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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Antici Group (Simplification)
Subject:	Omnibus VII (Digital Omnibus on AI) – 4 column document – AGS meeting on 1 April 2026

Delegations will find attached the 4 column document containing the Commission's proposal and the co-legislators' mandates.

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI)

- Examination of the European Parliament mandate and update on the kick-off trilogue

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI) (Text with EEA relevance)

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
	Formula					
G	1	2025/0359 (COD)	2025/0359 (COD)	2025/0359 (COD)		G
	Document Stage					
G	2	Proposal for a	Proposal for a	Proposal for a		G
	Document Type					
G	3	REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL		G
	Document Purpose					
G	4	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)	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)	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)		G
	EEA Relevance					
G	5	(Text with EEA relevance)	(Text with EEA relevance)	(Text with EEA relevance)		G
	Formula					
G	6	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		G

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Citation 1				
7	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,	
Citation 2				
8	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	
Citation 3				
9	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	
Citation 4				
10	Having regard to the opinion of the European Economic and Social Committee[1], _____ 1. OJ C , , p. .	Having regard to the opinion of the European Economic and Social Committee[1], _____ 1. OJ C , , p. .	Having regard to the opinion of the European Economic and Social Committee[1], _____ 1. OJ C , , p. .	
Citation 5				
11	Having regard to the opinion of the Committee of the Regions[1], _____ 1. OJ C , , p. .	Having regard to the opinion of the Committee of the Regions[1], _____ 1. OJ C , , p. .	Having regard to the opinion of the Committee of the Regions[1], _____ 1. OJ C , , p. .	
Citation 6				
12	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	
Formula				
13	Whereas:	Whereas:	Whereas:	
Recital 1				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 14	(1) Regulation (EU) 2024/1689 of the European Parliament and of the Council[1] 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. 1. Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).	(1) Regulation (EU) 2024/1689 of the European Parliament and of the Council[1] 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. 1. Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).	(1) Regulation (EU) 2024/1689 of the European Parliament and of the Council[1] 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. 1. Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).	G
Recital 2				
G 15	(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	(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	(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	G

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	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 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.	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 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.	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 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.	
Recital 3				
16	(3) Consequently, targeted amendments to Regulation (EU) 2024/1689 are necessary to address certain implementation challenges, with a view to the effective application of the relevant rules.	(3) Consequently, targeted amendments to Regulation (EU) 2024/1689 are necessary to address certain implementation challenges, with a view to the effective***, simple and uniform*** application of the relevant rules.	(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.	
Recital 3a				
16a		***(3a) Additionally, the Commission, the AI Office and Member States' competent***		

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		authorities should ensure that supervision, enforcement and monitoring of sectorial and national laws do not create overlaps, inconsistent interpretations or divergent enforcement in order to enable AI innovation in the private and public sector.		
Recital 4				
17	(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	(4) ***99,8% of all Union companies are small and medium-sized enterprises, the majority of which are micro and small enterprises.***[3a] 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	(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	

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	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[1] and Annex to Commission Recommendation 2025/3500/EC[2]. _____ 1. 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). 2. 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).	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 ***where appropriate while safeguarding the overarching objectives and level of protection afforded under Regulation (EU) 2024/1689[3b]***. 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~~[1]~~[4] and Annex to Commission Recommendation 2025/3500/EC~~[2]~~[5]. ***[3a] https://single-market-economy.ec.europa.eu/system/files/2023-08/Annual%20Report%20on%20European%20SMEs%202023_FINAL.pdf*** ***[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).*** ***[5] Commission Recommendation (EU) 2025/1099 of 21 May 2025 on the definition of small mid-cap***	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[1] and Annex to Commission Recommendation 2025/3500/EC[2]. _____ 1. 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). 2. 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).	

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		enterprises (OJ L, 2025/1099, 28.5.2025, ELI: http://data.europa.eu/eli/reco/2025/1099/oj). ~~*1. 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).*~~ ~~*2. 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)*~~.		
Recital 5				
18	(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	(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*~~***skills*** to make informed decisions regarding AI systems deployment. However, experience shared by stakeholders reveals that a ~~*one-size-fits-all*~~ solution ***imposing stringent obligations to ensure a sufficient level of AI literacy*** is not suitable for all types of providers and deployers in relation to the	(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	

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	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. The European Artificial Intelligence Board ('Board') 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	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 ***of AI systems to support*** ~~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~~. The European ~~Artificial Intelligence Board ('Board') will ensure recurrent exchange between the~~ Commission ~~and Member States on the topic, while the Apply AI Alliance will allow discussion with the wider~~	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**	

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	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.	~~*community. This amendment is without prejudice to the broader measures taken by the Commission and the Member States to*~~***should*** promote AI literacy and competences for the wider population, ~~*including learners, students, and citizens at different ages and*~~***and in order to support, facilitate and complement the efforts of providers, should be tasked to issue guidance on the practical implementation regarding the obligation on providers and deployers of AI systems, and should, together with the Member States, encourage and support AI literacy in society. This should include facilitating and complementing the efforts of providers and deployers of AI systems,*** in particular ~~*through education and training systems*~~***SMEs, as the implementation of the relevant obligations poses particular challenges for them. One possibility to facilitate AI literacy in the Union could be the creation of Public Private Partnerships (PPPs).***	**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).**	

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Recital 5a				
18a		***(5a) AI systems that alter, manipulate or artificially generates realistic images or videos depicting sexually explicit activities, or the intimate parts of an identifiable natural person, without that person's consent, cause harm to victims and violate fundamental rights to dignity and privacy. The proliferation of such technologies, often marketed as 'nudification' applications, has created an urgent need for explicit regulatory prohibition. Regulation (EU) 2024/1689 establishes a framework for prohibited AI practices, which is to be kept under review. This is without prejudice towards the rights, freedoms and principles recognised by Article 6 TEU and the Charter of Fundamental Rights of the European Union, and the exercise of the rights guaranteed therein to freedom of expression and information and the freedom of the arts and sciences. This prohibition should not apply to providers or deployers of AI systems who have put in place effective safety measures, such as technical and organisational measures, to prevent the generation of such depictions and to avoid continuously misuse, after***		

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		the system has been placed, on the market or put into service, despite the intention of the provider or deployer. Moreover, this prohibition should not prevent AI providers from developing their technical capabilities to alter, manipulate or artificially generate images or videos.		
Recital 6				
19	(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 Regulation (EU) 2024/1689 already provides a legal basis authorising 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[1]. Given that discrimination might result also from those other AI systems and models, it is therefore appropriate that Regulation (EU) 2024/1689 should provide for a legal basis for the processing of special categories of personal data also by providers and deployers of other AI systems and AI models as	(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 ~~*processing of*~~***providers of high-risk AI systems to process*** special categories of personal data ~~*under Article 9(2), point (g), of Regulation (EU) 2016/679 of the European Parliament and of the Council*~~[1]~~*.*~~ ~~*Given that*~~***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***	(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 ~~processing of~~**providers of high-risk AI systems to process** special categories of personal data ~~under Article 9(2), point (g), of Regulation (EU) 2016/679 of the European Parliament and of the Council~~[1]~~.~~ ~~Given that~~**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**	

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	well as deployers of high-risk AI systems. The legal basis is established in 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[2] and Article 10, point (a) of Directive (EU) 2016/680 of the European Parliament and of the Council[3] provides a legal basis allowing, where necessary for 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. 1. 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). 2. 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	***likely to affect the health and safety of persons, have a negative impact on fundamental rights or lead to*** discrimination ~~*might result also from those other AI systems and models*~~***prohibited under Union law. Accordingly***, ~~*it is therefore appropriate that Regulation (EU) 2024/1689 should provide for a legal basis for*~~ ***a substantial public interest exists to permit, where strictly necessary,*** the processing of special categories of personal data ***for the purposes of bias detection and correction. It is therefore necessary to extend the legal basis established under Regulation (EU) 2024/1689 so that it also applies to the*** also by providers and 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 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[2] and Article 10, point (a) of Directive (EU) 2016/680 of the European Parliament and of the Council[3] ~~*provides a legal basis*~~	**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. Nevertheless, biases likely to have those effects** might **also** result **from the actions of the deployers of high-risk AI systems. Furthermore, such biases could also arise in the case of** ~~also from those~~ other AI systems ~~and~~ **or** models**. For example, biases in eligibility or risk-scoring tools used to assess applications for various types of public permits or licences can restrict rights or effectively bar certain groups from access to public services, and biased AI-enabled fitness or wellness applications that do not constitute medical devices may**~~, it is therefore appropriate that Regulation (EU) 2024/1689 should~~ provide **skewed guidance with potential health implications. Accordingly, a substantial public interest exists to permit, exceptionally and where strictly necessary,** ~~for a legal basis for~~ the processing of special- categories of personal data **for the purposes of bias detection and correction. It is therefore necessary to extend the legal basis established under Regulation (EU) 2024/1689 so that**	

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	movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: http://data.europa.eu/eli/reg/2018/1725/oj). 3. 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).	~~*allowing, where necessary for the detection and removal of bias,*~~*.* *[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 ~~*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*~~*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 No 1247/2002/EC (OJ L 295, 21.11.2018, p*~~*and Directive (EU) 2016/680, as applicable*~~*. 39, ELI: http://data.europa.eu/eli/reg/2018/1725/oj).*	**it also applies to the** ~~also by~~ providers and 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[22] and Article 10, point (a) of Directive (EU) 2016/680 of the European Parliament and of the Council[3] ~~provides a~~[3]**. 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** ~~allowing, where necessary for 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~~	

	CLEAN	Commission Proposal	VS.EC	EP Mandate	VS.EC	Council Mandate	VS.EC	Draft Agreement
				_____ ~~1. 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).~~ ~~2. 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 No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: http://data.europa.eu/eli/reg/2018/1725/oj).~~ ~~3. 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).~~		~~Regulations (EU) 2016/679~~**mitigation activities in preparation for compliance with the high-risk requirements, including Article 10(2), points (f) and (g), of** Regulation (EU) ~~2018/1725 and Directive (EU) 2016/680, as applicable~~**2024/1689, the legal basis established by Article 4a should apply from entry into application of this Regulation**. _____ ~~1. 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).~~ ~~2. 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 No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: http://data.europa.eu/eli/reg/2018/1725/oj).~~ ~~3. 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~~		

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			~~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).~~	
Recital 6a				
19a			**(6a) Article 5 of Regulation (EU) 2024/1689 prohibits certain practices of AI systems that are particularly harmful and abusive, contradict certain Union values and violate certain fundamental rights. Article 5 is to be kept under review, as notably shown by Article 112(1) of that Regulation. In light of technological and societal developments since the adoption of that Regulation, including the deployment and widespread use of AI systems capable of generating non-consensual intimate images, videos and similar content ('NCII') and child sexual abuse material ('CSAM'), it is necessary to amend that list. NCII provide powerful new tools for sexual violence and abuse against individuals, especially women. Systems capable of generating, manipulating or reproducing such material pose a severe risk to victims' human dignity, personal autonomy, integrity and private life, with potentially serious lasting**	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			psychological and other harms and abuse at scale. CSAM, including wholly or partially synthetic content, constitutes a grave threat to the safety and fundamental rights of children. Systems capable of generating, manipulating or reproducing such material pose a grave risk to human dignity and the rights of the child, and risk normalising, amplifying and perpetuating sexual violence against children. Accordingly, an amendment to Article 5 of Regulation (EU) 2024/1689 is necessary both to protect women, children, other individuals and society from seriously harmful practices, thereby pursuing the objectives of that Regulation itself, and to bring clarity to providers and deployers as to the scope of their obligations, thereby addressing implementation challenges.	
Recital 6b				
19b			**(6b) It is necessary to define clearly the scope of the prohibition, including in particular the extent of providers and deployers' obligations. The prohibition should be limited to systems capable of generating, manipulating or reproducing NCII or CSAM. The concept of**	

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			'capability' should be defined as limited to two cases. First, it should cover systems intended to generate, manipulate or reproduce NCII or CSAM. Second, it should cover systems where such generation, manipulation or reproduction is a reasonably foreseeable and reproducible outcome and the system does not have effective technical safety measures and other safeguards to prevent, and where necessary correct, that outcome. The fact that such generation, manipulation or reproduction requires the use of specific prompts, prompt variations or repeated attempts does not exclude reproducibility where such outputs can be obtained without significant technical modifications. Effective technical measures and other safeguards to prevent the generation of such content could include data cleaning, refusal training, prompts safe design and output controls, content classification and filtering mechanisms, usage restrictions, abuse detection mechanisms, and notice and action and corrective measures. Where a system does enable the creation of intimate content, those technical	

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			safeguards and other measures would need to include a system to reliably demonstrate consent to such creation, for instance by user consent combined with user account authentication and controlled uploading of images or videos, in full compliance with Regulation (EU) 2016/679. The prohibition regarding NCII should be limited to realistic depictions of intimate parts or of sexual activity. This 'realism' refers to the depiction of the person's image and their body in a credible real-life manner, regardless of the realism of the context of that depiction and of whether it fully corresponds to the actual appearance of the body and the intimate parts of the depicted person. Conversely, it excludes cartoonish or physically impossible depictions of a person's body. The prohibition on CSAM should not prevent the placing on the market, putting into service or use of an AI system where a 'without right' defence applies under national law, as referred to in Article 5(1) of Directive 2011/93/EU. This includes activities carried out under domestic legal powers, such as the legitimate generation, manipulation or reproduction of	

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			child pornography by the authorities in order to conduct criminal proceedings or to prevent, detect or investigate crime.	
Recital 6c				
19c			**(6c) These prohibitions constitute justified interferences with the freedom of expression and information and the freedom to conduct a business. They pursue weighty objectives of general interest and protect the rights and freedoms of others, including under Articles 1, 3(1), 4, 7, 8, 21, 23 and 24 of the Charter of Fundamental Rights. They are closely tailored, including by being limited to realistic depictions of identifiable natural persons as regards NCII; impose an obligation of means rather than ends on providers and deployers; restrict only one means of content creation; exclude generation, manipulation and reproduction with the person's consent in the case of intimate images; and are aligned with existing Union law, including Directive 2011/93/EU and Directive 2024/1385. The interference respects the essence of Articles 11 and 16 of the**	

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			Charter, is prescribed by law, and is proportionate.	
Recital 7				
20	(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[1] and (EU) 2017/746[2] 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.	*deleted*	(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~~ **unified** 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[1] and (EU) 2017/746[2] of the European Parliament and of the Council, where such a procedure is established under that Union harmonisation legislation. The single application and **unified** 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. **The**	

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	_____ 1. 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) 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). 2. 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).		**unified assessment procedure has to be carried out with respect to the tasks and responsibilities of the authorities involved. 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.** _____ 1. 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) ~~No 178/2002~~**No 178/2002** and Regulation (EC) ~~No 1223/2009~~**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). 2. 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).	
Recital 8				
21	(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	*deleted*	(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	

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	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		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~~ **have the power to assess conformity of high-risk AI**	

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	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 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.		**systems** under ~~that Regulation within~~ **certain conditions for** 18 months from [the entry into application of this Regulation]. This amendment is without prejudice to Article 28 of Regulation (EU) 2024/1689**, thus conformity assessment bodies that wish to be designated and notified under that Regulation can submit an application at any time during and after these 18 months**. Moreover, Regulation (EU) 2024/1689 should be amended to clarify that 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 to that Regulation, the provider should follow the relevant conformity assessment procedure as required under that relevant harmonisation legislation.	
Recital 8a				
21a		***(8a) Regulation (EU) 2024/1689 and Regulation (EU) 2024/2847 complement each other so that the safety and cybersecurity of products with digital elements is ensured. It is necessary to ensure the alignment of Regulation (EU) 2024/1689 and Regulation (EU) 2024/2847, to allow for their***		

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		smooth implementation. Where high-risk AI systems fulfil the essential cybersecurity requirements set out in Regulation (EU) 2024/2847, they should be deemed to comply with the cybersecurity requirements set out in Article 15 of Regulation (EU) 2024/1689 in so far as those requirements are covered by the EU declaration of conformity or parts thereof issued pursuant to Regulation (EU) 2024/2847.		
Recital 8b				
21b		***(8b) For the purposes of this Regulation, the fact that an AI system is integrated into, or operates within, a product subject to Union harmonisation legislation on product safety should not, in itself, imply that the AI system performs a safety function. An AI system should be regarded as performing a safety function only where its functioning is necessary to ensure that the product or the AI system complies with applicable Union safety requirements. By contrast, functionalities intended solely for user assistance, performance optimisation, service efficiency, automation, convenience, or quality control of non-safety-related aspects should not be regarded as safety functions***		

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		under this Regulation, where their failure would not directly create risks to health or safety.		
Recital 9				
22	(9) To streamline compliance and reduce the associated costs, 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. 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 registration requirements would constitute a disproportionate compliance burden. Nevertheless, a provider 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.	(9) To streamline compliance and reduce the associated costs, ~~*providers of AI systems should not be required to register*~~***the registration of*** 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~~*. Given that*~~ ***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, the registration requirements 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~~*, imposing registration requirements would constitute a disproportionate compliance burden. Nevertheless*~~***. Furthermore***,	(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~~. Given that~~ **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, the registration requirements 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~~, imposing registration requirements would constitute a disproportionate compliance burden. Nevertheless~~**.**	

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		a provider ~~*who considers that an AI system falls under*~~***applying*** 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.	**Furthermore**, a provider ~~who considers that an AI system falls under~~ **applying** 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.	
Recital 10				
23	(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 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	(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 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	(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 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	

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	establish an AI regulatory sandbox at Union level for AI systems that are covered by Article 75(1) of Regulation (EU) 2024/1689. By leveraging these infrastructures and facilitating cross-border collaboration, coordination would be better streamlined and resources optimally utilised.	establish an AI regulatory sandbox at Union level for AI systems that are covered by Article 75(1) of Regulation (EU) 2024/1689. ***When discussions are held within the framework of the Board, the European Data Protection Supervisor and the AI Office, as part of their roles within the board, should provide feedback and exchange best practices on matters related to the establishment and operation of AI regulatory sandboxes that were established under their respective competences.*** By leveraging these infrastructures and facilitating cross-border collaboration, coordination would be ~~*better*~~ streamlined and resources optimally utilised. ***In order to foster innovation and facilitate the uptake of AI, SMEs, including startups, and SMCs should be provided with priority access to the AI regulatory sandboxes established by the AI Office. Where AI regulatory sandboxes, including the controlled environment to foster innovation, involve innovative AI systems that process personal data, the relevant national supervisory authorities should be involved in accordance with their tasks and powers.***	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.	

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Recital 11				
24	(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.	(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, ***subject to sufficient safeguards***.	(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.~~	
Recital 11a				
24a			**(11a) It is also appropriate to ensure that real-world testing of**	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			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, 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)	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			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. A consequential change to Article 3(57) is necessary. Article 76 does not apply in respect of products covered by the Union harmonisation legislation listed in Section B of Annex I, and so does not apply to testing in real-world conditions in respect of such products. Member States, including their relevant national	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			competent authorities or appropriate authorities, are responsible for ensuring compliance with these regimes.	
Recital 12				
G 25	(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.	(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.	(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.	G
Recital 12a				
25a		***(12a) In order to allow the AI Office to effectively exercise its duties under Regulation (EU) 2024/1689 and in light of the new powers conferred on it by this Regulation, adequate human, financial and technical resources should be provided, without prejudice to the budgetary procedure and existing financial instruments. In particular, the AI Office should have a sufficient number of personnel whose expertise include an in-depth understanding of AI technologies.***		
Recital 13				

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 26	(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.	(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.*~~	(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.~~	G
Recital 14				
27	(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. 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	(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 ***and AI systems referred to in Annex III, point 2*** 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	(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~~ **. The Commission has exclusive competence as regards general-purpose AI models under Article 88 of** that Regulation. ~~While sectoral authorities continue to remain responsible for the supervision~~ **To increase coherence, clarity and**	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	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[1]. Article 14 of Regulation (EU) 2019/1020 should apply mutatis mutandis. Furthermore, to ensure effective enforcement, the authorities involved in the application of Regulation (EU) 2024/1689 should cooperate actively in the exercise of those powers, in particular where enforcement actions need to be taken in the territory of a Member State. _____	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[1][11]. Article 14 of Regulation (EU) 2019/1020 should apply mutatis mutandis. Furthermore, to ensure effective enforcement, the authorities involved in the application of Regulation (EU) 2024/1689 should cooperate actively in the exercise of those powers, in particular where enforcement actions need to be taken in the territory of a Member State.	**effectiveness, and in light of the reach and impacts** 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~~ **linked to those competences, the scope of the AI Office's exclusive competence to supervise** systems based **on such models should be refined. In particular, the AI Office should have exclusive competence over AI systems built** on general-purpose AI models **not only where both the system and the model are** developed by the same provider ~~within the scope~~**, but also where they are developed by providers that form part** of the ~~AI Office's~~**same undertaking. However, in certain cases, notably where there is specific sectoral** supervision**, responsibility should remain with the relevant national competent authority**. **Accordingly, certain exceptions should be laid down. The personal scope of this exclusive competence should extend to the providers of those AI systems and to their deployers within the same undertaking. Other deployers should remain subject to national supervision and enforcement. Moreover,** this does not include AI	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	1. 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).	[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).*** ~~1. 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).~~	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[1]. Article 14 of Regulation (EU) 2019/1020 should apply mutatis mutandis. Furthermore, to ensure effective enforcement, the authorities involved in the application of Regulation (EU) 2024/1689 should cooperate actively in the exercise of those powers, in particular where enforcement actions need to be taken in the territory of a Member State.~~ ~~1. 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~~	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			~~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).~~	
Recital 14a				
27a				
Recital 15				
28	(15) Considering the existing supervisory and enforcement system under Regulation (EU) 2022/2065 of the European Parliament and of the Council[1], 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	(15) Considering the existing supervisory and enforcement system under Regulation (EU) 2022/2065 of the European Parliament and of the Council[1], 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	(15) **Additionally,** considering the existing supervisory and enforcement system under Regulation (EU) 2022/2065 of the European Parliament and of the Council[1], 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 **and effective** manner**. This is also**	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	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 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	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 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	**appropriate in light of the importance of such platforms and search engines, in view of their reach, impact and potential to cause complex and large societal harms. The personal scope of this exclusive competence should extend to the providers of those AI systems and to their deployers within the same undertaking**. 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 Regulation. In addition, the AI Office and the competent national authorities under (EU) 2024/1689	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	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. _____ 1. 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).	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. _____ 1. 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).	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. _____ 1. 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).	
Recital 16				

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
29	(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 powers listed in Article 14 of Regulation (EU) 2019/1020 should be conferred upon the AI Office. The Commission should therefore be empowered to adopt implementing acts to specify those powers, including 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. This should ensure that the AI Office has the necessary tools to effectively monitor and supervise compliance with Regulation (EU) 2024/1689.	(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 powers listed in Article 14 of Regulation (EU) 2019/1020 should be conferred upon the AI Office. The Commission should therefore be empowered to adopt implementing acts to specify those powers, including 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. This should ensure that the AI Office has the necessary tools to effectively monitor and supervise compliance with Regulation (EU) 2024/1689.	(16) ~~To further operationalise~~**When supervising and enforcing those AI systems,** the AI Office's ~~supervision and enforcement set out in Article 75(1) of~~ **has the same role and responsibility as a market surveillance authority under** Regulation (EU) 2024/1689**. Consequently, it is necessary for the AI Office to have all of the powers and responsibilities that market surveillance authorities have under that Regulation and under Regulation (EU) 2019/1020 ("the general powers"). These must ensure the appropriate and effective enforcement of the requirements and obligations set out by Regulation (EU) 2024/1689. However**, it is necessary to ~~further define the which of~~**specify and frame certain essential elements and other aspects of the general powers, as well as their safeguards ("the specifying provisions"). In particular, it is necessary to lay down provisions governing the relationship between the AI Office and national authorities; provisions specifying and constraining** the powers ~~listed~~**to request information and conduct on-site inspections; provisions governing investigations,**	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			including the possibility for binding commitments; and provisions specifying and constraining power to find non-compliance, impose fines and impose periodic penalties. Where a type of general power has been so specified, the AI Office may not circumvent the conditions and limits of those powers by relying on a related general power. Conversely, types of general power that are not specified and framed in respect of the AI Office – such as the power to adopt measures referred to in Article ~~14~~**16(3)** of Regulation (EU) 2019/1020 ~~should be conferred upon~~ **may be relied on by** the AI Office. The Commission should ~~therefore be empowered to~~ adopt **an** implementing ~~acts to specify those powers~~**act further defining the rules and the procedures for the exercise of the enforcement, monitoring and supervision tasks of the AI Office**, including **any necessary specification of the general powers. In exercising all of these powers, AI Office must comply**~~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. This~~	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			~~should ensure that~~**Charter of Fundamental Rights.** **Additionally,** the AI Office ~~has the necessary tools to effectively monitor and supervise compliance with Regulation (EU) 2024/1689~~**is subject to the safeguards and protection for fundamental rights laid down in the specifying provisions**.	
Recital 17				
30	(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.	(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.	(17) ~~Additionally, it is essential to ensure that effective~~**In addition to those** procedural **and fundamental rights** 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**, and the implementing act should establish detailed arrangements and procedural safeguards as regards proceedings in view of the possible adoption of fines or penalty payments**.	
Recital 18				
31	(18) To enable access to Union market for AI systems which are under the supervision by the AI	(18) To enable access to Union market for AI systems which are under the supervision by the AI	(18) To enable access to Union market for AI systems which are under the supervision by the AI	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	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.	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*~~***ensure that*** pre-market conformity assessments ~~*of*~~***are carried out for*** those systems. ***Furthermore, the AI Office should maintain organised records of communications with providers and deployers of general-purpose AI models with systemic risk. Such records should be documented in a consistent manner.***	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~~ **responsible for** pre-market conformity assessments of those systems.	
Recital 19				
32	(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	(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	(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	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	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.	documentation should be made to the competent market surveillance authority, which should respond to such requests ***without undue delay***, 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 tasks, powers and independence of the relevant national public authorities or bodies under their mandates. In particular, those 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 directly request information from operators pursuant to their mandate or other law.***	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 directly request information from operators pursuant to their mandate or other law.**	
Recital 19a				
32a			**(19a) The requirements for high-risk AI systems laid down in Regulation (EU) 2024/1689 address specific risks inherent to AI systems, including bias, unpredictable model behaviour, poor robustness or accuracy, vulnerabilities to attacks by third parties, lack of transparency of AI system. By addressing AI specific risks, that Regulation**	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			complements the requirements laid down in Union harmonisation legislation listed in its Annex I, without duplicating them. Regulation (EU) 2024/1689 provides mechanisms for economic operators to minimise the compliance burden. In particular, Articles 8(2) on the interplay with the sectoral legislation, 9(10) on risk management and 17(3) on quality management allow economic operators to integrate, when necessary and appropriate, an assessment of AI specific risks into existing risk and quality management systems. Article 40 further requires the Commission to specify that AI Act harmonised standards must be consistent with standards developed under the Union harmonisation legislation listed in Annex I. The Commission should provide guidance to assist economic operators of high-risk AI systems covered in Annex I in complying with this Regulation, including by providing guidance on application of Articles 8(2), 9(10) and 17(3) as mechanisms to minimise the compliance burden, in line with principles of complementary and proportionality.	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Recital 20				
33	(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.	(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~~ 3 months for providers who have already placed their systems on the market before the 2 August 2026.	(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.	
Recital 21				
G 34	(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	(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	(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	G

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	same type and model of high-risk AI system are subject to the grace 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.	same type and model of high-risk AI system are subject to the grace 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.	same type and model of high-risk AI system are subject to the grace 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.	
Recital 22				
35	(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	(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	(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	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	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, it is appropriate to 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	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,*~~ It is appropriate ~~*to put in place a mechanism that links the entry into*~~***that the date of*** 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*~~***of*** obligations ~~*for high-risk AI systems should apply after 6 months as regards*~~***on*** AI systems classified as high-risk pursuant to Article 6(2) and Annex III and ~~*after 12 months as regards*~~***on*** AI systems classified as high-risk pursuant to Article 6(1) and Annex I to Regulation (EU) 2024/1689~~*. However, this flexibility*~~	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~~put in place a mechanism that links the entry into~~ **align the implementation timeline and set the date for the** application~~to the availability of measures in support of compliance with~~ **of Sections 1, 2 and 3 of** 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~~ **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** ~~and~~	

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	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.	~~*should only be extended*~~ ***is postponed*** 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.	~~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**	

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			application of the rules across Member States.	
Recital 22a				
35a		***(22a) In order to ensure legal certainty and to avoid further delays in application of this Regulation, the Commission should ensure that measures in support of compliance with regard to Chapter III, Sections 1, 2, and 3 are in place in due time to ensure timely and effective implementation of the necessary provisions.***		
Recital 23				
36	(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)	(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)	(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)	

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	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.	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 ***with their monitoring obligations***, the Commission should be required to publish guidance ***on the post-market monitoring plan, including a template with elements to be included therein, by 2 February 2027***.	thereof to adopt implementing acts. **Given that the codes of practice referred to in Article 50(7) and 56(6) have limited legal effect, and in particular do not grant a presumption of conformity, it is not strictly necessary for these codes to be approved by an implementing act. Providers should be able to rely, under Article 53(4) and 54(2), on codes of practice assessed as adequate pursuant to Article 56(6).** 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.	
Recital 23a				
36a		***(23a) The parallel application of sectoral Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689 of the European Parliament and of the Council and***		

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		the requirements set out in that Regulation for high-risk artificial intelligence systems may lead to overlaps of requirements and unnecessary administrative burden for economic operators. Such overlaps could create legal uncertainty, increase compliance costs and potentially lead to competitive disadvantages, without providing additional benefits for the protection of health, safety or fundamental rights. In order to ensure a more coherent and proportionate regulatory framework and to simplify the application of requirements for artificial intelligence systems embedded in products regulated under Union harmonisation legislation, the references to the Union harmonisation legislation currently listed in Section A of Annex I to Regulation (EU) 2024/1689 should therefore be moved to Section B of that Annex. This approach clarifies that artificial intelligence systems integrated into products covered by those sectoral acts are subject to the requirements of this Regulation where relevant, while allowing the conformity assessment procedures and product safety requirements under the respective sectoral legislation to remain the primary		

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		framework. Any remaining gaps relating to artificial intelligence systems integrated into such products should be addressed within the relevant sectoral legislation.		
Recital 23b				
36b		***(23b) In order to safeguard the horizontal nature of this Regulation and ensure the proper functioning of the internal market, the relevant requirements laid down in Chapter III, Section 2 of this Regulation should be deemed to constitute essential health and safety requirements for high-risk AI systems covered by Union harmonisation legislation listed in Annex I and should be applied in a consistent and coherent manner across those sectoral frameworks. For this purpose, the Commission should be entitled to adopt delegated acts taking into account the requirements set out in Chapter III, Section 2 of this Regulation as regards their application to AI systems falling within its scope as well as relevant harmonised standards. In doing so, the Commission should not go beyond the requirements laid down in Regulation (EU) 2024/1689 for this purpose and should take into account the specific context of***		

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		sectorial legislation. Before adopting the acts referred to in the first subparagraph, the Commission should conduct open and transparent consultations with relevant stakeholders, including competent authorities, notified bodies, civil society and industry.		
Recital 24				
G 37	(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	(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	(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	G

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	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 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.	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 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.	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 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.	

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Recital 25				
38	(25) Regulation (EU) 2018/1139 of the European Parliament and the Council[1] 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. 1. Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of	(25) Regulation (EU) 2018/1139 of the European Parliament and the Council[1] 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. 1. Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of	(25) Regulation (EU) 2018/1139 of the European Parliament and the Council[1] 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. 1. Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of	

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	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).	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).	civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) ~~No 2111/2005~~**No 2111/2005**, (EC) ~~No 1008/2008~~**No 1008/2008**, (EU) ~~No 996/2010~~**No 996/2010**, (EU) ~~No 376/2014~~**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~~**No 552/2004 and (EC) No 216/2008** of the European Parliament and of the Council and Council Regulation (EEC) ~~No 3922/91(OJ~~**No 3922/91(OJ** L 212, 22.8.2018, pp. 1–122, ELI: http://data.europa.eu/eli/reg/2018/1139/oj).	
Recital 25a				
38a		***(25a) When implementing and enforcing this Regulation, national competent authorities, the AI office and the Commission should take into account the objectives set out in Article 1(1) of Regulation (EU) 2024/1689 and follow the principles of necessity, proportionality, legal certainty and technological neutrality, while at the same time ensuring that unnecessary administrative and compliance burdens are minimised.***		
Recital 26				
G 39	(26) In order to ensure legal certainty as soon as possible, with a view to the imminent general application of Regulation (EU)	(26) In order to ensure legal certainty as soon as possible, with a view to the imminent general application of Regulation (EU)	(26) In order to ensure legal certainty as soon as possible, with a view to the imminent general application of Regulation (EU)	G

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	2024/1689, this Regulation should enter into force as a matter of urgency,	2024/1689, this Regulation should enter into force as a matter of urgency,	2024/1689, this Regulation should enter into force as a matter of urgency,	
Recital 27				
39a			**(26a) 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,**	
Formula				
40	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	
Article 1				
41	Article 1 Amendments to Regulation (EU) 2024/1689	Article 1 Amendments to Regulation (EU) 2024/1689	Article 1 Amendments to Regulation (EU) 2024/1689	Article 1 Amendments to Regulation (EU) 2024/1689 Text Origin: Commission Proposal
Article 1, first paragraph				
42	Regulation (EU) 2024/1689 is amended as follows:	Regulation (EU) 2024/1689 is amended as follows:	Regulation (EU) 2024/1689 is amended as follows:	Regulation (EU) 2024/1689 is amended as follows: Text Origin: Commission Proposal
Article 1, first paragraph, point (1)				
43	(1) in Article 1(2), point (g) is replaced by the following:	(1) in Article 1(2), point (g) is replaced by the following:	(1) in Article 1(2), point (g) is replaced by the following:	(1) in Article 1(2), point (g) is replaced by the following:

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				Text Origin: Commission Proposal
Article 1, first paragraph, point (1), amending provision, numbered paragraph (g)				
G 44	‘ (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.; ’	‘ (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.; ’	‘ (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.; ’	‘ (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.; ’ Text Origin: Commission Proposal
Article 1, first paragraph, point (2)				
Y 45	(2) in Article 2, paragraph 2 is replaced by the following:	(2) in Article 2, paragraph 2 is replaced by the following:	(2) ~~in~~ Article 2~~, paragraph 2 is replaced by the following~~ **is amended as follows**:	
Article 1, first paragraph, point (2), amending provision, numbered paragraph (2)				
Y 46	‘ 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 57 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.; ’	‘ 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***, Articles 110a-110l*** and Articles 111 and 112 shall apply. Article 57 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.; ’	‘ 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 57~~**Articles 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.;**’** ’	

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Article 1, first paragraph, point (2a)					
G	46a			**(b) paragraph 7 is replaced by the following:**	***(b) paragraph 7 is replaced by the following:*** Text Origin: Council Mandate	G
Article 1, first paragraph, point (2b)					
G	46b			**(2b) '7. Union law on the protection of personal data, privacy and the confidentiality of communications applies to personal data processed in connection with the rights and obligations laid down in this Regulation. This Regulation shall not affect Regulation (EU) 2016/679 or (EU) 2018/1725, or Directive 2002/58/EC or (EU) 2016/680, without prejudice to Article 4a and Article 59 of this Regulation.'**	***(2b) '7. Union law on the protection of personal data, privacy and the confidentiality of communications applies to personal data processed in connection with the rights and obligations laid down in this Regulation. This Regulation shall not affect Regulation (EU) 2016/679 or (EU) 2018/1725, or Directive 2002/58/EC or (EU) 2016/680, without prejudice to Article 4a and Article 59 of this Regulation.'*** Text Origin: Council Mandate	G
Article 1, first paragraph, point (3)					
Y	47	(3) in Article 3, the following points (14a) and (14b) are inserted:	(3) in Article 3, the following points (14a) and (14b) are inserted:	(3) ~~in~~ Article 3~~, the following points (14a) and (14b) are inserted~~ **is amended as follows**:		Y
Article 1, first paragraph, point (3), amending provision, point (1)					
Y	47a			**(a) the following points (14a) and (14b) are inserted:**	' ***(a) the following points (14a) and (14b) are inserted:*** Text Origin: Council Mandate	Y

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
Article 1, first paragraph, point (3), amending provision, numbered paragraph (14a)						
G	48	‘ (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;	‘ (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;	‘ (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;	(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; Text Origin: Commission Proposal	G
Article 1, first paragraph, point (3), amending provision, numbered paragraph (14b)						
G	49	(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; ,	(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; ,	(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;	(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; , Text Origin: Commission Proposal	G
Article 1, first paragraph, point (3), amending provision, numbered paragraph (14ba)						
Y	49a			**(b) point (57) is replaced by the following:**		Y
Article 1, first paragraph, point (3), amending provision, numbered paragraph (14ba)						
Y	49b			**"testing in real-world conditions’ means the temporary testing of an AI system for its intended purpose in real-world conditions outside a laboratory or otherwise simulated environment, with a view to gathering reliable and robust data and to assessing and verifying the conformity of the AI system with the**		Y

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			requirements of this Regulation, or corresponding sectoral provisions as referred to in Article 60a, and it does not qualify as placing the AI system on the market or putting it into service within the meaning of this Regulation, provided that all the conditions laid down in Article 57, 60 or 60a are fulfilled;" ,		
Article 1, first paragraph, point (4)					
G	50	(4) Article 4 is replaced by the following:	(4) Article 4 is replaced by the following:	(4) Article 4 is replaced by the following: Text Origin: Commission Proposal	G
Article 1, first paragraph, point (4), amending provision, first paragraph					
G	51	‘ Article 4	‘ Article 4	‘ Article 4 Text Origin: Commission Proposal	G
Article 1, first paragraph, point (4), amending provision, second paragraph					
G	52	AI literacy	AI literacy	AI literacy , Text Origin: Commission Proposal	G
Article 1, first paragraph, point (4), amending provision, third paragraph					
Y	53	‘The Commission and Member States shall encourage providers and	***1.*** ‘~~*The Commission and Member States shall encourage*~~	‘The Commission and Member States shall encourage providers and	Y

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	deployers of AI systems to 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 systems are to be used.; '	Providers and deployers of AI systems ~~to~~***shall*** take measures to ~~*ensure a sufficient level*~~***support the improvement*** 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. ***This obligation does not cover any guarantee of a specific level of AI literacy of any individual.***;	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.~~;~~	
Article 1, first paragraph, point (4), amending provision, third paragraph a				
Y	53a	***2. The Commission shall issue guidance on the practical implementation of the obligation on providers and deployers of AI systems under paragraph 1.***		Y
Article 1, first paragraph, point (4), amending provision, third paragraph a				
Y	53b		**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).**	Y
Article 1, first paragraph, point (4), amending provision, third paragraph b				
Y	53c	***3. The Commission and the Member States shall encourage***		Y

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		and support AI literacy in society and among the general population and support, facilitate and complement the efforts of providers and deployers of AI systems, in particular SMEs, for example via the creation of Public Private Partnerships in fulfilling their obligation under paragraph 1.; ,			
Article 1, first paragraph, point (4), amending provision, third paragraph b					
Y	53d		**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.';** ,		Y
Article 1, first paragraph, point (5)					
G	54	(5) the following Article 4a is inserted in Chapter I:	(5) the following Article 4a is inserted in Chapter I:	(5) the following Article 4a is inserted in Chapter I: Text Origin: Commission Proposal	G
Article 1, first paragraph, point (5), amending provision, first paragraph					
G	55	' Article 4a	' Article 4a	' Article 4a	G

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				Text Origin: Commission Proposal
Article 1, first paragraph, point (5), amending provision, second paragraph				
56	Processing of special categories of personal data for bias detection and mitigation	Processing of special categories of personal data for bias detection and mitigation	Processing of special categories of personal data for bias detection and mitigation	Processing of special categories of personal data for bias detection and mitigation Text Origin: Commission Proposal
Article 1, first paragraph, point (5), amending provision, numbered paragraph (1)				
57	1.To the extent 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 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:	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 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:	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:	
Article 1, first paragraph, point (5), amending provision, numbered paragraph (1), point (a)				
58	(a) the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;	(a) the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;	(a) the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;	(a) the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;

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				Text Origin: Commission Proposal
Article 1, first paragraph, point (5), amending provision, numbered paragraph (1), point (b)				
59	(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;	(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;	(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;	(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; Text Origin: Commission Proposal
Article 1, first paragraph, point (5), amending provision, numbered paragraph (1), point (c)				
60	(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;	(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;	(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;	(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; Text Origin: Commission Proposal
Article 1, first paragraph, point (5), amending provision, numbered paragraph (1), point (d)				
61	(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties;	(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties;	(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties;	(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties;

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				Text Origin: Commission Proposal
Article 1, first paragraph, point (5), amending provision, numbered paragraph (1), point (e)				
G 62	(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;	(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;	(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;	(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; Text Origin: Commission Proposal
Article 1, first paragraph, point (5), amending provision, numbered paragraph (1), point (f)				
Y 63	(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.	(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.	(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 **strictly** necessary to detect and correct biases, and why that objective could not be achieved by processing other data.	
Article 1, first paragraph, point (5), amending provision, numbered paragraph (2)				
G 64	2.Paragraph 1 may apply to providers 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.;	2.~~*Paragraph 1 may apply to*~~ Providers 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***	2.~~Paragraph 1 may apply to~~ Providers 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**	2.~~*Paragraph 1 may apply to*~~ Providers 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***

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	’	***process special categories of personal data to the extent that:***	**process special categories of personal data to the extent that:**	***process special categories of personal data to the extent that:*** Text Origin: EP Mandate
Article 1, first paragraph, point (5), amending provision, numbered paragraph (2a), first subparagraph				
G 64a		***2.(a) processing is 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***		***2.(a) processing is 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*** Text Origin: EP Mandate
Article 1, first paragraph, point (5), amending provision, numbered paragraph (2a), second subparagraph				
G 64b		***(b) all of the conditions and safeguards set out in paragraph 1 are applied.***		***(b) all of the conditions and safeguards set out in paragraph 1 are applied.*** Text Origin: EP Mandate
Article 1, first paragraph, point (5), amending provision, numbered paragraph (2b)				
G 64c		***3.This paragraph does not create any obligation to conduct such bias detection and correction.’*** ,		***2b. This paragraph does not create any obligation to conduct such bias detection and correction.’*** , Text Origin: EP Mandate
Article 1, first paragraph, point (5), amending provision, numbered paragraph (2c)				

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G	64d			**(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**		G
	Article 1, first paragraph, point (5), amending provision, numbered paragraph (2b)					
G	64e			**(b) all of the conditions and safeguards set out in paragraph 1 are applied.**		G
	Article 1, first paragraph, point (5), amending provision, numbered paragraph (2c)					
G	64f			**This paragraph does not create any obligation to conduct such bias detection and correction.'**		G
	Article 1, first paragraph, point (5), amending provision, numbered paragraph (2d)					
Y	64g			**5a Article 5 is amended as follows:**		Y
	Article 1, first paragraph, point (5), amending provision, numbered paragraph (2e)					
Y	64h			**(a) the following points are added to paragraph 1, first subparagraph:**		Y
	Article 1, first paragraph, point (5), amending provision, numbered paragraph (2f)					
Y	64i			**(ba) the placing on the market, the putting into service or the use of an AI system capable of generating, manipulating or**		Y

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			reproducing realistic images, videos, audio or similar material of an identifiable natural person's intimate parts, or of an identifiable natural person engaged in sexually explicit activities, without that person's freely-given, specific, informed, unambiguous and explicit consent for that generation, manipulation or reproduction;	
Article 1, first paragraph, point (5), amending provision, numbered paragraph (2g)				
Y	64j		**(bb) the placing on the market, the putting into service or the use of an AI system capable of generating, manipulating or reproducing child pornography or pornographic performance within the meaning of Article 2, points (c) and (e), of Directive 2011/93/EU, save where a 'without right' defence applies under national law;'**	Y
Article 1, first paragraph, point (5), amending provision, numbered paragraph (2h)				
Y	64k		**(b) The following paragraphs are inserted:**	Y
Article 1, first paragraph, point (5), amending provision, numbered paragraph (2i)				
Y	64l		**1a. For the purposes of paragraph 1, first subparagraph, points (ba) and (bb), an AI system is capable of generating, manipulating or reproducing the content referred to in those points where:**	Y

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Article 1, first paragraph, point (5), amending provision, numbered paragraph (2j)				
64m			**(a) that generation, manipulation or reproduction is the intended purpose of the AI system; or**	
Article 1, first paragraph, point (5), amending provision, numbered paragraph (2k)				
64n			**(b) the system's design, training, architecture, capabilities or user-facing functionalities make that generation, manipulation or reproduction a reasonably foreseeable reproducible outcome, without requiring significant technical modification, and the system does not have effective technical safety measures and other safeguards to reliably prevent that generation, manipulation or reproduction and to reliably correct any observed or reported misuse.**	
Article 1, first paragraph, point (5), amending provision, numbered paragraph (2l)				
64o			**1b. The prohibition in paragraph 1, first subparagraph, point (ba) shall not affect the generation, manipulation or reproduction of other forms of nude content, such as content that does not depict identifiable natural persons, realistic partially nude depictions where intimate parts are not revealed, non-realistic artistic nude works, and satirical works that do not realistically depict identifiable natural persons**	

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			engaged in sexual activity or depict their intimate parts.' ,	
Article 1, first paragraph, point (5a), first subparagraph				
64p		***(5a) in Article 5, paragraph 1, subparagraph 1 the following point is added:***		
Article 1, first paragraph, point (5a), second subparagraph				
64q		***(ha) the placing on the market, the putting into service or the use of an AI system that alters, manipulates or artificially generates realistic images or videos so as to depict sexually explicit activities or the intimate parts of an identifiable natural person, without that person's consent.***		
Article 1, first paragraph, point (5a), third subparagraph				
64r		***This prohibition does not apply to providers or deployers of AI systems who have put in place effective safety measures to prevent the generation of such depictions and to avoid misuse continuously, after the system has been placed, on the market or put into service despite the intention of the provider or deployer.***		
Article 1, first paragraph, point (5a), fourth subparagraph				
64s		***This prohibition shall not prevent AI providers from developing any***		

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				capabilities referred to in the first subparagraph.				
Article 1, first paragraph, point (5a), first subparagraph								
Y	64t			***(5b) Article 6(1) is amended as follows:***				
Article 1, first paragraph, point (5b), second subparagraph								
Y	64u			***"1. Irrespective of whether an AI system is placed on the market or put into service independently of the products referred to in points (a) and (b), that AI system shall be considered to be high-risk where both of the following conditions are fulfilled:*** ***(a) the AI system is intended to be used as a safety component of a product and whose functioning is necessary to ensure that the product or AI system complies with applicable Union safety requirements, or the AI system is itself a product, covered by the Union harmonisation legislation listed in Annex I;*** ***(b) the product whose safety component pursuant to point (a) is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service of that product***				Y

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		pursuant to the Union harmonisation legislation listed in Annex I. ***"***		
Article 1, first paragraph, point (5c), first subparagraph				
Y	64v	***(5c) In Article 6, paragraph 1a is added:***		Y
Article 1, first paragraph, point (5c), second subparagraph				
Y	64w	***1a. For the purposes of this Regulation, functionalities intended solely for user assistance, performance optimisation, service efficiency, automation, convenience, or quality control of non-safety-related aspects shall not be regarded as safety functions under this Regulation, where their failure would not directly create risks to health or safety.'***		Y
Article 1, first paragraph, point (6)				
G	65	(6) in Article 6(4), paragraph 4 is replaced by the following:	(6) ~~in Article 6(4), paragraph 4 is replaced by the following:~~	*deleted*
Article 1, first paragraph, point (6), amending provision, numbered paragraph (4)				
G	*66*	' *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	' 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~~	*deleted*

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	shall provide the documentation of the assessment.; ,		~~shall provide the documentation of the assessment.;~~ ,	
Article 1, first paragraph, point (7)				
67	*(7)* Article 10 is amended as follows:	(7) Article 10 is amended as follows:	(7) Article 10 is amended as follows:	(7) Article 10 is amended as follows: Text Origin: Commission Proposal
Article 1, first paragraph, point (7)(a)				
68	(a) paragraph 1 is replaced by the following:	(a) paragraph 1 is replaced by the following:	(a) paragraph 1 is replaced by the following:	(a) paragraph 1 is replaced by the following: Text Origin: Commission Proposal
Article 1, first paragraph, point (7)(a), amending provision, numbered paragraph (1)				
69	‘ 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.; ,	‘ 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.; ,	‘ 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.; ,	‘ 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.; , Text Origin: Commission Proposal
Article 1, first paragraph, point (7)(b)				
70	(b) paragraph 5 is deleted;	(b) paragraph 5 is deleted;	(b) paragraph 5 is deleted;	(b) paragraph 5 is deleted;

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				Text Origin: Commission Proposal
Article 1, first paragraph, point (7)(c)				
71	(c) paragraph 6 is replaced by the following:	(c) paragraph 6 is replaced by the following:	(c) paragraph 6 is replaced by the following:	(c) paragraph 6 is replaced by the following: Text Origin: Commission Proposal
Article 1, first paragraph, point (7)(c), amending provision, numbered paragraph (6)				
72	‘ 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.; ’	‘ 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.; ’	‘ 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.; ’	‘ 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.; ’ Text Origin: Commission Proposal
Article 1, first paragraph, point (8)				
73	(8) in Article 11(1), the second subparagraph is replaced by the following:	(8) in Article 11(1), the second subparagraph is replaced by the following:	(8) in Article 11(1), the second subparagraph is replaced by the following:	(8) in Article 11(1), the second subparagraph is replaced by the following: Text Origin: Commission Proposal
Article 1, first paragraph, point (8), amending provision, first paragraph				
74	‘ 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	‘ 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	‘ 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	‘ 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

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	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 manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment.;	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 manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment.;	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**, and SMCs**, 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**, and SMCs**. Where an ~~SMC or~~ SME, including a start-up**, or an SMC**, opts to provide the information required in Annex IV in a simplified manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment.;	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***, and SMCs***, 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***, and SMCs***. Where an ~~*SMC or*~~ SME, including a start-up***, or an SMC***, opts to provide the information required in Annex IV in a simplified manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment.; Text Origin: Council Mandate
Article 1, first paragraph, point (9)				
75	(9) in Article 17, paragraph 2 is replaced by the following:	(9) in Article 17, paragraph 2 is replaced by the following:	(9) in Article 17, paragraph 2 is replaced by the following:	(9) in Article 17, paragraph 2 is replaced by the following: Text Origin: EP Mandate
Article 1, first paragraph, point (9), amending provision, numbered paragraph (2)				

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G 76	‘ 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.; ’	‘ 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.; ’	‘ 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**, or an SMC**. 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.; ’	‘ 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***, or an SMC***. 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.; ’ Text Origin: Council Mandate
Article 1, first paragraph, point (9a), first subparagraph				
Y 76a		***(9a) Article 25(2) is replaced by the following:***		Y
Article 1, first paragraph, point (9a), second subparagraph				
Y 76b		***"2. Where the circumstances referred to in paragraph 1 occur, the provider that initially placed the AI system on the market or put it into service shall no longer be considered to be a provider of that specific AI system for the purposes of this Regulation.*** ***That initial provider, as well as providers of general-purpose AI models whose models are integrated into high-risk AI systems, shall closely cooperate***		Y

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		with new providers and shall make available the necessary information and provide the reasonably expected technical access and other assistance that are required for the fulfilment of the obligations set out in this Regulation, in particular regarding the compliance with the conformity assessment of high-risk AI systems. ***This obligation shall include:*** ***(a) the provision of technical documentation sufficient to assess compliance with Article 16 requirements;*** ***(b) the disclosure of known limitations and failure modes that could affect high-risk applications;*** ***(c) the provision of reasonable technical access for testing and validation purposes.*** ***This paragraph shall not apply in cases where the initial provider has clearly specified that its AI system is not to be changed into a high-risk AI system and therefore does not fall under the obligation to hand over the documentation.'***		
Article 1, first paragraph, point (9b), first subparagraph				
76c		***(9b) in Article 27, paragraph 4 is replaced by the following:***		

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Article 1, first paragraph, point (9b), second subparagraph				
76d		***4. If any of the obligations laid down in this Article is already met through the data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the deployer shall, when conducting the fundamental rights impact assessment referred to in paragraph 1 of this Article include cross references to the relevant sections of that data protection impact assessment or include relevant parts of that data protection impact assessment into the fundamental rights impact assessment.***		
Article 1, first paragraph, point (10)				
77	(10) in Article 28, the following paragraph 8 is added:	*deleted*	(10) in Article 28~~,~~ the following ~~paragraph 8 is~~ **paragraphs are** added:	
Article 1, first paragraph, point (10), amending provision, numbered paragraph (8), first subparagraph				
78	‘ 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	*deleted*	‘ 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~~**ensure** that the conformity assessment body that applies for designation both under this	

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	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.		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~~**unified** 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~~ **unified** 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.**	
Article 1, first paragraph, point (10), amending provision, numbered paragraph (8), second subparagraph				
Y	79 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.	*deleted*	The single application and ~~single~~ **unified** 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.	Y
Article 1, first paragraph, point (10), amending provision, numbered paragraph (8), second subparagraph a				

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			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.	
79a				
Article 1, first paragraph, point (10), amending provision, numbered paragraph (8), third subparagraph				
80	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.; ,	*deleted*	The single application and ~~single~~ **unified** 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.**'**;	
Article 1, first paragraph, point (10), amending provision, numbered paragraph (8), third subparagraph a				
80a			**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**	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			application and unified assessment procedure referred to in paragraph 8, unless the Member State designates another notifying authority for this Regulation.'; ,	
Article 1, first paragraph, point (11)				
G 81	(11) in Article 29, paragraph 4 is replaced by the following:	(11) in Article 29, paragraph 4 is replaced by the following:	(11) in Article 29, paragraph 4 is replaced by the following:	G
Article 1, first paragraph, point (11), amending provision, numbered paragraph (4), first subparagraph				
G 82	' 4.For notified bodies which are designated under any other Union harmonisation legislation, all documents and certificates linked to those designations may be used to support and expedite their designation procedure under this Regulation, as appropriate.	' 4.For notified bodies which are designated under any other Union harmonisation legislation, all documents and certificates linked to those designations may be used to support and expedite their designation procedure under this Regulation, as appropriate.	' 4.For notified bodies which are designated under any other Union harmonisation legislation, all documents and certificates linked to those designations may be used to support and expedite their designation procedure under this Regulation, as appropriate.	G
Article 1, first paragraph, point (11), amending provision, numbered paragraph (4), second subparagraph				
Y 83	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.	*deleted*	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~~ **unified** 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.	Y

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Article 1, first paragraph, point (11), amending provision, numbered paragraph (4), third subparagraph				
G 84	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.; ’	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.; ’	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.; ’	‘ 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.; ’ Text Origin: Commission Proposal G
Article 1, first paragraph, point (12)				
G 85	(12) in Article 30, paragraph 2 is replaced by the following:	(12) in Article 30, paragraph 2 is replaced by the following:	(12) in Article 30, paragraph 2 is replaced by the following:	(12) in Article 30, paragraph 2 is replaced by the following: Text Origin: Commission Proposal G
Article 1, first paragraph, point (12), amending provision, numbered paragraph (2), first subparagraph				
G 86	‘ 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.	‘ 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.	‘ 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.	‘ 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. G

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				Text Origin: Commission Proposal	
Article 1, first paragraph, point (12), amending provision, numbered paragraph (2), second subparagraph					
G	87	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.; ,	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.; ,	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.; ,	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.; , Text Origin: Commission Proposal	G
Article 1, first paragraph, point (12a), first subparagraph					
Y	87a		***(12a) In Article 42, the following paragraph is inserted:***		Y
Article 1, first paragraph, point (12a), second subparagraph					
Y	87b		***'2a. Where an AI system is subject to the requirements of Regulation (EU) 2024/2847 as well as requirements set out in Article 15, and where those high-risk AI systems fulfil the essential cybersecurity requirements set out in Regulation (EU) 2024/2847,***		Y

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		they shall be presumed to comply with the cybersecurity requirements set out in Article 15 in so far as those requirements are covered by the EU declaration of conformity or parts thereof issued pursuant to Regulation (EU) 2024/2847.';		
Article 1, first paragraph, point (13)				
Y 88	(13) in Article 43, paragraph 3 is replaced by the following:	*deleted*	*(13)* in Article 43, paragraph 3 is replaced by the following:	Y
Article 1, first paragraph, point (13), amending provision, first paragraph				
Y 89	‘ 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.	*deleted*	‘ ‘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**, as well as points 3, 4.3, 4.4., 4.5, the fifth paragraph of point 4.6 and 5 of Annex VII.**	Y
Article 1, first paragraph, point (13), amending provision, second paragraph				

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Y 90	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 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].	*deleted*	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 designation in accordance with Section 4 at the latest [18 months from the entry into application of this Regulation].	Y
Article 1, first paragraph, point (13), amending provision, third paragraph				
Y 91	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	*deleted*	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	Y

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	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.		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.		
Article 1, first paragraph, point (13), amending provision, fourth paragraph					
Y	92 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.; ,	*deleted*	-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.; ,		Y
Article 1, first paragraph, point (14)					
G	93 (14) in Article 49, paragraph 2 is deleted;	*deleted*	(14) ~~in Article 49, paragraph 2 is deleted;~~	*deleted*	G
Article 1, first paragraph, point (15)					
G	*94* *(15)* in Article 50, paragraph 7 is replaced by the following:	(15) in Article 50, paragraph 7 is replaced by the following:	(15) in Article 50, paragraph 7 is replaced by the following:	(15) in Article 50, paragraph 7 is replaced by the following: Text Origin: Commission Proposal	G

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 1, first paragraph, point (15), amending provision, numbered paragraph (7)				
95	‘ 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 assess whether adherence to those codes of practice is adequate to ensure compliance with the obligation laid down in paragraph 2, 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).; ’	‘ 7.The ~~*AI Office*~~***Commission*** 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*~~***shall*** assess whether adherence to those codes of practice is adequate to ensure compliance with the obligation laid down in paragraph 2, 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).; ’	‘ 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~~**paragraphs 2 and 4 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).’; ’	
Article 1, first paragraph, point (16)				
96	(16) in Article 56(6), the first subparagraph is replaced by the following:	(16) in Article 56(6), the first subparagraph is replaced by the following:	(16) in Article ~~56(6), the first subparagraph~~**56, paragraph 6** is replaced by the following:	(16) in Article ~~*56(6), the first subparagraph*~~***56, paragraph 6*** is replaced by the following: Text Origin: Council Mandate
Article 1, first paragraph, point (16), amending provision, numbered paragraph (6)				

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Y	97	‘ 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.; ’	‘ 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 ***and other relevant competent authorities***, 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.; ’	‘ 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.; ’		Y
	Article 1, first paragraph, point (17)					
G	98	(17) Article 57 is amended as follows:	(17) Article 57 is amended as follows:	(17) Article 57 is amended as follows:		G
	Article 1, first paragraph, point (17a)					
Y	98a			**(-a)paragraph 1, first subparagraph, is replaced by the following:**		Y
	Article 1, first paragraph, point (17)(-a)					
Y	98b			**1.Member States shall ensure that their competent authorities establish at least one AI regulatory sandbox at national**		Y

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			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.'	
Article 1, first paragraph, point (17c)				
98c			**(-b) paragraph 3 is replaced by:**	
Article 1, first paragraph, point (17d)				
98d			**'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 .'**	
Article 1, first paragraph, point (17)(a)				
99	(a) the following paragraph 3a is inserted:	(a) the following paragraph 3a is inserted:	(a) the following ~~paragraph 3a is~~**paragraphs are** inserted:	
Article 1, first paragraph, point (17)(a), amending provision, first paragraph				
100	' The AI Office may also establish an AI regulatory sandbox at Union level for AI systems covered by Article 75(1). Such an AI regulatory	' The AI Office may also establish an AI regulatory sandbox at Union level for AI systems covered by Article 75(1). Such an AI regulatory	' **3a.** The AI Office may also establish an AI regulatory sandbox at Union level for AI systems covered by Article 75(1)**. For this**	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	sandbox shall be implemented in close cooperation with relevant competent authorities, in particular when Union legislation other than this Regulation is supervised in the AI regulatory sandbox, and shall provide priority access to SMEs.;	sandbox shall be implemented in close cooperation with relevant competent authorities, in particular when Union legislation other than this Regulation is supervised in the AI regulatory sandbox, and shall provide priority access to SMEs, ***including startups***.;	**purpose references to national competent authorities in this Chapter shall be construed, where relevant, as references to the AI Office**. 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 SMEs**, including start-ups, and SMCs** .;	
Article 1, first paragraph, point (17)(a), amending provision, first paragraph a				
Y	100a	***The AI Office shall ensure that, to the extent innovative AI systems referred to in paragraph 5 involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the national data protection authorities, the EDPB and those other national or competent authorities are associated with the operation of the AI regulatory sandbox established at Union level and involved in the supervision of those aspects to the extent that they relate to their respective tasks and powers, in accordance with Regulation (EU) 2016/679, Regulation (EU)***		Y

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		2018/1725 and Directive (EU)2018/680.; ,		
Article 1, first paragraph, point (17)(a), amending provision, first paragraph a				
Y 100b			**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.';** ,	Y
Article 1, first paragraph, point (17)(b)				
G 101	(b) paragraph 5 is replaced by the following:	(b) paragraph 5 is replaced by the following:	(b) paragraph 5 is replaced by the following:	(b) paragraph 5 is replaced by the following: Text Origin: Commission Proposal
Article 1, first paragraph, point (17)(b), amending provision, numbered paragraph (5)				
Y 102	' 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	' 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	' 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	Y

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	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.; ,	agreed between the providers or prospective providers and the competent ~~*authority*~~***authorities***, 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.; ,	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.;' ,	
Article 1, first paragraph, point (17)(c)				
103	(c) paragraph 9, point (e) is replaced by the following:	(c) paragraph 9, point (e) is replaced by the following:	(c) paragraph 9, point (e) is replaced by the following:	(c) paragraph 9, point (e) is replaced by the following: Text Origin: Commission Proposal
Article 1, first paragraph, point (17)(c), amending provision, numbered paragraph (e)				
104	' (e) facilitating and accelerating access to the Union market for AI systems, in particular when provided by SMCs and SMEs, including start-ups.; ,	' (e) facilitating and accelerating access to the Union market for AI systems, in particular when provided by SMCs and SMEs, including start-ups.; ,	' (e) facilitating and accelerating access to the Union market for AI systems, in particular when provided by ~~SMCs and~~ SMEs, including start-ups**, and SMCs**.; ,	' (e) facilitating and accelerating access to the Union market for AI systems, in particular when provided by ~~*SMCs and*~~ SMEs, including start-ups***, and SMCs***.; , Text Origin: Council Mandate
Article 1, first paragraph, point (17)(d)				
105	(d) paragraph 13 is replaced by the following:	(d) paragraph 13 is replaced by the following:	(d) ~~paragraph 13 is replaced by the following:~~	
Article 1, first paragraph, point (17)(d), amending provision, numbered paragraph (13)				
106	'	'	'	

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	13. The AI regulatory sandboxes shall be designed and implemented in such a way that they facilitate cross-border cooperation between national competent authorities.;	13. The AI regulatory sandboxes shall be designed and implemented in such a way that they facilitate cross-border cooperation between national competent authorities.;	13. ~~The AI regulatory sandboxes shall be designed and implemented in such a way that they facilitate cross-border cooperation between national competent authorities.;~~	
Article 1, first paragraph, point (17)(e)				
107	(e) paragraph 14 is replaced by the following:		(e) paragraph 14 is replaced by the following:	
Article 1, first paragraph, point (17)(e), amending provision, numbered paragraph (14)				
108	14. National competent authorities shall coordinate their activities and cooperate within the framework of the Board. They shall support the joint establishment and operation of AI regulatory sandboxes, including in different sectors.;	14. National competent authorities shall coordinate their activities and cooperate within the framework of the Board. They shall support the joint establishment and operation of AI regulatory sandboxes, including in different sectors.;	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.**'**;	
Article 1, first paragraph, point (17)(e), amending provision, numbered paragraph (14), first subparagraph				
108a		***14. When discussions are held within the framework of the Board, the European Data Protection Supervisor and the AI office shall, as part of their roles within the Board, also provide their feedback and exchange best practices on matters related to the establishment and operation of AI regulatory***		

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		sandboxes established under their respective competences.; ,		
Article 1, first paragraph, point (18)				
109	(18) Article 58, paragraph 1, is replaced by the following:	(18) Article 58, paragraph 1, is replaced by the following:	(18) Article 58, paragraph 1, is replaced by the following:	
Article 1, first paragraph, point (18), amending provision, numbered paragraph (1)				
110	‘ 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:	‘ 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:	‘ 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:	
Article 1, first paragraph, point (18), amending provision, numbered paragraph (1), point (a)				
111	(a) eligibility and selection criteria for participation in the AI regulatory sandbox;	(a) eligibility and selection criteria for participation in the AI regulatory sandbox;	(a) eligibility and selection criteria for participation in the AI regulatory sandbox;	
Article 1, first paragraph, point (18), amending provision, numbered paragraph (1), point (b)				
112	(b) procedures for the application, participation, monitoring, exiting from and termination of the AI regulatory sandbox, including the sandbox plan and the exit report;	(b) procedures for the application, participation, monitoring, exiting from and termination of the AI regulatory sandbox, including the sandbox plan and the exit report;	(b) procedures for the application, participation, monitoring, exiting from and termination of the AI regulatory sandbox, including the sandbox plan and the exit report;	
Article 1, first paragraph, point (18), amending provision, numbered paragraph (1), point (c)				

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G	113	(c) the terms and conditions applicable to the participants;	(c) the terms and conditions applicable to the participants;	(c) the terms and conditions applicable to the participants;		G
	Article 1, first paragraph, point (18), amending provision, numbered paragraph (1), point (d)					
Y	114	(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 EU level.; ’	(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, ***the involvement and supervision by the competent data protection authorities*** and the coordination and cooperation at national and EU level.; ’	(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 ~~EU~~**Union** level.**’**; ’		Y
	Article 1, first paragraph, point (19)					
G	115	(19) Article 60 is amended as follows:	(19) Article 60 is amended as follows:	(19) Article 60 is amended as follows:		G
	Article 1, first paragraph, point (19)(a)					
G	116	(a) in paragraph 1, the first subparagraph is replaced by the following:	(a) in paragraph 1, the first subparagraph is replaced by the following:	(a) in paragraph 1, the first subparagraph is replaced by the following:		G
	Article 1, first paragraph, point (19)(a), amending provision, first paragraph					
Y	117	‘ 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	‘ 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*~~	‘ 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		Y

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		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.; ’,	~~*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.; ’,	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.; ’,		
Article 1, first paragraph, point (19)(b)						
G	118	(b) paragraph 2 is replaced by the following:	(b) paragraph 2 is replaced by the following:	(b) paragraph 2 is replaced by the following:		G
Article 1, first paragraph, point (19)(b), amending provision, numbered paragraph (2)						
Y	119	‘ 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.; ’,	‘ 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.; ’,	‘ 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.; ’,		Y
Article 1, first paragraph, point (20)						
G	120	(20) the following Article 60a is inserted:	(20) the following Article 60a is inserted:	(20) the following Article 60a is inserted:		G
Article 1, first paragraph, point (20), amending provision, first paragraph						
G	121	‘ Article 60a	‘ Article 60a	‘ Article 60a		G
Article 1, first paragraph, point (20), amending provision, second paragraph						

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G	122	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	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	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		G
Article 1, first paragraph, point (20), amending provision, numbered paragraph (1)						
Y	123	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, in accordance with this Article and a voluntary real-world testing agreement, without prejudice to the prohibitions under Article 5.	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, in accordance with this Article and a voluntary real-world testing agreement, without prejudice to the prohibitions under Article 5.	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 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~~.		Y
Article 1, first paragraph, point (20), amending provision, numbered paragraph (2)						
Y	124	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	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	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~~		Y

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	listed in Section B of Annex I in real-world conditions.	listed in Section B of Annex I in real-world conditions.	~~listed in Section B of Annex I in real-world conditions.~~	
Article 1, first paragraph, point (20), amending provision, numbered paragraph (2a)				
Y	124a		**2a. 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.**	Y
Article 1, first paragraph, point (20), amending provision, numbered paragraph (2b)				
Y	124b		**2b. Member States shall notify the Commission of any draft framework measures in good time before their adoption. The Commission may 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.**	Y
Article 1, first paragraph, point (20), amending provision, numbered paragraph (3)				

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125	3.Member States, the Commission, 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 and test AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex.	3.Member States, the Commission, ***and national competent authorities such as*** 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 and test AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex.	3.Member States~~, the Commission, market surveillance~~ **that have adopted framework measures shall ensure that the relevant national competent authorities, appropriate** 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**.	
Article 1, first paragraph, point (20), amending provision, numbered paragraph (4)				
126	4.The signatories of the voluntary real-world testing agreement, shall specify conditions of the testing in real world conditions and establish detailed elements of the real-world testing plan for AI systems 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 detailed elements of the real-world testing plan for AI systems covered by Union harmonisation legislation listed in Section B of Annex I.	4.~~The signatories of the voluntary real-world~~ Testing ~~agreement~~**as referred to in the first paragraph, as well as the national measures implementing this Article**, shall ~~specify conditions of the testing in real-world conditions and establish detailed~~**respect the following essential** elements ~~of the real-world testing plan for AI systems covered~~	

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			~~by Union harmonisation legislation listed in Section B of Annex I.~~**:**	
Article 1, first paragraph, point (20), amending provision, numbered paragraph (4a)				
Y	126a		**(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;**	Y
Article 1, first paragraph, point (20), amending provision, numbered paragraph (4b)				
Y	126b		**(b) A real-world testing plan shall be agreed between the provider or prospective provider and the national competent authority or appropriate authority;**	Y
Article 1, first paragraph, point (20), amending provision, numbered paragraph (4c)				
Y	126c		**(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.**	Y
Article 1, first paragraph, point (20), amending provision, numbered paragraph (4d)				
Y	126d		**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**	Y

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			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.	
Article 1, first paragraph, point (20), amending provision, numbered paragraph (5)				
Y 127	5.Article 60(2), (5) and (9) shall apply.; ,	5.Article 60(2), (5) and (9) shall apply.; ,	5.~~Article 60(2), (5) and (9) shall apply.;~~ ,	Y
Article 1, first paragraph, point (21)				
G 128	(21) Article 63(1) is replaced by the following:	(21) Article 63(1) is replaced by the following:	(21) Article 63(1) is replaced by the following:	G
Article 1, first paragraph, point (21), amending provision, numbered paragraph (1)				
Y 129	‘ 1.SMEs, including start-ups, may comply with certain elements of the quality management system required by Article 17 in a simplified manner. 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	‘ 1.SMEs, including start-ups, ***and micro enterprises*** may comply with certain elements of the quality management system required by Article 17 in a simplified manner. 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 ***and micro enterprises***, without affecting the level of protection or the need for	‘ 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	Y

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	requirements in respect of high-risk AI systems.; ,	compliance with the requirements in respect of high-risk AI systems.; ,	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.'; ,	
Article 1, first paragraph, point (21a), first subparagraph				
Y 129a		***(21a) In Article 64, paragraph 2a is added:***		Y
Article 1, first paragraph, point (21a), second subparagraph				
Y 129b		***'(2a) Without prejudice to the budgetary procedure and through existing financial instruments, the AI Office shall be allocated with adequate human, financial and technical resources, and with infrastructure to fulfil their tasks, to effectively perform its duties and exercise its powers in respect of the enforcement of Regulation (EU) 2024/1689. In particular, the AI Office shall have a sufficient number of personnel permanently available with in-depth competences and technical expertise. The AI Board shall assess competence and resource requirements.'***		Y
Article 1, first paragraph, point (22)				
G 130	(22) Article 69 is amended as follows:	(22) Article 69 is amended as follows:	(22) Article 69 is amended as follows:	G

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Article 1, first paragraph, point (22)(a)				
131	(a) paragraph 2 is replaced by the following:	(a) paragraph 2 is replaced by the following:	(a) paragraph 2 is replaced by the following:	
Article 1, first paragraph, point (22)(a), amending provision, numbered paragraph (2)				
132	‘ 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).; ’	‘ 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).; ’	‘ 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).; ’	
Article 1, first paragraph, point (22)(b)				
133	(b) paragraph 3 is deleted.	*deleted*	(b) ~~paragraph 3 is deleted.~~	
Article 1, first paragraph, point (23)				
134	(23) in Article 70, paragraph 8 is replaced by the following:	(23) in Article 70, paragraph 8 is replaced by the following:	(23) in Article 70, paragraph 8 is replaced by the following:	
Article 1, first paragraph, point (23), amending provision, numbered paragraph (8)				
135	‘ 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.	‘ 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.	‘ 8.National competent authorities may provide guidance and advice on the implementation of this Regulation, in particular to ~~SMCs and~~ SMEs, including start-ups**, and SMCs**, taking into account the guidance and advice of the Board and the Commission, as appropriate.	

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		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.;	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.;	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.;	
Article 1, first paragraph, point (24)					
G	136	(24) in Article 72, paragraph 3 is replaced by the following:	(24) in Article 72, paragraph 3 is replaced by the following:	(24) in Article 72, paragraph 3 is replaced by the following:	G
Article 1, first paragraph, point (24), amending provision, numbered paragraph (3)					
Y	137	‘ 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.;	‘ 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, ***including a template with elements to be included by 2 February 2027***.;	‘ 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 September 2027**.’;	Y
Article 1, first paragraph, point (25)					
G	138	(25) Article 75 is amended as follows:	(25) Article 75 is amended as follows:	(25) Article 75 is amended as follows:	G
Article 1, first paragraph, point (25)(a)					

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G	139	(a) the heading of Article 75 is replaced by the following:	(a) the heading of Article 75 is replaced by the following:	(a) the heading of Article 75 is replaced by the following:		G
	Article 1, first paragraph, point (25)(a), amending provision, first paragraph					
G	140	‘ Market surveillance and control of AI systems and mutual assistance; ’	‘ Market surveillance and control of AI systems and mutual assistance; ’	‘ Market surveillance and control of AI systems and mutual assistance; ’		G
	Article 1, first paragraph, point (25)(b)					
G	141	(b) paragraph 1 is replaced by the following:	(b) paragraph 1 is replaced by the following:	(b) paragraph 1 is replaced by the following:		G
	Article 1, first paragraph, point (25)(b), amending provision, numbered paragraph (1), first subparagraph					
Y	142	‘ 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 that model and that system are developed by the same provider, the AI Office shall be exclusively competent for the supervision and enforcement of that system with the obligations 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 that constitute or that are integrated into a	‘ 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 belonging to the same group of undertakings***, the AI Office shall ~~*be exclusively competent for the supervision and enforcement of that system with*~~***have powers to supervise and enforce*** the obligations of this Regulation in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. The AI Office shall also ~~*be exclusively*~~	‘ 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 that model and that system are developed by the same provider,~~ The AI Office shall ~~be exclusively competent for the supervision and enforcement of that system with the obligations 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 that constitute or that are integrated into a~~		Y

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	designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065.	~~*competent for the supervision and enforcement of*~~***have powers to supervise and enforce*** the obligations under this Regulation in relation to AI ~~*system*~~***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. ***Where the Commission has not initiated proceedings for the same infringement, the competent authority of a Member State in which the main establishment of the provider of very large online platform or of very large online search engine is located, or where their legal representative is established, may have the powers to supervise and enforce the obligations under this Regulation.***	~~designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065.~~**the following AI systems:**	
Article 1, first paragraph, point (25)(b), amending provision, numbered paragraph (1), first subparagraph a				
Y	142a	***Notwithstanding the first subparagraph, the supervision and enforcement powers of the AI Office, do 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 this Regulation.***		Y

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Article 1, first paragraph, point (25)(b), amending provision, numbered paragraph (1), first subparagraph a									
Y	142b					**(a) AI systems based on general-purpose AI models where that model and that system are developed by the same provider, or by providers that are part of the same undertaking as that provider, with the exception of:**			Y
Article 1, first paragraph, point (25)(b), amending provision, numbered paragraph (1), first subparagraph b									
Y	142c					**(i) AI systems related to products covered by the Union harmonisation listed in Annex I;**			Y
Article 1, first paragraph, point (25)(b), amending provision, numbered paragraph (1), first subparagraph c									
Y	142d					**(ii) AI systems referred to in Annex III, point (2);**			Y
Article 1, first paragraph, point (25)(b), amending provision, numbered paragraph (1), first subparagraph d									
Y	142e					**(iii)AI systems provided by law enforcement authorities, border management authorities, and financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law; and**			Y
Article 1, first paragraph, point (25)(b), amending provision, numbered paragraph (1), first subparagraph e									
Y	142f					**(iv)AI systems referred to in Annex III, point (8) for what concerns the administration of justice; and**			Y
Article 1, first paragraph, point (25)(b), amending provision, numbered paragraph (1), first subparagraph f									

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142g			**(b) 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.**	
Article 1, first paragraph, point (25)(b), amending provision, numbered paragraph (1), first subparagraph g				
142h			**The exclusive competence referred to in the first subparagraph shall apply to the providers of those systems. It shall also apply to the deployers of those systems, but only when they are also the provider or part of the same undertaking as the provider.**	
Article 1, first paragraph, point (25)(b), amending provision, numbered paragraph (1), first subparagraph h				
142i			**For the purposes of exercising that competence, the AI Office shall have the tasks and responsibilities assigned by this Regulation to market surveillance authorities. Regulation (EU) 2019/1020 shall apply mutatis mutandis.**	
Article 1, first paragraph, point (25)(b), amending provision, numbered paragraph (1), second subparagraph				
143	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	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	~~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~~	

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	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.	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.	~~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.~~	
Article 1, first paragraph, point (25)(b), amending provision, numbered paragraph (1), second subparagraph a				
Y	143a		**(c) the following paragraphs are inserted:**	Y
Article 1, first paragraph, point (25)(b), amending provision, numbered paragraph (1), second subparagraph b				
Y	143b		**1ab. By way of derogation from Article 73, providers of high-risk AI systems subject to the AI Office's competence under paragraph 1 shall report any serious incidents to the AI Office. Article 73(2)-(9) shall apply mutatis mutandis. The AI Office shall promptly transmit the relevant information to the market surveillance authority of the Member State in whose territory the operator or its legal representative is situated.**	Y
Article 1, first paragraph, point (25)(b), amending provision, numbered paragraph (1), third subparagraph				
Y	144	The authorities involved in the application of this Regulation shall cooperate actively in the exercise of these powers, in particular where enforcement actions need to be taken in the territory of a Member State.;	The authorities involved in the application of this Regulation shall cooperate actively in the exercise of these powers, in particular where enforcement actions need to be taken in the territory of a Member State.;	**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 ~~these~~ **its** powers, ~~in particular~~ **including,** where **necessary, in connection**	Y

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	'	'	**with inspections or other** enforcement ~~actions need to be taken~~ **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 it the necessary assistance, requesting, where appropriate, the assistance of the police or an equivalent enforcement authority, to enable it to conduct its on-site inspection.**	
Article 1, first paragraph, point (25)(b), amending provision, numbered paragraph (1), third subparagraph a				
144a			**1b. When making a decision as referred to in Article 75b(1), the Commission shall, without undue delay, send a copy of the request or the decision referred to in the first subparagraph to the relevant market surveillance authority of the Member State in whose**	

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			territory the operator or its legal representative is situated. In good time before conducting an inspection under Article 75b(4), the Commission shall inform the market surveillance authority of the Member State in whose territory the operator or its legal representative is situated.	
Article 1, first paragraph, point (25)(b), amending provision, numbered paragraph (1), third subparagraph b				
Y	144b		**1ba. When taking investigatory or enforcement action in the territory of a Member State that involves access to a public authority's data or AI system, the AI Office shall be assisted by the relevant market surveillance authority.**	Y
Article 1, first paragraph, point (25)(b), amending provision, numbered paragraph (1), third subparagraph c				
Y	144c		**1c. Before taking a decision that would have the effect of prohibiting or restricting the AI system being made available or put into service on a national market, or a decision to withdraw or recall the AI system from the market, the AI Office shall, without undue delay, notify the market surveillance authority competent for that market of the relevant decision. The AI Office shall consult the authorities involved in the application of this Regulation, where appropriate,**	Y

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			on any matter relating to the application and enforcement of this Regulation. ,	
Article 1, first paragraph, point (25)(ba), first subparagraph				
144d		***(ba) in Article 75, paragraph 1a is inserted:***		
Article 1, first paragraph, point (25)(ba), second subparagraph				
144e		***1a. In the implementation and enforcement of this Regulation, the AI Office shall promote innovation, competitiveness and the protection of fundamental rights, taking them into consideration in the exercise of their functions. The AI Office shall coordinate closely with the competent data protection authorities designated pursuant to Regulation (EU) 2016/679 in matters involving the processing of personal data falling within the scope of that Regulation.'***		
Article 1, first paragraph, point (25)(c)				
145	(c) the following paragraphs 1a to 1c are inserted:	(c) the following paragraphs 1a to 1c are inserted:	(c) ~~the following paragraphs 1a to 1c are inserted:~~	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1a)				
146	' 1a. The Commission shall adopt an implementing act to define the enforcement powers and the	' 1a. The Commission shall adopt an implementing act to define the enforcement powers and the	' 1a. ~~The Commission shall adopt an implementing act to define the enforcement powers and the~~	

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	procedures for the exercise of those powers of the AI Office, including its ability to impose penalties, such as fines or other 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.	procedures for the exercise of those powers of the AI Office, including its ability to impose penalties, such as fines or other 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.	~~procedures for the exercise of those powers of the AI Office, including its ability to impose penalties, such as fines or other 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.~~	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1b)				
Y	147	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.	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.	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.~~	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), first subparagraph				
Y	148	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	1c. The Commission shall ~~organise and carry out~~ ***, subject to Article 28(8), ensure that*** 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 ***are carried out*** 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	~~1c~~**1d**. The Commission shall ~~organise and carry out~~ **be responsible for** 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	Y

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	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.	this Regulation and may be placed on the market or put into service in the Union in accordance with this Regulation. The Commission ~~*may*~~***shall*** 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.	Regulation and may be placed on the market or put into service in the Union in accordance with this Regulation. The Commission ~~may~~ **shall** 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~~ **If a notified body to which** the Commission ~~when exercising its powers~~ **has delegated tasks** under this paragraph **does not perform those tasks adequately, the Commission may withdraw the delegation with immediate effect**.	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph				
G	149 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 the Commission to the notified bodies in accordance with this Article shall be directly paid by the provider to the notified body.; ,	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 the Commission to the notified bodies in accordance with this Article shall be directly paid by the provider to the notified body.; ,	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 the Commission to the notified bodies in accordance with this Article shall be directly paid by the provider to the notified body.;	G
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph a				

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Y	149a			**(25a) The following articles are inserted after Article 75:**		Y
	Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph b					
Y	149b			**‘Article 75a**		Y
	Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph c					
Y	149c			**Enforcement of obligations and starting an investigation in respect of AI systems supervised by the AI Office**		Y
	Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph d					
Y	149d			**1.When exercising its tasks of supervision and enforcement outlined in Article 75(1), the AI Office shall have all the powers of a market surveillance authority provided for in this Section, as well as all the powers listed in Article 14(4), Article 16 and 17 of Regulation (EU) 2019/1020, save where the relevant type of power is specified in Articles 75-75e of this Regulation. The AI Office shall be empowered to take appropriate measures and decisions to adequately exercise its supervisory and enforcement powers. The AI Office shall also be authorised to fully reclaim from the relevant operator the totality of the costs of its supervision and enforcement activities with respect to instances of non-compliance, including**		Y

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			costs for human and technical resources, in accordance with Article 15 of Regulation (EU) 2019/1020.	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph e				
Y	149e		**2.Where the AI Office has reasonable grounds to suspect non-compliance with this Regulation by a provider or a deployer of an AI system referred to in Article 75(1), it may adopt a decision initiating an investigation into that non-compliance. Upon the initiation of such an investigation, the AI Office shall notify the operator of the AI system concerned.**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph f				
Y	149f		**The AI Office may exercise its investigatory powers on its own initiative or following a complaint received under Article 85 of this Regulation, even before initiating an investigation pursuant to this paragraph.**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph g				
Y	149g		**Where a market surveillance authority has reason to suspect non-compliance with this Regulation by a provider or a deployer of an AI system referred to in Article 75(1), it may send a**	Y

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			request to the AI Office to assess the matter.	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph h				
Y 149h			**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 the 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. The result of such investigations shall be shared with the Member State's relevant competent authorities.**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph i				
Y 149i			**Article 75b**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph j				
Y 149j			**Requests for information and power to conduct inspections**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph k				
Y 149k			**1.In order to carry out the tasks assigned to it under this Section,**	Y

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			the AI Office 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 that operator with this Regulation.	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph l				
149l			**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. Where the request is a simple request, the AI Office shall additionally indicate that although there is no obligation to provide the information requested, in the case of a voluntary reply, the information must be correct and not misleading, and indicate the potential fines provided for in Article 75d(4) for supplying incorrect or misleading information. When requesting information by decision, the AI Office shall additionally indicate the fines provided for in Article 75d(4) for supplying incomplete, incorrect or misleading**	

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			information, and indicate the right to have the decision reviewed by the Court of Justice of the European Union.	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph m				
Y 149m			**2.The operators referred to in paragraph 1 or their legal representatives shall supply the information required by a decision under paragraph 1.**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph n				
Y 149n			**3.In order to carry out the tasks assigned to it under this Section, and in addition to the prerogatives and powers of market surveillance authorities under this Regulation and Regulation (EU) 2019/1020, the AI Office may:**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph o				
Y 149o			**(a) order the operators to provide access to, and explanations relating to, their AI systems; or**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph p				
Y 149p			**(b) 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.**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph q				

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149q			**4.In order to carry out the tasks assigned to it under this Section, the 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 shall be empowered to:**	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph r				
149r			**(a) enter any of the business premises, land or property located in the Union of the operator concerned;**	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph s				
149s			**(b) examine the books, data and other material relevant to the execution of their tasks, irrespective of the medium on which they are stored;**	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph t				
149t			**(c) take or obtain in any form copies of or extracts from such books, data and other records;**	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph u				
149u			**(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**	

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			inspection, and to record the answers.	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph v				
Y	149v		**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 Article 75d(4), and the right to have the decision reviewed by the Court of Justice of the European Union.**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph w				
Y	149w		**5.If an on-site inspection provided for in paragraph 4, first subparagraph, point (a), 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.**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph x				
Y	149x		**6.Where an authorisation as referred to in paragraph 5 is applied for, the national judicial authority shall promptly verify that the coercive measures envisaged are neither arbitrary nor excessive having regard to the**	Y

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			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 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.	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph y				
y	149y		**7.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**	y

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			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.	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph z				
Y	149z		**Article 75c**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph aa				
Y	149aa		**Commitments**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph ab				
Y	149ab		**If, during proceedings under 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:**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph ac				

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Y	149ac					**(a) where there has been a material change in any of the facts on which the decision was based;**			Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph ad									
Y	149ad					**(b) where the operator acts contrary to its commitments; or**			Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph ae									
Y	149ae					**(c) where the decision was based on incomplete, incorrect or misleading information provided by the operator concerned.**			Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph af									
Y	149af					**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.**			Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph ag									
Y	149ag					**Article 75d**			Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph ah									
Y	149ah					**Non-compliance, fines and periodic penalties**			Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph ai									
Y	149ai					**1.The AI Office shall adopt a non-compliance decision where it finds**			Y

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			that the operator does not comply with the relevant provisions of this Regulation or with commitments made binding pursuant to Article 75c.	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph aj				
Y	149aj		**2.Before adopting a decision pursuant to paragraph 1, 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.**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph ak				
Y	149ak		**3.In the decision pursuant to the 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**	Y

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			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.	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph al				
Y	149al		**4.A decision of non-compliance may be accompanied by the imposition of penalties pursuant to Article 99(1) and (3)-(7), which shall apply mutatis mutandis to the AI Office in the execution of its supervision and enforcement tasks outlined in Article 75(1) of this Regulation.**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph am				
Y	149am		**In particular, the following shall be subject to administrative fines as referred to in Article 99(4):**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph an				
Y	149an		**(a) infringement of the relevant provisions of this Regulation;**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph ao				
Y	149ao		**(b) failure to comply with a decision referred to in Article 75b(1) or (4), or failure to comply with obligations or measures as**	Y

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			referred to in Article 14(4) or 16(3) of Regulation (EU) 2019/1020; and	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph ap				
Y 149ap			**(c) failure to comply with a commitment made binding by a decision pursuant to Article 75c.**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph aq				
Y 149aq			**Additionally, the supply of incorrect, incomplete or misleading information to the Commission in reply to a request shall be subject to administrative fines as referred to in Article 99(5).**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph ar				
Y 149ar			**5.The AI Office may adopt a decision imposing periodic penalty payments to compel the operators 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**	Y

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			measures as referred to in 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 be effective and proportionate, and where applicable shall not exceed 5% of the average daily income or worldwide annual turnover in the preceding financial year per day, calculated from the date appointed by the decision.	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph as				
Y	149as		**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.**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph at				
Y	149at		**7.Funds collected through the imposition of fines or periodic penalty payments under this Article shall contribute to the general budget of the Union.**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph au				

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Y	149au					**7a. The powers conferred on the AI Office by this Article shall be subject to a limitation period of five years. Time shall begin to run on the day on which the infringement is committed. However, the case of continuing or repeated infringements, time shall begin to run on the day on which the infringement ceases.**			Y
	Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph av								
Y	149av					**The power of the AI Office to enforce decisions taken pursuant to this Article shall be subject to a limitation period of five years. The limitation period shall begin to run on the day on which the decision becomes final.**			Y
	Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph aw								
Y	149aw					**The implementing act referred to in Article 75e(3) shall specify the first and second subparagraphs of this paragraph, including the circumstances in which the limitation periods shall be interrupted.**			Y
	Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph ax								
Y	149ax					**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**			Y

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			decision shall apply with immediate effect.	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph ay				
149ay			**Article 75e**	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph az				
149az			**Safeguards and further specification**	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph ba				
149ba			**1.The powers conferred on the AI Office under this Regulation 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.**	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph bb				
149bb			**2.Article 18 of Regulation (EU) 2019/1020 shall apply mutatis mutandis to the operators subject to the AI Office's competence pursuant to Article 75(1), without prejudice to more specific procedural rights provided for in this Regulation.**	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph bc				
149bc			**2a. The rights of defence and of access to the file of the parties concerned shall be fully respect in**	

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			proceedings in view of the possible adoption of fines or penalty payments as referred to in Article 75d(4-5).	
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph bd				
Y 149bd			**2b. The Commission shall publish the decisions it adopts pursuant to Articles 75a, 75c and 75d. Such publication shall state the names of the parties and the main content of the decision, including any penalties imposed. The publication shall have regard to the rights and legitimate interests of any person concerned in the protection of their confidential information.**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph be				
Y 149be			**2c. The information collected pursuant to Article 75b shall be used only for the purpose of this Regulation.**	Y
Article 1, first paragraph, point (25)(c), amending provision, numbered paragraph (1c), second subparagraph bf				
Y 149bf			**3.The Commission shall adopt implementing acts to further define the rules and the procedures for the exercise of the enforcement, monitoring and supervision tasks of the AI Office under this Section. Those implementing acts shall also contain detailed arrangements and procedural safeguards for**	Y

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			proceedings in view of the possible adoption of fines or penalty payments as referred to in Article 75d(4-5). The implementing acts 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, and on the procedure when objections are raised by the market surveillance authority of a Member State. '	
Article 1, first paragraph, point (26)				
150	(26) Article 77 is amended as follows:	(26) Article 77 is amended as follows:	(26) Article 77 is amended as follows:	
Article 1, first paragraph, point (26a)				
150a				
Article 1, first paragraph, point (26)(a)				
151	(a) the heading is replaced by the following:	(a) the heading is replaced by the following:	(a) the heading is replaced by the following:	
Article 1, first paragraph, point (26)(a), amending provision, first paragraph				
152	' Powers of authorities protecting fundamental rights and cooperation with market surveillance authorities	' Powers of authorities protecting fundamental rights and cooperation with market surveillance authorities	'Powers of authorities protecting fundamental rights and cooperation	

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		’	’	with market surveillance authorities’ ’	
Article 1, first paragraph, point (26)(b)					
G	153	(b) paragraph 1 is replaced by the following:	(b) paragraph 1 is replaced by the following:	(b) paragraph 1 is replaced by the following:	G
Article 1, first paragraph, point (26)(b), amending provision, numbered paragraph (1)					
Y	154	‘ 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.; ’	‘ 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 ***machine-readable*** format ***by electronic means*** where access to that information or documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction. ***This paragraph is without prejudice to the tasks, powers and independence of the relevant national public authorities or bodies under their mandates in accordance with Union and national law***; ’	‘ 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.’**; ’	Y

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Article 1, first paragraph, point (26)(c)				
155	(c) the following paragraph 1a and 1b are inserted:	(c) the following paragraph 1a, ***1b and 1ba*** ~~*and 1b*~~ are inserted:	(c) the following paragraph 1a and 1b are inserted:	
Article 1, first paragraph, point (26)(c), amending provision, numbered paragraph (1a)				
156	‘ 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.	‘ 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 ***and without undue delay***.	‘ 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.	
Article 1, first paragraph, point (26)(c), amending provision, numbered paragraph (1b)				
157	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	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 ***while respecting their respective competences, tasks, powers and independence***. This shall include, in particular, exchange of information where necessary for the effective	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	

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	the respective other Union legislation.; ’	supervision or enforcement of this Regulation and the respective other Union legislation.;	the respective other Union legislation.; ’	
Article 1, first paragraph, point (26)(c), amending provision, numbered paragraph (1ba)				
Y	157a		***1ba. Requests for assistance shall contain all the necessary information, including the purpose of and reasons for the request.*** ’		
Article 1, first paragraph, point (27)				
G	158	(27) Article 95, paragraph 4 is replaced by the following:	(27) Article 95, paragraph 4 is replaced by the following:	(27) Article 95, paragraph 4 is replaced by the following:	
Article 1, first paragraph, point (27), amending provision, numbered paragraph (4)				
G	159	‘ 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.; ’	‘ 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.; ’	‘ 4.The AI Office and the Member States shall take into account the specific interests and needs of ~~SMCs and~~ SMEs, including start-ups**, and SMCs**, when encouraging and facilitating the drawing up of codes of conduct.;	G
Article 1, first paragraph, point (27), amending provision, numbered paragraph (4a)				
Y	159a			**(28) Article 96 is amended as follows:**	
Article 1, first paragraph, point (27), amending provision, numbered paragraph (4b)				
Y	159b			**(a) in paragraph 1, the following point (g) is added:**	

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Article 1, first paragraph, point (27), amending provision, numbered paragraph (4c)				
159c			**'(g)the practical implementation of Articles 8(2), 9(10) and 17(3) in line with the principle of complementarity and proportionality, with a view to ensuring consistency, avoiding duplication and minimising additional burdens when complying with the requirements of this Regulation and the requirements of the Union harmonisation legislation listed in Section A of Annex I.;** '	
Article 1, first paragraph, point (28)				
160	(28) in Article 96(1), the second subparagraph is replaced by the following:	(28) in Article 96(1), ***point (a) and*** the second subparagraph ~~is~~***are*** replaced by the following:	~~(28)~~**(b)** ~~in Article 96(1)~~ **paragraph 1**, the second subparagraph is replaced by the following:	
Article 1, first paragraph, point (28), first subparagraph				
160a		***(28) (a) the application of the requirements and obligations referred to in Articles 8 to 15 and in Articles 25 and 26;***		
Article 1, first paragraph, point (28), first subparagraph, amending provision, first paragraph -a				
160b		' ***1a. In Article 96, paragraph 1, subparagraph 1, the following point is inserted:***		
Article 1, first paragraph, point (28), first subparagraph, amending provision, first paragraph -b				

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Y	160c		***'(fa) the application of the obligations referred to in Article 27, including the possibility to reference or include relevant sections or parts of the data protection impact assessment into the fundamental rights impact assessment pursuant to Article 27(4) of this Regulation, using, where relevant, standardised templates. '***		
Article 1, first paragraph, point (28), amending provision, first paragraph					
Y	161	‘ When issuing such guidelines, the Commission shall 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.; ’	When issuing such guidelines, the Commission shall 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.; ’	‘ **‘**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**, and SMCs**, of local public authorities and of the sectors most likely to be affected by this Regulation.**’;’** ’	
Article 1, first paragraph, point (29)					
G	162	(29) Article 99 is amended as follows:	(29) Article 99 is amended as follows:	(29) Article 99 is amended as follows:	
Article 1, first paragraph, point (29a)					
	162a				
Article 1, first paragraph, point (29)(a)					
G	163	(a) paragraph 1 is replaced by the following:	(a) paragraph 1 is replaced by the following:	(a) paragraph 1 is replaced by the following:	
Article 1, first paragraph, point (29)(a), amending provision, numbered paragraph (1)					

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
164	‘ 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.; ’	‘ 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.; ’	‘ 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 **administrative fines,** warnings and non-monetary measures, applicable to **any infringement** ~~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 SMCs**, and their economic viability when imposing penalties.**’**; ’	
Article 1, first paragraph, point (29a)(aa), first subparagraph				
164a		***(aa) in paragraph 4 the following point (da) is inserted:***		
Article 1, first paragraph, point (29a)(aa), second subparagraph				
164b		***‘(da) obligations of providers and third parties, including providers of general purpose AI models,***		

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		pursuant to Article 25(2), (3) and (4);'		
Article 1, first paragraph, point (29)(b)				
G 165	(b) paragraph 6 is replaced by the following:	(b) paragraph 6 is replaced by the following:	(b) paragraph 6 is replaced by the following:	G
Article 1, first paragraph, point (29)(b), amending provision, numbered paragraph (6)				
G 166	' 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.; '	' 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.; '	' 6.In the case of ~~SMCs and~~ SMEs, including start-ups**, and SMCs**, 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.;' '	G
Article 1, first paragraph, point (29b)				
Y 166a		***In Article 99, paragraph 6a is inserted:***		Y
Article 1, first paragraph, point (29c)				
Y 166b		***6a. 'In the case of SMCs, with the exception of providers of general-purpose AI models with systemic risk, each fine referred to in this Article shall be up to the percentages or amount referred to in paragraphs 4 and 5, whichever is lower.'***		Y
Article 1, first paragraph, point (29e)				

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R 166c		***(29a) The following articles: Article 110a – Article 110l are inserted:*** ***Article 110a*** ***Amendment to Regulation (EU) 2023/1230*** ***In Article 8 of Regulation (EU) 2023/1230, the following paragraphs 2 and 3 are added:*** ***'2. The Commission is empowered to adopt delegated acts in accordance with Article 48 to amend the essential health and safety requirements set out in Annex III in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.*** ***3. When adopting delegated acts pursuant to paragraph 2 of this Article or Common Specifications pursuant to Article 20 of this Regulation concerning machinery and related products***		R

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.' ***Article 110b*** ***Amendment to Regulation (EU) 2025/2509*** ***In Article 5 of Regulation (EU) 2025/2509, the following paragraphs 4 and 5 are added:*** ***'4. The Commission is empowered to adopt delegated acts in accordance with Article 53 to amend the essential safety requirements set out in Annex II in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant***		

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		requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation. ***5. When adopting delegated acts pursuant to paragraph 4 of this Article or Common Specifications pursuant to Article 16 of this Regulation concerning toys that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.'*** ***Article 110c*** ***Amendment to Directive 2013/53/EU*** ***In Article 4 of Directive 2013/53/EU, the following paragraphs 3 and 4 are added:*** ***'3. The Commission is empowered to adopt delegated acts***		

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		in accordance with Article 50 to amend the essential requirements set out in Annex I in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation. ***4. When adopting delegated acts pursuant to paragraph 3 of this Article or Common Specifications pursuant to Article 14a of this Regulation concerning products that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond***		

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		the requirements laid down in Regulation (EU) 2024/1689.' ***Article 110d*** ***Amendment to Directive 2014/33/EU*** ***In Article 5 of Directive 2014/33/EU, the following paragraphs 3 and 4 are added:*** ***'3. The Commission is empowered to adopt delegated acts in accordance with Article 42 to amend the essential health and safety requirements set out in Annex I in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.*** ***4. When adopting delegated acts pursuant to paragraph 3 of this Article or Common Specifications pursuant to Article 14a of this Regulation concerning lifts and safety components for lifts that are high-risk AI systems as***		

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		referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.' ***Article 110e*** ***Amendment to Directive 2014/34/EU*** ***In Article 4 of Directive 2014/34/EU, the following paragraphs 2 and 3 are added:*** ***'2. The Commission is empowered to adopt delegated acts in accordance with Article 39 to amend the essential health and safety requirements set out in Annex II in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter***		

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		III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation. ***3. When adopting delegated acts pursuant to paragraph 2 of this Article or Common Specifications pursuant to Article 12a of this Regulation concerning products that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.'*** ***Article 110f*** ***Amendment to Directive 2014/53/EU*** ***In Article 3 of Directive 2014/53/EU, the following paragraphs 5 and 6 are added:*** ***'5. The Commission is empowered to adopt delegated acts in accordance with Article 45 to***		

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		amend the essential requirements in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation. ***6. When adopting delegated acts pursuant to paragraph 5 of this Article or Common Specifications pursuant to Article 16a of this Regulation concerning radio equipment that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.'***		

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		Article 110g ***Amendment to Directive 2014/68/EU*** ***In Article 4 of Directive 2014/68/EU, the following paragraphs 4 and 5 are added:*** ***'4. The Commission is empowered to adopt delegated acts in accordance with Article 44 to amend the general safety and performance essential safety requirements set out in Annex I in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.*** ***5. When adopting delegated acts pursuant to paragraph 4 of this Article or Common Specifications pursuant to Article 12a of this Regulation concerning products that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of***		

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		the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.' ***Article 110h*** ***Amendment to Regulation (EU) 2016/424*** ***In Article 6 of Regulation (EU) 2016/424, the following paragraphs 2 and 3 are added:*** ***'2. The Commission is empowered to adopt delegated acts in accordance with Article 44 to amend the essential requirements set out in Annex II in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and***		

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		safety requirements for the purpose of this Regulation. ***3. When adopting delegated acts pursuant to paragraph 2 of this Article or Common Specifications pursuant to Article 12a of this Regulation concerning cableway installations, subsystems and safety components that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.'*** ***Article 110i*** ***Amendment to Regulation (EU) 2016/425*** ***In Article 5 of Regulation (EU) 2016/425, the following paragraphs 2 and 3 are added:*** ***'2. The Commission is empowered to adopt delegated acts in accordance with Article 44 to amend the essential health and***		

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		safety requirements set out in Annex II in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation. ***3. When adopting delegated acts pursuant to paragraph 2 of this Article or Common Specifications pursuant to Article 14a of this Regulation concerning personal protective equipment that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.'***		

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		Article 110j ***Amendment to Regulation (EU) 2016/426*** ***In Article 5 of Regulation (EU) 2016/426, the following paragraphs 2 and 3 are added:*** ***'2. The Commission is empowered to adopt delegated acts in accordance with Article 41 to amend the essential requirements set out in Annex I in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.*** ***3. When adopting delegated acts pursuant to paragraph 2 of this Article or Common Specifications pursuant to Article 13a of this Regulation concerning appliances or fitting that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European***		

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		Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.' ***Article 110k*** ***Amendment to Regulation (EU) 2017/745*** ***In Article 5 of Regulation (EU) 2017/745, the following paragraphs 7 and 8 are added:*** ***'7. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend the general safety and performance requirements set out in Annex I in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to***		

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		constitute essential health and safety requirements for the purpose of this Regulation. ***8. When adopting implementing acts pursuant to paragraph 6 of this Article, delegated acts pursuant to paragraph 7 of this Article or Common Specifications pursuant to Article 9 of this Regulation concerning devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.'*** ***Article 110l*** ***Amendment to Regulation (EU) 2017/746*** ***In Article 5 of Regulation (EU) 2017/746, the following paragraphs 7 and 8 are added:*** ***'7. The Commission is empowered to adopt delegated acts***		

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		in accordance with Article 107 to amend the general safety and performance requirements set out in Annex I in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation. ***8. When adopting implementing acts pursuant to paragraph 6 of this Article, delegated acts pursuant to paragraph 7 of this Article or Common Specifications pursuant to Article 9 of this Regulation concerning devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard***		

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		to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.'		
Article 1, first paragraph, point (30)				
G 167	(30) Article 111 is amended as follows:	(30) Article 111 is amended as follows:	(30) Article 111 is amended as follows:	G
Article 1, first paragraph, point (30)(a)				
G 168	(a) paragraph 2 is replaced by the following:	(a) paragraph 2 is replaced by the following:	(a) paragraph 2 is replaced by the following:	G
Article 1, first paragraph, point (30)(a), amending provision, numbered paragraph (2)				
G 169	' 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	' 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	' 2.Without prejudice to the application of Article 5 as referred to in Article ~~113(3)~~**113**, 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	G

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		down in this Regulation by 2 August 2030.; ,	down in this Regulation by 2 August 2030.; ,	down in this Regulation by 2 August 2030.; ,	
Article 1, first paragraph, point (30)(b)					
G	170	(b) the following paragraph 4 is added:	(b) the following paragraph 4 is added:	(b) the following paragraph 4 is added:	
Article 1, first paragraph, point (30)(b), amending provision, numbered paragraph (4)					
Y	171	‘ 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.; ,	‘ 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*~~***November 2026***.; ,	‘ 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.; ,	
Article 1, first paragraph, point (31)					
G	172	(31) Article 113 is amended as follows:	(31) Article 113 is amended as follows:	(31) Article 113 is amended as follows:	
Article 1, first paragraph, point (31a)					
Y	172a			**(-a)in the third paragraph, point (a) is replaced by the following:**	
Article 1, first paragraph, point (31b)					
Y	172b			**'(a)Chapters I and II shall apply from 2 February 2025, except for Article 5(1), first subparagraph, points (ba) and (bb), Article 5(1a)**	

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			and Article 5(1b) which shall apply from 2 February 2027;'	
Article 1, first paragraph, point (31)(a)				
173	(a) in the third paragraph, point (d) is added:	(a) in the third paragraph, point (d) is added:	(a) in the third paragraph, point ~~(d) is added~~**(c) is replaced by the following**:	
Article 1, first paragraph, point (31)(a), amending provision, numbered paragraph (d), first subparagraph				
174	' (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:	' (d) Chapter III, Sections 1, 2, and 3, ***with the exception of Article 6(5),*** 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:*~~**;**	' (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:~~	
Article 1, first paragraph, point (31)(a), amending provision, numbered paragraph (d), first subparagraph, point (i)				
175	(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	*deleted*	(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~~	
Article 1, first paragraph, point (31)(a), amending provision, numbered paragraph (d), first subparagraph, point (ii)				
176	(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.	*deleted*	(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.~~	
Article 1, first paragraph, point (31)(a), amending provision, numbered paragraph (d), second subparagraph				
177	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	~~*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*~~	~~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~~	

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	follow the adoption of that decision, Chapter III, Sections 1, 2, and 3, shall apply:	~~*follow the adoption of that decision, Chapter III, Sections 1, 2, and 3, shall apply:*~~	~~follow the adoption of that decision, Chapter III, Sections 1, 2, and 3, shall apply:~~	
Article 1, first paragraph, point (31)(a), amending provision, numbered paragraph (d), second subparagraph, point (i)				
G 178	(i) on 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and	(i) on 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and	(i) on 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and	G
Article 1, first paragraph, point (31)(a), amending provision, numbered paragraph (d), second subparagraph, point (ii)				
G 179	(ii) on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.; ’,	(ii) on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.; ’,	(ii) on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.; ’,	G
Article 1, first paragraph, point (31)(b)				
G 180	(b) in the third paragraph, point (e) is added:	(b) in the third paragraph, point (e) is added:	(b) in the third paragraph, point ~~(e)~~**(d)** is added:	G
Article 1, first paragraph, point (31)(b), amending provision, numbered paragraph (e)				
G 181	‘ (e) Articles 102 to 110 shall apply from [the date of entry into application of this Regulation].; ’,	‘ (e) Articles 102 to 110 shall apply from [the date of entry into application of this Regulation].; ’,	‘ ~~(e)~~**(d)** Articles 102 to 110 shall apply from [the date of entry into ~~application~~ **force** of this **amending** Regulation].’; ’,	G
Article 1, first paragraph, point (31a)				
R 181a		***(31a) In Annex I, Section A is deleted***		R
Article 1, first paragraph, point (31b)				

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R 181b		***(31b) (31b) In Annex I, Section B, the following points are added:*** ***'20a. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24);*** ***20b. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1);*** ***20c. Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90);*** ***20d. Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251);*** ***20e. Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws***		R

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		of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309);		
		20f. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62);		
		20g. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164);		
		20h. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1);		
		20i. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and		

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		repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);		
		20j. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99);		
		20k. 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) 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);		
		20l. 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).		
		20m. Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and		

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			repealing Directive 2006/42/EC of the European Parliament and of the Council Directive 73/361/EEC.'		
Article 1, first paragraph, point (32)					
G	182	(32) in Annex VIII, section B is deleted;	(32) in Annex VIII, section B, ***points 7 and 9 are*** ~~*is*~~ deleted;	(32) in Annex VIII, section B, **points 7 and 9 are** ~~is~~ deleted;	G
Article 1, first paragraph, point (33)					
G	183	(33) the following Annex XIV is added:	(33) the following Annex XIV is added:	(33) the following Annex XIV is added:	G
Article 1, first paragraph, point (33), amending provision, first paragraph					
G	184	' Annex XIV	' Annex XIV	'Annex XIV	G
Article 1, first paragraph, point (33), amending provision, second paragraph					
G	185	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	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	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	G
Article 1, first paragraph, point (33), amending provision, numbered paragraph (1), first subparagraph					
G	186	1.Introduction	1.Introduction	1.Introduction	G
Article 1, first paragraph, point (33), amending provision, numbered paragraph (1), second subparagraph					
G	187	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 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 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	G

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		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.	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.	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.	
Article 1, first paragraph, point (33), amending provision, numbered paragraph (2)					
G	188	2.List of Codes, categories, and corresponding AI systems	2.List of Codes, categories, and corresponding AI systems	2.List of Codes, categories, and corresponding AI systems	
Article 1, first paragraph, point (33), amending provision, numbered paragraph (2), point (1)					
Y	189	1.AI systems subject to Annex I of the AI Act	1.AI systems subject to Annex I of the AI Act	1.~~AI systems subject to Annex I of the AI Act~~	
Article 1, first paragraph, point (33), amending provision, numbered paragraph (2), Table					
G	190	Table	Table	Table Deletion	
Article 1, first paragraph, point (33), amending provision, numbered paragraph (2), point (2)					
Y	191	2.AI systems subject to Annex III.1 of the AI Act	2.AI systems subject to Annex III.1 of the AI Act	2.~~AI systems subject to Annex III.1 of the AI Act~~	
Article 1, first paragraph, point (33), amending provision, numbered paragraph (2), Table					
G	192	Table	Table	Table Deletion	
Article 1, first paragraph, point (33), amending provision, numbered paragraph (2), point (3)					
Y	193	3.AI technology-specific codes	3.AI technology-specific codes	3.~~AI technology-specific codes~~	
Article 1, first paragraph, point (33), amending provision, numbered paragraph (2), point (3)(a)					
Y	194	a) Symbolic AI, expert systems and mathematical optimization	a) Symbolic AI, expert systems and mathematical optimization	a) ~~Symbolic AI, expert systems and mathematical optimization~~	

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Article 1, first paragraph, point (33), amending provision, numbered paragraph (2), point (3), Table					
G	195	Table	Table	Table Deletion	G
Article 1, first paragraph, point (33), amending provision, numbered paragraph (2), point (3)(b)					
Y	196	b) Machine learning, excluding GPAI and single modality generative AI	b) Machine learning, excluding GPAI and single modality generative AI	b) ~~Machine learning, excluding GPAI and single modality generative AI~~	Y
Article 1, first paragraph, point (33), amending provision, numbered paragraph (2), point (3), Table					
G	197	Table	Table	Table Deletion	G
Article 1, first paragraph, point (33), amending provision, numbered paragraph (2), point (3)(c)					
Y	198	c) AI systems based on GPAI or single modality generative AI	c) AI systems based on GPAI or single modality generative AI	c) ~~AI systems based on GPAI or single modality generative AI~~	Y
Article 1, first paragraph, point (33), amending provision, numbered paragraph (2), point (3), Table					
G	199	Table	Table	Table Deletion	G
Article 1, first paragraph, point (33), amending provision, numbered paragraph (2), point (3)(d)					
Y	200	d) Agentic AI	d) Agentic AI	d) ~~Agentic AI~~	Y
Article 1, first paragraph, point (33), amending provision, numbered paragraph (2), point (3), Table					
G	201	Table	Table	Table Deletion	G
Article 1, first paragraph, point (33), amending provision, numbered paragraph (3), first subparagraph					
G	202	3.Application for designation	3.Application for designation	3.Application for designation	G
Article 1, first paragraph, point (33), amending provision, numbered paragraph (3), second subparagraph					
Y	203	Conformity assessment bodies shall use the lists of codes, categories and corresponding types of AI systems set out in this Annex when	Conformity assessment bodies shall use the lists of codes, categories and corresponding types of AI systems set out in this Annex when	Conformity assessment bodies shall use the lists of codes, categories and corresponding types of AI systems set out in this Annex when	Y

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	specifying the types of AI systems in the application for designation referred to in Article 29 of this Regulation.. '	specifying the types of AI systems in the application for designation referred to in Article 29 of this Regulation.. '	specifying the types of AI systems in the application for designation referred to in Article 29 of this Regulation.. '	
Article 2				
G 204	Article 2 Amendments to Regulation (EU) 2018/1139	Article 2 Amendments to Regulation (EU) 2018/1139	Article 2 Amendments to Regulation (EU) 2018/1139	G
Article 2, first paragraph				
G 205	Regulation (EU) 2018/1139 is amended as follows:	Regulation (EU) 2018/1139 is amended as follows:	Regulation (EU) 2018/1139 is amended as follows:	G
Article 2, first paragraph, point (1)				
G 206	(1) in Article 27, the following paragraph is added:	(1) in Article 27, the following paragraph is added:	(1) in Article 27, the following paragraph is added:	G
Article 2, first paragraph, point (1), amending provision, numbered paragraph (3)				
G 207	' 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[1], the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.; '	' 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[1], the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.; '	' 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[1], the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.; '	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	1. Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).	1. Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).	1. Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).	
Article 2, first paragraph, point (2)				
G 208	(2) in Article 31, the following paragraph is added:	(2) in Article 31, the following paragraph is added:	(2) in Article 31, the following paragraph is added:	G
Article 2, first paragraph, point (2), amending provision, numbered paragraph (3)				
G 209	‘ 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.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.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.; ,	G
Article 2, first paragraph, point (3)				
G 210	(3) in Article 32, the following paragraph is added:	(3) in Article 32, the following paragraph is added:	(3) in Article 32, the following paragraph is added:	G
Article 2, first paragraph, point (3), amending provision, numbered paragraph (3)				

		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
Y	211	‘ 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.; ,	‘ 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.; ,	‘ 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.;’ ,		Y
Article 2, first paragraph, point (4)						
G	212	(4) in Article 36, the following paragraph is added:	(4) in Article 36, the following paragraph is added:	(4) in Article 36, the following paragraph is added:		G
Article 2, first paragraph, point (4), amending provision, numbered paragraph (3)						
G	213	‘ 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.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.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.; ,		G
Article 2, first paragraph, point (5)						

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	214	(5) in Article 39 the following paragraph is added:	(5) in Article 39 the following paragraph is added:	(5) in Article 39 the following paragraph is added:		G
Article 2, first paragraph, point (5), amending provision, numbered paragraph (3)						
G	215	‘ 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.; ’	‘ 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.; ’	‘ 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.; ’		G
Article 2, first paragraph, point (6)						
G	216	(6) in Article 50, the following paragraph is added:	(6) in Article 50, the following paragraph is added:	(6) in Article 50, the following paragraph is added:		G
Article 2, first paragraph, point (6), amending provision, numbered paragraph (3)						
G	217	‘ 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.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.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.; ’		G

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 2, first paragraph, point (7)					
G	218	(7) in Article 53, the following paragraph is added:	(7) in Article 53, the following paragraph is added:	(7) in Article 53, the following paragraph is added:	G
Article 2, first paragraph, point (7), amending provision, numbered paragraph (3)					
Y	219	‘ 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.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.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.- ,	Y
Article 3					
G	220	Article 3 Entry into force and application	Article 3 Entry into force and application	Article 3 Entry into force and application	G
Article 3, first paragraph					
G	221	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 enter into force on the third day following that of its publication in the Official Journal of the European Union.	This Regulation shall enter into force on the third day following that of its publication in the Official Journal of the European Union.	G
Article 3, second paragraph					
G	222	This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.	G

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
Formula						
G	223	Done at Brussels,	Done at Brussels,	Done at Brussels,		G
Formula						
G	224	For the European Parliament	For the European Parliament	For the European Parliament		G
Formula						
G	225	The President	The President	The President		G
Formula						
G	226	For the Council	For the Council	For the Council		G
Formula						
G	227	The President	The President	The President		G

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Commission Proposal Table

PUBLIC

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.
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.

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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.
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.

Council Mandate Table

PUBLIC

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.
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.

Commission Proposal Table

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AIA Code	
AIB 0201	Remote biometric identification systems under Annex III.1.a. of the AI Act intended to be put into service by Union institutions, bodies, offices or agencies.
AIB 0202	Biometric categorisation AI systems under Annex III.1.b. of the AI Act intended to be put into service by Union institutions, bodies, offices or agencies.
AIB 0203	Emotion recognition AI systems under Annex III.1.c. of the AI Act intended to be put into service by Union institutions, bodies, offices or agencies.
AIB 0204	Remote biometric identification systems under Annex III.1.a. of the AI Act intended to be put into service by law enforcement, immigration or asylum authorities.
AIB 0205	Biometric categorisation AI systems under Annex III.1.b. of the AI Act intended to be put into service by law enforcement, immigration or asylum authorities.
AIB 0206	Emotion recognition AI systems under Annex III.1.c. of the AI Act intended to be put into service by law enforcement, immigration or asylum authorities.
AIB 0207	Remote biometric identification systems under Annex III.1.a. of the AI Act (general).
AIB 0208	Biometric categorisation AI systems under Annex III.1.b. of the AI Act (general).
AIB 0209	Emotion recognition AI systems under Annex III.1.c. of the AI Act (general).

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AIA Code	
AIB 0201	Remote biometric identification systems under Annex III.1.a. of the AI Act intended to be put into service by Union institutions, bodies, offices or agencies.
AIB 0202	Biometric categorisation AI systems under Annex III.1.b. of the AI Act intended to be put into service by Union institutions, bodies, offices or agencies.
AIB 0203	Emotion recognition AI systems under Annex III.1.c. of the AI Act intended to be put into service by Union institutions, bodies, offices or agencies.
AIB 0204	Remote biometric identification systems under Annex III.1.a. of the AI Act intended to be put into service by law enforcement, immigration or asylum authorities.
AIB 0205	Biometric categorisation AI systems under Annex III.1.b. of the AI Act intended to be put into service by law enforcement, immigration or asylum authorities.
AIB 0206	Emotion recognition AI systems under Annex III.1.c. of the AI Act intended to be put into service by law enforcement, immigration or asylum authorities.
AIB 0207	Remote biometric identification systems under Annex III.1.a. of the AI Act (general).
AIB 0208	Biometric categorisation AI systems under Annex III.1.b. of the AI Act (general).
AIB 0209	Emotion recognition AI systems under Annex III.1.c. of the AI Act (general).

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AIA Code	
AIB 0201	Remote biometric identification systems under Annex III.1.a. of the AI Act intended to be put into service by Union institutions, bodies, offices or agencies.
AIB 0202	Biometric categorisation AI systems under Annex III.1.b. of the AI Act intended to be put into service by Union institutions, bodies, offices or agencies.
AIB 0203	Emotion recognition AI systems under Annex III.1.c. of the AI Act intended to be put into service by Union institutions, bodies, offices or agencies.
AIB 0204	Remote biometric identification systems under Annex III.1.a. of the AI Act intended to be put into service by law enforcement, immigration or asylum authorities.
AIB 0205	Biometric categorisation AI systems under Annex III.1.b. of the AI Act intended to be put into service by law enforcement, immigration or asylum authorities.
AIB 0206	Emotion recognition AI systems under Annex III.1.c. of the AI Act intended to be put into service by law enforcement, immigration or asylum authorities.
AIB 0207	Remote biometric identification systems under Annex III.1.a. of the AI Act (general).
AIB 0208	Biometric categorisation AI systems under Annex III.1.b. of the AI Act (general).
AIB 0209	Emotion recognition AI systems under Annex III.1.c. of the AI Act (general).

Commission Proposal Table

AIA Code	
AIH 0101	Logic- and knowledge-based AI systems that infer from encoded knowledge or symbolic representation, expert systems
AIH 0102	Logic-based AI systems, excluding basic data processing

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AIA Code	
AIH 0101	Logic- and knowledge-based AI systems that infer from encoded knowledge or symbolic representation, expert systems
AIH 0102	Logic-based AI systems, excluding basic data processing

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AIA Code	
AIH 0101	Logic- and knowledge-based AI systems that infer from encoded knowledge or symbolic representation, expert systems
AIH 0102	Logic-based AI systems, excluding basic data processing

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AIA Code	
AIH 0201	AI systems that process structured data
AIH 0202	AI systems that process signal and audio data
AIH 0203	AI systems that process text data
AIH 0204	AI systems that process image and video
AIH 0205	AI systems that learn from their environment, excluding agentic AI

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AIA Code	
AIH 0201	AI systems that process structured data
AIH 0202	AI systems that process signal and audio data
AIH 0203	AI systems that process text data
AIH 0204	AI systems that process image and video
AIH 0205	AI systems that learn from their environment, excluding agentic AI

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AIA Code	
AIH 0201	AI systems that process structured data
AIH 0202	AI systems that process signal and audio data
AIH 0203	AI systems that process text data
AIH 0204	AI systems that process image and video
AIH 0205	AI systems that learn from their environment, excluding agentic AI

Commission Proposal Table

AIA Code	
AIH 0301	Single modality generative AI systems
AIH 0302	Multimodal generative AI systems, including AI systems based on GPAI models

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EP Mandate Table

AIA Code	
AIH 0301	Single modality generative AI systems
AIH 0302	Multimodal generative AI systems, including AI systems based on GPAI models

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Council Mandate Table

AIA Code	
AIH 0301	Single modality generative AI systems
AIH 0302	Multimodal generative AI systems, including AI systems based on GPAI models

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Commission Proposal Table

AIA Code	
AIH 0401	Agentic AI

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EP Mandate Table

AIA Code	
AIH 0401	Agentic AI

PUBLIC

Council Mandate Table

AIA Code	
AIH 0401	Agentic AI

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