevant guidance is available well in advance of the application of Chapter III, Sections 1, 2 and 3, as amended by Article 1(31) of the Digital Omnibus on AI. his would allow providers to prepare compliant technical documentation and operational post-market monitoring arrangements in a timely manner, thus supporting the effective implementation of the AI Act.
	DE (Comments): **Information exchange between ECB, MSAs and financial supervisory authorities** Against the backdrop of Article 74 (6) and (7) AI Act, it is important to ensure an efficient flow of information between MSAs and the different financial supervisory authorities (both ECB and all national financial supervisory authorities) where this is necessary for carrying out market surveillance and financial supervisory duties. In particular, it should be analysed in how far information collected by MSAs must be shared with financial supervisory authorities
(25) Article 75 is amended as follows:	FR (Comments):

Second presidency compromise text	Drafting suggestions and Comments
	France is still assessing the modification and has a general scrutiny reserve on article 75, 75a, 75b, 75c, 75d, and 75e. NL (Comments): As previously emphasized we foresee a number of potential challenges. In case the most recent compromise text remains in effect, we will be faced with the following: 1. The AI Office will exercise extensive oversight over providers and deployers. In some cases lacking the expertise in the specific domain concerned. This could impose unnecessary burdens on providers and deployers. This could lead to an infringement on national competences. For example when government organizations, law enforcement or the judiciary deploy AI-systems based on GPAI-models, this could lead to an onsite investigation by the AI Office on national premises. Lastly, this may potentially put a large number of AI-systems deployed in local or national contexts in scope of the AI Office's exclusive competence. 2. When the AI Office decides not to supervise a particular case, a regulatory gap may emerge. National supervisory authorities would be unable to intervene, even if they suspect non compliance. 3. Furthermore, we anticipate that this challenge will only be larger. As it becomes increasingly easy for smaller organizations to develop General Purpose AI (GPAI) models—a trend that aligns with current expectations—the remit of exclusive oversight by the AI Office is likely to expand. To prevent this we propose to limit the supervisory competence of the AI Office to the obligations for the provider. As we foresee that the aforementioned will especially have an impact on deployers, we want at a minimum to exclude this. Additionally we would suggest to exclude the AI-systems in Annex-III, points 2, 5a, 6, 7 and 8, as well as 1 as far as concerned law enforcement and the independence of the judiciary, since we

Second presidency compromise text	Drafting suggestions and Comments
	suspect that these issues could also arise in the context of provider obligations. We would like to exclude the aforementioned domains, as we foresee challenges with the exclusive supervisory competence with respect to infringement of exclusive national competences. PL (Comments): **The second priority for Poland.** Of particular importance to Poland is the proposed amendment to Article 75, which significantly expands the European Commission's powers over Member State supervisory authorities. Recognizing the technical and organizational advantages of this solution, Poland highlights a number of significant issues related to the potential entry into force of the provision in its new proposed wording. We emphasize the need for the European Commission to uphold the principles of subsidiarity and proportionality in this area. Due to the nature of Regulation 2024/1689, this must be applied in accordance with its provisions, among others, public security and the protection of fundamental rights. If the current trend of concentration of the GPAI model provider sector continues, this could result in a de facto transfer of most supervisory functions in the AI area from the national to the European level. The phrase "that model and that system are developed by the same provider" also appears problematic, as it could lead to a false separation of model providers from system providers in business practice (e.g., by establishing separate, but de facto fully dependent legal entities) or other formal and legal means of avoiding oversight. It would be necessary to clearly indicate in the text of the provision that recognition of the relationship between the model and system provider is functional, not merely formal. An important issue remains the issue of oversight – through access to models, systems, and data – which the European Commission would de

Second presidency compromise text	Drafting suggestions and Comments
	facto exercise over many public institutions using AI tools, particularly in areas beyond the scope of single market regulations. Access to data from public institutions using AI models and systems, including the personal data of users, employees and citizens subjected to AI systems, could lead to de facto access to vast datasets containing personal data, including sensitive personal data, of millions of users in Member States. Therefore, for the adoption of the proposed provision (aimed at ensuring effective European Commission oversight of GPAI model providers), Poland believes it would be necessary to introduce a detailed scope of oversight that would prevent, among other things, de-anonymization or identification of individuals whose personal data are contained in the database in the case of public institutions. The relationship between the proposed regulations and the European cybersecurity system requires separate consideration. The AI Authority's supervisory authority over GPAI models and related systems (introduced by the proposed Article 75) should ensure coordination with both EU and national cybersecurity authorities, bodies established under Regulation 2024/1689, and other European security regulations. At the same time, the Authority will need to have adequate technical resources (including those to ensure data security and confidentiality) and human resources to assess and respond to incidents in GPAI systems with the same effectiveness as specialized agencies or national entities. Incident response and cyberthreat response regulations and procedures must be integrated across various European legal acts to ensure the coherence of the cybersecurity system not only at the European level but also across individual Member States. AI systems or those using AI within a cybersecurity system are another element whose use, both by response teams and attackers, should be prepared for and taken into account in the cyber threat defense system, but in the context of the entire security ecosystem. SK

Second presidency compromise text	Drafting suggestions and Comments
	(Comments): We welcome the proposed modifications providing for greater involvement of national authorities when decisions of the AI Office have an impact on the national market (Article 75a(3)), as well as the possibility for the AI Office to delegate proceedings on AI systems to national authorities. At the same time, we consider it important to ensure that national authorities are able to raise concerns or provide input on their own initiative, and not only upon request by the AI Office. Allowing such proactive engagement would strengthen cooperation, and ensure that relevant national considerations are duly taken into account.
	SE (Comments): Some of the amendments and the addition of new articles would normally require a major process of careful impact assessment, especially matters that have an impact on national authorities. National authorities may assist others to the extent that it is a matter of gathering information or other measures that they are already able to do under their mandate, but the AI Office should not be able to require a national authority to act outside the authorities national market surveillance powers as regards to what measures can be taken and against which liable parties. The same applies even if national authorities were to act within their powers, but for a completely different purpose than for what was given. Depending on the scope of future requests for assistance from the AI Office, as well as whether requests from the AI Office should have priority over nationally planned efforts, it becomes a question of resources whether this is manageable for national authorities.
(a) the heading of Article 75 is replaced by the following:	
‘**Market surveillance and control of AI systems and mutual assistance**’;	DE

Second presidency compromise text	Drafting suggestions and Comments
	(Comments): Our examination regarding art. 75ff. is ongoing. We support the consolidation of market surveillance for VLOPs and VLOSEs at the AI Office in general. We also believe it to be important that the AI Office oversees AI systems developed by providers of GPAI models with systemic risk as long as these AI systems are not covered by Annex I . We recognize that the proposal may unburden national market surveillance authorities. However, we continue to remain skeptical of further centralization of oversight of AI systems within the AI Office, particularly where it would dis-place established sector-specific supervisory authorities, such as in the financial sector (Annex III, 5b and c). These sectors should be granted the same exemption from centralization as Annex I. As GPAI development spreads across sectors more systems would shift from national oversight to the AI Office, un-dermining the AI Acts decentralized approach and smooth inte-gration into existimng structures. Additionally, Art. 75 would arbi-trarily change supervisory responsibility based on the model´s developer rather than the system´s risk resulting in fragmented oversight.
(b) paragraph 1 is replaced by the following:	ES (Comments): **No objections are raised to this proposal.**
‘1. Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I **and AI systems referred to in Annex III, point 2**, and that model and that system are developed by the same provider **or by providers that are part of the same undertaking**, the AI Office shall be exclusively competent for the supervision and enforcement of that system with the obligations **for providers laid down in** ~~of~~ this Regulation in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. The AI Office shall also be exclusively	AT (Drafting suggestions): Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I and AI systems referred to in Annex III, point 2 **and those high-risk AI systems supervised in accordance with Article 74 (8), as well as Article 5**, and that model and that system are developed by the same provider or by providers that are part

Second presidency compromise text	Drafting suggestions and Comments
competent for the supervision and enforcement of the obligations under this Regulation in relation to AI systems that constitute or that are integrated into a designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065.	of the same undertaking, the AI Office shall be exclusively competent for the supervision and enforcement of that system with the obligations for providers laid down in of this Regulation in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. The AI Office shall also be exclusively competent for the supervision and enforcement of the obligations under this Regulation in relation to AI systems that constitute or that are integrated into a designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065. AT (Comments): AT: We note that there is a fundamental incompatibility between the notion of general-purpose AI system and high-risk AI system, as according to Art 3 (66), 'general-purpose AI system' means an AI system which is based on a general-purpose AI model and which has the capability to serve a variety of purposes, both for direct use as well as for integration in other AI systems. For high-risk AI systems on the other hand, which are products under the NLF, the intended purpose provides an anchor for meeting all regulatory obligations: only a limited, specified intended purpose can be used to test compliance with requirements or to assess conformity of the product, whether through internal control or by a notified body. That means that in the current provisions of the AI Act, all high-risk AI systems are ***necessarily and by definition*** excluded from the supervision of the AI Office (see also Art 25 (1) c, which specifies that a modification of a general-purpose AI system for an intended purpose that needs be classified as high-risk leads to the modifying organisation assuming the role of provider). However, introducing the exclusion of Annex I implies that general-purpose AI systems can *simultaneously* have an intended purpose *as well as a general purpose*. Even though there is no intention to change the definition of general-purpose AI system in a manner which would justify such an interpretation, the

Second presidency compromise text	Drafting suggestions and Comments
	supervision of sensitive areas such as law enforcement, migration, asylum, border control and democratic processes (which includes *all national judicial authorities*) must remain by an independent authority at the national level. As market surveillance authorities have deep insight into internal processes as well as data related to the AI systems supervised, it is not possible even at national level to assign the supervision of high-risk AI systems placed on the market, put into use or deployed in these sensitive areas to any authority at will, as these authorities must be set up in a manner that ensures their powers cannot be used by any other organisation within the chain of accountability and command to interfere with internal processes of organisations falling within these sensitive areas. These conditions may vary between Member States and cannot be met by an EU authority, in particular if this authority cannot by any stretch be construed to be independent from political functions. We would furthermore like to stress that it is possible, even likely, for organisations falling within the category of law enforcement, migration, border control, asylum and democratic processes to be both providers of general-purpose AI models and to build general-purpose AI systems for their internal purposes, which would place them directly in the role of provider of general-purpose AI systems supervised by the AI Office. Whether or not high-risk AI systems can even fall under the definition of general-purpose AI system or not, a supervision of these types of organisations by the AI Office cannot be supported. As for the exclusion of prohibitions from the regulatory remit of the AI Office, enforcement of fundamental rights must necessarily remain at national level as any measures taken by market surveillance authorities are based on assessments under a market surveillance framework whose risk-based framework is inadequate for the supervision of fundamental rights (because certain fundamental rights must be protected regardless of the likelihood harm). CZ

Second presidency compromise text	Drafting suggestions and Comments
	(Comments): **The meaning of the term 'undertaking' is unclear. See Article 99(3), (4) and (5), where the same term is used to describe a single person (the offender). If this term is to be used in the context of Article 75, it should be clearly defined in order to avoid misinterpretation and ensure legal clarity. Alternatively, different wording could be considered.** EE (Drafting suggestions): Where an AI system is based on a general-purpose AI model, ~~with the exclusion~~ **excluding** AI systems related to products covered by the Union harmonisation legislation listed in Annex I and AI systems referred to in Annex III, point 2, **and where** the model and that system are developed by the same provider or by providers that are part of the same undertaking, the AI Office shall be ~~exclusively~~ competent for the supervision and enforcement of that system ~~with the obligations of this~~ **'s** obligations of this Regulation **in cases involving cross-border aspects and** in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. The AI Office shall also be ~~exclusively~~ competent for the supervision and enforcement of the obligations under this Regulation in relation to AI systems that constitute or are integrated into a designated very large online platform or a very large online search engine within the meaning of Regulation (EU) 2022/2065, **in cases involving cross-border aspects and without prejudice to the powers of the competent national authorities.** EE (Comments): In its current phrasing, the provision's compatibility with the principles of subsidiarity, proportionality, and Member State supervisory competence is legally questionable. Granting the AI Office "exclusive competence" leave questions, why national authorities would be insufficient and applies

Second presidency compromise text	Drafting suggestions and Comments
	regardless of risk or cross-border impact. Exclusive competence restricts national authorities' role and Member States´ sovereignty. Centralizing supervision at the EU level without coordination mechanisms may go beyond what is necessary. IE (Comments): IE is seeking clarification as to whether Article 75 is applicable to credit scoring systems based on Gen AI model developed by the same provider, given that Article 75(1) provides for an exclusive competence of the AI Office, while Article 74(6) provides for a competence of NCAs for high-risk AI systems in financial services. IE proposes a draft amendment to the omnibus text in respect of Article 75, under Article 1(25)(b) to provide clearer coherency with Regulation (EU) 2022/2065 ("Digital Services Act"). Our rationale for this proposal is outlined further below in our observations: Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I and AI systems referred to in Annex III, point 2, and that model and that system are developed by the same provider or by providers that are part of the same undertaking, the AI Office shall be exclusively competent for the supervision and enforcement of that system with the obligations for providers laid down in of this Regulation in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. **Where the relevant competent authority in the Member State of establishment has not taken action in relation to the same infringement, the** The AI Office shall also

Second presidency compromise text	Drafting suggestions and Comments
	be exclusively competent for the supervision and enforcement of the obligations under this Regulation in relation to AI systems that constitute or that are integrated into a designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065. ***Observations*** Noting IEs previous comments on the Digital Omnibus on AI Regulation, and those of other Member States, it is of concern that that issues raised regarding the proposed exclusive competency of the EU AI Office in respect of AI systems that constitute or are integrated into a designated VLOP or VLOSE within the meaning of the DSA (per Article 1(25)(b) of the text), have not been addressed. Again, IE urges caution about the further centralisation of supervision and enforcement powers and expansion of the European Commission's role as a regulator until there has been time to assess whether the novel division of competences under the DSA, for example, has been a success. IE has provided above a drafting suggestion we believe is more clearly aligned with the competencies shared under the DSA between the European Commission and Digital Services Coordinators, in respect of due diligence obligations (and as set out in Recitals 124, 125 and Article 56(1) of the DSA). By way of example, enforcement of obligations on deployers under Article 50(3) & (4) of the EU AI Act, which help lay down technical requirements in respect of transparency are coherent with DSCs' shared responsibilities in enforcing advertising transparency (per Article 26 of the DSA) in respect of VLOPs and VLOSEs, and in respect of the transparency obligations regarding political advertising under the TTPA, responsibility for which falls to, or is shared with other competent authorities, by a number of DSCs.

Second presidency compromise text	Drafting suggestions and Comments
	The Omnibus and Compromise Texts, including new text under Article 1(25)(c)(1aa) regarding deployers, diminish the role of national competent authorities, and serve to undermine the country-of-origin principle, with consequences beyond the EU AI Act. IT (Comments): While we understand the rationale underpinning this revised version, we consider it essential to further clarify the notion of "undertaking", in order to avoid legal uncertainty in delineating the respective remits of the AI Office and the MSAs. In the absence of such clarification, the concept of "undertaking" may be subject to divergent interpretations across Member States, potentially resulting in inconsistencies in enforcement and conflicts of competence between the AI Office and the MSAs. Against this background, and in the interest of legal certainty and harmonisation, should the intention be to encompass all the undertakings within the same economic perimeter, it could be considered whether a reference to the notion of "group" would be more appropriate. NL (Drafting suggestions): '1. Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I **and AI systems referred to in Annex III, point 2**, and that model and that system are developed by the

Second presidency compromise text	Drafting suggestions and Comments
	same provider **or by providers that are part of the same undertaking**, the AI Office shall be exclusively competent for the supervision and enforcement of that system with the obligations for providers laid down in of this Regulation in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. **For AI systems referred to in Annex III point 5a, 6, 7 and 8, the competence of the AI Office is without prejudice to the competences of the relevant national competent authorities under this regulation**. The AI Office shall also be exclusively competent for the supervision and enforcement of the obligations under this Regulation in relation to AI systems that constitute or that are integrated into a designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065. PL (Drafting suggestions): Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I and AI systems referred to in Annex III, point 2, and that model and that system are developed by the same provider or by providers that are part of the same undertaking, the AI Office shall be ~~**exclusively**~~ competent for the supervision and enforcement of that system with the obligations for providers laid down in of this Regulation in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. The AI Office shall also be ~~**exclusively**~~ competent for the supervision and enforcement of the obligations under this Regulation in relation to AI system**s** that constitute or that are integrated into a designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065.
	PL (Drafting suggestions):

Second presidency compromise text	Drafting suggestions and Comments
	A new paragraph is added: In exercising its supervisory powers over AI systems and general-purpose AI models, the AI Office shall coordinate its actions with relevant EU and national cybersecurity authorities, and take into account applicable cybersecurity regulations.
~~When exercising its tasks of supervision and enforcement under the first subparagraph, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and in Regulation (EU) 2019/1020. The AI Office shall be empowered to take appropriate measures and decisions to adequately exercise its supervisory and enforcement powers. Article 14 of Regulation (EU) 2019/1020 shall apply mutatis mutandis.~~	
(c) the following paragraphs ~~1a to 1c~~ are inserted:	
1aa. When a deployer is part of the same undertaking as a general-purpose AI model provider and an AI system provider under the scope of paragraph 1, the AI Office shall be exclusively competent for the supervision and enforcement of the obligations for deployers laid down in this Regulation.	AT (Drafting suggestions): 1aa. When a deployer is part of the same undertaking as a general-purpose AI model provider and an AI system provider under the scope of paragraph 1, the AI Office shall be exclusively competent for the supervision and enforcement of the obligations for deployers laid down in this Regulation**, with the exception of AI systems referred to in Annex I and in Annex III, point 2 and those high-risk AI systems supervised in accordance with Article 74 (8), as well as Article 5**. AT (Comments): AT: see comments on paragraph 1 CZ (Comments):

Second presidency compromise text	Drafting suggestions and Comments
	The meaning of the term 'undertaking' is unclear. See Article 99(3), (4) and (5), where the same term is used to describe a single person (the offender). If this term is to be used in the context of Article 75, it should be clearly defined in order to avoid misinterpretation and ensure legal clarity. Alternatively, different wording could be considered. EE (Drafting suggestions): When a deployer is part of the same undertaking as a general-purpose AI model provider and an AI system provider under the scope of paragraph 1, the AI Office shall be ~~exclusively~~ competent for the supervision and enforcement of the obligations for deployers laid down in this Regulation. NL (Drafting suggestions): **~~1aa. When a deployer is part of the same undertaking as a general-purpose AI model provider and an AI system provider under the scope of paragraph 1, the AI Office shall be exclusively competent for the supervision and enforcement of the obligations for deployers laid down in this Regulation.~~** NL (Comments): Alternatively as mentioned in the previous comment: 1aa. When a deployer is part of the same undertaking as a general-purpose AI model provider and an AI system provider under the scope of paragraph 1, the AI Office shall be exclusively competent for the supervision and enforcement of the obligations for deployers laid down in this Regulation. **For AI systems referred to in Annex III point 5a, 6, 7 and 8, the competence of the AI Office is without prejudice to the competences of the relevant national competent authorities under this regulation.**

Second presidency compromise text	Drafting suggestions and Comments
	SE (Comments): SE supports the amendments.
1ab. By way of derogation from Article 73(1), providers of high-risk AI systems referred to in paragraph 1 shall report any serious incidents to the AI Office.	PT (Comments): Portugal requests clarification regarding how this direct reporting obligation to the AI Office will be coordinated with national market surveillance authorities, particularly where serious incidents occur in a specific Member State or have territorial effects requiring national-level intervention. Further clarification would also be welcome on the subsequent allocation of investigative and corrective measures, and whether national authorities will retain any complementary role in follow-up enforcement.
1a. The authorities involved in the application of this Regulation shall cooperate actively **and afford the AI Office the necessary assistance for**~~in~~ the exercise of t~~hose~~**its** powers**, including, where necessary, in connection with inspections or other enforcement measures carried out in the territory of a Member State. To this end, the competent authorities shall enjoy the powers provided for under this Regulation and Regulation (EU) 2019/1020, and where relevant and limited to what is necessary to fulfil their tasks under this paragraph, in accordance with the applicable national procedures. Where the AI Office finds that a natural or legal person opposes or obstructs an inspection ordered pursuant to Article 75a, the national competent authority of the Member State concerned shall afford them the necessary assistance, requesting, where appropriate, the assistance of the police or an equivalent enforcement authority, to enable them to conduct their on-site inspection**~~in particular~~	CZ (Drafting suggestions): 1a. The authorities involved in the application of this Regulation shall ~~**cooperate actively and**~~ afford the AI Office the necessary assistance for the exercise of its powers, including, where necessary, in connection with inspections or other enforcement measures carried out in the territory of a Member State. ~~**To this end, the competent authorities shall enjoy the powers provided for under this Regulation and Regulation (EU) 2019/1020, and where relevant and limited to what is necessary to fulfil their tasks under this paragraph, in accordance with the applicable national procedures**~~. Where the AI Office finds that a natural or legal person opposes or obstructs an inspection ordered pursuant to Article 75a, the national competent authority of the Member State concerned shall afford them the necessary assistance, requesting, where appropriate, the assistance of the

Second presidency compromise text	Drafting suggestions and Comments
~~where enforcement actions need to be taken in the territory of a Member State~~ .;	police or an equivalent enforcement authority, to enable them to conduct their on-site inspection. CZ (Comments): If the authorities are required to provide the necessary assistance, the obligation of "active cooperation" appears redundant. Moreover, the framework for such cooperation is now defined in Article 75b(7), which lays down the territorial provisions and prevents an excessive transfer of supervisory obligations. SE (Comments): Market Surveillance Regulation provides the possibility to refuse a request for supervisory action under certain circumstances. One such circumstance is when complying with the request would significantly impair the authority's ability to perform its own tasks. It cannot be excluded that a request for assistance from the AI Office may be extensive and resource- intensive, potentially affecting the agency's regular activities and prioritisation. SE therefore recommends introducing in the AI Act a provision equivalent to Article 23(3) of the Market Surveillance Regulation allowing for the possibility to refuse a request for assistance under clearly defined conditions.
	PL (Drafting suggestions): A new paragraph is added:

Second presidency compromise text	Drafting suggestions and Comments
	Where enforcement actions need to be taken in the territory of a Member State and involve access to system AI public sector , they shall be conducted in cooperation with the competent national authorities.
1b. When making a simple request or decision as referred to in Article 75b(1) ,the Commission shall, without delay, send a copy of the request or decision referred to in the first subparagraph to the relevant national competent authority of the Member State in whose territory the operator or its legal representative is situated.	AT (Drafting suggestions): 1b. When making a simple request or decision as referred to in Article 75b(1) **pursuant to Article 14 (4) d-i and k of Regulation (EU) 2019/1020**,the Commission shall, without delay, send a copy of the request or decision referred to in the first subparagraph to the relevant national competent authority **or authorities competent for the supervision of the relevant obligation or obligations in** ~~of~~ the Member State in whose territory the operator or its legal representative is situated. AT (Comments): AT: The current text does not take into account that high-risk AI systems may fall into multiple categories (both of high-risk, e.g. a biometric identification system used for monitoring and detecting prohibited behaviour of students during tests would fall under Annex III point 1a-b and 3d as well as Art 50 (1), in addition to potentially constituting a prohibited practice as per Art 5 (1) c and f) which may be supervised by different market surveillance authorities. In addition, it is more appropriate to refer to the powers provided under the relevant provisions of Regulation (EU) 1029/1020, as these provide the operational framework for market surveillance activities of the AI Office. SE (Comments): SE supports the amendments.

Second presidency compromise text	Drafting suggestions and Comments
1c. Before taking a decision that would have the effect of prohibiting or restricting the AI system's being made available on a national market or put into service, to withdraw the AI system from that market or to recall it, the AI Office shall without undue delay notify the relevant national market surveillance authority. The AI Office may consult the authorities involved in the application of this Regulation, where appropriate, on any matter relating to the application and enforcement of this Regulation.	AT (Drafting suggestions): 1c. Before taking a decision **pursuant to Article 16 (2) and (3) of Regulation (EU) 2019/1020**~~that would have the effect of prohibiting or restricting the AI system's being made available on a national market or put into service, to withdraw the AI system from that market or to recall it~~, the AI Office shall without undue delay notify the relevant ~~national~~ market surveillance authority **or authorities competent for the supervision of the relevant obligation or obligations in the Member State or Member States in which the AI system in question has been made available or put into service**. The AI Office **shall** ~~may~~ consult the authorities involved in the application of this Regulation, where appropriate, on any matter relating to the application and enforcement of this Regulation. AT (Comments): AT: See comments on 1b for distributed governance structures at national level and need for clarity on powers provided under Regulation (EU) 1020/2019 SE (Comments): SE supports the amendments.
~~(c) the following paragraphs 1a to 1c are inserted:~~	
~~'1a. The Commission shall adopt an implementing act to define the enforcement powers and the procedures for the exercise of those powers of the AI Office, including its ability to impose penalties, such as fines or other~~	

Second presidency compromise text	Drafting suggestions and Comments
~~administrative sanctions, in accordance with the conditions and ceilings identified in Article 99, in relation to AI systems referenced to in paragraphs 1 and 1a of this Article that are found to be non-compliant with this Regulation, in the context of its monitoring and supervision tasks under this Article.~~	
‘1b. Article 18 of Regulation (EU) 2019/1020 shall apply mutatis mutandis to providers of AI systems referred to in paragraph 1, without prejudice to more specific procedural rights provided for in this Regulation.’	
‘1c. The Commission shall organise and carry out pre-market conformity assessments and tests of AI systems referred to in paragraph 1 that are classified as high-risk and subject to third-party conformity assessment under Article 43 before such AI systems are placed on the market or put into service. These tests and assessments shall verify that the systems comply with the relevant requirements of this Regulation and may be placed on the market or put into service in the Union in accordance with this Regulation. The Commission may entrust the performance of these tests or assessments to notified bodies designated under this Regulation, in which case the notified body shall act on behalf of the Commission. Article 34(1) and (2) shall apply *mutatis mutandis* to the Commission when exercising its powers under this paragraph.	AT (Comments): AT: Notwithstanding our strong opposition to Art 75(1) acting as a derogation from Art 74 and superceding nationally defined supervision structures, we note that the provision of Art 43(1) last sentence remains applicable which requires the market surveillance authorities referred to in Art 74(8) or 9 to act as notified bodies – which would be the AI Office. ES (Drafting suggestions): The Commission shall organise and carry out pre-market conformity assessments and tests of AI systems referred to in paragraph 1 that are classified as high-risk and subject to third-party conformity assessment under Article 43 before such AI systems are placed on the market or put into service. **These tests and assessments shall verify that the systems comply with the relevant requirements of this Regulation and may be placed on the market or put into service in the Union in accordance with this Regulation**

Second presidency compromise text	Drafting suggestions and Comments
	For the purposes of that assessment, the Commission shall demonstrate the compliance with the requirements laid down in Article 31, and undergo the notification procedure set down in article 30. The notification authority shall be established, organised and operated so as to safeguard the objectivity and impartiality of its activities and to avoid any conflicts of interests with conformity assessment bodies. The Member States shall nominate experts qualified in the assessment of conformity assessment bodies to participate in the notification activities referred in this article. ES (Comments): **This does not constitute a red line, but it would be highly desirable.** The independence of the Commission in exercising its market surveillance functions could be significantly undermined if it were to also assume responsibility for the conformity assessment of systems within its exclusive competence. Furthermore, it must be established whether, for the purpose of conducting conformity assessments, the Commission is likewise required to demonstrate compliance with the requirements set out in Article 31, and whether such activities are subject to assessment, designation, notification, and oversight by a national authority. Lastly, it is deemed necessary to clarify the proposal whereby the Commission may rely on Notified Bodies for the execution of testing and conformity assessments, with a view to precluding any discriminatory recurrence or undue preference toward specific bodies.
The fees for testing and assessment activities shall be levied on the provider of a high-risk AI system who has applied for third-party conformity assessment to the Commission. The costs related to the services entrusted by	

Second presidency compromise text	Drafting suggestions and Comments
the Commission to the notified bodies in accordance with this Article shall be directly paid by the provider to the notified body.’;	
The following ~~Article 75a~~articles ~~is~~ are inserted after Article 75:	DE (Comments): From our understanding from the explanatory note some parts have been added regarding Art. 75, 75a and 75b in order to reg-ulate it directly in the AI Act instead of an implementing act. We wonder if all the provisions are needed (especially the new Art. 75 b) and, if so,more flexibility is provided without regulating this matter directly in the AI Act
‘Article 75a	
~~Investigation and~~ Eenforcement of obligations and starting an investigation in respect of AI systems supervised by the AI Office	
1. When exercising its tasks of supervision and enforcement outlined in Article 75(1), the AI Office shall have the powers set out in this Regulation. It shall additionally have all the powers of a market surveillance authority provided for in this Section and in Regulation (EU) 2019/1020, save where the relevant type of power is specified and framed in this Article or Articles 75b-75e . The AI Office shall be empowered to take appropriate measures and decisions to adequately exercise its supervisory and enforcement powers. ~~Article 14 of Regulation (EU) 2019/1020 shall apply mutatis mutandis.~~ The AI Office shall also be authorised to fully reclaim from the relevant operator the totality of the costs of its activities with respect to instances of non-compliance, including costs for human and technical resources, in accordance with Article 15 of Regulation (EU) 2019/1020.	AT (Drafting suggestions): 1. When exercising its tasks of supervision and enforcement outlined in Article 75(1), the AI Office shall have the powers set out in this Regulation. It shall additionally have all the powers of a market surveillance authority provided for in this Section and in **Article 14 (4) of** Regulation (EU) 2019/1020, save where the relevant type of power is specified and framed in this Article or Articles 75b-75e. The AI Office shall be empowered to take appropriate measures and decisions to adequately exercise its supervisory and enforcement powers. ~~Article 14 of Regulation (EU) 2019/1020 shall apply mutatis mutandis.~~ The AI Office shall also be authorised to fully reclaim from the relevant operator the totality of the costs of its activities with respect to instances of non-compliance, including costs for human and

Second presidency compromise text	Drafting suggestions and Comments
	technical resources, in accordance with Article 15 of Regulation (EU) 2019/1020. **The requirements for national competent authorities set out in Article 70 apply to the AI Office.** AT (Comments): AT: It is necessary to be specific about which powers are accorded to the AI Office in its role as market surveillance authority because Regulation (EU) 2019/1020 also sets out the role of the Commission, which must be separated from that of the AI Office acting as market surveillance authority. When carrying out duties as a market surveillance authority, the AI Office shall be guaranteed with and obliged to the same provisions as national Market Surveillance Authorities concerning independency and impartiality and the provision of sufficient ressources. ES (Drafting suggestions): FI (Comments): NL has voiced concerns related to the new articles under the number 75 and the infringement of national competences, when the AI Office has exclusive supervisory power over AI-systems used in the law enforcement ie judiciary domain. Finland is studying the issue.
	AT (Drafting suggestions): **1a. Articles 79 and 80 apply to the enforcement of the AI Office with the AI Office taking the role of market surveillance authority.**

Second presidency compromise text	Drafting suggestions and Comments
	AT (Comments): AT: The new provisions in the Presidency compromise text introduce new complexities of market surveillance activities, whereas it remains unclear how to handle Art 79-80.
2. Where the AI Office has reasonable grounds to suspect non-compliance with this Regulation of an AI system referred to in Article 75 (~~paragraph~~1), it ~~shall~~ may adopt a decision ~~for opening a proceeding~~ to start an investigation. The AI Office may exercise that power on its own initaitive or following a complaint received under Article 85. Upon the ~~initiating such proceedings~~ starting of such an investigation, the AI Office shall notify the operator of the AI system concerned.	AT (Drafting suggestions): 2. Where the AI Office has reasonable grounds to suspect non-compliance with this Regulation of an AI system referred to in Article 75 (1), **Article 16 (1-3) of Regulation (EU) 2019/1020 applies.**~~it may adopt a decision to start an investigation. The AI Office may exercise that power on its own initaitive or following a complaint received under Article 85. Upon the starting of such an investigation, the AI Office shall notify the operator of the AI system concerned.~~ AT (Comments): AT: In cases of non-compliance, market surveillance authorities **are obliged to take corrective measures, regardless of whether or not an investigation has been launched**; Art. 16(1-2) of Regulation (EU) 2019/1020 cannot be construed to be optional, therefore a permission to launch an investigation cannot be reconciled with the requirements of the NLF. The requirement to inform the operator of the AI system concerned is incompatible with the powers afforded by Art 14(4)d-e and j of Regulation (EU) 2019/1020. The launch of investigations is already provided for by Art. 14(4)f of Regulation (EU) 2019/1020. IE (Comments):

Second presidency compromise text	Drafting suggestions and Comments
	The AI Office should consult the relevant national market surveillance authorities before this, with a view to avoiding duplications and perhaps the provision of intelligence. A clear mechanism is needed here
~~For the purposes of investigating compliance of operators of the systems falling under the scope of Article 75, paragraph 1, with the obligations laid down in this Regulation, The~~ The AI Office may exercise its investigatory powers on ~~at~~ its own initiative or following a complaint received under Article 85 of this Regulation, even before ~~opening proceedings~~ starting an investigation pursuant to this paragraph.	AT (Drafting suggestions): The AI Office may **launch an investigation or take any corrective measures pursuant to Art. 16 of Regulation (EU) 2019/1020** ~~exercise its investigatory powers on at its own initiative or~~ following a complaint received under Article 85 of this Regulation~~, even before starting an investigation pursuant to this paragraph~~. AT (Comments): AT: While the reference to Art 85 is welcome, the ability to launch investigations is already set out by Art 14(4) f of Regulation (EU) 2019/1020. Furthermore, depending on the type and severity of complaint received and the setting, market surveillance authorities may need to request corrective measures before a detailed investigation is launched.
3. The exercise of the AI Office's task of supervision and enforcement outlined in paragraph 1 may include the appointment of independent external experts and auditors, as well as experts, investigative teams and auditors from Member State's competent authorities with the agreement of the authority concerned, to assist the AI Office in monitoring the effective implementation and compliance with the relevant provisions of this Regulation and to provide specific expertise or knowledge to the AI Office.	ES (Drafting suggestions): 3. The exercise of the AI Office's task of supervision and enforcement outlined in paragraph 1 may include the appointment of independent external experts and auditors, as well as experts, investigative teams and auditors from Member State's competent authorities with the agreement of the authority concerned, to assist the AI Office in monitoring the effective implementation and compliance with the relevant provisions of this Regulation and to provide specific expertise or knowledge to the AI Office.

Second presidency compromise text	Drafting suggestions and Comments
	The result of such investigations will be shared with the Member State's competent authorities. ES (Comments): **This does not constitute a red line, but it would be highly desirable.** It would be desirable that all the relevant findings from external audits are shared with the relevant national competent authorities to improve coordination. SE (Comments): See comment under Article 75(1a). It cannot be excluded that a request for assistance from the AI Office may be extensive and resource- intensive, potentially affecting the agency's regular activities and prioritisation. SE therefore recommends introducing in the AI Act a provision equivalent to Article 23(3) of the Market Surveillance Regulation, allowing for the possibility to refuse a request for assistance under clearly defined conditions.
<u>Article 75b</u>	IE (Comments): In relation to the powers of the AI Office under Article 75b, we note that this proposed provision concerns the powers of investigation of the AI Office. It also provides for national competent authorities to carry out investigations, inspections or fact-finding measure "at the request of the AI Office". How would this affect the independence of national competent authorities (in particular, in circumstances where those authorities may be established in law as independent bodies)?

Second presidency compromise text	Drafting suggestions and Comments
	We respectfully suggest that there should be further discussion on the impact of this, particularly in circumstances where national competent authorities may have functions under several different legal frameworks.
Requests for information and power to conduct inspections	CZ (Comments): **The Czech Republic considers that the current compromise text does not explicitly clarify whether the AI Office may conduct on-site inspections in private premises of natural persons. In the interest of legal certainty and proportionality, the Czech Republic believes that the Regulation should clearly define the scope and limits of such investigatory powers, including appropriate safeguards and procedural guarantees.**
13. In order to carry out the tasks assigned to it under this Section, the AI Office may, by simple request or by decision, require ~~the~~ an operator subject to its competence under Article 75(1) to provide information that is necessary for the purpose of assessing compliance of the operator with this Regulation.	AT (Drafting suggestions): In order to carry out the tasks assigned to it under this Section, the AI Office **has the powers under Article 14(4) a-c of Regulation (EU) 2019/1020** ~~may, by simple request or by decision, require an operator subject to its competence under Article 75(1) to provide information that is necessary for the purpose of assessing compliance of the operator with this Regulation.~~ AT (Comments): AT: It is not necessary to introduce the complexity of a simple request vs. a decision, as this would limit the powers afforded to market surveillance authorities unduly.
When sending such requests for information to the operator concerned, the AI Office shall state the legal basis and the purpose of the request, specify what information is required and set the period within which the	AT (Drafting suggestions):

Second presidency compromise text	Drafting suggestions and Comments
information is to be provided. When the request is a simple request, it shall additionally indicate that there is no obligation to provide information but that, in case of a voluntary reply, the information must be correct and not misleading, and indicate the potential fines provided for in Article 99 for supplying incorrect or misleading information. ~~, and the fines provided for in Article 99 for supplying incorrect, incomplete or misleading information.~~ When requesting information by decision, it shall ~~further~~ additionally indicate the fines provided for in Article 99 for supplying incomplete, incorrect or misleading information, and indicate the right to have the decision reviewed by the Court of Justice of the European Union.	When sending such requests for information to the operator concerned, the AI Office shall state the legal basis and the purpose of the request, specify what information is required and set the period within which the information is to be provided. ~~When the request is a simple request, **i**~~**It** shall additionally indicate that there is no obligation to provide information but that, in case of a voluntary reply, the information must be correct and not misleading, and indicate the potential fines provided for in Article 99 for supplying ~~incorrect or misleading information. When requesting information by decision, it shall additionally indicate the fines provided for in Article 99 for supplying~~ incomplete, incorrect or misleading information, and indicate the right to have ~~the~~ **any** decision**s taken** reviewed by the Court of Justice of the European Union. AT (Comments): AT: Information about procedural safeguards must be included at all times, see also Art 18 Regulation (EU) 2019/1020.
2. The operators referred to in paragraph 1 or their legal representatives shall supply the information required by a decision under paragraph 1.	AT (Drafting suggestions): ~~2. The operators referred to in paragraph 1 or their legal representatives shall supply the information required by a decision under paragraph 1.~~ AT (Comments): AT: This is duplicative of the obligations of market actors set out elsewhere in the AI Act.
34. In order to carry out the tasks assigned to it under this Section, the AI Office may order the operators to provide access to, and explanations relating to, their AI systems. Such actions may include,	AT (Drafting suggestions):

Second presidency compromise text	Drafting suggestions and Comments
imposing an obligation on the operator to retain all data and documents deemed to be necessary to assess the implementation of and compliance with the obligations under this Regulation.	~~34. In order to carry out the tasks assigned to it under this Section, the AI Office may order the operators to provide access to, and explanations relating to, their AI systems. Such actions may include, imposing an obligation on the operator to retain all data and documents deemed to be necessary to assess the implementation of and compliance with the obligations under this Regulation.~~ AT (Comments): AT: This power is already covered by Art. 14(4) of Regulation (EU) 2019/1020 and as an obligation it is already covered by Art 7(1) of Regulation (EU) 2019/1020, as well as e.g. Art 74(12-13) AI Act. CZ (Comments): **All MSAs should have a power to impose an obligation on the operator to retain all data and documents deemed to be necessary to assess the implementation of and compliance with the obligations under this Regulation (not only AI Office).**
4. In order to carry out the tasks assigned to it under this Section, t~~T~~he AI Office may conduct all necessary remote or on-site inspections, announced or unannounced. The officials of the AI Office authorised to conduct an inspection ~~may~~shall be empowered to:	AT (Drafting suggestions): 4. In order to carry out the tasks assigned to it under this Section, the AI Office **shall exercise the powers under Article 14(4) d-e and j of Regulation (EU) 2019/1020.** ~~may conduct all necessary remote or on-site inspections, announced or unannounced. The officials of the AI Office authorised to conduct an inspection shall be empowered to:~~ AT (Comments):

Second presidency compromise text	Drafting suggestions and Comments
	AT: It should be checked whether the provision of the power to conduct "all necessary remote or on-site inspections, announced or unannounced" is even necessary, as the AI Office should have all powers of a market surveillance authority accordiung to the Austrian suggestion of Art75a: "When exercising its tasks of supervision and enforcement outlined in Article 75(1), the AI Office shall have the powers set out in this Regulation. It shall additionally have all the powers of a market surveillance authority provided for in this Section and in **Article 14 (4) of** Regulation (EU) 2019/1020". Also Art 74 (12) already enables remote access for market surveillance authorities.]
(a) enter any of the business premises, land or property located in the Union of the operator concerned;	AT (Drafting suggestions): ~~(a) enter any of the business premises, land or property located in the Union of the operator concerned;~~
(b) examine the books, data and other material relevant to the execution of their tasks, irrespective of the medium on which they are stored;	AT (Drafting suggestions): ~~(b) examine the books, data and other material relevant to the execution of their tasks, irrespective of the medium on which they are stored;~~
(c) take or obtain in any form copies of or extracts from such books, data and other records;	AT (Drafting suggestions): ~~(c) take or obtain in any form copies of or extracts from such books, data and other records;~~
(d) ask any of the persons subject to the inspection, or their representatives, or staff, for oral or written explanations on factors or	AT (Drafting suggestions):

Second presidency compromise text	Drafting suggestions and Comments
documents relating to the subject matter and purpose of the inspection, and to record the answers.	~~(d) ask any of the persons subject to the inspection, or their representatives, or staff, for oral or written explanations on factors or documents relating to the subject matter and purpose of the inspection, and to record the answers.~~
The operator concerned shall submit to on-site inspections ordered by decision of the Commission. The decision shall specify the subject matter and purpose of the investigation, the relevant penalties referred to in paragraph 9, and the right to have the decision reviewed by the Court of Justice of the European Union.	AT (Drafting suggestions): ~~The operator concerned shall submit to on-site inspections ordered by decision of the Commission. The decision shall specify the subject matter and purpose of the investigation, the relevant penalties referred to in paragraph 9, and the right to have the decision reviewed by the Court of Justice of the European Union.~~ AT (Comments): AT: This provision unduly limits the powers of market surveillance authorities set out in Art 14(4)d of Regulation (EU) 2019/1020 and repeats the duty of cooperation set out in Art 7 of that Regulation.
5. If an on-site inspection provided for in Article 75a(4) requires authorisation by a judicial authority in accordance with national law, the AI Office shall apply for such an authorisation. The AI Office may also apply for such authorisation as a precautionary measure.	
~~6~~2. Where an authorisation as referred to in paragraph 1 is applied for, the national judicial authority shall promptly verify that the coercive measures envisaged are neither arbitrary nor excessive having regard to the subject matter of the investigation or inspection and the documents provided by the AI Office with the decision. In its verification of the proportionality of coercive measures, the national judicial authority may ask the AI Office for detailed explanations, in particular relating to the grounds the AI Office has for suspecting that an infringement of this	ES (Comments): **No objections are raised to this proposal.**

Second presidency compromise text	Drafting suggestions and Comments
Regulation has taken place and the seriousness of the suspected infringement and, where relevant, the nature of the involvement of the person subject to the coercive measures. However, the national judicial authority shall not review the necessity of the investigation or inspection nor demand information from the case file of the Commission. In accordance with the Treaties, the legality of the Commission's decision is subject to review only by the Court of Justice of the European Union.	
74~~b~~. At the request of the AI Office, the competent authority of a Member State may in its own territory carry out any investigation, inspection or other fact-finding measure on behalf and for the account of the AI Office in order to establish whether there has been an infringement of this Regulation. The officials of the competent authorities of the Member States who are responsible for conducting these investigations, inspections, or fact-finding measures as well as those authorised or appointed by them shall exercise their powers in accordance with their national law.	ES (Comments): **No objections are raised to this proposal.** IT (Comments): We have some concerns on the new provisions concerning the supervisory, inspection and sanctioning powers of the AI Office, with the possibility of involving the national MSAs MT (Drafting suggestions): At the request of the AI Office, **where justified by the nature or scale of the case, and where there is reason to believe that there is non-compliance with this Regulation,** the competent authority of a Member State may in its own territory carry out any investigation, inspection or other fact-finding measure on behalf and for the account of the AI Office in order to establish whether there has been an infringement of this Regulation. The officials of the competent authorities of the Member States who are responsible for conducting these investigations, inspections, or fact-finding measures as well as those authorised or appointed by them shall exercise their powers in accordance with their national law. MT

Second presidency compromise text	Drafting suggestions and Comments
	(Comments): Malta recommends this textual amendment to ensure that there is appropriate justification for AI Office carrying out such requests. This insertion clarifies that requests by the AI Office for investigative measures by national authorities are limited to situations where such intervention is objectively justified by the nature or scale or of the suspected non-compliance. This clarification is consistent with the approach reflected in Article 56 and recital 112 of Regulation (EU) 2024/2847, as well as with the safeguard mechanism under Article 28 of Regulation (EU) 2023/988, under which Union-level intervention is justified only where risks or non-compliance cannot be effectively addressed by Member States acting individually. It thereby ensures compliance with the principles of subsidiarity and proportionality. SE (Comments): See comment under Article 75(1a). It cannot be excluded that a request for assistance from the AI Office may be extensive and resource- intensive, potentially affecting the agency's regular activities and prioritisation. SE therefore recommends introducing in the AI Act a provision equivalent to Article 23(3) of the Market Surveillance Regulation, allowing for the possibility to refuse a request for assistance under clearly defined conditions.
<u>Article 75c Commitments</u>	AT (Comments): AT: We note that commitments made by operators are not relevant within the framework of the NLF, which simply requires operators to take corrective measures that can be ordained by the market surveillance authority. As such, this entire Article could be deleted, and if it is not

Second presidency compromise text	Drafting suggestions and Comments
	deleted, it raises serious questions about whether this proposed article limits the powers of the AI Office as market surveillance authority.
If, during proceedings under ~~this~~ Article 75a(2), the operator concerned offers commitments to ensure compliance with the relevant provisions of this Regulation, the AI Office may by decision make those commitments binding on the operator concerned and declare that there are no further grounds for action. The AI Office may, upon request or on its own initiative, reopen the proceedings:	AT (Drafting suggestions): **1.** If, during proceddings
a) where there has been a material change in any of the facts on which the decision was based;	AT (Drafting suggestions): a) where there has been a material change in any of the facts on which the decision was based**, including when an AI system presents a risk according to Article 79**; AT (Comments): AT: The relation of these commitments to AI systems presenting a risk remains unclear.
b) where the operator acts contrary to its commitments; or	
c) where the decision was based on incomplete, incorrect or misleading information provided by the operator concerned.	
Where the AI Office considers that the commitments offered by the operator concerned are unable to ensure effective compliance with the relevant provisions of this Regulation, it shall reject those commitments in a reasoned decision when concluding the proceedings.	IT (Drafting suggestions): **Where the AI Office considers that the commitments offered by the operator concerned are unable to ensure effective compliance with**

Second presidency compromise text	Drafting suggestions and Comments
	the relevant provisions of this Regulation, it shall reject those commitments in a reasoned non-compliance decision when concluding the investigation proceedings.
	AT (Drafting suggestions): **2. The provisions under paragraph 1 remain without prejudice to the power of the AI Office to request corrective actions pursuant to Article 14(4) g and Article 16 of Regulation (EU) 2019/1020 or to take corrective actions pursuant to Article 14(4)h and Article 16 of that Regulation.** AT (Comments): AT: New paragraph 2. The power of market surveillance authorities to conduct investigations or impose corrective action cannot be limited by commitments made by operators.
Article 75d	
Non-compliance, fines and periodic penalties	
1~~6~~. The AI Office shall adopt a non-compliance decision where it finds that the operator does not comply with the relevant provisions of this Regulation or with commitments made binding pursuant to Article 75c~~., ordering, where relevant, the operator concerned to take the necessary measures to ensure compliance with the decision.~~	AT (Drafting suggestions): **Without prejudice to Article 16 of Regulation (EU) 2019/1020, t**~~T~~he AI Office shall adopt a non-compliance decision where it finds that the operator does not comply with the relevant provisions of this Regulation**, including the obligation to take corrective actions,** or with commitments made binding pursuant to Article 75c. AT (Comments):

Second presidency compromise text	Drafting suggestions and Comments
	AT: The inclusion of commitments here requires a specific mention of corrective actions in order to ensure that commitments cannot be misconstrued as the only corrective powers of the AI Office. In this context, Article 18 of Regulation (EU) 2019/1020 applies mutis mutandis. The non-compliance decision may be understood as a measure as laid down in Article 16 of Regulation (EU) 2019/1020. It shall be clear, that Aritcle 75d (1) does not limit the provisions of Article 16 of Regulation (EU) 2019/1020, but rather establishes a specific or additional measure in comparison to Article 16.
2. Before adopting a decision of non-compliance, the AI Office shall communicate its preliminary findings to the operator concerned. In the preliminary findings, the Commission shall explain the measures that it considers taking, or that it considers that the operator concerned should take, in order to effectively address the preliminary findings.	
3. In the decision pursuant to the ~~first sentence~~ paragraph 1, the AI Office shall, where relevant, order the operator concerned to take the necessary measures to ensure compliance with the decision within a reasonable period specified therein and to provide information on the measures that that operator intends to take to comply with the decision. The operator concerned shall provide the AI Office with a description of the measures it has taken to ensure compliance with the decision upon their implementation. Prior to requesting any measure, the AI Office may engage in a structured dialogue with the operator of the AI system in question. During this dialogue, the operator may propose commitments in accordance with paragraph Article 75c~~5~~.	
~~4~~7. A decision of non-compliance may be accompanied by the imposition of penalties pursuant to Article 99, which shall apply mutatis mutandis to the AI Office in the execution of its supervision and	

Second presidency compromise text	Drafting suggestions and Comments
enforcement tasks outlined in Article 75(~~, paragraph 1~~), of this Regulation.	
5. ~~9.~~ The AI Office may ~~impose~~ adopt a decision imposing periodic penalty payments to compel the persons referred to in ~~paragraph 4~~ subject to its competence pursuant to Article 75(1) to submit to an investigation, to comply with an information request ordered by a decision adopted under paragraph Article 75b(1)~~3~~, to submit to an on-site inspection ordered by a decision pursuant to ~~paragraph 4~~ Article 75b(4), ~~or~~ to provide correct or complete answers or explanations in response to such an investigation, request or inspection, to comply with commitments made legally binding by a decision pursuant to Article 75c, or to comply with a decision pursuant to the first paragraph of this Article. Those penalty payments shall by effective and proportionate, and where applicable shall not exceed 5% of the average daily income or worldwide annual turnover in the preceeding financial year per day, calculated from the date appionted by the decision.	AT (Drafting suggestions): **Without prejudice to paragraph 4, t**~~T~~he AI Office may adopt a decision imposing periodic penalty payments to compel the **operators** ~~persons referred to in~~ subject to its competence pursuant to Article 75(1) to submit to an investigation, to comply with an information request ordered by a decision adopted under paragraph Article 75b(1), to submit to an on-site inspection ordered by a decision pursuant to Article 75b(4), to provide correct or complete answers or explanations in response to such an investigation, request or inspection, to comply with **corrective actions pursuant to Article 16 of Regulation (EU) 2019/1020 or** commitments made legally binding by a decision pursuant to Article 75c, or to comply with a decision pursuant to the first paragraph of this Article. Those penalty payments shall by effective and proportionate, and where applicable shall not exceed 5% of the average daily income or worldwide annual turnover in the preceeding financial year per day, calculated from the date appionted by the decision. AT (Comments): AT: Periodic penalty payments may be one type of fine imposed, but it must be clarified that this is not the only type of fine which is possible. In addition, a reference to corrective actions is missing. ES (Comments): **This does not constitute a red line, but it would be highly desirable.**

Second presidency compromise text	Drafting suggestions and Comments
	Spain seeks clarification regarding the introduction of a 5% maximum cap on periodic penalty payments in such cases, as Article 99 does not establish such a limitation for other operators.
6. The Court of Justice of the European Union shall have unlimited jurisdiction to review decisions of the Commission fixing a fine or periodic penalty payment under this article. It may cancel, reduce or increase the fine or periodic penalty payment imposed.	
7. Funds collected by imposition of fines or periodic penalty payments under this Article shall contribute to the general budget of the Union.	
8. Where the AI Office determines that there are no grounds to adopt a decision of non-compliance, it shall close the proceeding by a decision. The decision shall apply with immediate effect.	
Article 75e	
Safeguards and further specification	
	AT (Drafting suggestions): **1. Articles 77, 79(5) to (9) and 81 apply to measures taken by the AI Office, with the AI Office assuming the role of market surveillance authority set out there.** AT (Comments): AT: The Union safeguard procedure for corrective measures must be ensured. If the changes to Art 77 are retained in the final compromise, it is also necessary to clarify that the AI Office would have to provide this

Second presidency compromise text	Drafting suggestions and Comments
	information to the Art. 77 authorities for the AI systems under its supervision.
13. The powers conferred on the AI Office under Articles 75 and 75ba shall not be used to require the disclosure of information or documents that are subject to legal professional privilege or journalistic material privilege, or whose disclosure would otherwise violate the Charter of Fundamental Rights.'	AT (Drafting suggestions): **1.2.**
2. Article 18 of Regulation (EU) 2019/1020 shall apply *mutatis mutandis* to the persons subject to the AI Office's competence pursuant to Article 75(1), without prejudice to more specific procedural rights provided for in this Regulation.	AT (Drafting suggestions): **2.3.**
310. The Commission shall adopt an implementing act to further define the investigatory and enforcement powers and the procedures for the exercise of the monitoring and supervision tasks of the AI Office under this Section, including its ability to impose penalties, such as fines or other administrative sanctions as well as concerning the procedural rights outlined in Article 18 of Regulation (EU) 2019/1020. The implementing act shall also lay down the modalities of collaboration and consultation with the authorities involved in the application of this Regulation, including on the exchange of information where necessary for the effective supervision or enforcement of this Regulation.'	AT (Drafting suggestions): **3.4.** ES (Comments): **This does not constitute a red line, but it would be highly desirable.** Spain sees the need to clarify in such acts a safeguard clause for instances where national Market Surveillance Authorities (MSAs) could disagree with the criteria or decision adopted by the AI Office, yet are required to enforce it at the national level, consistent with the provisions laid out in Article 81(1) and (2). NL (Comments): The ability to impose penalties is defined is an essential part of this legislation and should therefore primarily be defined in the legislation itself.

Second presidency compromise text	Drafting suggestions and Comments
	We propose to amend article 101 of the AI Act to reflect the same limits to fines imposed by the European Commission as the AI Act imposes on member state authorities, see proposed addition of article 29[a].
	ES (Drafting suggestions):
~~**The following Article 75b is inserted:**~~	
~~**'Article 75b**~~	
~~**Judicial authorisation and fundamental rights**~~	
~~**1. If an on-site inspection provided for in Article 75a(4) requires authorisation by a judicial authority in accordance with national law, the AI Office shall apply for such an authorisation. The AI Office may also apply for such authorisation as a precautionary measure.**~~	
~~**2. Where an authorisation as referred to in paragraph 1 is applied for, the national judicial authority shall promptly verify that the coercive measures envisaged are neither arbitrary nor excessive having regard to the subject matter of the investigation or inspection and the documents provided by the AI Office with the decision. In its verification of the proportionality of coercive measures, the national judicial authority may ask the AI Office for detailed explanations, in particular relating to the grounds the AI Office has for suspecting that an infringement of this Regulation has taken place and the seriousness of the suspected infringement and, where relevant, the nature of the involvement of the person subject to the coercive measures. However, the national judicial authority shall not review the necessity of the investigation or inspection nor demand information from the case file of the Commission. In**~~	

Second presidency compromise text	Drafting suggestions and Comments
~~**accordance with the Treaties, the legality of the Commission's decision is subject to review only by the Court of Justice of the European Union.**~~	
~~**3. The powers conferred on the AI Office under Articles 75 and 75a shall not be used to require the disclosure of information or documents that are subject to legal professional privilege or journalistic material privilege, or whose disclosure would otherwise violate the Charter of Fundamental Rights.'**~~	
	DE (Drafting suggestions): **Art. 76 (2) should be replaced by the following:** **2) Where testing in real world conditions is conducted for AI systems that are supervised within an AI regulatory sandbox under Article 58, the market surveillance authorities shall verify the compliance with Article 57 as part of their supervisory role for the AI regulatory sandbox. Those authorities may, as appropriate, allow the testing in real world conditions to be conducted by the provider or prospective provider, in derogation from the conditions set out in Article 60(4), points (f) and (g).** DE (Comments): Article 76(2) establishes the rules for the supervision of testing of AI systems in real world conditions within an AI regulatory sandbox (as defined in Article 58) by market surveillance authorities and refers to Article 60 for the applicable regulations. We believe this is an incorrect reference, as Article 60 relates to the testing of high-risk AI systems (rather than AI systems of any risk level that may participate in an AI regulatory sandbox) outside of AI regulatory sandboxes (rather than within the framework of an AI regulatory sandboxes). Instead, it is assumed that a reference to Article

Second presidency compromise text	Drafting suggestions and Comments
	57 was intended. As this point has not yet been addressed by the AI Digital Omnibus proposal, we suggest addressing this ambiguity now. The intention is to allow flexibility from those specific high-risk testing requirements, not to verify compliance with the entire Article 60 process. The second reference to Article 60 needs to remain therefore.
(26) Article 77 is amended as follows:	
(a) the heading is replaced by the following:	
'**Powers of authorities protecting fundamental rights and cooperation with market surveillance authorities**'	
(b) paragraph 1 is replaced by the following:	
'1. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights, including the right to non-discrimination, shall have the power to make a request and access any information or documentation created or maintained from the relevant market surveillance authority under this Regulation in accessible language and format where access to that information or documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction. **This article is without prejudice to the competences, tasks, powers and independence of the relevant national public authorities or bodies under their mandates.**';	AT (Drafting suggestions): National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights, including the right to non-discrimination, shall have the power to make a request and access any information or documentation created or maintained ~~from the relevant market surveillance authority~~ under this Regulation **from providers or deployers** in accessible language and format where access to that information or documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction. This article is without prejudice to the competences, tasks, powers and independence of the relevant national public authorities or bodies under their mandates. AT (Comments):

Second presidency compromise text	Drafting suggestions and Comments
	AT: We have repeatedly noted that the gatekeeping function of market surveillance authorities in this context does not constitute a simplification of procedures for market actors, who will instead now necessarily and in all cases be obliged to interact with two instead of one authority. It furthermore is unduly burdensome for market surveillance authorities to request information. We are furthermore concerned that this new formulation implies that market surveillance authorities are obliged to use their powers pursuant to Art 14(4) on behalf of other authorities, e.g. conduct on-site inspections for the purposes of investigating whether consumer protection obligations related to advertising have been met, which would be highly questionable from a procedural perspective . DE (Drafting suggestions): 1. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights, including the right to non-discrimination, shall have the power to make a request and access any information or documentation created or maintained from the relevant market surveillance authority under this Regulation in accessible language and format where access to that information or documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction. This **article** is without prejudice to the competences, tasks, powers and independence of the relevant national public authorities or bodies under their mandates.'; DE (Comments): The current wording lacks clarity as to whether the last sentence refers only to paragraph 1 or to all paragraphs of the article 77. Since the content is particularly relevant due to the planned amendments (the insertion of

Second presidency compromise text	Drafting suggestions and Comments
	paragraphs 1a and 1b), the applicability to the entire article should be clarified. LV (Drafting suggestions): National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights, including the right to non-discrimination, shall have the power to make a request and access any information or documentation created or maintained from the relevant market surveillance authority under this Regulation in accessible language and format where access to that information or documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction. **This article is without prejudice to the competences, tasks, powers and independence of the relevant national public authorities or bodies under their mandates.**' **Those authorities and bodies retain any power they have to directly request information from operators pursuant to their mandate or other law.** LV (Comments): Drafting suggestion is in line with the Recital 19. Preserving the direct documentation and information access powers of the fundamental rights authorities is necessary for them to fulfill their mandates and retain their independence. Requiring them to obtain information only through MSAs can create risks of delays, information filtering, dependency on MSA capacity and, at the same time, increase the administrative burden on MSAs. Moreover, limiting the powers of the fundamnetal rights authorities could conflict with Article 3 and 8 of the Directive (EU) 2024/1499 and Article 3 and 8 of the Directive (EU) 2024/1500.
(c) the following paragraph 1a and 1b are inserted:	

Second presidency compromise text	Drafting suggestions and Comments
'1a. Subject to the conditions specified in this Article, the market surveillance authority shall grant the relevant public authority or body referred to in paragraph 1 access to such information or documentation, including by requesting such information or documentation from the provider or the deployer, where necessary.'	
'1b. Market surveillance authorities and public authorities or bodies referred to in paragraph 1 shall cooperate closely and provide each other with mutual assistance necessary for fulfilling their respective mandates, with a view to ensuring coherent application of this Regulation and Union law protecting fundamental rights and streamlining procedures. This shall include, in particular, exchange of information where necessary for the effective supervision or enforcement of this Regulation and the respective other Union legislation.';	
(27) Article 95, paragraph 4 is replaced by the following:	
'4. The AI Office and the Member States shall take into account the specific interests and needs of SMCs and SMEs, including start-ups, when encouraging and facilitating the drawing up of codes of conduct.';	DE (Comments): See comment Art. 63
(28) in Article 96(1), the second subparagraph is replaced by the following:	
'When issuing such guidelines, the Commission shall **involve the AI Board and** pay particular attention to the needs of SMCs and SMEs including start-ups, of local public authorities and of the sectors most likely to be affected by this Regulation.';	DE (Comments): See comment Art. 63
	DE (Drafting suggestions): Art. 6 (5) is amended as follows:

Second presidency compromise text	Drafting suggestions and Comments
	5. The Commission shall, after consulting the European Artificial Intelligence Board (the 'Board'), and no later than 2 February 2026, provide guidelines specifying the practical implementation of this Article in line with Article 96 together with a comprehensive list of practical examples of use cases of AI systems that are high-risk and not high-risk. **These guidelines shall be updated in line with Article 96(2).** Article 96 (2) is amended as follows 2. At the request of ~~the Member States~~ **AI Board** or the AI Office, or on its own initiative, the Commission shall update guidelines previously adopted ~~when deemed necessary~~. **When the AI Board requests such an update, the Commission shall present its draft update to the AI Board within three months. The adoption of updates to the guidelines by the Commission shall be subject to the approval of the AI Board.** DE (Comments): We advocate for a greater involvement of the EU member states in the process of updating the EU Commission's guidelines. This is necessary to ensure greater consistency, more practically rel-evant and more timely guidelines clarifying key questions of the AI Act's scope. Germany will submit such a proposal to the pres-idency.The guidelines on AI systems should be updated in a timely mat-ter, inter alia to clarify that systems primarily based on statistical models (such as linear logistic regression) do not qualify as AI systems under the AI Act and are therefore excluded from its scope.
(29) Article 99 is amended as follows:	FR (Comments): The lack of reference to some obligations of the AI Act in article 99, which sets the above limits of financial sanctions for some breaches, risks leading to

Second presidency compromise text	Drafting suggestions and Comments
	an interpretation on the fact that breach to obligations not strictly mentionned in article 99 are not financially punishable. This creates an uncertainty for Member States, which are required to make these obligations effective and enforceable, and may lead to less effective compliance by operation. It is therefore preferable to clarity the Member States's room for maneuver by amending the recitals so as to explicitly allow them to set financial penalties for breaches not explicitly mentionned in article 99.
(a) paragraph 1 is replaced by the following:	
	DE (Comments): See comment Art. 63
'1. In accordance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties and other enforcement measures, which may also include warnings and non-monetary measures, applicable to **any** infringement~~s~~ of this Regulation by operators, and shall take all measures necessary to ensure that they are properly and effectively implemented, thereby taking into account the guidelines issued by the Commission pursuant to Article 96. The penalties provided for shall be effective, proportionate and dissuasive. The Member States shall take into account the interests of SMCs and SMEs, including start-ups, and their economic viability when imposing penalties.';	BE (Drafting suggestions): 1. In accordance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties and other enforcement measures, which may also include warnings and non-monetary measures, applicable to infringements of this Regulation by operators, and shall take all measures necessary to ensure that they are properly and effectively implemented, thereby taking into account the guidelines issued by the Commission pursuant to Article 96. The penalties provided for shall be effective, proportionate and dissuasive. The Member States shall take into account the interests of ~~**SMCs and**~~ SMEs, including start-ups, and their economic viability when imposing penalties.'; BE (Comments): To increase their capacity to innovate, Belgium supports the extension of simplification measures from SMEs to SMCs, including regarding technical

Second presidency compromise text	Drafting suggestions and Comments
	documentation and quality management. However, to ensure a level playing field and adequate protection for SMEs, this extension must be limited to the simplification of administrative procedures. We are not in favor of extending financial support measures to SMCs. We could therefore envisaged such extension to SMCs for the proposed Articles except for Article 99. Furthermore, BE is mindful of the threshold defined for SMEs in the context of OMNIBUS IV and the concept that will be adopted for the digital omnibus, and reiterates that, in BE's view, this threshold should not be too high. EE (Drafting suggestions): '1. In accordance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties and other enforcement measures, which may also include warnings and non-monetary measures, applicable **to any infringement** of this Regulation by operators, and shall take all measures necessary to ensure that they are properly and effectively implemented, thereby taking into account the guidelines issued by the Commission pursuant to Article 96. The penalties provided for shall be effective, proportionate and dissuasive. ~~**The Member States shall take into account the interests of SMCs and SMEs, including start-ups, and their economic viability when imposing penalties.'**~~ EE (Comments): Penalties are meant to hold the violator accountable and ensure compliance. The penality should be proportionate to violator´s acts and size. Thus, the phrasing should focus instead on proportionality. Under proportionality, one can take into account e.g. the nature, gravity, and duration of the infringement. Thus, the last sentence is duplicating the idea of the proportionality principle.

Second presidency compromise text	Drafting suggestions and Comments
(b) paragraph 6 is replaced by the following:	
'6. In the case of SMCs and SMEs, including start-ups, each fine referred to in this Article shall be up to the percentages or amount referred to in paragraphs 3, 4 and 5, whichever thereof is lower.';	BE (Drafting suggestions): 6. In the case of ~~**SMCs and**~~ SMEs, including start-ups, each fine referred to in this Article shall be up to the percentages or amount referred to in paragraphs 3, 4 and 5, whichever thereof is lower.' DE (Comments): See comment Art. 63
	NL (Drafting suggestions): (29a) (a) the heading of Article 101 is replaced by the following: Penalties imposed by the Commission 1. The Commission may impose on providers of general-purpose AI models fines not exceeding 3 % of their annual total worldwide turnover in the preceding financial year or EUR 15 000 000, whichever is higher., when the Commission finds that the provider intentionally or negligently: (a) infringed the relevant provisions of this Regulation; (b) failed to comply with a request for a document or for information pursuant to Article 91, or supplied incorrect, incomplete or misleading information; (c) failed to comply with a measure requested under Article 93; (d) failed to make available to the Commission access to the general-purpose AI model or general-purpose AI model with systemic risk with a view to conducting an evaluation pursuant to Article 92.

Second presidency compromise text	Drafting suggestions and Comments
	(b) the following paragraph 1a is inserted: 1a. The Commission may impose on providers of AI-systems referred to in article 75 fines of up to EUR 35 000 000 or, if the offender is an undertaking, up to 7 % of its total worldwide annual turnover for the preceding financial year, whichever is higher, when the Commission finds that the provider intentionally or negligently infringed on the prohibition of the AI practices referred to in Article 5. (c) The following paragraph 1b is inserted: 1b. The Commission may impose on providers of AI-systems referred to in article 75 fines of up to EUR 15 000 000 or, if the offender is an undertaking, up to 3 % of its total worldwide annual turnover for the preceding financial year, whichever is higher when the Commission finds that the provider intentionally or negligently infringed on the obligations of providers pursuant to Article 16 or the transparency obligations for pursuant to Article 50.; (d) The following paragraph 1c is inserted: 1c. The Commission may impose on providers of AI-systems referred to in article 75 fines of up to EUR 7 500 000 or, if the offender is an undertaking, up to 1 % of its total worldwide annual turnover for the preceding financial year, whichever is higher, when the Commission finds that the provider intentionally or negligently supplied incorrect, incomplete or misleading information to the Commission in reply to a request. Before adopting the decision pursuant to this article, the Commission shall communicate its preliminary findings to the provider of the general-purpose AI model and give it an opportunity to be heard. NL (Comments):

Second presidency compromise text	Drafting suggestions and Comments
	The ability to impose penalties is defined is an essential part of this legislation and should therefore primarily be defined in the legislation itself. We propose to amend article 101 of the AI Act to reflect the same limits to fines imposed by the European Commission as the AI Act imposes on member state authorities.
(30) Article 111 is amended as follows:	
(a) paragraph 2 is replaced by the following:	
'2. Without prejudice to the application of Article 5 as referred to in Article 113(3), third paragraph, point (a), this Regulation shall apply to operators of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before the date of application of Chapter III and corresponding obligations referred to in Article 113, only if, as from that date, those systems are subject to significant changes in their designs. In any case, the providers and deployers of high-risk AI systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations laid down in this Regulation by 2 August 2030.';	ES (Drafting suggestions): '2. Without prejudice to the application of Article 5 as referred to in Article 113(3), third paragraph, point (a), this Regulation shall apply to operators of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before the date of application of Chapter III and corresponding obligations referred to in Article 113~~, only if, as from that date, those systems are subject to significant changes in their designs. In any case, the providers and deployers of high-risk AI systems intended to be used by public authorities~~ shall **be brought into compliance with** ~~take the necessary steps to comply with the requirements and obligations laid down in~~ this Regulation by 2 August 2030.'; ES (Comments): **This does not constitute a red line, but it would be highly desirable.** The fact that the application of the AI Act to high-risk AI systems (HRAIS) already placed on the market or put into service is contingent solely upon the occurrence of significant changes leaves such high-risk systems devoid of effective regulatory oversight.

Second presidency compromise text	Drafting suggestions and Comments
	For this reason, Spain proposes that high-risk systems falling within the scope of Article 111, notwithstanding the absence of significant changes, be mandated to comply with the requirements and obligations laid down in this Regulation by 2 August 2030. This would ensure parity with the applicable to systems utilised by public authorities.
(b) the following paragraph 4 is added:	PL (Comments): **The first priority for Poland. This is a key red line for Poland.** We would like to share our concerns regarding the proposed six-month transitional period for the marking obligations under Article 50(2). Given the rapid development and societal impact of generative AI applications, regulators should adapt as swiftly as possible to emerging risks rather than postpone safeguards. While we acknowledge the technical challenges of implementing machine-readable "invisible marking" solutions, we are concerned that delaying the obligations set out in Article 50(2) – including watermarking, metadata and cryptographic signatures – **could have significant societal consequences, particularly in the current geopolitical and electoral context**. Importantly, the discussion on implementation timelines should also account for the role of invisible marking under Article 50(2). This technical mechanism is critical for the effective functioning of platform moderation systems, fact-checking tools and supervisory activities carried out by regulators. Invisible marking is not an AI-label for humans, but rather **could have significant societal consequences, particularly in** (social media algorithms, fact-checking tools and regulators) **that enable identifying AI-generated content**. Similarly, for fact-checking organisations and media entities, invisible marking provides a verifiable technical indicator that can accelerate verification procedures and prioritise investigative resources. From a regulatory oversight perspective, Article 50(2) represents one of the few ex ante technical safeguards designed to prevent the large-scale dissemination of manipulative AI-generated content. Machine-readable provenance signals support evidence-based supervision, facilitate cross-platform cooperation and enable the auditing of compliance

Second presidency compromise text	Drafting suggestions and Comments
	with transparency obligations. A delay in the entry into application of these obligations risks creating a regulatory gap during which AI-generated content will remain largely indistinguishable from authentic content at scale, undermining the ability of platforms, media organisations, fact-checkers and public authorities to detect and mitigate manipulated content. Moreover, Article 50(2) represents **one of the few ex ante technical safeguards against large-scale dissemination of AI-generated manipulative content**. A delay in the entry into application of these obligations risks creating a regulatory gap during which AI-generated content will remain largely indistinguishable from authentic content at scale. **This may undermine the ability of platforms, media organisations, fact-checkers and public authorities to detect and mitigate manipulated content.** Conversely, the fast implementation of Article 50(2) should be seen as an important element of building the democracy resilience and decreasing the risk of potential societal harm. In light of these concerns, **we strongly advocate to maintain the current entry into application date** for Article 50(2) obligations on 2 August 2026, to mitigate the above mentioned risks. At the same time, listening to the discussion in the ASG, in an effort to find a balanced compromise, **we consider introducing a shorter transitional period: three months for the technical marking obligations** (until 2 November 2026), **while postponing the application of penalties and enforcement measures for six months** (until 2 February 2027) could be a compromise option. This could provide additional time for providers to adopt Commission's guidelines and standards while addressing the societal-related concerns.
'4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.';	AT (Drafting suggestions): ~~'4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.';~~ AT

Second presidency compromise text	Drafting suggestions and Comments
	(Comments): AT: Sufficient time has been available to implement these measures. Market surveillance authorities can take corrective measures to induce compliance which do not necessarily entail fines. BE (Drafting suggestions): ~~4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.';~~ BE (Comments): BE is **not in favour** of introducing this six-month grace period. Despite the technical difficulties of implementing this obligation in the absence of guidelines, Belgium considers that postponing the application of such a labelling obligation would raise major questions about the protection of individuals and transparency in relation to deepfakes, issues that cannot be deferred without considerable risk. DE (Drafting suggestions): *"(b) the following paragraph 4 is added:* 4a. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with article 50(2) by 2 February 2027.'; ***4b. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, whose intended purpose is exclusively for industrial***

Second presidency compromise text	Drafting suggestions and Comments
	applications, shall take the necessary steps in order to comply with article 50(2) by 2 August 2027.'"] DE (Comments): Regarding the transparency obligation (point 30 of the Compromise Text), we have examined the proposed grace period regarding that obligation in general. Our examination includes the recognition that article 50 is important for democracy, which is why a quick entry into force is crucial. However, particularly in the context of B2B uses of AI systems, it is problematic that the implementation process with the Code of practice is delayed. The companies need time to implement the requirement. EL (Drafting suggestions): ~~'4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.';~~ EL (Comments): As already mentioned in our comments on the 1st Compromise text, we oppose the introduction of a 6 month-long extension to the obligation of existing providers of generative systems in regard to their obligations under Art.50. Transparency obligations are one of the obligations with the highest impact for EU citizens right now, considering the current AI systems market in the EU.

Second presidency compromise text	Drafting suggestions and Comments
	Thus, we would strongly encourage the removal of the newly suggested par.4 to Art.111 of the AI Act. ES (Drafting suggestions): ~~**4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.';**~~ ES (Comments): **This does not constitute a red line, but it would be highly desirable.** **This position is aligned with Poland's proposal to maintain the original date (2 August 2026).** It is imperative to note that digital forgeries generated via synthetic content represent a pre-eminent challenge due to their potential to deceive millions of individuals, particularly vulnerable groups such as minors or persons at risk of social exclusion. Consequently, this proposal could effectively result in a delay in the oversight of the unregulated dissemination of synthetic content, including impersonation and potentially deceptive material. PL (Drafting suggestions): ~~4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been~~

Second presidency compromise text	Drafting suggestions and Comments
	~~placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.~~
(31) Article 113 is amended as follows:	DE (Comments): Of course, the timely availability of support measures is key and indispensable, especially harmonized European standards. Hence, the COM proposal in principle goes into the right direction. However, COM's proposal risks adding complexity and prolonging uncertainty. We therefore prefer fixed predictable timeline extensions instead of flexible extensions. Only fixed predictable timeline extensions ensure legal certainty and allow for sound preparation. If the final omnibus includes COM's proposal for a flexible timeline, it is indispensable to include a stronger role for the Member States/AI Board in assessing whether the support measures are adequate, especially because the market surveillance of the high-risk AI systems is with the Member states. Moreover, it should also be clarified which criteria are used to assess the adequacy of the available support measures. We prefer a fixed timeline extension of 12 months, both for Annex I and Annex III, accompanied by close monitoring of the relevant standards, guidelines, implementing Acts and other necessary deliverables. HU (Comments): We agree with the new deadlines. However, as we suggested earlier, we also propose the postponement the obligation on the establishment of the MS national regulatory sandboxes. We believe that regulatory AI sandboxes will be relevant primarily for High-Risk system providers/deployers, therefore the effective usage of these sandboxes will really begin when the High-Risk obligations are fully known (by the adoption of the standards) and are

Second presidency compromise text	Drafting suggestions and Comments
	applicable (at the proposed fix dates in the new revised text). Therefore, we suggest that – as it is in the published text of AIA – that the establishment deadline of MS operated AI regulatory sandboxes shall be aligned to the new application date of the High-Risk measures of AIA. Obviously, the earlier date - December 2. 2027 – shall be taken into account is this regard. SE (Comments): SE strongly supports the amendments set out below to Article 113, which change the date of entry into force for the specified provisions, in accordance with: ”[…] on 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.; […]”
(a) in the third paragraph, point (**cd**) is ~~added~~**replaced by the following**:	
‘(d) Chapter III, Sections 1, 2, and 3, shall apply ~~following the adoption of a decision of the Commission confirming that adequate measures in support of compliance with Chapter III are available, from the following dates:~~	AT (Drafting suggestions): ‘(d) **Sanctions according to Article 99 for** Chapter III, Sections 1, 2, and 3, shall apply AT (Comments): AT: Our concerns regarding measures to support innovation and the protection of citizens and consumers remain unresolved and we continue to prefer the entry into application of the requirements as planned with a delay in the possibility for market surveillance authorities to impose penalties. This would give market surveillance authorities the possibility to provide guidance or request other corrective measures in the meantime. DK

Second presidency compromise text	Drafting suggestions and Comments
	(Drafting suggestions): ‘(d) Chapter III, Sections 1, 2, and 3, **shall otherwise stated directly in the articles** apply DK (Comments): We would again like to support the amendments of 1(31) and we believe these should be agreed upon as quickly as possible to provide the necessary legal clarity. Nevertheless, as the text stands now, it seems that we have also prolonged the deadline for the Commission to issue the much-needed guidelines on high-risk classification in article 6.5 of the AI Act. The original deadline was the 2nd of February this year. While that deadline obviously has not been met, we should ensure that these guidelines are available at least 6 months before entry into application of the high-risk requirements as originally foreseen. We are open to other solutions to address this issue. EE (Comments): We support postponing the obligations for providers of high-risk AI systems under the AI Regulation to allow additional time for the development of standards and guidelines. Once these are established, both public and private sectors should have sufficient time to align their activities accordingly. Implementation deadlines must be clear and fixed, rather than flexible, to ensure legal certainty and predictability. Harmonised standards, technical specifications, and guidelines are essential for companies providing or using AI systems, as they facilitate cost-effective compliance and ensure system quality and trust. As the development of these materials has taken longer than expected, we support postponing the application of high-risk AI obligations. IT

Second presidency compromise text	Drafting suggestions and Comments
	(Drafting suggestions): '(d) Chapter III, Sections 1, 2, and 3, and **Chapter VI** shall apply ~~following the adoption of a decision of the Commission confirming that adequate measures in support of compliance with Chapter III are available, from the following dates:~~
~~(i) 6 months after the adoption of that decision as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and~~	
~~(ii) 12 months after the adoption of the decision as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.~~	
~~In the absence of the adoption of the decision within the meaning of subparagraph 1, or where the dates below are earlier than those that follow the adoption of that decision, Chapter III, Sections 1, 2, and 3, shall apply:~~	EE (Drafting suggestions): The Commission must provide standards, common specifications and guidelines in support of compliance with AI Act before new deadlines, taking into account that implementers need time to adjust to the new requirements.
(i) on 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and	IT (Drafting suggestions): (i) on 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, **and as regards the rules on the establishment and operation of regulatory sandboxes**, and SE (Comments): SE supports the amendments.

Second presidency compromise text	Drafting suggestions and Comments
(ii) on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.**;**	SE (Comments): SE supports the amendments.
	DE (Comments): We also suggest an extension of the deadline under Art. 113 (b) AI Act for determining national supervisory structures or a standstill period before initiating infringement proceedings
(b) in the third paragraph, point (e) is added:	
'~~3.~~**(e)** Articles 102 to 110 shall apply from [the date of entry into ~~application~~**force** of this **amending** Regulation].';	
(32) in Annex VIII, section B**, points 7 and 9 are** ~~is~~ deleted;	AT (Drafting suggestions): in Annex VIII, section B, point~~s 7 and~~ 9 **is** ~~are~~ deleted; AT (Comments): AT: Without significantly clarifying the extent of the information to be provided under point 6, it is not clear whether the deletion of point 7 would be counterproductive and instead lead to more requests by market surveillance authorities. DE (Comments):

Second presidency compromise text	Drafting suggestions and Comments
	In general we welcome to further asssess whether all requirements of Annex VIII are needed, We are, however, sceptical regarding the deletion of requirements 7 and 9 in Annex VIII, Section B IT (Drafting suggestions): ~~in Annex VIII, section B,~~ **~~points 7 and 9 are~~** ~~is deleted;~~ IT (Comments): Iwe do not agree with the proposal to delete the information set out in Annex VIII point 7 and 9. In particular, "the brief summary of the reasons why an AI system is classified as not high-risk under the procedure outlined in Article 6(3)" (point 7, Annex VIII), is of crucial importance for the MSAs. The information provided in point 6 alone is insufficient for a preliminary evaluation of the rationale behind the application of the filters specified in Article 6.3 of the AI Act and to determine whether to activate the procedure under Article 80 of the AI Act, as well as to establish the priority for doing so. Additionally, the information in point 9 indicating "any Member States in which the AI system has been placed on the market, put into service, or made available in the Union," is also important for assessing the relevance of the AI systems and the potential cross-border issues that may arise. We could be open only to the deletion of the information under point 9 for AI systems that are considered not high-risk, not for all the AI systems. SE (Drafting suggestions): (32) in Annex VIII, **~~points 7 and 9 are~~** section B **is** deleted; SE (Comments):

Second presidency compromise text	Drafting suggestions and Comments
	As SE supports the removal of the registration requirement, Annex VIII, Section B should be deleted.
	DE (Comments): Clarification of Annex III, point 5(b) Annex III, point 5(b) of the AI Act should be amended and clarified in order to ensure consistency with the recitals and to provide a legally certain delineation of different use cases: In particular, the exemption explicitly referred to in Recital 58 for AI systems intended under Union law for supervisory purposes relating to the calculation of capital requirements should also be explicitly reflected in the wording of Annex III, point 5(b).
(33) the following Annex XIV is added:	DE (Drafting suggestions): ~~(33) the following Annex XIV is added:~~ DE (Comments): See comment for Art. 30.
'Annex XIV	DE (Drafting suggestions): ~~'Annex XIV~~
The list of codes, categories and corresponding types of AI systems for the purpose of the notification procedure referred to in Article 30 specifying the scope of the designation as notified bodies	DE (Drafting suggestions):

Second presidency compromise text	Drafting suggestions and Comments
	~~**The list of codes, categories and corresponding types of AI systems for the purpose of the notification procedure referred to in Article 30 specifying the scope of the designation as notified bodies**~~
1. Introduction	DE (Drafting suggestions): ~~1. Introduction~~
Conformity assessment of high-risk AI systems under this Regulation may require involvement of conformity assessment bodies. Only conformity assessment bodies that have been designated in accordance with this Regulation may carry out conformity assessments and only for the activities related to the types of AI systems concerned. The list of codes, categories, and corresponding types of AI systems sets the scope of the designation of conformity assessment bodies notified under Article 30 of this Regulation.	DE (Drafting suggestions): ~~Conformity assessment of high-risk AI systems under this Regulation may require involvement of conformity assessment bodies. Only conformity assessment bodies that have been designated in accordance with this Regulation may carry out conformity assessments and only for the activities related to the types of AI systems concerned. The list of codes, categories, and corresponding types of AI systems sets the scope of the designation of conformity assessment bodies notified under Article 30 of this Regulation.~~
2. List of Codes, categories, and corresponding AI systems	DE (Drafting suggestions): ~~2. List of Codes, categories, and corresponding AI systems~~
1. AI systems subject to Annex I of the AI Act	
	FR (Drafting suggestions): AIA Code AIP 0101 AI systems subject to Annex I.A.1. of the AI Act. AIP 0102 AI systems subject to Annex I.A.2. of the AI Act.

Second presidency compromise text	Drafting suggestions and Comments
	AIP 0103 AI systems subject to Annex I.A.3. of the AI Act. AIP 0104 AI systems subject to Annex I.A.4. of the AI Act. AIP 0105 AI systems subject to Annex I.A.5. of the AI Act. AIP 0106 AI systems subject to Annex I.A.6. of the AI Act. AIP 0107 AI systems subject to Annex I.A.7. of the AI Act. AIP 0108 AI systems subject to Annex I.A.8. of the AI Act. AIP 0109 AI systems subject to Annex I.A.9. of the AI Act. AIP 0110 AI systems subject to Annex I.A.10. of the AI Act. ~~**AIP 0111 AI systems subject to Annex I.A.11. of the AI Act.**~~ ~~**AIP 0112 AI systems subject to Annex I.A.12. of the AI Act.**~~ FR (Comments): To be read in conjunction with the proposed revisions to Article 30, with a view to facilitating the process of designating notified bodies for MDs or IVDs under the IVDM There are already two NANDO codes for medical devices and two NANDO codes for in vitro diagnostic medical devices, attesting to the conformity assessment competences of notified bodies already designated under the MD/IVD regulations. The deletion of the two cross-cutting codes relating to Regulations (EU) 2017/745 and (EU) 2017/746 aims to reduce the administrative burden associated with the designation of the notified bodies concerned, without changing the level of competence required to assess medical devices or in vitro diagnostic medical devices, which are high-risk AI systems.
[…]	
2. AI systems subject to Annex III.1 of the AI Act	

Second presidency compromise text	Drafting suggestions and Comments
[…]	
3. AI technology-specific codes	
a) Symbolic AI, expert systems and mathematical optimization	AT (Drafting suggestions): Symbolic AI **approaches**~~, expert systems and mathematical optimization~~ AT (Comments): AT: Symbolic AI approaches include expert systems
[…]	
b) Machine learning, excluding GPAI and single modality generative AI	AT (Drafting suggestions): **Subsymbolic AI approaches**~~Machine learning, excluding GPAI and single modality generative AI~~ AT (Comments): AT: Mathematical optimisation as well as the other categories proposed by the EC are included in subsymbolic AI approaches
[…]	
c) AI systems based on GPAI or single modality generative AI	AT (Drafting suggestions):

Second presidency compromise text	Drafting suggestions and Comments
	Bilateral or other AI approaches ~~AI systems based on GPAI or single modality generative AI~~ AT (Comments): AT: Bilateral approaches combine symbolic and subsymbolic approaches and can therefore not be subsumed under either; in addition, necessity to retain flexibility for future developments, hence the "other" category
[…]	
d) Agentic AI	AT (Drafting suggestions): ~~*d) Agentic AI*~~ AT (Comments): AT: Agentic AI may be composed of one or several approaches of AI technology, it is, however, in itself not a certain category of technology and should therefore be deleted.
[…]	
3. Application for designation	
Conformity assessment bodies shall use the lists of codes, categories and corresponding types of AI systems set out in this Annex when specifying the types of AI systems in the application for designation referred to in Article 29 of this Regulation.'.	

Second presidency compromise text	Drafting suggestions and Comments
Article 2	
Amendments to Regulation (EU) 2018/1139	ES (Comments): **Those comments are devliverd from the Spanish supervisor of civil aviation regarding modification on their regulation.** Spain requests clarification regarding what appears to be a systemic inconsistency: while the proposal introduces new provisions for implementing acts in Articles 27, 50, and 53, it omits parallel updates for the corresponding delegated acts provided for in Articles 28 and 54. Given that previous amendments—such as those introduced by Article 108 of the Artificial Intelligence Act—have always ensured symmetry between implementing and delegated acts when dealing with AI systems acting as safety components, we ask the Commission to clarify whether this omission is a deliberate decision or a mere drafting error. **This does not constitute a red line, but it would be highly desirable.**
Regulation (EU) 2018/1139 is amended as follows:	
(1) in Article 27, the following paragraph is added:	
'3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council[14], the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.';	

Second presidency compromise text	Drafting suggestions and Comments
14 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, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).	
(2) in Article 31, the following paragraph is added:	
'3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.';	
(3) in Article 32, the following paragraph is added:	
'3. When adopting delegated acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.';	
(4) in Article 36, the following paragraph is added:	
'3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.';	

Second presidency compromise text	Drafting suggestions and Comments
(5) in Article 39 the following paragraph is added:	
'3. When adopting delegated acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.';	
(6) in Article 50, the following paragraph is added:	
'3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.';	
(7) in Article 53, the following paragraph is added:	
'3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'.	
Article 3	
Entry into force and application	

Second presidency compromise text	Drafting suggestions and Comments
This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.	
This Regulation shall be binding in its entirety and directly applicable in all Member States.	
Done at Brussels,	
For the European Parliament *For the Council*	
The President *The President*	