Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Formula				
1	2021/0106 (COD)	2021/0106 (COD)	2021/0106 (COD)	2021/0106 (COD) Text Origin: Commission Proposal
Proposal Title				
2	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS Text Origin: Commission Proposal
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3	THE EUROPEAN PARLIAMENT	THE EUROPEAN PARLIAMENT	THE EUROPEAN PARLIAMENT	THE EUROPEAN PARLIAMENT

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Citation 1				
G 4	Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 16 and 114 thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 16 and 114 thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 16 and 114 thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 16 and 114 thereof, Text Origin: Commission Proposal
Citation 2				
G 5	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,	Having regard to the proposal from the European Commission, Text Origin: Commission Proposal
Citation 3				
G 6	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,	After transmission of the draft legislative act to the national parliaments, Text Origin: Commission Proposal
Citation 4				
G 7				

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	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. […].	Having regard to the opinion of the European Economic and Social Committee[1], _____ 1. OJ C […], […], p. […]. Text Origin: Commission Proposal
Citation 4a				
G 7a		***Having regard to the opinion of the European Central Bank,***		***Having regard to the opinion of the European Central Bank[1],*** _____ ***1. Reference to ECB opinion*** Text Origin: EP Mandate
Citation 4b				
G 7b		***Having regard to the joint opinion of the European Data Protection Board and the European Data Protection Supervisor,***		***Having regard to the joint opinion of the European Data Protection Board and the European Data Protection Supervisor,*** Text Origin: EP Mandate
Citation 5				
G 8	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. […].	Having regard to the opinion of the Committee of the Regions[1], _____ 1. OJ C […], […], p. […]. Text Origin: Commission Proposal

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Citation 5a				
8a			***5a Having regard to the opinion of the European Central Bank[1],*** _____ ***1. Reference to ECB opinion***	
Citation 6				
9	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure, Text Origin: Commission Proposal
Formula				
10	Whereas:	Whereas:	Whereas:	Whereas: Text Origin: Commission Proposal
Recital 1				
11	(1) The purpose of this Regulation is to improve the functioning of the internal market by laying down a uniform legal framework in particular for the development, marketing and use of artificial intelligence in conformity with Union values. This Regulation pursues a number of overriding	(1) The purpose of this Regulation is to ~~improve the functioning of the internal market by laying down a uniform legal framework in particular for the development, marketing and use~~***promote the uptake of human centric and trustworthy artificial intelligence and to ensure a high level of***	(1) The purpose of this Regulation is to improve the functioning of the internal market by laying down a uniform legal framework in particular for the development, marketing and use of artificial intelligence in conformity with Union values. This Regulation pursues a number of overriding	(1) The purpose of this Regulation is to improve the functioning of the internal market by laying down a uniform legal framework in particular for the development, ~~marketing and~~ ***placing on the market, putting into service and the*** use of artificial intelligence ***systems in the Union*** in conformity with

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	reasons of public interest, such as a high level of protection of health, safety and fundamental rights, and it ensures the free movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the development, marketing and use of AI systems, unless explicitly authorised by this Regulation.	***protection of health, safety, fundamental rights, democracy and rule of law and the environment from harmful effects*** of artificial intelligence ***systems in the Union while supporting innovation and improving the functioning of the internal market***~~*in conformity with Union values*~~. This Regulation ~~*pursues a number of overriding reasons of public interest, such as a high level of protection of health, safety and fundamental rights, and it*~~ ***lays down a uniform legal framework in particular for the development, the placing on the market, the putting into service and the use of artificial intelligence in conformity with Union values and*** ensures the free movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the development, marketing and use of ***Artificial Intelligence systems (***AI systems***)***, unless explicitly authorised by this Regulation. ***Certain AI systems can also have an impact on democracy and rule of law and the environment. These concerns are specifically addressed in the critical sectors and use cases listed in the annexes to this Regulation.***	reasons of public interest, such as a high level of protection of health, safety and fundamental rights, and it ensures the free movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the development, marketing and use of AI systems, unless explicitly authorised by this Regulation.	Union values~~*. This Regulation pursues a number of overriding reasons of public interest, such as*~~***, to promote the uptake of human centric and trustworthy artificial intelligence while ensuring*** a high level of protection of health, safety ~~*and*~~***,*** fundamental rights ***enshrined in the Charter, including democracy and rule of law and environmental protection, against harmful effects of artificial intelligence systems in the Union and to support innovation. This regulation***~~*and it*~~ ensures the free movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the development, marketing and use of ***Artificial Intelligence systems (***AI systems***)***, unless explicitly authorised by this Regulation.
Recital 1a				

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G 11a		***(1a) This Regulation should preserve the values of the Union facilitating the distribution of artificial intelligence benefits across society, protecting individuals, companies, democracy and rule of law and the environment from risks while boosting innovation and employment and making the Union a leader in the field***		***(1a) This Regulation should be applied in conformity with the values of the Union enshrined in the Charter facilitating the protection of individuals, companies, democracy and rule of law and the environment while boosting innovation and employment and making the Union a leader in the uptake of trustworthy AI.*** G
Recital 2				
G 12	(2) Artificial intelligence systems (AI systems) can be easily deployed in multiple sectors of the economy and society, including cross border, and circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that artificial intelligence is safe and is developed and used in compliance with fundamental rights obligations. Differing national rules may lead to fragmentation of the internal market and decrease legal certainty for operators that develop or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured, while divergences hampering the free circulation of AI systems and related products and services within the	(2) ~~*Artificial intelligence systems* (~~AI systems~~)~~ can be easily deployed in multiple sectors of the economy and society, including cross border, and circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that artificial intelligence is ***trustworthy and*** safe and is developed and used in compliance with fundamental rights obligations. Differing national rules may lead to fragmentation of the internal market and decrease legal certainty for operators that develop or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured ***in order to achieve trustworthy AI***, while divergences hampering the free circulation,	(2) Artificial intelligence systems (AI systems) can be easily deployed in multiple sectors of the economy and society, including cross border, and circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that artificial intelligence is safe and is developed and used in compliance with fundamental rights obligations. Differing national rules may lead to fragmentation of the internal market and decrease legal certainty for operators that develop***, import*** or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured, while divergences hampering the free circulation of AI systems and related products and services within	(2) ~~*Artificial intelligence systems* (~~AI systems~~)~~ can be easily deployed in multiple sectors of the economy and society, including cross border, and circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that artificial intelligence is ***trustworthy and*** safe and is developed and used in compliance with fundamental rights obligations. Differing national rules may lead to fragmentation of the internal market and decrease legal certainty for operators that develop***, import*** or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured ***in order to achieve trustworthy AI***, while divergences hampering the free G

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	internal market should be prevented, by laying down uniform obligations for operators and guaranteeing the uniform protection of overriding reasons of public interest and of rights of persons throughout the internal market based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). To the extent that this Regulation contains specific rules on the protection of individuals with regard to the processing of personal data concerning restrictions of the use of AI systems for 'real-time' remote biometric identification in publicly accessible spaces for the purpose of law enforcement, it is appropriate to base this Regulation, in as far as those specific rules are concerned, on Article 16 of the TFEU. In light of those specific rules and the recourse to Article 16 TFEU, it is appropriate to consult the European Data Protection Board.	***innovation, deployment and uptake*** of AI systems and related products and services within the internal market should be prevented, by laying down uniform obligations for operators and guaranteeing the uniform protection of overriding reasons of public interest and of rights of persons throughout the internal market based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). ~~*To the extent that this Regulation contains specific rules on the protection of individuals with regard to the processing of personal data concerning restrictions of the use of AI systems for 'real-time' remote biometric identification in publicly accessible spaces for the purpose of law enforcement, it is appropriate to base this Regulation, in as far as those specific rules are concerned, on Article 16 of the TFEU. In light of those specific rules and the recourse to Article 16 TFEU, it is appropriate to consult the European Data Protection Board.*~~	the internal market should be prevented, by laying down uniform obligations for operators and guaranteeing the uniform protection of overriding reasons of public interest and of rights of persons throughout the internal market based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). To the extent that this Regulation contains specific rules on the protection of individuals with regard to the processing of personal data concerning restrictions of the use of AI systems for 'real-time' remote biometric identification in publicly accessible spaces for the purpose of law enforcement, it is appropriate to base this Regulation, in as far as those specific rules are concerned, on Article 16 of the TFEU. In light of those specific rules and the recourse to Article 16 TFEU, it is appropriate to consult the European Data Protection Board.	circulation***, innovation, deployment and uptake*** of AI systems and related products and services within the internal market should be prevented, by laying down uniform obligations for operators and guaranteeing the uniform protection of overriding reasons of public interest and of rights of persons throughout the internal market based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). To the extent that this Regulation contains specific rules on the protection of individuals with regard to the processing of personal data concerning restrictions of the use of AI systems for~~ *'real-time'* remote biometric identification ~~*in publicly accessible spaces*~~***for the purpose of law enforcement, for the use of AI systems for risk assessments of natural persons for the purpose of law enforcement and for the use of AI systems of biometric categorization*** for the purpose of law enforcement, it is appropriate to base this Regulation, in as far as those specific rules are concerned, on Article 16 of the TFEU. In light of those specific rules and the recourse to Article 16 TFEU, it is appropriate to consult the European Data Protection Board.
Recital 2a				

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G 12a		*(2a) As artificial intelligence often relies on the processing of large volumes of data, and many AI systems and applications on the processing of personal data, it is appropriate to base this Regulation on Article 16 TFEU, which enshrines the right to the protection of natural persons with regard to the processing of personal data and provides for the adoption of rules on the protection of individuals with regard to the processing of personal data.*		G
Recital 2b				
G 12b		*(2b) The fundamental right to the protection of personal data is safeguarded in particular by Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive 2016/680. Directive 2002/58/EC additionally protects private life and the confidentiality of communications, including providing conditions for any personal and non-personal data storing in and access from terminal equipment. Those legal acts provide the basis for sustainable and responsible data processing, including where datasets include a mix of personal and nonpersonal data. This Regulation does not seek*		G

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		to affect the application of existing Union law governing the processing of personal data, including the tasks and powers of the independent supervisory authorities competent to monitor compliance with those instruments. This Regulation does not affect the fundamental rights to private life and the protection of personal data as provided for by Union law on data protection and privacy and enshrined in the Charter of Fundamental Rights of the European Union (the 'Charter').		
Recital 2c				
G 12c		*(2c) Artificial intelligence systems in the Union are subject to relevant product safety legislation that provides a framework protecting consumers against dangerous products in general and such legislation should continue to apply. This Regulation is also without prejudice to the rules laid down by other Union legal acts related to consumer protection and product safety, including including Regulation (EU) 2017/2394, Regulation (EU) 2019/1020 and Directive 2001/95/EC on general product safety and Directive 2013/11/EU.*		G

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Recital 2d				
G 12d		***(2d) In accordance with Article 114(2) TFEU, this Regulation complements and should not undermine the rights and interests of employed persons. This Regulation should therefore not affect Union law on social policy and national labour law and practice, that is any legal and contractual provision concerning employment conditions, working conditions, including health and safety at work and the relationship between employers and workers, including information, consultation and participation. This Regulation should not affect the exercise of fundamental rights as recognised in the Member States and at Union level, including the right or freedom to strike or to take other action covered by the specific industrial relations systems in Member States, in accordance with national law and/or practice. Nor should it affect concertation practices, the right to negotiate, to conclude and enforce collective agreement or to take collective action in accordance with national law and/or practice. It should in any event not prevent the Commission from proposing specific legislation on the rights and freedoms of workers affected by AI systems.***		G

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Recital 2e				
G 12e		***(2e) This Regulation should not affect the provisions aiming to improve working conditions in platform work set out in Directive ... [COD 2021/414/EC].***		G
Recital 2f				
G 12f		***(2f) This Regulation should help in supporting research and innovation and should not undermine research and development activity and respect freedom of scientific research. It is therefore necessary to exclude from its scope AI systems specifically developed for the sole purpose of scientific research and development and to ensure that the Regulation does not otherwise affect scientific research and development activity on AI systems. Under all circumstances, any research and development activity should be carried out in accordance with the Charter, Union law as well as the national law.***		G
Recital 3				
G 13	(3) Artificial intelligence is a fast evolving family of technologies that	(3) Artificial intelligence is a fast evolving family of technologies that	(3) Artificial intelligence is a fast evolving family of technologies that	(3) Artificial intelligence is a fast evolving family of technologies that G

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	can contribute to a wide array of economic and societal benefits across the entire spectrum of industries and social activities. By improving prediction, optimising operations and resource allocation, and personalising digital solutions available for individuals and organisations, the use of artificial intelligence can provide key competitive advantages to companies and support socially and environmentally beneficial outcomes, for example in healthcare, farming, education and training, infrastructure management, energy, transport and logistics, public services, security, justice, resource and energy efficiency, and climate change mitigation and adaptation.	can ~~contribute~~***and already contributes*** to a wide array of economic***, environmental*** and societal benefits across the entire spectrum of industries and social activities ***if developed in accordance with relevant general principles in line with the Charter and the values on which the Union is founded***. By improving prediction, optimising operations and resource allocation, and personalising digital solutions available for individuals and organisations, the use of artificial intelligence can provide key competitive advantages to companies and support socially and environmentally beneficial outcomes, for example in healthcare, farming, ***food safety,*** education and training, ***media, sports, culture,*** infrastructure management, energy, transport and logistics, ***crisis management,*** public services, security, justice, resource and energy efficiency, ***environmental monitoring, the conservation and restoration of biodiversity and ecosystems*** and climate change mitigation and adaptation.	can contribute to a wide array of economic and societal benefits across the entire spectrum of industries and social activities. By improving prediction, optimising operations and resource allocation, and personalising digital solutions available for individuals and organisations, the use of artificial intelligence can provide key competitive advantages to companies and support socially and environmentally beneficial outcomes, for example in healthcare, farming, education and training, infrastructure management, energy, transport and logistics, public services, security, justice, resource and energy efficiency, and climate change mitigation and adaptation.	~~can contribute~~***contributes*** to a wide array of economic***, environmental*** and societal benefits across the entire spectrum of industries and social activities. By improving prediction, optimising operations and resource allocation, and personalising digital solutions available for individuals and organisations, the use of artificial intelligence can provide key competitive advantages to companies and support socially and environmentally beneficial outcomes, for example in healthcare, farming, ***food safety,*** education and training, ***media, sports, culture,*** infrastructure management, energy, transport and logistics, public services, security, justice, resource and energy efficiency, ***environmental monitoring, the conservation and restoration of biodiversity and ecosystems*** and climate change mitigation and adaptation.
Recital 3a				
G 13a		***(3a) To contribute to reaching the carbon neutrality targets, European companies should seek to utilise all***		G

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		available technological advancements that can assist in realising this goal. Artificial Intelligence is a technology that has the potential of being used to process the ever-growing amount of data created during industrial, environmental, health and other processes. To facilitate investments in AI-based analysis and optimisation tools, this Regulation should provide a predictable and proportionate environment for low-risk industrial solutions.		
Recital 4				
G 14	(4) At the same time, depending on the circumstances regarding its specific application and use, artificial intelligence may generate risks and cause harm to public interests and rights that are protected by Union law. Such harm might be material or immaterial.	(4) At the same time, depending on the circumstances regarding its specific application and use, ***as well as the level of technological development,*** artificial intelligence may generate risks and cause harm to public ***or private*** interests and ***fundamental*** rights ***of natural persons*** that are protected by Union law. Such harm might be material or immaterial***, including physical, psychological, societal or economic harm***.	(4) At the same time, depending on the circumstances regarding its specific application and use, artificial intelligence may generate risks and cause harm to public interests and rights that are protected by Union law. Such harm might be material or immaterial.	(4) At the same time, depending on the circumstances regarding its specific application***, use, and level of technological development*** ~~and use~~, artificial intelligence may generate risks and cause harm to public interests and ***fundamental*** rights that are protected by Union law. Such harm might be material or immaterial***, including physical, psychological, societal or economic harm***. G
Recital 4a				
G 14a		***(4a) Given the major impact that artificial intelligence can have on***		***(4a) Given the major impact that artificial intelligence can have on*** G

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		society and the need to build trust, it is vital for artificial intelligence and its regulatory framework to be developed according to Union values enshrined in Article 2 TEU, the fundamental rights and freedoms enshrined in the Treaties, the Charter, and international human rights law. As a pre-requisite, artificial intelligence should be a human-centric technology. It should not substitute human autonomy or assume the loss of individual freedom and should primarily serve the needs of the society and the common good. Safeguards should be provided to ensure the development and use of ethically embedded artificial intelligence that respects Union values and the Charter.		***society and the need to build trust, it is vital for artificial intelligence and its regulatory framework to be developed according to Union values enshrined in Article 2 TEU, the fundamental rights and freedoms enshrined in the Treaties, the Charter. As a pre-requisite, artificial intelligence should be a human-centric technology. It should serve as a tool for people, with the ultimate aim of increasing human well-being.*** ***(4aa) In order to ensure a consistent and high level of protection of public interests as regards health, safety and fundamental rights, common rules for all high-risk AI systems should be established. Those rules should be consistent with the Charter of fundamental rights of the European Union (the Charter) and should be non-discriminatory and in line with the Union's international trade commitments. They should also take into account the European Declaration on Digital Rights and Principles for the Digital Decade (2023/C 23/01) and the Ethics Guidelines for Trustworthy Artificial Intelligence (AI) of the High-Level Expert Group on Artificial Intelligence.***
Recital 5				

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G 15	(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and safety and the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council[1], and it ensures the protection of ethical principles, as specifically requested by the European Parliament[2]. _____ 1. European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6. 2. European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and	(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and safety ~~and the~~, protection of fundamental rights, ***democracy and rule of law and the environment,*** as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market, ***the*** ~~and~~ putting into service ***and the use*** of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. ***These rules should be clear and robust in protecting fundamental rights, supportive of new innovative solutions, and enabling to a European ecosystem of public and private actors creating AI systems in line with Union values.*** By laying down those rules ***as well as measures in support of innovation with a particular focus on SMEs and start-ups***, this Regulation supports the objective ***of promoting the AI made in Europe,*** of the Union of being a global leader in the development of secure, trustworthy	(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and safety and the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules ***and building on the work of the High-level Expert Group on Artificial Intelligence as reflecetd in the Guidelines for Trustworthy Artificial Intelligence in the EU***, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence~~,~~ as stated by the European Council[1], and it ensures the protection of ethical principles, as specifically requested by the European Parliament[2]. _____ 1. ***[1]*** European Council, Special	(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and safety and the protection of fundamental rights, ***including democracy, rule of law and environmental protection*** as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market ~~and~~, putting into service ***and use*** of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. ***These rules should be clear and robust in protecting fundamental rights, supportive of new innovative solutions, enabling to a European ecosystem of public and private actors creating AI systems in line with Union values and unlocking the potential of the digital transformation across all regions of the Union.*** By laying down those rules ***as well as measures in support of innovation with a particular focus on SMEs including startups***, this Regulation supports the

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	related technologies, 2020/2012(INL).	and ethical artificial intelligence, as stated by the European Council[1], and it ensures the protection of ethical principles, as specifically requested by the European Parliament[2]. _____ 1. European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6. 2. European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).	meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6. 2. *[2]* European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).	objective of ***promoting the European human-centric approach to AI and*** ~~*the Union of*~~ being a global leader in the development of secure, trustworthy and ethical artificial intelligence~~,~~ as stated by the European Council[1], and it ensures the protection of ethical principles, as specifically requested by ***the*** the European Parliament[2]. _____ 1. European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6. 2. European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).
Recital 5a				
G 15a			***(5a) The harmonised rules on the placing on the market, putting into service and use of AI systems laid down in this Regulation should apply across sectors and, in line with its New Legislative Framework approach, should be without prejudice to existing Union law, notably on data protection, consumer protection, fundamental rights, employment and product safety, to which this Regulation is complementary. As a consequence all rights and remedies afforded by such Union law to consumers and***	***(5a) The harmonised rules on the placing on the market, putting into service and use of AI systems laid down in this Regulation should apply across sectors and, in line with its New Legislative Framework approach, should be without prejudice to existing Union law, notably on data protection, consumer protection, fundamental rights, employment, and protection of workers, and product safety, to which this Regulation is complementary. As a consequence all rights and remedies provided for*** G

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			other persons who may be negatively impacted by AI systems, including as regards the compensation of possible damages pursuant to Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, remain unaffected and fully applicable. On top of that, this Regulation aims to strengthen the effectiveness of such existing rights and remedies by establishing specific requirements and obligations, including in respect of transparency, technical documentation and record-keeping of AI systems. Furthermore, the obligations placed on various operators involved in the AI value chain under this Regulation should apply without prejudice to national laws, in compliance with Union law, having the effect of limiting the use of certain AI systems where such laws fall outside the scope of this Regulation or pursue other legitimate public interest objectives than those pursued by this Regulation. For example, national labour law and the laws on the protection of minors (i.e. persons below the age of 18) taking into account the United Nations General Comment No 25 (2021) on	*by such Union law to consumers, and other persons who may be negatively impacted by AI systems, including as regards the compensation of possible damages pursuant to Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, remain unaffected and fully applicable. Furthermore, in the context of employment and protection of workers, this Regulation should therefore not affect Union law on social policy and national labour law, in compliance with Union law, concerning employment and working conditions, including health and safety at work and the relationship between employers and workers. This Regulation should also not affect the exercise of fundamental rights as recognised in the Member States and at Union level, including the right or freedom to strike or to take other action covered by the specific industrial relations systems in Member States as well as, the right to negotiate, to conclude and enforce collective agreements or to take collective action in accordance with national law. [This Regulation should not affect the provisions aiming to*

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			children's rights, insofar as they are not specific to AI systems and pursue other legimitate public interest objectives, should not be affected by this Regulation.	***improve working conditions in platform work set out in Directive ... [COD 2021/414/EC]] On top of that, this Regulation aims to strengthen the effectiveness of such existing rights and remedies by establishing specific requirements and obligations, including in respect of transparency, technical documentation and record-keeping of AI systems. Furthermore, the obligations placed on various operators involved in the AI value chain under this Regulation should apply without prejudice to national laws, in compliance with Union law, having the effect of limiting the use of certain AI systems where such laws fall outside the scope of this Regulation or pursue other legitimate public interest objectives than those pursued by this Regulation. For example, national labour law and the laws on the protection of minors (i.e. persons below the age of 18) taking into account the United Nations General Comment No 25 (2021) on children's rights, insofar as they are not specific to AI systems and pursue other legimitate public interest objectives, should not be affected by this Regulation.*** ***(5aa) The fundamental right to the protection of personal data is safeguarded in particular by***

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				Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive 2016/680. Directive 2002/58/EC additionally protects private life and the confidentiality of communications, including by way of providing conditions for any personal and non-personal data storing in and access from terminal equipment. Those Union legal acts provide the basis for sustainable and responsible data processing, including where datasets include a mix of personal and non-personal data. This Regulation does not seek to affect the application of existing Union law governing the processing of personal data, including the tasks and powers of the independent supervisory authorities competent to monitor compliance with those instruments. ***It also does not affect the obligations of providers and deployers of AI systems in their role as data controllers or processors stemming from national or Union law on the protection of personal data in so far as the design, the development or the use of AI systems involves the processing of personal data. It is also appropriate to clarify that data subjects continue to enjoy all the rights and guarantees awarded to them by such Union law, including the***

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				rights related to solely automated individual decision-making, including profiling. Harmonised rules for the placing on the market, the putting into service and the use of AI systems established under this Regulation should facilitate the effective implementation and enable the exercise of the data subjects' rights and other remedies guaranteed under Union law on the protection of personal data and of other fundamental rights. ***(5ab) This Regulation should be without prejudice to the provisions regarding the liability of intermediary service providers set out in Directive 2000/31/EC of the European Parliament and of the Council [as amended by the Digital Services Act].***
Recital 5a				
G 15b		***(5a) Furthermore, in order to foster the development of AI systems in line with Union values, the Union needs to address the main gaps and barriers blocking the potential of the digital transformation including the shortage of digitally skilled workers, cybersecurity concerns, lack of investment and access to investment, and existing and***		G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		potential gaps between large companies, SME's and start-ups. Special attention should be paid to ensuring that the benefits of AI and innovation in new technologies are felt across all regions of the Union and that sufficient investment and resources are provided especially to those regions that may be lagging behind in some digital indicators.		
Recital 6				
G 16	(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be based on the key functional characteristics of the software, in particular the ability, for a given set of human-defined objectives, to generate outputs such as content, predictions, recommendations, or decisions which influence the environment with which the system interacts, be it in a physical or digital dimension. AI systems can be designed to operate with varying levels of autonomy and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without	(6) The notion of AI system ***in this Regulation*** should be clearly defined ***and closely aligned with the work of international organisations working on artificial intelligence*** to ensure legal certainty, ***harmonization and wide acceptance,*** while providing the flexibility to accommodate ~~future~~***the rapid*** technological developments ***in this field. Moreover, it***~~. The definition~~ should be based on ~~the key functional~~***key*** characteristics of ~~the software, in particular the ability, for a given set of human-defined objectives, to generate outputs such as content, predictions, recommendations, or decisions which influence the environment with which the system interacts, be it in a physical or digital dimension.~~***artificial intelligence, such as its learning, reasoning or modelling capabilities,***	(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be based on ~~the~~ key functional characteristics of ~~the software,~~ ***artificial intelligence such as its learning, reasoning or modelling capabilities, distinguishing it from simpler software systems and programming approaches.*** In particular***, for the purposes of this Regulation AI systems should have*** the ability, ~~for a given~~***on the basis of machine and/or human-based data and inputs, to infer the way to achieve a*** set of ~~human-defined~~***final*** objectives ***given to them by humans, using machine learning and/or logic- and knowledge based approaches and to produce***~~, to generate~~ outputs such as	(6) The notion of AI system ***in this Regulation*** should be clearly defined ***and closely aligned with the work of international organisations working on artificial intelligence*** to ensure legal certainty, ***facilitate international convergence and wide acceptance,*** while providing the flexibility to accommodate ~~future~~***the rapid*** technological developments~~. The definition~~ ***in this field.*** ***Moreover, it*** should be based on ~~the key functional~~ ***key*** characteristics of ~~the software, in particular the ability, for a given set of human-defined objectives, to generate~~***artificial intelligence systems, that distinguish it from simpler traditional software systems or programming approaches and should not cover systems that are based on the rules defined solely by*** G

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	being integrated therein (non-embedded). The definition of AI system should be complemented by a list of specific techniques and approaches used for its development, which should be kept up-to–date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list.	***so as to distinguish it from simpler software systems or programming approaches. AI systems are designed to operate with varying levels of autonomy, meaning that they have at least some degree of independence of actions from human controls and of capabilities to operate without human intervention. The term "machine-based" refers to the fact that AI systems run on machines. The reference to explicit or implicit objectives underscores that*** AI systems can ~~*be designed to operate with varying levels of autonomy and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality*~~***operate according to explicit human-defined objectives or to implicit objectives. The objectives of the AI system may be different from the intended purpose of the AI system in a specific context. The reference to predictions includes content, which is considered in this Regulation a form of prediction as one*** of the ~~*product without being integrated therein (non-embedded). The definition of AI system*~~***possible outputs produced by an AI system. For the purposes of this Regulation, environments*** should be	content ***for generative AI systems (e.g. text, video or images)***, predictions, recommendations~~,~~ or decisions***, influencing*** ~~*which influence*~~ the environment with which the system interacts, be it in a physical or digital dimension. ***A system that uses rules defined solely by natural persons to automatically execute operations should not be considered an AI system.*** AI systems can be designed to operate with varying levels of autonomy and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded). The ~~*definition of AI system should be complemented by a list of specific techniques and approaches used for its development, which should be kept up-to–date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list*~~***concept of the autonomy of an AI system relates to the degree to which such a system functions without human involvement***.	***natural persons to automatically execute operations. A key characteristic of AI systems is their capability to infer. This inference refers to the process of obtaining the*** outputs***,*** such as ~~*content, predictions*~~***predictions, content***, recommendations, or decisions***,*** which ***can*** influence ~~*the environment with which the system interacts, be it in a physical or digital dimension. AI systems can be designed to operate with varying levels of autonomy and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded). The definition of*~~***physical and virtual environments and to a capability of AI systems to derive models and/or algorithms from inputs/data. The techniques that enable inference while building an AI system include machine learning approaches that learn from data how to achieve certain objectives; and logic- and knowledge-based approaches that infer from encoded knowledge or symbolic representation of the task to be solved. The capacity of an AI system to infer goes beyond basic data processing, enable learning, reasoning or modelling.***

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		~~complemented by a list of specific techniques and approaches used for its development, which should be kept up-to-date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list~~***understood as the contexts in which the AI systems operate, whereas outputs generated by the AI system, meaning predictions, recommendations or decisions, respond to the objectives of the system, on the basis of inputs from said environment. Such output further influences said environment, even by merely introducing new information to it***.		***The term "machine-based" refers to the fact that AI systems run on machines. The reference to explicit or implicit objectives underscores that AI systems can operate according to explicit defined objectives or to implicit objectives. The objectives of the*** AI system ~~should be complemented by a list of~~ ***may be different from the intended purpose of the AI system in a*** specific ~~techniques and approaches used for its development, which~~***context. For the purposes of this Regulation, environments*** should be ~~kept up-to-date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list~~***understood as the contexts in which the AI systems operate, whereas outputs generated by the AI system, reflect different functions performed by AI systems and include predictions, content, recommendations or decisions.*** ***AI systems are designed to operate with varying levels of autonomy, meaning that they have some degree of independence of actions from human involvement and of capabilities to operate without human intervention. The adaptiveness that an AI system could exhibit after deployment,***

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				refers to self-learning capabilities, allowing the system to change while in use. AI systems can be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded). Text Origin: GSC
Recital 6a				
G 16a			***(6a) Machine learning approaches focus on the development of systems capable of learning and inferring from data to solve an application problem without being explicitly programmed with a set of step-by-step instructions from input to output. Learning refers to the computational process of optimizing from data the parameters of the model, which is a mathematical construct generating an output based on input data. The range of problems addressed by machine learning typically involves tasks for which other approaches fail, either because there is no suitable formalisation of the problem, or because the resolution of the problem is intractable with***	G

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			non-learning approaches. Machine learning approaches include for instance supervised, unsupervised and reinforcement learning, using a variety of methods including deep learning with neural networks, statistical techniques for learning and inference (including for instance logistic regression, Bayesian estimation) and search and optimisation methods.	
Recital 6a				
G 16b		***(6a) AI systems often have machine learning capacities that allow them to adapt and perform new tasks autonomously. Machine learning refers to the computational process of optimizing the parameters of a model from data, which is a mathematical construct generating an output based on input data. Machine learning approaches include, for instance, supervised, unsupervised and reinforcement learning, using a variety of methods including deep learning with neural networks. This Regulation is aimed at addressing new potential risks that may arise by delegating control to AI systems, in particular to those AI systems that can evolve after deployment. The function and outputs of many of these AI systems are based on***		G

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		abstract mathematical relationships that are difficult for humans to understand, monitor and trace back to specific inputs. These complex and opaque characteristics (black box element) impact accountability and explainability. Comparably simpler techniques such as knowledge-based approaches, Bayesian estimation or decision-trees may also lead to legal gaps that need to be addressed by this Regulation, in particular when they are used in combination with machine learning approaches in hybrid systems.		
Recital 6b				
G 16c			***(6b) Logic- and knowledge based approaches focus on the development of systems with logical reasoning capabilities on knowledge to solve an application problem. Such systems typically involve a knowledge base and an inference engine that generates outputs by reasoning on the knowledge base. The knowledge base, which is usually encoded by human experts, represents entities and logical relationships relevant for the application problem through formalisms based on rules, ontologies, or knowledge graphs. The inference engine acts on the***	G

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			knowledge base and extracts new information through operations such as sorting, searching, matching or chaining. Logic- and knowledge based approaches include for instance knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning, expert systems and search and optimisation methods.	
Recital 6b				
G 16d		***(6b) AI systems can be used as stand-alone software system, integrated into a physical product (embedded), used to serve the functionality of a physical product without being integrated therein (non-embedded) or used as an AI component of a larger system. If this larger system would not function without the AI component in question, then the entire larger system should be considered as one single AI system under this Regulation.***		G
Recital 6c				
G 16e			***(6c) In order to ensure uniform conditions for the implementation of this Regulation as regards***	G

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			machine learning approaches and logic- and knowledged based approaches and to take account of market and technological developments, implementing powers should be conferred on the Commission.	
Recital 6a				
G 16f			***(6d) The notion of 'user' referred to in this Regulation should be interpreted as any natural or legal person, including a public authority, agency or other body, using an AI system under whose authority the system is used. Depending on the type of AI system, the use of the system may affect persons other than the user.***	***(6a) The notion of 'deployer' referred to in this Regulation should be interpreted as any natural or legal person, including a public authority, agency or other body, using an AI system under its authority, except where the AI system is used in the course of a personal non professional activity. Depending on the type of AI system, the use of the system may affect persons other than the deployer.*** G
Recital 7				
G 17	(7) The notion of biometric data used in this Regulation is in line with and should be interpreted consistently with the notion of biometric data as defined in Article 4(14) of Regulation (EU) 2016/679 of the European Parliament and of the Council[1], Article 3(18) of Regulation (EU) 2018/1725 of the European Parliament and of the	(7) The notion of biometric data used in this Regulation is in line with and should be interpreted consistently with the notion of biometric data as defined in Article 4(14) of Regulation (EU) 2016/679 of the European Parliament and of the Council[1]***. Biometrics-based data are additional data resulting from specific technical processing***	(7) The notion of biometric data used in this Regulation ~~is in line with and~~ should be interpreted consistently with the notion of biometric data as defined in Article 4(14) of Regulation (EU) 2016/679 of the European Parliament and of the Council[1], Article 3(18) of Regulation (EU) 2018/1725 of the European Parliament and of the	(7) The notion of biometric data used in this Regulation ~~is in line with and~~ should be interpreted ~~consistently with~~***in light of*** the notion of biometric data as defined in Article 4(14) of Regulation (EU) 2016/679 of the European Parliament and of the Council [1], Article 3(18) of Regulation (EU) 2018/1725 of the European G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Council[2] and Article 3(13) of Directive (EU) 2016/680 of the European Parliament and of the Council[3]. _____ 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). 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) 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 (Law Enforcement Directive) (OJ L 119, 4.5.2016, p. 89).	***relating to physical, physiological or behavioural signals of a natural person, such as facial expressions, movements, pulse frequency, voice, key strikes or gait, which may or may not allow or confirm the unique identification of a natural person***~~, *Article 3(18) of Regulation (EU) 2018/1725 of the European Parliament and of the Council*[2] *and Article 3(13) of Directive (EU) 2016/680 of the European Parliament and of the Council*[3]~~. _____ 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). ~~*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)*~~ ~~*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*~~	Council[2] and Article 3(13) of Directive (EU) 2016/680 of the European Parliament and of the Council[3]. _____ 1. ***[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). 2. ***[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) 3. ***[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 (Law Enforcement Directive) (OJ L 119, 4.5.2016, p. 89).	Parliament and of the Council ***[2]*** ~~[2]~~ and Article 3(13) of Directive (EU) 2016/680 of the European Parliament and of the Council ***[3].Biometric data can allow for the authentication, identification or categorisation of natural persons and for the recognition of emotions of natural persons.***~~[3].~~ _____ 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). 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) 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 (Law Enforcement Directive) (OJ L 119, 4.5.2016, p. 89).

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		~~2008/977/JHA (Law Enforcement Directive) (OJ L 119, 4.5.2016, p. 89).~~		
Recital 7a				
17a		***(7a) The notion of biometric identification as used in this Regulation should be defined as the automated recognition of physical, physiological, behavioural, and psychological human features such as the face, eye movement, facial expressions, body shape, voice, speech, gait, posture, heart rate, blood pressure, odour, keystrokes, psychological reactions (anger, distress, grief, etc.) for the purpose of establishing an individual's identity by comparing biometric data of that individual to stored biometric data of individuals in a database (one-to-many identification), irrespective of whether the individual has given its consent or not.***		***(7a) The notion of biometric identification as used in this Regulation should be defined as the automated recognition of physical, physiological and behavioural human features such as the face, eye movement, body shape, voice, prosody, gait, posture, heart rate, blood pressure, odour, keystrokes characteristics, for the purpose of establishing an individual's identity by comparing biometric data of that individual to stored biometric data of individuals in a reference database, irrespective of whether the individual has given its consent or not.*** ***This excludes AI systems intended to be used for biometric verification, which includes authentication, whose sole purpose is to confirm that a specific natural person is the person he or she claims to be and to confirm the identity of a natural person for the sole purpose of having access to a service, unlocking a device or having security access to premises.***
Recital 7b				

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G 17b		*(7b) The notion of biometric categorisation as used in this Regulation should be defined as assigning natural persons to specific categories or inferring their characteristics and attributes such as gender, sex, age, hair colour, eye colour, tattoos, ethnic or social origin, health, mental or physical ability, behavioural or personality, traits language, religion, or membership of a national minority or sexual or political orientation on the basis of their biometric or biometric-based data, or which can be inferred from such data.*		*(7b) The notion of biometric categorisation as used in this Regulation should be defined as assigning natural persons to specific categories on the basis of their biometric data. Such specific categories can relate to aspects such as sex, age, hair colour, eye colour, tattoos, behavioural or personality traits, language, religion, membership of a national minority, sexual or political orientation. This does not include biometric categorization systems that are a purely ancillary feature intrinsically linked to another commercial service meaning that the feature cannot, for objective technical reasons, be used without the principal service and the integration of that feature or functionality is not a means to circumvent the applicability of the rules of this Regulation. For example, filters categorizing facial or body features used on online marketplaces could constitute such an ancillary feature as they can only be used in relation to the principal service which consists in selling a product by allowing the consumer to preview the display of the product on him or herself and help the consumer to make a purchase decision. Filters used on online social network services* G

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				which categorise facial or body features to allow users to add or modify pictures or videos could also be considered as ancillary feature as such filter cannot be used without the principal service of the social network services consisting in the sharing of content online.
Recital 8				
G 18	(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database, and without prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used. Considering their different characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between 'real-time' and 'post' remote biometric identification systems. In the case of 'real-time' systems, the capturing of the biometric data, the comparison and the identification occur all	(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database, and without prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used***, exlcuding verification systems which merely compare the biometric data of an individual to their previously provided biometric data (one-to-one)***. Considering their different characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between 'real-time' and 'post' remote biometric	(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons ***typically*** at a distance***, without their active involvement,*** through the comparison of a person's biometric data with the biometric data contained in a reference ~~*database, and without prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used. Considering*~~***data repository, irrespectively of the particular technology, processes or types of biometric data used. Such remote biometric identification systems are typically used to perceive (scan) multiple persons or their behaviour simultaneously in order to facilitate***	(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons ***without their active involvement, typically*** at a distance***,*** through the comparison of a person's biometric data with the biometric data contained in a reference database, ~~*and*~~***irrespectively of the particular technology, processes or types of biometric data used. Such remote biometric identification systems are typically used to perceive multiple persons or their behaviour simultaneously in order to facilitate significantly the identification of natural persons*** without ~~*prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used. Considering their different*~~ G

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	instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the 'real-time' use of the AI systems in question by providing for minor delays. 'Real-time' systems involve the use of 'live' or 'near-'live' material, such as video footage, generated by a camera or other device with similar functionality. In the case of 'post' systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.	identification systems. In the case of 'real-time' systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the 'real-time' use of the AI systems in question by providing for minor delays. 'Real-time' systems involve the use of 'live' or 'near-'live' material, such as video footage, generated by a camera or other device with similar functionality. In the case of 'post' systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned. ***Given that the notion of biometric identification is independent from the individual's consent, this definition applies even when warning notices are placed in the location that is under surveillance of the remote biometric identification system, and is not de facto annulled by pre-enrolment.***	***significantly the identification of a number of persons without*** their ~~*different characteristics and manners in which they are used*~~***active involvement. Such a definition excludes verification/authentication systems whose sole purpose would be to confirm that a specific natural person is the person he or she claims to be***, as well as ***systems that are used to confirm the identity of a natural person for the sole purpose of having access to a service, a device or premises. This exclusion is justified by the fact that such systems are likely to have a minor impact on fundamental rights of natural persons compared to***~~*the different risks involved, a distinction should be made between 'real-time' and 'post'*~~ remote biometric identification systems ***which may be used for the processing of the biometric data of a large number of persons***. In the case of 'real-time' systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the 'real-time' use of the AI systems in question by providing for minor delays. 'Real-	~~*characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between 'real-time' and 'post' remote*~~***their active involvement. This excludes AI systems intended to be used for biometric verification, which includes authentication, whose sole purpose is to confirm that a specific natural person is the person he or she claims to be and to confirm the identity of a natural person for the sole purpose of having access to a service, unlocking a device or having security access to premises. This exclusion is justified by the fact that such systems are likely to have a minor impact on fundamental rights of natural persons compared to the remote biometric identification systems which may be used for the processing of the*** biometric ~~*identification systems*~~***data of a large number of persons without their active involvement***. In the case of 'real-time' systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the 'real-time' use of the AI systems in question by

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			time' systems involve the use of 'live' or 'near-'live' material, such as video footage, generated by a camera or other device with similar functionality. In the case of 'post' systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by -closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.	providing for minor delays. 'Real-time' systems involve the use of 'live' or 'near-'live' material, such as video footage, generated by a camera or other device with similar functionality. In the case of 'post' systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.
Recital 8a				
G 18a		***(8a) The identification of natural persons at a distance is understood to distinguish remote biometric identification systems from close proximity individual verification systems using biometric identification means, whose sole purpose is to confirm whether or not a specific natural person presenting themselves for identification is permitted, such as in order to gain access to a service, a device, or premises.***		G
Recital 8a				

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G 18b				***(8a) The notion of emotion recognition system for the purpose of in this regulation should be defined as an AI system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric data. This refers to emotions or intentions such as happiness, sadness, anger, surprise, disgust, embarrassment, excitement, shame, contempt, satisfaction and amusement. It does not include physical states, such as pain or fatigue. It refers for example to systems used in detecting the state of fatigue of professional pilots or drivers for the purpose of preventing accidents. It does also not include the mere detection of readily apparent expressions, gestures or movements, unless they are used for identifying or inferring emotions. These expressions can be basic facial expressions such as a frown or a smile, or gestures such as the movement of hands, arms or head, or characteristics of a person's voice, for example a raised voice or whispering.*** G
Recital 9				
G 19	(9) For the purposes of this	(9) For the purposes of this	(9) For the purposes of this	(9) For the purposes of this G

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	Regulation the notion of publicly accessible space should be understood as referring to any physical place that is accessible to the public, irrespective of whether the place in question is privately or publicly owned. Therefore, the notion does not cover places that are private in nature and normally not freely accessible for third parties, including law enforcement authorities, unless those parties have been specifically invited or authorised, such as homes, private clubs, offices, warehouses and factories. Online spaces are not covered either, as they are not physical spaces. However, the mere fact that certain conditions for accessing a particular space may apply, such as admission tickets or age restrictions, does not mean that the space is not publicly accessible within the meaning of this Regulation. Consequently, in addition to public spaces such as streets, relevant parts of government buildings and most transport infrastructure, spaces such as cinemas, theatres, shops and shopping centres are normally also publicly accessible. Whether a given space is accessible to the public should however be determined on a case-by-case basis, having regard to the specificities of the individual situation at hand.	Regulation the notion of publicly accessible space should be understood as referring to any physical place that is accessible to the public, irrespective of whether the place in question is privately or publicly owned ***and regardless of the potential capacity restrictions***. Therefore, the notion does not cover places that are private in nature and normally not freely accessible for third parties, including law enforcement authorities, unless those parties have been specifically invited or authorised, such as homes, private clubs, offices, warehouses and factories.~~–~~ Online spaces are not covered either, as they are not physical spaces. However, the mere fact that certain conditions for accessing a particular space may apply, such as admission tickets or age restrictions, does not mean that the space is not publicly accessible within the meaning of this Regulation. Consequently, in addition to public spaces such as streets, relevant parts of government buildings and most transport infrastructure, spaces such as cinemas, theatres, ***sports grounds, schools, universities, relevant parts of hospitals and banks, amusement parks, festivals,*** shops and shopping centres are normally also publicly accessible. Whether a given space is accessible to the public should	Regulation the notion of publicly accessible space should be understood as referring to any physical place that is accessible to ~~the public,~~ ***an undetermined number of natural persons, and*** irrespective of whether the place in question is privately or publicly owned. ~~Therefore, the notion does not cover places that are private in nature and normally not freely accessible for third parties, including law enforcement authorities, unless those parties have been specifically invited or authorised, such as homes, private clubs, offices, warehouses and factories~~***and irrepective of the activity for which the place may be used, such as commerce (for instance, shops, restaurants, cafés), services (for instance, banks, professional activities, hospitality), sport (for instance, swimming pools, gyms, stadiums), transport (for instance, bus, metro and railway stations, airports, means of transport), entertainment (for instance, cinemas, theatres, museums, concert and conference halls) leisure or otherwise (for instance, public roads and squares, parks, forests, playgrounds)***. ~~Online spaces are not covered either, as they are not physical spaces. However, the mere fact that~~ ***A place should be classified as***	Regulation the notion of publicly accessible space should be understood as referring to any physical place that is accessible to ~~the public,~~ ***an undetermined number of natural persons, and*** irrespective of whether the place in question is privately or publicly owned~~. Therefore, the notion does not cover places that are private in nature and normally not freely accessible for third parties, including law enforcement authorities, unless those parties have been specifically invited or authorised, such as homes, private clubs, offices, warehouses and factories~~ ***and irrespective of the activity for which the place may be used, such as commerce (for instance, shops, restaurants, cafés), services (for instance, banks, professional activities, hospitality), sport (for instance, swimming pools, gyms, stadiums), transport (for instance, bus, metro and railway stations, airports, means of transport), entertainment (for instance, cinemas, theatres, museums, concert and conference halls) leisure or otherwise (for instance, public roads and squares, parks, forests, playgrounds)***. ~~Online spaces are not covered either, as they are not physical spaces. However, the mere fact that~~ ***A place should be classified as***

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		however be determined on a case-by-case basis, having regard to the specificities of the individual situation at hand.	***publicly accessible also if, regardless of potential capacity or security restrictions, access is subject to*** certain ***predetermined*** conditions***, which can be fulfilled by an undetermined number of persons*** ~~*for accessing a particular space may apply*~~, such as ~~*admission tickets or age restrictions,*~~ ***purchase of a ticket or title of transport, prior registration or having a certain age. By contrast, a place should not be considered publicly accessible if access is limited to specific and defined natural persons through either Union or national law directly related to public safety or security or through the clear manifestation of will by the person having the relevant authority on the place. The factual possibility of access alone (e.g. an unlocked door, an open gate in a fence)*** does not ~~*mean*~~***imply*** that the ~~*space is not*~~***place is*** publicly accessible ~~*within the meaning of this Regulation. Consequently, in addition to public*~~***in the presence of indications or circumstances suggesting the contrary (e.g. signs prohibiting or restricting access). Company and factory premises as well as offices and workplaces that are intended to be accessed only by relevant employees and service providers are places that are not publicly accessible. Publicly accessible***	***publicly accessible also if, regardless of potential capacity or security restrictions, access is subject to*** certain ***predetermined*** conditions***, which can be fulfilled by an undetermined number of persons*** ~~*for accessing a particular space may apply*~~, such as ~~*admission tickets or age restrictions,*~~ ***purchase of a ticket or title of transport, prior registration or having a certain age. By contrast, a place should not be considered publicly accessible if access is limited to specific and defined natural persons through either Union or national law directly related to public safety or security or through the clear manifestation of will by the person having the relevant authority on the place. The factual possibility of access alone (e.g. an unlocked door, an open gate in a fence)*** does not ~~*mean*~~***imply*** that the ~~*space is not*~~ ***place is*** publicly accessible ~~*within the meaning of this Regulation. Consequently, in addition to public spaces such as streets,*~~***in the presence of indications or circumstances suggesting the contrary (e.g. signs prohibiting or restricting access). Company and factory premises as well as offices and workplaces that are intended to be accessed only by*** relevant ~~*parts of government buildings and most transport infrastructure, spaces*~~

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			spaces ~~such as streets, relevant parts of government buildings and most transport infrastructure, spaces~~ ***should not include prisons or border control areas. Some other areas may be composed of both not publicly accessible and publicly accessible areas,*** such as ~~cinemas, theatres, shops and shopping centres are normally also publicly accessible~~***the hallway of a private residential building necessary to access a doctor's office or an airport. Online spaces are not covered either, as they are not physical spaces***. Whether a given space is accessible to the public should however be determined on a case-by-case basis, having regard to the specificities of the individual situation at hand.	***employees and service providers are places that are not publicly accessible. Publicly accessible spaces should not include prisons or border control. Some other areas may be composed of both not publicly accessible and publicly accessible areas,*** such as ~~cinemas, theatres, shops and shopping centres are normally also publicly accessible~~***the hallway of a private residential building necessary to access a doctor's office or an airport. Online spaces are not covered either, as they are not physical spaces***. Whether a given space is accessible to the public should however be determined on a case-by-case basis, having regard to the specificities of the individual situation at hand.
Recital 9a				
G 19a		***(9a) It is important to note that AI systems should make best efforts to respect general principles establishing a high-level framework that promotes a coherent human-centric approach to ethical and trustworthy AI in line with the Charter of Fundamental Rights of the European Union and the values on which the Union is founded, including the protection of fundamental rights, human agency***		G

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		and oversight, technical robustness and safety, privacy and data governance, transparency, non-discrimination and fairness and societal and environmental wellbeing.		
Recital 9b				
G 19b		*(9b) 'AI literacy' refers to skills, knowledge and understanding that allows providers, users and affected persons, taking into account their respective rights and obligations in the context of this Regulation, to make an informed deployment of AI systems, as well as to gain awareness about the opportunities and risks of AI and possible harm it can cause and thereby promote its democratic control. AI literacy should not be limited to learning about tools and technologies, but should also aim to equip providers and users with the notions and skills required to ensure compliance with and enforcement of this Regulation. It is therefore necessary that the Commission, the Member States as well as providers and users of AI systems, in cooperation with all relevant stakeholders, promote the development of a sufficient level of AI literacy, in all sectors of society, for people of all ages, including*		*(9b) In order to obtain the greatest benefits from AI systems while protecting fundamental rights, health and safety and to enable democratic control, AI literacy should equip providers, deployers and affected persons with the necessary notions to make informed decisions regarding AI systems. These notions may vary with regard to the relevant context and can include understanding the correct application of technical elements during the AI system's development phase, the measures to be applied during its use, the suitable ways in which to interpret the AI system's output, and, in the case of affected persons, the knowledge necessary to understand how decisions taken with the assistance of AI will impact them. In the context of the application this Regulation, AI literacy should provide all relevant actors in the AI value chain with the insights required to ensure the appropriate compliance and its* G

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		women and girls, and that progress in that regard is closely followed.		***correct enforcement. Furthermore, the wide implementation of AI literacy measures and the introduction of appropriate follow-up actions could contribute to improving working conditions and ultimately sustain the consolidation, and innovation path of trustworthy AI in the Union. The European Artificial Intelligence Board should support the Commission , to promote AI literacy tools, public awareness and understanding of the benefits, risks, safeguards, rights and obligations in relation to the use of AI systems. In cooperation with the relevant stakeholders, the Commission and the Member States should facilitate the drawing up of voluntary codes of conduct to advance AI literacy among persons dealing with the development, operation and use of AI .***
Recital 10				
G 20	(10) In order to ensure a level playing field and an effective protection of rights and freedoms of individuals across the Union, the rules established by this Regulation should apply to providers of AI systems in a non-discriminatory manner, irrespective of whether they are established within the Union or	(10) In order to ensure a level playing field and an effective protection of rights and freedoms of individuals across the Union ***and on international level***, the rules established by this Regulation should apply to providers of AI systems in a non-discriminatory manner, irrespective of whether they	(10) In order to ensure a level playing field and an effective protection of rights and freedoms of individuals across the Union, the rules established by this Regulation should apply to providers of AI systems in a non-discriminatory manner, irrespective of whether they are established within the Union or	(10) In order to ensure a level playing field and an effective protection of rights and freedoms of individuals across the Union, the rules established by this Regulation should apply to providers of AI systems in a non-discriminatory manner, irrespective of whether they are established within the Union or G

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	in a third country, and to users of AI systems established within the Union.	are established within the Union or in a third country, and to ~~users~~***deployers*** of AI systems established within the Union. ***In order for the Union to be true to its fundamental values, AI systems intended to be used for practices that are considered unacceptable by this Regulation, should equally be deemed to be unacceptable outside the Union because of their particularly harmful effect to fundamental rights as enshrined in the Charter. Therefore it is appropriate to prohibit the export of such AI systems to third countries by providers residing in the Union.***	in a third country, and to users of AI systems established within the Union.	in a third country, and to ~~users~~***deployers*** of AI systems established within the Union.
Recital 11				
G 21	(11) In light of their digital nature, certain AI systems should fall within the scope of this Regulation even when they are neither placed on the market, nor put into service, nor used in the Union. This is the case for example of an operator established in the Union that contracts certain services to an operator established outside the Union in relation to an activity to be performed by an AI system that would qualify as high-risk and whose effects impact natural persons located in the Union. In those circumstances, the AI system used	(11) In light of their digital nature, certain AI systems should fall within the scope of this Regulation even when they are neither placed on the market, nor put into service, nor used in the Union. This is the case for example of an operator established in the Union that contracts certain services to an operator established outside the Union in relation to an activity to be performed by an AI system that would qualify as high-risk and whose effects impact natural persons located in the Union. In those circumstances, the AI system used	(11) In light of their digital nature, certain AI systems should fall within the scope of this Regulation even when they are neither placed on the market, nor put into service, nor used in the Union. This is the case for example of an operator established in the Union that contracts certain services to an operator established outside the Union in relation to an activity to be performed by an AI system that would qualify as high-risk ~~*and whose effects impact natural persons located in the Union*~~. In those circumstances, the AI system used	(11) In light of their digital nature, certain AI systems should fall within the scope of this Regulation even when they are neither placed on the market, nor put into service, nor used in the Union. This is the case for example of an operator established in the Union that contracts certain services to an operator established outside the Union in relation to an activity to be performed by an AI system that would qualify as high-risk ~~*and whose effects impact natural persons located in the Union*~~. In those circumstances, the AI system used

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	by the operator outside the Union could process data lawfully collected in and transferred from the Union, and provide to the contracting operator in the Union the output of that AI system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and users of AI systems that are established in a third country, to the extent the output produced by those systems is used in the Union. Nonetheless, to take into account existing arrangements and special needs for cooperation with foreign partners with whom information and evidence is exchanged, this Regulation should not apply to public authorities of a third country and international organisations when acting in the framework of international agreements concluded at national or European level for law enforcement and judicial cooperation with the Union or with its Member States. Such agreements have been concluded bilaterally between Member States and third countries or between the European Union, Europol and other EU agencies and	by the operator outside the Union could process data lawfully collected in and transferred from the Union, and provide to the contracting operator in the Union the output of that AI system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and users ***deployers*** of AI systems that are established in a third country, to the extent the output produced by those systems is ***intended to be*** used in the Union. Nonetheless, to take into account existing arrangements and special needs for cooperation with foreign partners with whom information and evidence is exchanged, this Regulation should not apply to public authorities of a third country and international organisations when acting in the framework of international agreements concluded at national or European level for law enforcement and judicial cooperation with the Union or with its Member States. Such agreements have been concluded bilaterally between Member States and third countries or between the European Union, Europol and other EU	by the operator outside the Union could process data lawfully collected in and transferred from the Union, and provide to the contracting operator in the Union the output of that AI system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and users of AI systems that are established in a third country, to the extent the output produced by those systems is used in the Union. Nonetheless, to take into account existing arrangements and special needs for ***future*** cooperation with foreign partners with whom information and evidence is exchanged, this Regulation should not apply to public authorities of a third country and international organisations when acting in the framework of international agreements concluded at national or European level for law enforcement and judicial cooperation with the Union or with its Member States. Such agreements have been concluded bilaterally between Member States and third countries or between the European Union, Europol and other EU agencies and	by the operator outside the Union could process data lawfully collected in and transferred from the Union, and provide to the contracting operator in the Union the output of that AI system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and ~~users~~***deployers*** of AI systems that are established in a third country, to the extent the output produced by those systems is ***intended to be*** used in the Union. Nonetheless, to take into account existing arrangements and special needs for ***future*** cooperation with foreign partners with whom information and evidence is exchanged, this Regulation should not apply to public authorities of a third country and international organisations when acting in the framework of ***cooperation or*** international agreements concluded at national or European level for law enforcement and judicial cooperation with the Union or with its Member States***, under the condition that this third country or international organisations provide adequate safeguards with respect to***

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	third countries and international organisations.	agencies and third countries and international organisations. ***This exception should nevertheless be limited to trusted countries and international organisation that share Union values.***	third countries and international organisations. ***Recipient Member States authorities and Union institutions, offices, bodies and bodies making use of such outputs in the Union remain accountable to ensure their use comply with Union law. When those international agreements are revised or new ones are concluded in the future, the contracting parties should undertake the utmost effort to align those agreements with the requirements of this Regulation.***	***the protection of fundamental rights and freedoms of individuals. Where relevant, this may also cover activities of entities entrusted by the third countries to carry out specific tasks in support of such law enforcement and judicial cooperation. Such framework for cooperation or*** ~~*. Such*~~ agreements have been ~~*concluded*~~ ***established*** bilaterally between Member States and third countries or between the European Union, Europol and other EU agencies and third countries and international organisations. ***The authorities competent for supervision of the law enforcement and judicial authorities under the AI Act should assess whether these frameworks for cooperation or international agreements include adequate safeguards with respect to the protection of fundamental rights and freedoms of individuals. Recipient Member States authorities and Union institutions, offices and bodies making use of such outputs in the Union remain accountable to ensure their use complies with Union law. When those international agreements are revised or new ones are concluded in the future, the contracting parties should undertake the utmost effort to align those agreements with the requirements of this Regulation.***

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Recital 12				
22	(12) This Regulation should also apply to Union institutions, offices, bodies and agencies when acting as a provider or user of an AI system. AI systems exclusively developed or used for military purposes should be excluded from the scope of this Regulation where that use falls under the exclusive remit of the Common Foreign and Security Policy regulated under Title V of the Treaty on the European Union (TEU). This Regulation should be without prejudice to the provisions regarding the liability of intermediary service providers set out in Directive 2000/31/EC of the European Parliament and of the Council [as amended by the Digital Services Act].	(12) This Regulation should also apply to Union institutions, offices, bodies and agencies when acting as a provider or ~~user~~***deployer*** of an AI system. AI systems exclusively developed or used for military purposes should be excluded from the scope of this Regulation where that use falls under the exclusive remit of the Common Foreign and Security Policy regulated under Title V of the Treaty on the European Union (TEU). This Regulation should be without prejudice to the provisions regarding the liability of intermediary service providers set out in Directive 2000/31/EC of the European Parliament and of the Council [as amended by the Digital Services Act].	(12) This Regulation should also apply to Union institutions, offices, bodies and agencies when acting as a provider or user of an AI system. ~~*AI systems exclusively developed or used for military purposes should be excluded from the scope of this Regulation where that use falls under the exclusive remit of the Common Foreign and Security Policy regulated under Title V of the Treaty on the European Union (TEU). This Regulation should be without prejudice to the provisions regarding the liability of intermediary service providers set out in Directive 2000/31/EC of the European Parliament and of the Council [as amended by the Digital Services Act].*~~	(12) This Regulation should also apply to Union institutions, offices, bodies and agencies when acting as a provider or ~~user~~***deployer*** of an AI system. ~~*AI systems exclusively developed or used for military purposes should be excluded from the scope of this Regulation where that use falls under the exclusive remit of the Common Foreign and Security Policy regulated under Title V of the Treaty on the European Union (TEU). This Regulation should be without prejudice to the provisions regarding the liability of intermediary service providers set out in Directive 2000/31/EC of the European Parliament and of the Council [as amended by the Digital Services Act].*~~
Recital 12a				
22a			***(12a) If and insofar AI systems are placed on the market, put into service, or used with or without modification of such systems for military, defence or national security purposes, those should be excluded from the scope of this Regulation regardless of which type of entity is carrying out those***	***(12a) If and insofar AI systems are placed on the market, put into service, or used with or without modification of such systems for military, defence or national security purposes, those should be excluded from the scope of this Regulation regardless of which type of entity is carrying out those***

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			activities, such as whether it is a public or private entity. As regards military and defence purposes, such exclusion is justified both by Article 4(2) TEU and by the specifities of the Member States' and the common Union defence policy covered by Chapter 2 of Title V of the Treaty on European Union (TEU) that are subject to public international law, which is therefore the more appropriate legal framework for the regulation of AI systems in the context of the use of lethal force and other AI systems in the context of military and defence activities. As regards national security purposes, the exclusion is justified both by the fact that national security remains the sole responsibility of Member States in accordance with Article 4(2) TEU and by the specific nature and operational needs of national security activities and specific national rules applicable to those activities. Nonetheless, if an AI system developed, placed on the market, put into service or used for military, defence or national security purposes is used outside those temporarily or permanently for other purposes (for example, civilian or humanitarian purposes, law enforcement or public security purposes), such a system would fall within the scope of this Regulation.	***activities, such as whether it is a public or private entity. As regards military and defence purposes, such exclusion is justified both by Article 4(2) TEU and by the specifities of the Member States' and the common Union defence policy covered by Chapter 2 of Title V of the Treaty on European Union (TEU) that are subject to public international law, which is therefore the more appropriate legal framework for the regulation of AI systems in the context of the use of lethal force and other AI systems in the context of military and defence activities. As regards national security purposes, the exclusion is justified both by the fact that national security remains the sole responsibility of Member States in accordance with Article 4(2) TEU and by the specific nature and operational needs of national security activities and specific national rules applicable to those activities. Nonetheless, if an AI system developed, placed on the market, put into service or used for military, defence or national security purposes is used outside those temporarily or permanently for other purposes (for example, civilian or humanitarian purposes, law enforcement or public security purposes), such a system would fall within the scope of this Regulation.***

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			In that case, the entity using the system for other than military, defence or national security purposes should ensure compliance of the system with this Regulation, unless the system is already compliant with this Regulation. AI systems placed on the market or put into service for an excluded (i.e. military, defence or national security) and one or more non excluded purposes (e.g. civilian purposes, law enforcement, etc.), fall within the scope of this Regulation and providers of those systems should ensure compliance with this Regulation. In those cases, the fact that an AI system may fall within the scope of this Regulation should not affect the possibility of entities carrying out national security, defence and military activities, regardless of the type of entity carrying out those activities, to use AI systems for national security, military and defence purposes, the use of which is excluded from the scope of this Regulation. An AI system placed on the market for civilian or law enforcement purposes which is used with or without modification for military, defence or national security purposes should not fall within the scope of this Regulation, regardless of the type of entity carrying out those activities.	*In that case, the entity using the system for other than military, defence or national security purposes should ensure compliance of the system with this Regulation, unless the system is already compliant with this Regulation. AI systems placed on the market or put into service for an excluded (i.e. military, defence or national security) and one or more non excluded purposes (e.g. civilian purposes, law enforcement, etc.), fall within the scope of this Regulation and providers of those systems should ensure compliance with this Regulation. In those cases, the fact that an AI system may fall within the scope of this Regulation should not affect the possibility of entities carrying out national security, defence and military activities, regardless of the type of entity carrying out those activities, to use AI systems for national security, military and defence purposes, the use of which is excluded from the scope of this Regulation. An AI system placed on the market for civilian or law enforcement purposes which is used with or without modification for military, defence or national security purposes should not fall within the scope of this Regulation, regardless of the type of entity carrying out those activities.*

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Recital 12b				
G 22b			***(12b) This Regulation should be without prejudice to the provisions regarding the liability of intermediary service providers set out in Directive 2000/31/EC of the European Parliament and of the Council [as amended by the Digital Services Act].***	G
Recital 12c				
G 22c			***(12c) This Regulation should not undermine research and development activity and should respect freedom of science. It is therefore necessary to exclude from its scope AI systems specifically developed and put into service for the sole purpose of scientific research and development and to ensure that the Regulation does not otherwise affect scientific research and development activity on AI systems. As regards product oriented research activity by providers, the provisions of this Regulation should also not apply. This is without prejudice to the obligation to comply with this Regulation when an AI system falling into the scope of this Regulation is placed on the market***	***(12c) This Regulation should support innovation, respect freedom of science, and should not undermine research and development activity. It is therefore necessary to exclude from its scope AI systems and models specifically developed and put into service for the sole purpose of scientific research and development. Moreover, it is necessary to ensure that the Regulation does not otherwise affect scientific research and development activity on AI systems or models prior to being placed on the market or put into service. As regards product oriented research, testing and development activity regarding AI systems or models, the provisions of this Regulation should also not apply***	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			or put into service as a result of such research and development activity and to the application of provisions on regulatory sandboxes and testing in real world conditions. Furthermore, without prejudice to the foregoing regarding AI systems specifically developed and put into service for the sole purpose of scientific research and development, any other AI system that may be used for the conduct of any reaserch and development activity should remain subject to the provisions of this Regulation. Under all circumstances, any research and development activity should be carried out in accordance with recognised ethical and professional standards for scientific research.	*prior to these systems and models being put into service or placed on the market. This is without prejudice to the obligation to comply with this Regulation when an AI system falling into the scope of this Regulation is placed on the market or put into service as a result of such research and development activity and to the application of provisions on regulatory sandboxes and testing in real world conditions. Furthermore, without prejudice to the foregoing regarding AI systems specifically developed and put into service for the sole purpose of scientific research and development, any other AI system that may be used for the conduct of any research and development activity should remain subject to the provisions of this Regulation. Under all circumstances, any research and development activity should be carried out in accordance with recognised ethical and professional standards for scientific research and should be conducted according to applicable Union law.*
Recital 12d				
G 22d		*(12a) The developers of free and open-source AI components should not be mandated under this*		G

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		Regulation to comply with requirements targeting the AI value chain and, in particular, not towards the provider that has used that free and open-source AI component. Developers of free and open-source AI components should however be encouraged to implement widely adopted documentation practices, such as model and data cards, as a way to accelerate information sharing along the AI value chain, allowing the promotion of trustworthy AI systems in the Union.		
Recital 12e				
G 22e			***(12d) In the light of the nature and complexity of the value chain for AI systems, it is essential to clarify the role of actors who may contribute to the development of AI systems, notably high-risk AI systems. In particular, it is necessary to clarify that general purpose AI systems are AI systems that are intended by the provider to perform generally applicable functions, such as image/speech recognition, and in a plurality of contexts. They may be used as high-risk AI systems by themselves or be components of other high risk AI systems. Therefore, due to their particular nature and in order to ensure a fair***	G

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			sharing of responsibilities along the AI value chain, such systems should be subject to proportionate and more specific requirements and obligations under this Regulation while ensuring a high level of protection of fundamental rights, health and safety. In addition, the providers of general purpose AI systems, irrespective of whether they may be used as high-risk AI systems as such by other providers or as components of high-risk AI systems, should cooperate, as appropriate, with the providers of the respective high-risk AI systems to enable their compliance with the relevant obligations under this Regulation and with the competent authorities established under this Regulation. In order to take into account the specific characteristics of general purpose AI systems and the fast evolving market and technological developments in the field, implementing powers should be conferred on the Commission to specify and adapt the application of the requirements established under this Regulation to general purpose AI systems and to specify the information to be shared by the providers of general purpose AI systems in order to enable the providers of the respective high-risk AI system to comply with their obligations under this Regulation.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 12f				
22f				
Recital 12g				
22g				
Recital 12h				
22h				
Recital 13				
23	(13) In order to ensure a consistent and high level of protection of public interests as regards health, safety and fundamental rights, common normative standards for all high-risk AI systems should be established. Those standards should be consistent with the Charter of fundamental rights of the European Union (the Charter) and should be non-discriminatory and in line with the Union's international trade commitments.	(13) In order to ensure a consistent and high level of protection of public interests as regards health, safety and fundamental rights ***as well as democracy and rule of law and the environment***, common normative standards for all high-risk AI systems should be established. Those standards should be consistent with the Charter***, the European Green Deal, the Joint Declaration on Digital*** ~~*of fundamental*~~ Rights of the ~~*European*~~ Union ~~*(the Charter*~~***and the Ethics Guidelines for Trustworthy Artificial Intelligence (AI***) ***of the High-Level Expert Group on Artificial Intelligence,*** and should be non-discriminatory and in line with the Union's international trade commitments.	(13) In order to ensure a consistent and high level of protection of public interests as regards health, safety and fundamental rights, common normative standards for all high-risk AI systems should be established. Those standards should be consistent with the Charter of fundamental rights of the European Union (the Charter) and should be non-discriminatory and in line with the Union's international trade commitments.	

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Recital 14				
24	(14) In order to introduce a proportionate and effective set of binding rules for AI systems, a clearly defined risk-based approach should be followed. That approach should tailor the type and content of such rules to the intensity and scope of the risks that AI systems can generate. It is therefore necessary to prohibit certain artificial intelligence practices, to lay down requirements for high-risk AI systems and obligations for the relevant operators, and to lay down transparency obligations for certain AI systems.	(14) In order to introduce a proportionate and effective set of binding rules for AI systems, a clearly defined risk-based approach should be followed. That approach should tailor the type and content of such rules to the intensity and scope of the risks that AI systems can generate. It is therefore necessary to prohibit certain ***unacceptable*** artificial intelligence practices, to lay down requirements for high-risk AI systems and obligations for the relevant operators, and to lay down transparency obligations for certain AI systems.	(14) In order to introduce a proportionate and effective set of binding rules for AI systems, a clearly defined risk-based approach should be followed. That approach should tailor the type and content of such rules to the intensity and scope of the risks that AI systems can generate. It is therefore necessary to prohibit certain artificial intelligence practices, to lay down requirements for high-risk AI systems and obligations for the relevant operators, and to lay down transparency obligations for certain AI systems.	(14) In order to introduce a proportionate and effective set of binding rules for AI systems, a clearly defined risk-based approach should be followed. That approach should tailor the type and content of such rules to the intensity and scope of the risks that AI systems can generate. It is therefore necessary to prohibit certain ***unacceptable*** artificial intelligence practices, to lay down requirements for high-risk AI systems and obligations for the relevant operators, and to lay down transparency obligations for certain AI systems.
Recital 14a				
24a				***(14a) While the risk-based approach is the basis for a proportionate and effective set of binding rules, it is important to recall the 2019 Ethics Guidelines for Trustworthy AI developed by the independent High-Level Expert Group on AI (HLEG) appointed by the Commission. In those Guidelines the HLEG developed seven non-binding ethical principles for AI which should help ensure that AI is trustworthy and***

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				ethically sound. The seven principles include: human agency and oversight; technical robustness and safety; privacy and data governance; transparency; diversity, non-discrimination and fairness; societal and environmental well-being and accountability. Without prejudice to the legally binding requirements of this Regulation and any other applicable Union law, these Guidelines contribute to the design of a coherent, trustworthy and human-centric Artificial Intelligence, in line with the Charter and with the values on which the Union is founded. According to the Guidelines of HLEG, human agency and oversight means that AI systems are developed and used as a tool that serves people, respects human dignity and personal autonomy, and that is functioning in a way that can be appropriately controlled and overseen by humans. Technical robustness and safety means that AI systems are developed and used in a way that allows robustness in case of problems and resilience against attempts to alter the use or performance of the AI system so as to allow unlawful use by third parties, and minimise unintended harm . Privacy and data governance means that AI systems

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				are developed and used in compliance with existing privacy and data protection rules, while processing data that meets high standards in terms of quality and integrity. Transparency means that AI systems are developed and used in a way that allows appropriate traceability and explainability, while making humans aware that they communicate or interact with an AI system, as well as duly informing deployers of the capabilities and limitations of that AI system and affected persons about their rights. Diversity, non-discrimination and fairness means that AI systems are developed and used in a way that includes diverse actors and promotes equal access, gender equality and cultural diversity, while avoiding discriminatory impacts and unfair biases that are prohibited by Union or national law. Social and environmental well-being means that AI systems are developed and used in a sustainable and environmentally friendly manner as well as in a way to benefit all human beings, while monitoring and assessing the long-term impacts on the individual, society and democracy. The application of these principles should be translated, when possible, in the design and use of AI models. They should in

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				any case serve as a basis for the drafting of codes of conduct under this Regulation. All stakeholders, including industry, academia, civil society and standardisation organisations, are encouraged to take into account as appropriate the ethical principles for the development of voluntary best practices and standards.
Recital 15				
G 25	(15) Aside from the many beneficial uses of artificial intelligence, that technology can also be misused and provide novel and powerful tools for manipulative, exploitative and social control practices. Such practices are particularly harmful and should be prohibited because they contradict Union values of respect for human dignity, freedom, equality, democracy and the rule of law and Union fundamental rights, including the right to non-discrimination, data protection and privacy and the rights of the child.	(15) Aside from the many beneficial uses of artificial intelligence, that technology can also be misused and provide novel and powerful tools for manipulative, exploitative and social control practices. Such practices are particularly harmful and ***abusive and*** should be prohibited because they contradict Union values of respect for human dignity, freedom, equality, democracy and the rule of law and Union fundamental rights, including the right to non-discrimination, data protection and privacy and the rights of the child.	(15) Aside from the many beneficial uses of artificial intelligence, that technology can also be misused and provide novel and powerful tools for manipulative, exploitative and social control practices. Such practices are particularly harmful and should be prohibited because they contradict Union values of respect for human dignity, freedom, equality, democracy and the rule of law and Union fundamental rights, including the right to non-discrimination, data protection and privacy and the rights of the child.	(15) Aside from the many beneficial uses of artificial intelligence, that technology can also be misused and provide novel and powerful tools for manipulative, exploitative and social control practices. Such practices are particularly harmful and ***abusive and*** should be prohibited because they contradict Union values of respect for human dignity, freedom, equality, democracy and the rule of law and Union fundamental rights, including the right to non-discrimination, data protection and privacy and the rights of the child. G
Recital 16				
G 26	(16) The placing on the market, putting into service or use of certain AI systems intended to distort human behaviour, whereby physical	(16) The placing on the market, putting into service or use of certain AI systems ~~intended to distort~~***with the objective to or the effect of***	(16) ***AI-enabled manipulative techniques can be used to persuade persons to engage in unwanted behaviours, or to deceive them by***	(16) ***AI-enabled manipulative techniques can be used to persuade persons to engage in unwanted behaviours, or to deceive them by*** G

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	or psychological harms are likely to occur, should be forbidden. Such AI systems deploy subliminal components individuals cannot perceive or exploit vulnerabilities of children and people due to their age, physical or mental incapacities. They do so with the intention to materially distort the behaviour of a person and in a manner that causes or is likely to cause harm to that or another person. The intention may not be presumed if the distortion of human behaviour results from factors external to the AI system which are outside of the control of the provider or the user. Research for legitimate purposes in relation to such AI systems should not be stifled by the prohibition, if such research does not amount to use of the AI system in human-machine relations that exposes natural persons to harm and such research is carried out in accordance with recognised ethical standards for scientific research.	***materially distorting*** human behaviour, whereby physical or psychological harms are likely to occur, should be forbidden. ***This limitation should be understood to include neuro-technologies assisted by AI systems that are used to monitor, use, or influence neural data gathered through brain-computer interfaces insofar as they are materially distorting the behaviour of a natural person in a manner that causes or is likely to cause that person or another person significant harm.*** Such AI systems deploy subliminal components individuals cannot perceive or exploit vulnerabilities of ~~children and people~~***individuals and specific groups of persons*** due to their ***known or predicted personality traits,*** age, physical or mental incapacities***, social or economic situation***. They do so with the intention to ***or the effect of*** materially ~~distort~~***distorting*** the behaviour of a person and in a manner that causes or is likely to cause ***significant*** harm to that or another person ***or groups of persons, including harms that may be accumulated over time***. The intention ***to distort the behaviour*** may not be presumed if the distortion ~~of human behaviour~~ results from factors external to the AI system which are outside of the	***nudging them into decisions in a way that subverts and impairs their autonomy, decision-making and free choices.*** The placing on the market, putting into service or use of certain AI systems ~~intended to distort~~***materially distorting*** human behaviour, whereby physical or psychological harms are likely to occur, ***are particularly dangerous and*** should ***therefore*** be forbidden. Such AI systems deploy subliminal components ~~individuals~~***such as audio, image, video stimuli that persons*** cannot perceive ***as those stimuli are beyond human perception or other subliminal techniques that subvert or impair person's autonomy, decision-making or free choices in ways that people are not consciously aware of, or even if aware not able to control or resist, for example in cases of machine-brain interfaces or virtual reality. In addition, AI systems may also otherwise*** ~~or~~ exploit vulnerabilities of ~~children and people~~***a specific group of persons*** due to their age, ~~physical or mental incapacities. They do so~~***disability within the meaning of Directive (EU) 2019/882, or a specific social or economic situation that is likely to make those persons more vulnerable to exploitation such as persons living in extreme poverty, ethnic or***	***nudging them into decisions in a way that subverts and impairs their autonomy, decision-making and free choices.*** The placing on the market, putting into service or use of certain AI systems ~~intended to distort~~***with the objective to or the effect of materially distorting*** human behaviour, whereby ***significant harms, in particular having sufficiently important adverse impacts on*** physical***, psychological health or financial interests*** ~~or psychological harms~~ are likely to occur, ***are particularly dangerous and*** should ***therefore*** be forbidden. Such AI systems deploy subliminal components ~~individuals~~***such as audio, image, video stimuli that persons*** cannot perceive ***as those stimuli are beyond human perception or other manipulative or deceptive techniques that subvert or impair person's autonomy, decision-making or free choices in ways that people are not consciously aware of, or even if aware they are still deceived or not able to control or resist. This could be for example, facilitated by machine-brain interfaces or virtual reality as they allow for a higher degree of control of what stimuli are presented to persons, insofar as they may be materially distorting their behaviour in a significantly***

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		control of the provider or the user, ***such as factors that may not be reasonably foreseen and mitigated by the provider or the deployer of the AI system. In any case, it is not necessary for the provider or the deployer to have the intention to cause the significant harm, as long as such harm results from the manipulative or exploitative AI-enabled practices. The prohibitions for such AI practices is complementary to the provisions contained in Directive 2005/29/EC, according to which unfair commercial practices are prohibited, irrespective of whether they carried out having recourse to AI systems or otherwise. In such setting, lawful commercial practices, for example in the field of advertising, that are in compliance with Union law should not in themselves be regarded as violating prohibition***. Research for legitimate purposes in relation to such AI systems should not be stifled by the prohibition, if such research does not amount to use of the AI system in human-machine relations that exposes natural persons to harm and such research is carried out in accordance with recognised ethical standards for scientific research ***and on the basis of specific informed consent of the individuals that are exposed to them or, where***	***religious minorities. Such AI systems can be placed on the market, put into service or used*** with the ~~intention to~~ ***objective to or the effect of*** materially ~~distort~~***distorting*** the behaviour of a person and in a manner that causes or is ***reasonably*** likely to cause ***physical or phycological*** harm to that or another person ***or groups of persons, including harms that may be accumulated over time***. The intention ***to distort the behaviour*** may not be presumed if the distortion ~~of human behaviour~~ results from factors external to the AI system which are outside of the control of the provider or the user, ***meaning factors that may not be reasonably foreseen and mitigated by the provider or the user of the AI system. In any case, it is not necessary for the provider or the user to have the intention to cause the physical or psychological harm, as long as such harm results from the manipulative or exploitative AI-enabled practices. The prohibitions for such AI practices are complementary to the provisions contained in Directive 2005/29/EC, notably that unfair commercial practices leading to economic or financial harms to consumers are prohibited under all circumstances, irrespective of whether they are put in place through AI systems or***	***harmful manner.*** ***In addition, AI systems may also otherwise*** ~~or~~ exploit vulnerabilities of ~~children and people~~***a person or a specific group of persons*** due to their age, ~~physical or mental incapacities. They do so~~***disability within the meaning of Directive (EU) 2019/882, or a specific social or economic situation that is likely to make those persons more vulnerable to exploitation such as persons living in extreme poverty, ethnic or religious minorities. Such AI systems can be placed on the market, put into service or used*** with the ~~intention to~~ ***objective to or the effect of*** materially ~~distort~~***distorting*** the behaviour of a person and in a manner that causes or is ***reasonably*** likely to cause ***significant*** harm to that or another person ***or groups of persons, including harms that may be accumulated over time and should therefore be prohibited***. The intention ***to distort the behaviour*** may not be presumed if the distortion ~~of human behaviour~~ results from factors external to the AI system which are outside of the control of the provider or the ~~user. Research for legitimate purposes in relation to such AI systems should not be stifled by the prohibition, if such research does not amount to use of the AI system in human-~~

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		applicable, of their legal guardian.	***otherwise. The prohibitions of manipulative and exploitative practices in this Regulation should not affect lawful practices in the context of medical treatment such as psychological treatment of a mental disease or physical rehabilitation, when those practices are***~~. Research for legitimate purposes in relation to such AI systems should not be stifled by the prohibition, if such research does not amount to use of the AI system in human-machine relations that exposes natural persons to harm and such research is~~ carried out in accordance with ~~recognised ethical~~***the applicable medical*** standards ~~for scientific research~~***and legislation. In addition, common and legitimate commercial practices that are in compliance with the applicable law should not in themselves be regarded as constituting harmful manipulative AI practices***.	~~machine-relations that exposes natural persons to harm and such research is~~***deployer, meaning factors that may not be reasonably foreseen and mitigated by the provider or the deployer of the AI system. In any case, it is not necessary for the provider or the deployer to have the intention to cause significant harm, as long as such harm results from the manipulative or exploitative AI-enabled practices. The prohibitions for such AI practices are complementary to the provisions contained in Directive 2005/29/EC, notably unfair commercial practices leading to economic or financial harms to consumers are prohibited under all circumstances, irrespective of whether they are put in place through AI systems or otherwise.*** ***The prohibitions of manipulative and exploitative practices in this Regulation should not affect lawful practices in the context of medical treatment such as psychological treatment of a mental disease or physical rehabilitation, when those practices are*** carried out in accordance with ~~recognised ethical~~***the applicable legislation and medical*** standards***, for example explicit consent of the individuals or their legal representatives . In addition, common and legitimate***

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				commercial practices, for example in the field of advertising, that are in compliance with the applicable law should not in themselves be regarded as constituting harmful manipulative AI practices ~~*for scientific research*~~.
Recital 16a				
G 26a		***(16a) AI systems that categorise natural persons by assigning them to specific categories, according to known or inferred sensitive or protected characteristics are particularly intrusive, violate human dignity and hold great risk of discrimination. Such characteristics include gender, gender identity, race, ethnic origin, migration or citizenship status, political orientation, sexual orientation, religion, disability or any other grounds on which discrimination is prohibited under Article 21 of the Charter of Fundamental Rights of the European Union, as well as under Article 9 of Regulation (EU)2016/769. Such systems should therefore be prohibited.***		***(16a) Biometric categorisation systems that are based on individuals' biometric data, such as an individual person's face or fingerprint, to deduce or infer an individuals' political opinions, trade union membership, religious or philosophical beliefs, race, sex life or sexual orientation should be prohibited. This prohibition does not cover the lawful labelling, filtering or categorisation of biometric datasets acquired in line with Union or national law according to biometric data, such as the sorting of images according to hair colour or eye colour, which can for example be used in the area of law enforcement.*** G
Recital 17				
G 27	(17) AI systems providing social	(17) AI systems providing social	(17) AI systems providing social	(17) AI systems providing social G

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	scoring of natural persons for general purpose by public authorities or on their behalf may lead to discriminatory outcomes and the exclusion of certain groups. They may violate the right to dignity and non-discrimination and the values of equality and justice. Such AI systems evaluate or classify the trustworthiness of natural persons based on their social behaviour in multiple contexts or known or predicted personal or personality characteristics. The social score obtained from such AI systems may lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof in social contexts, which are unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. Such AI systems should be therefore prohibited.	scoring of natural persons for general purpose ~~by public authorities or on their behalf~~ may lead to discriminatory outcomes and the exclusion of certain groups. They ~~may~~ violate the right to dignity and non-discrimination and the values of equality and justice. Such AI systems evaluate or classify ~~the trustworthiness of~~ natural persons ***or groups*** based on ***multiple data points and time occurrences related to*** their social behaviour in multiple contexts or known***, inferred*** or predicted personal or personality characteristics. The social score obtained from such AI systems may lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof in social contexts, which are unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. Such AI systems should be therefore prohibited.	scoring of natural persons ~~for general purpose~~ by public authorities or ~~on their behalf~~***by private actors*** may lead to discriminatory outcomes and the exclusion of certain groups. They may violate the right to dignity and non-discrimination and the values of equality and justice. Such AI systems evaluate or classify ~~the trustworthiness of~~ natural persons based on their social behaviour in multiple contexts or known or predicted personal or personality characteristics. The social score obtained from such AI systems may lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof in social contexts, which are unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. ***AI systems entailing such unacceptable scoring practices***~~Such AI systems~~ should be therefore prohibited. ***This prohibition should not affect lawful evaluation practices of natural persons done for one or more specific purpose in compliance with the law.***	scoring of natural persons ~~for general purpose~~ by public ~~authorities or on their behalf~~ ***or private actors*** may lead to discriminatory outcomes and the exclusion of certain groups. They may violate the right to dignity and non-discrimination and the values of equality and justice. Such AI systems evaluate or classify ~~the trustworthiness of natural persons~~***natural persons or groups thereof*** based on ***multiple data points related to*** their social behaviour in multiple contexts or known***, inferred*** or predicted personal or personality characteristics ***over certain periods of time***. The social score obtained from such AI systems may lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof in social contexts, which are unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. ***AI systems entailing such unacceptable scoring practices leading to such detrimental or unfavorable outcomes*** ~~Such AI systems~~ should be therefore prohibited. ***This prohibition should not affect lawful evaluation practices of natural persons done***

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				for a specific purpose in compliance with national and Union law.
Recital 18				
28	(18) The use of AI systems for 'real-time' remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement is considered particularly intrusive in the rights and freedoms of the concerned persons, to the extent that it may affect the private life of a large part of the population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems operating in 'real-time' carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities.	(18) The use of AI systems for 'real-time' remote biometric identification of natural persons in publicly accessible spaces ~~for the purpose of law enforcement is considered~~ ***is*** particularly intrusive ~~in~~***to*** the rights and freedoms of the concerned persons, ~~to the extent that it may~~***and can ultimately*** affect the private life of a large part of the population, evoke a feeling of constant surveillance***, give parties deploying biometric identification in publicly accessible spaces a position of uncontrollable power*** and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights ***at the core to the Rule of Law. Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities***. In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems	(18) The use of AI systems for 'real-time' remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement is considered particularly intrusive in the rights and freedoms of the concerned persons, to the extent that it may affect the private life of a large part of the population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems operating in 'real-time' carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities.	(18) The use of AI systems for 'real-time' remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement is ~~considered~~ particularly intrusive ~~in~~ ***to*** the rights and freedoms of the concerned persons, to the extent that it may affect the private life of a large part of the population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. ***Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, race, sex or disabilities.*** ~~-~~In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems operating in 'real-time' carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement

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		operating in 'real-time' carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities. ***The use of those systems in publicly accessible places should therefore be prohibited. Similarly, AI systems used for the analysis of recorded footage of publicly accessible spaces through 'post' remote biometric identification systems should also be prohibited, unless there is pre-judicial authorisation for use in the context of law enforcement, when strictly necessary for the targeted search connected to a specific serious criminal offense that already took place, and only subject to a pre-judicial authorisation.***		activities.
Recital 19				
G 29	(19) The use of those systems for the purpose of law enforcement should therefore be prohibited, except in three exhaustively listed and narrowly defined situations, where the use is strictly necessary to achieve a substantial public interest, the importance of which outweighs the risks. Those situations involve the search for potential victims of crime, including missing children; certain threats to the life or physical safety of natural persons or of a	*deleted*	(19) The use of those systems for the purpose of law enforcement should therefore be prohibited, except in ~~*three*~~ exhaustively listed and narrowly defined situations, where the use is strictly necessary to achieve a substantial public interest, the importance of which outweighs the risks. Those situations involve the search for potential victims of crime, including missing children; certain threats to the life or physical safety of natural persons or of a	(19) The use of those systems for the purpose of law enforcement should therefore be prohibited, except in ~~*three*~~ exhaustively listed and narrowly defined situations, where the use is strictly necessary to achieve a substantial public interest, the importance of which outweighs the risks. Those situations involve the search for ~~*potential*~~ ***certain*** victims of crime~~,~~ including missing ~~*children*~~***people***; certain threats to the life or physical safety of natural

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	terrorist attack; and the detection, localisation, identification or prosecution of perpetrators or suspects of the criminal offences referred to in Council Framework Decision 2002/584/JHA[1] if those criminal offences are punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years and as they are defined in the law of that Member State. Such threshold for the custodial sentence or detention order in accordance with national law contributes to ensure that the offence should be serious enough to potentially justify the use of 'real-time' remote biometric identification systems. Moreover, of the 32 criminal offences listed in the Council Framework Decision 2002/584/JHA, some are in practice likely to be more relevant than others, in that the recourse to 'real-time' remote biometric identification will foreseeably be necessary and proportionate to highly varying degrees for the practical pursuit of the detection, localisation, identification or prosecution of a perpetrator or suspect of the different criminal offences listed and having regard to the likely differences in the seriousness, probability and scale of the harm or possible negative consequences.		terrorist attack; and the detection, localisation, identification or prosecution of perpetrators or suspects of the criminal offences referred to in Council Framework Decision 2002/584/JHA[1] if those criminal offences are punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years and as they are defined in the law of that Member State. Such threshold for the custodial sentence or detention order in accordance with national law contributes to ensure that the offence should be serious enough to potentially justify the use of 'real-time' remote biometric identification systems. Moreover, of the 32 criminal offences listed in the Council Framework Decision 2002/584/JHA, some are in practice likely to be more relevant than others, in that the recourse to 'real-time' remote biometric identification will foreseeably be necessary and proportionate to highly varying degrees for the practical pursuit of the detection, localisation, identification or prosecution of a perpetrator or suspect of the different criminal offences listed and having regard to the likely differences in the seriousness, probability and scale of the harm or possible negative consequences. ***In***	persons or of a terrorist attack; and the ~~*detection,*~~ localisation~~,~~ ~~*identification or prosecution*~~ ***or identification*** of perpetrators or suspects of the criminal offences referred to in ~~*Council Framework Decision 2002/584/JHA*[1]~~ ***Annex IIa*** if those criminal offences are punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least ~~*three*~~ ***four*** years and as they are defined in the law of that Member State. Such threshold for the custodial sentence or detention order in accordance with national law contributes to ensure that the offence should be serious enough to potentially justify the use of 'real-time' remote biometric identification systems. Moreover, ***the list of criminal offences as referred in Annex IIa is based on*** ~~*of*~~ the 32 criminal offences listed in the Council Framework Decision 2002/584/JHA[1]***, taking into account that*** ~~,~~ some are in practice likely to be more relevant than others, in that the recourse to 'real-time' remote biometric identification will foreseeably be necessary and proportionate to highly varying degrees for the practical pursuit of the ~~*detection,*~~ localisation~~,~~ ~~*identification or prosecution*~~ ***or identification*** of a perpetrator or suspect of the different criminal

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	_____ 1. Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).		***addition, this Regulation should preserve the ability for law enforcement, border control, immigration or asylum authorities to carry out identity checks in the presence of the person that is concerned in accordance with the conditions set out in Union and national law for such checks. In particular, law enforcement, border control, immigration or asylum authorities should be able to use information systems, in accordance with Union or national law, to identify a person who, during an identity check, either refuses to be identified or is unable to state or prove his or her identity, without being required by this Regulation to obtain prior authorisation. This could be, for example, a person involved in a crime, being unwilling, or unable due to an accident or a medical condition, to disclose their identity to law enforcement authorities.*** _____ 1. ***[1]*** Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).	offences listed and having regard to the likely differences in the seriousness, probability and scale of the harm or possible negative consequences. ***An imminent threat to life or physical safety of natural persons could also result from a serious disruption of critical infrastructure, as defined in Article 2, point (a) of Directive 2008/114/EC, where the disruption or destruction of such critical infrastructure would result in an imminent threat to life or physical safety of a person, including through serious harm to the provision of basic supplies to the population or to the exercise of the core function of the State.*** ***In addition, this Regulation should preserve the ability for law enforcement, border control, immigration or asylum authorities to carry out identity checks in the presence of the person that is concerned in accordance with the conditions set out in Union and national law for such checks. In particular, law enforcement, border control, immigration or asylum authorities should be able to use information systems, in accordance with Union or national law, to identify a person who, during an identity check, either refuses to be***

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				identified or is unable to state or prove his or her identity, without being required by this Regulation to obtain prior authorisation. This could be, for example, a person involved in a crime, being unwilling, or unable due to an accident or a medical condition, to disclose their identity to law enforcement authorities. _____ 1. Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).
Recital 20				
G 30	(20) In order to ensure that those systems are used in a responsible and proportionate manner, it is also important to establish that, in each of those three exhaustively listed and narrowly defined situations, certain elements should be taken into account, in particular as regards the nature of the situation giving rise to the request and the consequences of the use for the rights and freedoms of all persons concerned and the safeguards and conditions provided for with the use. In addition, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement should be subject	*deleted*	(20) In order to ensure that those systems are used in a responsible and proportionate manner, it is also important to establish that, in each of those ~~*three*~~ exhaustively listed and narrowly defined situations, certain elements should be taken into account, in particular as regards the nature of the situation giving rise to the request and the consequences of the use for the rights and freedoms of all persons concerned and the safeguards and conditions provided for with the use. In addition, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement should be subject	(20) In order to ensure that those systems are used in a responsible and proportionate manner, it is also important to establish that, in each of those ~~*three*~~ exhaustively listed and narrowly defined situations, certain elements should be taken into account, in particular as regards the nature of the situation giving rise to the request and the consequences of the use for the rights and freedoms of all persons concerned and the safeguards and conditions provided for with the use. In addition, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement should ***only be*** G

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	to appropriate limits in time and space, having regard in particular to the evidence or indications regarding the threats, the victims or perpetrator. The reference database of persons should be appropriate for each use case in each of the three situations mentioned above.		to appropriate limits in time and space, having regard in particular to the evidence or indications regarding the threats, the victims or perpetrator. The reference database of persons should be appropriate for each use case in each of the ~~three~~ situations mentioned above.	***deployed to confirm the specifically target individual's identity and should be limited to what is strictly necessary concerning the period of time as well as geographic and personal scope*** ~~be subject to appropriate limits in time and space~~, having regard in particular to the evidence or indications regarding the threats, the victims or perpetrator. The ***use of the 'real-time' remote biometric identification system in publicly accessible spaces should only be authorised if the law enforcement authority has completed a fundamental rights impact assessment and, unless provided otherwise in this Regulation, has registered the system in the database as set out in this Regulation. The*** reference database of persons should be appropriate for each use case in each of the ~~three~~ situations mentioned above.
Recital 21				
G 31	(21) Each use of a 'real-time' remote biometric identification system in publicly accessible spaces for the purpose of law enforcement should be subject to an express and specific authorisation by a judicial authority or by an independent administrative authority of a	*deleted*	(21) Each use of a 'real-time' remote biometric identification system in publicly accessible spaces for the purpose of law enforcement should be subject to an express and specific authorisation by a judicial authority or by an independent administrative authority of a	(21) Each use of a 'real-time' remote biometric identification system in publicly accessible spaces for the purpose of law enforcement should be subject to an express and specific authorisation by a judicial authority or by an independent administrative authority ***whose*** G

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	Member State. Such authorisation should in principle be obtained prior to the use, except in duly justified situations of urgency, that is, situations where the need to use the systems in question is such as to make it effectively and objectively impossible to obtain an authorisation before commencing the use. In such situations of urgency, the use should be restricted to the absolute minimum necessary and be subject to appropriate safeguards and conditions, as determined in national law and specified in the context of each individual urgent use case by the law enforcement authority itself. In addition, the law enforcement authority should in such situations seek to obtain an authorisation as soon as possible, whilst providing the reasons for not having been able to request it earlier.		Member State. Such authorisation should in principle be obtained prior to the use~~, except~~ ***of the system with a view to identify a person or persons. Exceptions to this rule should be allowed*** in duly justified situations of urgency, that is, situations where the need to use the systems in question is such as to make it effectively and objectively impossible to obtain an authorisation before commencing the use. In such situations of urgency, the use should be restricted to the absolute minimum necessary and be subject to appropriate safeguards and conditions, as determined in national law and specified in the context of each individual urgent use case by the law enforcement authority itself. In addition, the law enforcement authority should in such situations seek to obtain an authorisation as soon as possible, whilst providing the reasons for not having been able to request it earlier.	***decision is binding*** of a Member State. Such authorisation should in principle be obtained prior to the use~~, except~~ ***of the system with a view to identify a person or persons. Exceptions to this rule should be allowed*** in duly justified situations of urgency, that is, situations where the need to use the systems in question is such as to make it effectively and objectively impossible to obtain an authorisation before commencing the use. In such situations of urgency, the use should be restricted to the absolute minimum necessary and be subject to appropriate safeguards and conditions, as determined in national law and specified in the context of each individual urgent use case by the law enforcement authority itself. In addition, the law enforcement authority should in such situations ~~seek to obtain an~~ ***request such*** authorisation ~~as soon as possible,~~ whilst providing the reasons for not having been able to request it earlier, ***without undue delay and, at the latest within 24 hours. If such authorisation is rejected, the use of real-time biometric identification systems linked to that authorisation should be stopped with immediate effect and all the data related to such use should be discarded and deleted. Such data includes input data directly***

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				acquired by an AI system in the course of the use of such system as well as the results and outputs of the use linked to that authorisation. It should not include input legally acquired in accordance with another national or Union law. In any case, no decision producing an adverse legal effect on a person may be taken solely based on the output of the remote biometric identification system.
Recital 21a				
G 31a				***(21a) In order to carry out their tasks in accordance with the requirements set out in this Regulation as well as in national rules, the relevant market surveillance authority and the national data protection authority should be notified of each use of the 'real-time biometric identification system'. National market surveillance authorities and the national data protection authorities that have been notified should submit to the Commission an annual report on the use of 'real-time biometric identification systems'.*** G
Recital 22				
G 32				G

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	(22) Furthermore, it is appropriate to provide, within the exhaustive framework set by this Regulation that such use in the territory of a Member State in accordance with this Regulation should only be possible where and in as far as the Member State in question has decided to expressly provide for the possibility to authorise such use in its detailed rules of national law. Consequently, Member States remain free under this Regulation not to provide for such a possibility at all or to only provide for such a possibility in respect of some of the objectives capable of justifying authorised use identified in this Regulation.	*deleted*	*(22)* Furthermore, it is appropriate to provide, within the exhaustive framework set by this Regulation that such use in the territory of a Member State in accordance with this Regulation should only be possible where and in as far as the Member State in question has decided to expressly provide for the possibility to authorise such use in its detailed rules of national law. Consequently, Member States remain free under this Regulation not to provide for such a possibility at all or to only provide for such a possibility in respect of some of the objectives capable of justifying authorised use identified in this Regulation.	(22) Furthermore, it is appropriate to provide, within the exhaustive framework set by this Regulation that such use in the territory of a Member State in accordance with this Regulation should only be possible where and in as far as the Member State in question has decided to expressly provide for the possibility to authorise such use in its detailed rules of national law. Consequently, Member States remain free under this Regulation not to provide for such a possibility at all or to only provide for such a possibility in respect of some of the objectives capable of justifying authorised use identified in this Regulation. ***These national rules should be notified to the Commission at the latest 30 days following their adoption.***
Recital 23				
G 33	(23) The use of AI systems for 'real-time' remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement necessarily involves the processing of biometric data. The rules of this Regulation that prohibit, subject to certain exceptions, such use, which are based on Article 16 TFEU, should apply as lex specialis in	*deleted*	(23) The use of AI systems for 'real-time' remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement necessarily involves the processing of biometric data. The rules of this Regulation that prohibit, subject to certain exceptions, such use, which are based on Article 16 TFEU, should apply as ***lex specialis***~~lex~~	(23) The use of AI systems for 'real-time' remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement necessarily involves the processing of biometric data. The rules of this Regulation that prohibit, subject to certain exceptions, such use, which are based on Article 16 TFEU, should apply as lex specialis in G

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	respect of the rules on the processing of biometric data contained in Article 10 of Directive (EU) 2016/680, thus regulating such use and the processing of biometric data involved in an exhaustive manner. Therefore, such use and processing should only be possible in as far as it is compatible with the framework set by this Regulation, without there being scope, outside that framework, for the competent authorities, where they act for purpose of law enforcement, to use such systems and process such data in connection thereto on the grounds listed in Article 10 of Directive (EU) 2016/680. In this context, this Regulation is not intended to provide the legal basis for the processing of personal data under Article 8 of Directive 2016/680. However, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for purposes other than law enforcement, including by competent authorities, should not be covered by the specific framework regarding such use for the purpose of law enforcement set by this Regulation. Such use for purposes other than law enforcement should therefore not be subject to the requirement of an authorisation under this Regulation and the applicable detailed rules of national law that may give effect to it.		~~*specialis*~~ in respect of the rules on the processing of biometric data contained in Article 10 of Directive (EU) 2016/680, thus regulating such use and the processing of biometric data involved in an exhaustive manner. Therefore, such use and processing should only be possible in as far as it is compatible with the framework set by this Regulation, without there being scope, outside that framework, for the competent authorities, where they act for purpose of law enforcement, to use such systems and process such data in connection thereto on the grounds listed in Article 10 of Directive (EU) 2016/680. In this context, this Regulation is not intended to provide the legal basis for the processing of personal data under Article 8 of Directive 2016/680. However, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for purposes other than law enforcement, including by competent authorities, should not be covered by the specific framework regarding such use for the purpose of law enforcement set by this Regulation. Such use for purposes other than law enforcement should therefore not be subject to the requirement of an authorisation under this Regulation and the applicable detailed rules of national law that may give effect to it.	respect of the rules on the processing of biometric data contained in Article 10 of Directive (EU) 2016/680, thus regulating such use and the processing of biometric data involved in an exhaustive manner. Therefore, such use and processing should only be possible in as far as it is compatible with the framework set by this Regulation, without there being scope, outside that framework, for the competent authorities, where they act for purpose of law enforcement, to use such systems and process such data in connection thereto on the grounds listed in Article 10 of Directive (EU) 2016/680. In this context, this Regulation is not intended to provide the legal basis for the processing of personal data under Article 8 of Directive 2016/680. However, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for purposes other than law enforcement, including by competent authorities, should not be covered by the specific framework regarding such use for the purpose of law enforcement set by this Regulation. Such use for purposes other than law enforcement should therefore not be subject to the requirement of an authorisation under this Regulation and the applicable detailed rules of national law that may give effect to it.

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Recital 24				
34	(24) Any processing of biometric data and other personal data involved in the use of AI systems for biometric identification, other than in connection to the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement as regulated by this Regulation, including where those systems are used by competent authorities in publicly accessible spaces for other purposes than law enforcement, should continue to comply with all requirements resulting from Article 9(1) of Regulation (EU) 2016/679, Article 10(1) of Regulation (EU) 2018/1725 and Article 10 of Directive (EU) 2016/680, as applicable.	(24) Any processing of biometric data and other personal data involved in the use of AI systems for biometric identification, other than in connection to the use of 'real-time' remote biometric identification systems in publicly accessible spaces ~~for the purpose of law enforcement~~ as regulated by this Regulation~~,~~ ~~including where those systems are used by competent authorities in publicly accessible spaces for other purposes than law enforcement,~~ should continue to comply with all requirements resulting from Article 9(1) of Regulation (EU) 2016/679, Article 10(1) of Regulation (EU) 2018/1725 and Article 10 of Directive (EU) 2016/680, as applicable.	(24) Any processing of biometric data and other personal data involved in the use of AI systems for biometric identification, other than in connection to the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement as regulated by this Regulation, ~~including where those systems are used by competent authorities in publicly accessible spaces for other~~ ***should continue to comply with all requirements resulting from Article 10 of Directive (EU) 2016/680. For*** purposes ***other*** than law enforcement, ~~should continue to comply with all requirements resulting from~~ Article 9(1) of Regulation (EU) 2016/679~~,~~ ***and*** Article 10(1) of Regulation (EU) 2018/1725 ~~and Article 10 of Directive (EU) 2016/680, as applicable~~***prohibit the processing of biometric data for the purpose of uniquely identifying a natural person, unless one of the situations in the respective second paragraphs of those two articles applies***.	(24) Any processing of biometric data and other personal data involved in the use of AI systems for biometric identification, other than in connection to the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement as regulated by this Regulation, ~~including where those systems are used by competent authorities in publicly accessible spaces for other~~ ***should continue to comply with all requirements resulting from Article 10 of Directive (EU) 2016/680.*** ***For*** purposes ***other*** than law enforcement, ~~should continue to comply with all requirements resulting from~~ Article 9(1) of Regulation (EU) 2016/679~~,~~ ***and*** Article 10(1) of Regulation (EU) 2018/1725 ~~and~~***prohibit the processing of biometric data subject to limited exceptions as provided in those articles. In application of*** Article ~~10 of Directive (EU) 2016/680, as applicable~~***9(1) of Regulation (EU) 2016/679, the use of remote biometric identification for purposes other than law enforcement has already been subject to prohibition decisions by national data protection authorities***.

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Recital 25				
35	(25) In accordance with Article 6a of Protocol No 21 on the position of the United Kingdom and Ireland in respect of the area of freedom, security and justice, as annexed to the TEU and to the TFEU, Ireland is not bound by the rules laid down in Article 5(1), point (d), (2) and (3) of this Regulation adopted on the basis of Article 16 of the TFEU which relate to the processing of personal data by the Member States when carrying out activities falling within the scope of Chapter 4 or Chapter 5 of Title V of Part Three of the TFEU, where Ireland is not bound by the rules governing the forms of judicial cooperation in criminal matters or police cooperation which require compliance with the provisions laid down on the basis of Article 16 of the TFEU.	(25) In accordance with Article 6a of Protocol No 21 on the position of the United Kingdom and Ireland in respect of the area of freedom, security and justice, as annexed to the TEU and to the TFEU, Ireland is not bound by the rules laid down in Article 5(1), point (d), ~~(2) and (3)~~ of this Regulation adopted on the basis of Article 16 of the TFEU which relate to the processing of personal data by the Member States when carrying out activities falling within the scope of Chapter 4 or Chapter 5 of Title V of Part Three of the TFEU, where Ireland is not bound by the rules governing the forms of judicial cooperation in criminal matters or police cooperation which require compliance with the provisions laid down on the basis of Article 16 of the TFEU.	(25) In accordance with Article 6a of Protocol No 21 on the position of the United Kingdom and Ireland in respect of the area of freedom, security and justice, as annexed to the TEU and to the TFEU, Ireland is not bound by the rules laid down in Article 5(1), point (d), (2)***, (3) and (4)*** ~~and (3)~~ of this Regulation adopted on the basis of Article 16 of the TFEU which relate to the processing of personal data by the Member States when carrying out activities falling within the scope of Chapter 4 or Chapter 5 of Title V of Part Three of the TFEU, where Ireland is not bound by the rules governing the forms of judicial cooperation in criminal matters or police cooperation which require compliance with the provisions laid down on the basis of Article 16 of the TFEU.	(25) In accordance with Article 6a of Protocol No 21 on the position of the United Kingdom and Ireland in respect of the area of freedom, security and justice, as annexed to the TEU and to the TFEU, Ireland is not bound by the rules laid down in Article 5(1), point (d), (2)***, (3), (3a), (4) and (5), Article 5(1)(ba) to the extent it applies to the use of biometric categorisation systems for activities in the field of police cooperation and judicial cooperation in criminal matters, Article 5(1)(da) to the extent it applies to the use of AI systems covered by that provision and Article 29(6a)*** ~~and (3)~~ of this Regulation adopted on the basis of Article 16 of the TFEU which relate to the processing of personal data by the Member States when carrying out activities falling within the scope of Chapter 4 or Chapter 5 of Title V of Part Three of the TFEU, where Ireland is not bound by the rules governing the forms of judicial cooperation in criminal matters or police cooperation which require compliance with the provisions laid down on the basis of Article 16 of the TFEU.

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Recital 26				
G 36	(26) In accordance with Articles 2 and 2a of Protocol No 22 on the position of Denmark, annexed to the TEU and TFEU, Denmark is not bound by rules laid down in Article 5(1), point (d), (2) and (3) of this Regulation adopted on the basis of Article 16 of the TFEU, or subject to their application, which relate to the processing of personal data by the Member States when carrying out activities falling within the scope of Chapter 4 or Chapter 5 of Title V of Part Three of the TFEU.	(26) In accordance with Articles 2 and 2a of Protocol No 22 on the position of Denmark, annexed to the TEU and TFEU, Denmark is not bound by rules laid down in Article 5(1), point (d)~~, (2) and (3)~~ of this Regulation adopted on the basis of Article 16 of the TFEU, or subject to their application, which relate to the processing of personal data by the Member States when carrying out activities falling within the scope of Chapter 4 or Chapter 5 of Title V of Part Three of the TFEU.	(26) In accordance with Articles 2 and 2a of Protocol No 22 on the position of Denmark, annexed to the TEU and TFEU, Denmark is not bound by rules laid down in Article 5(1), point (d), (2)***, (3) and (4)*** ~~and (3)~~ of this Regulation adopted on the basis of Article 16 of the TFEU, or subject to their application, which relate to the processing of personal data by the Member States when carrying out activities falling within the scope of Chapter 4 or Chapter 5 of Title V of Part Three of the TFEU.	(26) In accordance with Articles 2 and 2a of Protocol No 22 on the position of Denmark, annexed to the TEU and TFEU, Denmark is not bound by rules laid down in Article 5(1), point (d), (2)***, (3), (3a), (4) and (5), Article 5(1)(ba) to the extent it applies to the use of biometric categorisation systems for activities in the field of police cooperation and judicial cooperation in criminal matters, Article 5(1)(da) to the extent it applies to the use of AI systems covered by that provision and Article 29(6a)*** ~~and (3)~~ of this Regulation adopted on the basis of Article 16 of the TFEU, or subject to their application, which relate to the processing of personal data by the Member States when carrying out activities falling within the scope of Chapter 4 or Chapter 5 of Title V of Part Three of the TFEU. G
Recital 26a				
G 36a		***(26a) AI systems used by law enforcement authorities or on their behalf to make predictions, profiles or risk assessments based on profiling of natural persons or data analysis based on personality traits and characteristics, including the person's location, or past criminal***		***(26a) In line with the presumption of innocence, natural persons in the EU should always be judged on their actual behaviour. Natural persons should never be judged on AI-predicted behaviour based solely on their profiling, personality traits or characteristics, such as*** G

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		behaviour of natural persons or groups of persons for the purpose of predicting the occurrence or reoccurrence of an actual or potential criminal offence(s) or other criminalised social behaviour or administrative offences, including fraud-predicition systems, hold a particular risk of discrimination against certain persons or groups of persons, as they violate human dignity as well as the key legal principle of presumption of innocence. Such AI systems should therefore be prohibited.		***nationality, place of birth, place of residence, number of children, debt, their type of car, without a reasonable suspicion of that person being involved in a criminal activity based on objective verifiable facts and without human assessment thereof. Therefore, risk assessments of natural persons in order to assess the risk of them offending or for predicting the occurrence of an actual or potential criminal offence solely based on the profiling of a natural person or on assessing their personality traits and characteristics should be prohibited. In any case, this prohibition does not refer to nor touch upon risk analytics that are not based on the profiling of individuals or on the personality traits and characteristics of individuals, such as AI systems using risk analytics to assess the risk of financial fraud by undertakings based on suspicious transactions or risk analytic tools to predict the likelihood of localisation of narcotics or illicit goods by customs authorities, for example based on known trafficking routes.***
Recital 26b				
G 36b		***(26b) The indiscriminate and untargeted scraping of biometric***		***(26b) The placing on the market, putting into service for this specific*** G

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		data from social media or CCTV footage to create or expand facial recognition databases add to the feeling of mass surveillance and can lead to gross violations of fundamental rights, including the right to privacy. The use of AI systems with this intended purpose should therefore be prohibited.		*purpose, or use of AI systems that create or expand facial recognition databases through the untargeted scraping of facial images from the internet or CCTV footage should be prohibited, as this practice adds to the feeling of mass surveillance and can lead to gross violations of fundamental rights, including the right to privacy.*
Recital 26c				
G 36c		*(26c) There are serious concerns about the scientific basis of AI systems aiming to detect emotions, physical or physiological features such as facial expressions, movements, pulse frequency or voice. Emotions or expressions of emotions and perceptions thereof vary considerably across cultures and situations, and even within a single individual. Among the key shortcomings of such technologies, are the limited reliability (emotion categories are neither reliably expressed through, nor unequivocally associated with, a common set of physical or physiological movements), the lack of specificity (physical or physiological expressions do not perfectly match emotion categories) and the limited generalisability (the effects of context and culture are*		*(26c) There are serious concerns about the scientific basis of AI systems aiming to identify or infer emotions, particularly as expression of emotions vary considerably across cultures and situations, and even within a single individual. Among the key shortcomings of such systems are the limited reliability, the lack of specificity and the limited generalizability. Therefore, AI systems identifying or inferring emotions or intentions of natural persons on the basis of their biometric data may lead to discriminatory outcomes and can be intrusive to the rights and freedoms of the concerned persons. Considering the imbalance of power in the context of work or education, combined with the intrusive nature of these systems, such systems could lead to* G

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		not sufficiently considered). Reliability issues and consequently, major risks for abuse, may especially arise when deploying the system in real-life situations related to law enforcement, border management, workplace and education institutions. Therefore, the placing on the market, putting into service, or use of AI systems intended to be used in these contexts to detect the emotional state of individuals should be prohibited.		***detrimental or unfavourable treatment of certain natural persons or whole groups thereof. Therefore, the placing on the market, putting into service, or use of AI systems intended to be used to detect the emotional state of individuals in situations related to the workplace and education should be prohibited. This prohibition should not cover AI systems placed on the market strictly for medical or safety reasons, such as systems intended for therapeutical use.***
Recital 26d				
G 36d		***(26d) Practices that are prohibited by Union legislation, including data protection law, non-discrimination law, consumer protection law, and competition law, should not be affected by this Regulation.***		***(26d) Practices that are prohibited by Union legislation, including data protection law, non-discrimination law, consumer protection law, and competition law, should not be affected by this Regulation.*** G
Recital 27				
G 37	(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable	(27) High-risk AI systems should only be placed on the Union market ~~or~~, put into service ***or used*** if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable	(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable	(27) High-risk AI systems should only be placed on the Union market ~~or~~, put into service ***or used*** if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable G

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	risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any.	risks to important Union public interests as recognised and protected by Union law***, including fundamental rights, democracy, the rule or law or the environment. In order to ensure alignment with sectoral legislation and avoid duplications, requirements for high-risk AI systems should take into account sectoral legislation laying down requirements for high-risk AI systems included in the scope of this Regulation, such as Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In Vitro Diagnostic Devices or Directive 2006/42/EC on Machinery***. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any.***Given the rapid pace of technological development, as well as the potential changes in the use of AI systems, the list of high-risk areas and use-cases in Annex III should nonetheless be subject to permanent review through the exercise of regular assessment.***	risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any.	risks to important Union public interests as recognised and protected by Union law. ***Following the New Legislative Framework approach, as clarified in Commission notice the 'Blue Guide' on the implementation of EU product rules 2022 (C/2022/3637) the general rule is that several pieces of the EU legislation, such as Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In Vitro Diagnostic Devices or Directive 2006/42/EC on Machinery, may have to be taken into consideration for one product, since the making available or putting into service can only take place when the product complies with all applicable Union harmonisation legislation. To ensure consistency and avoid unnecessary administrative burden or costs, providers of a product that contains one or more high-risk artificial intelligence system, to which the requirements of this Regulation as well as requirements of the Union harmonisation legislation listed in Annex II, Section A apply, should have a flexibility on operational decisions on how to ensure compliance of a product that contains one or more artificial intelligence systems with all applicable requirements of the Union harmonised legislation in a***

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				best way. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any.
Recital 28				
G 38	(28) AI systems could produce adverse outcomes to health and safety of persons, in particular when such systems operate as components of products. Consistently with the objectives of Union harmonisation legislation to facilitate the free movement of products in the internal market and to ensure that only safe and otherwise compliant products find their way into the market, it is important that the safety risks that may be generated by a product as a whole due to its digital components, including AI systems, are duly prevented and mitigated. For instance, increasingly autonomous robots, whether in the context of manufacturing or personal assistance and care should be able to safely operate and performs their functions in complex environments. Similarly, in the health sector where the stakes for life and health are particularly high, increasingly sophisticated	(28) AI systems could ~~produce~~***have an*** adverse ~~outcomes~~***impact*** to health and safety of persons, in particular when such systems operate as ***safety*** components of products. Consistently with the objectives of Union harmonisation legislation to facilitate the free movement of products in the internal market and to ensure that only safe and otherwise compliant products find their way into the market, it is important that the safety risks that may be generated by a product as a whole due to its digital components, including AI systems, are duly prevented and mitigated. For instance, increasingly autonomous robots, whether in the context of manufacturing or personal assistance and care should be able to safely operate and performs their functions in complex environments. Similarly, in the health sector where the stakes for life and health are particularly	(28) AI systems could produce adverse outcomes to health and safety of persons, in particular when such systems operate as components of products. Consistently with the objectives of Union harmonisation legislation to facilitate the free movement of products in the internal market and to ensure that only safe and otherwise compliant products find their way into the market, it is important that the safety risks that may be generated by a product as a whole due to its digital components, including AI systems, are duly prevented and mitigated. For instance, increasingly autonomous robots, whether in the context of manufacturing or personal assistance and care should be able to safely operate and performs their functions in complex environments. Similarly, in the health sector where the stakes for life and health are particularly high, increasingly sophisticated	(28) AI systems could ~~produce~~***have an*** adverse ~~outcomes~~***impact*** to health and safety of persons, in particular when such systems operate as ***safety*** components of products. Consistently with the objectives of Union harmonisation legislation to facilitate the free movement of products in the internal market and to ensure that only safe and otherwise compliant products find their way into the market, it is important that the safety risks that may be generated by a product as a whole due to its digital components, including AI systems, are duly prevented and mitigated. For instance, increasingly autonomous robots, whether in the context of manufacturing or personal assistance and care should be able to safely operate and performs their functions in complex environments. Similarly, in the health sector where the stakes for life and health are particularly G

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	diagnostics systems and systems supporting human decisions should be reliable and accurate. The extent of the adverse impact caused by the AI system on the fundamental rights protected by the Charter is of particular relevance when classifying an AI system as high-risk. Those rights include the right to human dignity, respect for private and family life, protection of personal data, freedom of expression and information, freedom of assembly and of association, and non-discrimination, consumer protection, workers' rights, rights of persons with disabilities, right to an effective remedy and to a fair trial, right of defence and the presumption of innocence, right to good administration. In addition to those rights, it is important to highlight that children have specific rights as enshrined in Article 24 of the EU Charter and in the United Nations Convention on the Rights of the Child (further elaborated in the UNCRC General Comment No. 25 as regards the digital environment), both of which require consideration of the children's vulnerabilities and provision of such protection and care as necessary for their well-being. The fundamental right to a high level of environmental protection enshrined in the Charter and implemented in Union policies	high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate. ~~The extent of the adverse impact caused by the AI system on the fundamental rights protected by the Charter is of particular relevance when classifying an AI system as high-risk. Those rights include the right to human dignity, respect for private and family life, protection of personal data, freedom of expression and information, freedom of assembly and of association, and non-discrimination, consumer protection, workers' rights, rights of persons with disabilities, right to an effective remedy and to a fair trial, right of defence and the presumption of innocence, right to good administration. In addition to those rights, it is important to highlight that children have specific rights as enshrined in Article 24 of the EU Charter and in the United Nations Convention on the Rights of the Child (further elaborated in the UNCRC General Comment No. 25 as regards the digital environment), both of which require consideration of the children's vulnerabilities and provision of such protection and care as necessary for their well-being. The fundamental right to a high level of environmental protection enshrined in the Charter~~	diagnostics systems and systems supporting human decisions should be reliable and accurate. The extent of the adverse impact caused by the AI system on the fundamental rights protected by the Charter is of particular relevance when classifying an AI system as high-risk. Those rights include the right to human dignity, respect for private and family life, protection of personal data, freedom of expression and information, freedom of assembly and of association, and non-discrimination, consumer protection, workers' rights, rights of persons with disabilities, right to an effective remedy and to a fair trial, right of defence and the presumption of innocence, right to good administration. In addition to those rights, it is important to highlight that children have specific rights as enshrined in Article 24 of the EU Charter and in the United Nations Convention on the Rights of the Child (further elaborated in the UNCRC General Comment No. 25 as regards the digital environment), both of which require consideration of the children's vulnerabilities and provision of such protection and care as necessary for their well-being. The fundamental right to a high level of environmental protection enshrined in the Charter and implemented in Union policies	high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate. ~~The extent of the adverse impact caused by the AI system on the fundamental rights protected by the Charter is of particular relevance when classifying an AI system as high-risk. Those rights include the right to human dignity, respect for private and family life, protection of personal data, freedom of expression and information, freedom of assembly and of association, and non-discrimination, consumer protection, workers' rights, rights of persons with disabilities, right to an effective remedy and to a fair trial, right of defence and the presumption of innocence, right to good administration. In addition to those rights, it is important to highlight that children have specific rights as enshrined in Article 24 of the EU Charter and in the United Nations Convention on the Rights of the Child (further elaborated in the UNCRC General Comment No. 25 as regards the digital environment), both of which require consideration of the children's vulnerabilities and provision of such protection and care as necessary for their well-being. The fundamental right to a high level of environmental protection enshrined in the Charter~~

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	should also be considered when assessing the severity of the harm that an AI system can cause, including in relation to the health and safety of persons.	~~*and implemented in Union policies should also be considered when assessing the severity of the harm that an AI system can cause, including in relation to the health and safety of persons.*~~	should also be considered when assessing the severity of the harm that an AI system can cause, including in relation to the health and safety of persons.	~~*and implemented in Union policies should also be considered when assessing the severity of the harm that an AI system can cause, including in relation to the health and safety of persons.*~~
Recital 28a				
G 38a		***(28a) The extent of the adverse impact caused by the AI system on the fundamental rights protected by the Charter is of particular relevance when classifying an AI system as high-risk. Those rights include the right to human dignity, respect for private and family life, protection of personal data, freedom of expression and information, freedom of assembly and of association, and non-discrimination, right to education consumer protection, workers' rights, rights of persons with disabilities, gender equality, intellectual property rights, right to an effective remedy and to a fair trial, right of defence and the presumption of innocence, right to good administration. In addition to those rights, it is important to highlight that children have specific rights as enshrined in Article 24 of the EU Charter and in the United Nations Convention on the Rights of the Child (further elaborated in***		***(28a) The extent of the adverse impact caused by the AI system on the fundamental rights protected by the Charter is of particular relevance when classifying an AI system as high-risk. Those rights include the right to human dignity, respect for private and family life, protection of personal data, freedom of expression and information, freedom of assembly and of association, and non-discrimination, right to education consumer protection, workers' rights, rights of persons with disabilities, gender equality, intellectual property rights, right to an effective remedy and to a fair trial, right of defence and the presumption of innocence, right to good administration. In addition to those rights, it is important to highlight that children have specific rights as enshrined in Article 24 of the EU Charter and in the United Nations Convention on the Rights of the Child (further elaborated in*** G

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		the UNCRC General Comment No. 25 as regards the digital environment), both of which require consideration of the children's vulnerabilities and provision of such protection and care as necessary for their well-being. The fundamental right to a high level of environmental protection enshrined in the Charter and implemented in Union policies should also be considered when assessing the severity of the harm that an AI system can cause, including in relation to the health and safety of persons or to the environment.		***the UNCRC General Comment No. 25 as regards the digital environment), both of which require consideration of the children's vulnerabilities and provision of such protection and care as necessary for their well-being. The fundamental right to a high level of environmental protection enshrined in the Charter and implemented in Union policies should also be considered when assessing the severity of the harm that an AI system can cause, including in relation to the health and safety of persons.***
Recital 29				
G 39	(29) As regards high-risk AI systems that are safety components of products or systems, or which are themselves products or systems falling within the scope of Regulation (EC) No 300/2008 of the European Parliament and of the Council[1], Regulation (EU) No 167/2013 of the European Parliament and of the Council[2], Regulation (EU) No 168/2013 of the European Parliament and of the Council[3], Directive 2014/90/EU of the European Parliament and of the Council[4], Directive (EU) 2016/797 of the European Parliament and of	(29) As regards high-risk AI systems that are safety components of products or systems, or which are themselves products or systems falling within the scope of Regulation (EC) No 300/2008 of the European Parliament and of the Council[1], Regulation (EU) No 167/2013 of the European Parliament and of the Council[2], Regulation (EU) No 168/2013 of the European Parliament and of the Council[3], Directive 2014/90/EU of the European Parliament and of the Council[4], Directive (EU) 2016/797 of the European Parliament and of	(29) As regards high-risk AI systems that are safety components of products or systems, or which are themselves products or systems falling within the scope of Regulation (EC) No 300/2008 of the European Parliament and of the Council[1], Regulation (EU) No 167/2013 of the European Parliament and of the Council[2], Regulation (EU) No 168/2013 of the European Parliament and of the Council[3], Directive 2014/90/EU of the European Parliament and of the Council[4], Directive (EU) 2016/797 of the European Parliament and of	(29) As regards high-risk AI systems that are safety components of products or systems, or which are themselves products or systems falling within the scope of Regulation (EC) No 300/2008 of the European Parliament and of the Council[1], Regulation (EU) No 167/2013 of the European Parliament and of the Council[2], Regulation (EU) No 168/2013 of the European Parliament and of the Council[3], Directive 2014/90/EU of the European Parliament and of the Council[4], Directive (EU) 2016/797 of the European Parliament and of G

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	the Council[5], Regulation (EU) 2018/858 of the European Parliament and of the Council[6], Regulation (EU) 2018/1139 of the European Parliament and of the Council[7], and Regulation (EU) 2019/2144 of the European Parliament and of the Council[8], it is appropriate to amend those acts to ensure that the Commission takes into account, on the basis of the technical and regulatory specificities of each 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 this Regulation when adopting any relevant future delegated or implementing acts on the basis of those acts. _____ 1. Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72). 2. Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1). 3. Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52).	the Council[5], Regulation (EU) 2018/858 of the European Parliament and of the Council[6], Regulation (EU) 2018/1139 of the European Parliament and of the Council[7], and Regulation (EU) 2019/2144 of the European Parliament and of the Council[8], it is appropriate to amend those acts to ensure that the Commission takes into account, on the basis of the technical and regulatory specificities of each sector, and without interfering with existing governance, conformity assessment, ***market surveillance*** and enforcement mechanisms and authorities established therein, the mandatory requirements for high-risk AI systems laid down in this Regulation when adopting any relevant future delegated or implementing acts on the basis of those acts. _____ 1. Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72). 2. Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1). 3. Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52).	the Council[5], Regulation (EU) 2018/858 of the European Parliament and of the Council[6], Regulation (EU) 2018/1139 of the European Parliament and of the Council[7], and Regulation (EU) 2019/2144 of the European Parliament and of the Council[8], it is appropriate to amend those acts to ensure that the Commission takes into account, on the basis of the technical and regulatory specificities of each 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 this Regulation when adopting any relevant future delegated or implementing acts on the basis of those acts. _____ 1. ***[1]*** Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72). 2. ***[2]*** Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1). 3. ***[3]*** Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60,	the Council[5], Regulation (EU) 2018/858 of the European Parliament and of the Council[6], Regulation (EU) 2018/1139 of the European Parliament and of the Council[7], and Regulation (EU) 2019/2144 of the European Parliament and of the Council[8], it is appropriate to amend those acts to ensure that the Commission takes into account, on the basis of the technical and regulatory specificities of each 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 this Regulation when adopting any relevant future delegated or implementing acts on the basis of those acts. _____ 1. 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	4. Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146). 5. Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44). 6. Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1). 7. Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1). 8. Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament	4. Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146). 5. Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44). 6. Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1). 7. Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1). 8. 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Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1). 8. Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament

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	and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1).	and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1).	(EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1).	and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1). Text Origin: Commission Proposal
Recital 30				
G 40	(30) As regards AI systems that are safety components of products, or which are themselves products, falling within the scope of certain Union harmonisation legislation, it is appropriate to classify them as high-risk under this Regulation if the product in question undergoes the conformity assessment procedure with a third-party conformity assessment body pursuant to that relevant Union harmonisation legislation. In particular, such products are machinery, toys, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, radio equipment, pressure equipment, recreational craft equipment, cableway installations, appliances	(30) As regards AI systems that are safety components of products, or which are themselves products, falling within the scope of certain Union harmonisation ~~legislation~~***law listed in Annex II***, it is appropriate to classify them as high-risk under this Regulation if the product in question undergoes the conformity assessment procedure ***in order to ensure compliance with essential safety requirements*** with a third-party conformity assessment body pursuant to that relevant Union harmonisation ~~legislation~~***law***. In particular, such products are machinery, toys, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, radio equipment, pressure	(30) As regards AI systems that are safety components of products, or which are themselves products, falling within the scope of certain Union harmonisation legislation, it is appropriate to classify them as high-risk under this Regulation if the product in question undergoes the conformity assessment procedure with a third-party conformity assessment body pursuant to that relevant Union harmonisation legislation. In particular, such products are machinery, toys, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, radio equipment, pressure equipment, recreational craft equipment, cableway installations, appliances	(30) As regards AI systems that are safety components of products, or which are themselves products, falling within the scope of certain Union harmonisation legislation ***listed in Annex II***, it is appropriate to classify them as high-risk under this Regulation if the product in question undergoes the conformity assessment procedure with a third-party conformity assessment body pursuant to that relevant Union harmonisation legislation. In particular, such products are machinery, toys, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, radio equipment, pressure equipment, recreational craft equipment, cableway installations, G

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	burning gaseous fuels, medical devices, and in vitro diagnostic medical devices.	equipment, recreational craft equipment, cableway installations, appliances burning gaseous fuels, medical devices, and in vitro diagnostic medical devices.	burning gaseous fuels, medical devices, and in vitro diagnostic medical devices.	appliances burning gaseous fuels, medical devices, and in vitro diagnostic medical devices.
Recital 31				
G 41	(31) The classification of an AI system as high-risk pursuant to this Regulation should not necessarily mean that the product whose safety component is the AI system, or the AI system itself as a product, is considered 'high-risk' under the criteria established in the relevant Union harmonisation legislation that applies to the product. This is notably the case for Regulation (EU) 2017/745 of the European Parliament and of the Council[1] and Regulation (EU) 2017/746 of the European Parliament and of the Council[2], where a third-party conformity assessment is provided for medium-risk and high-risk products. _____ 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). 2. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5	(31) The classification of an AI system as high-risk pursuant to this Regulation should not ~~necessarily~~ mean that the product whose safety component is the AI system, or the AI system itself as a product, is considered 'high-risk' under the criteria established in the relevant Union harmonisation ~~legislation~~***law*** that applies to the product. This is notably the case for Regulation (EU) 2017/745 of the European Parliament and of the Council[1] and Regulation (EU) 2017/746 of the European Parliament and of the Council[2], where a third-party conformity assessment is provided for medium-risk and high-risk products. _____ 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). 2. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5	(31) The classification of an AI system as high-risk pursuant to this Regulation should not necessarily mean that the product whose safety component is the AI system, or the AI system itself as a product, is considered 'high-risk' under the criteria established in the relevant Union harmonisation legislation that applies to the product. This is notably the case for Regulation (EU) 2017/745 of the European Parliament and of the Council[1] and Regulation (EU) 2017/746 of the European Parliament and of the Council[2], where a third-party conformity assessment is provided for medium-risk and high-risk products. _____ 1. ***[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). 2. ***[2]*** Regulation (EU) 2017/746 of the European Parliament and of the Council	(31) The classification of an AI system as high-risk pursuant to this Regulation should not necessarily mean that the product whose safety component is the AI system, or the AI system itself as a product, is considered 'high-risk' under the criteria established in the relevant Union harmonisation legislation that applies to the product. This is notably the case for Regulation (EU) 2017/745 of the European Parliament and of the Council[1] and Regulation (EU) 2017/746 of the European Parliament and of the Council[2], where a third-party conformity assessment is provided for medium-risk and high-risk products. G _____ 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). 2. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5

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	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).	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).	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).	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). Text Origin: Commission Proposal
Recital 32				
G 42	(32) As regards stand-alone AI systems, meaning high-risk AI systems other than those that are safety components of products, or which are themselves products, it is appropriate to classify them as high-risk if, in the light of their intended purpose, they pose a high risk of harm to the health and safety or the fundamental rights of persons, taking into account both the severity of the possible harm and its probability of occurrence and they are used in a number of specifically pre-defined areas specified in the Regulation. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems.	(32) As regards stand-alone AI systems, meaning high-risk AI systems other than those that are safety components of products, or which are themselves products ***and that are listed in one of the areas and use cases in Annex III***, it is appropriate to classify them as high-risk if, in the light of their intended purpose, they pose a ~~high~~***significant*** risk of harm to the health and safety or the fundamental rights of persons ***and, where the AI system is used as a safety component of a critical infrastructure, to the environment . Such significant risk of harm should be identified by assessing on the one hand the effect of such risk with respect to its level of severity, intensity,*** ~~, taking into account both the severity of the possible harm and its~~ probability of occurrence and ~~they are used in a number of specifically pre-defined areas specified in the Regulation~~***duration combined altogether and on the other hand whether the risk can***	(32) As regards ~~stand-alone AI systems, meaning~~ high-risk AI systems other than those that are safety components of products, or which are themselves products, it is appropriate to classify them as high-risk if, in the light of their intended purpose, they pose a high risk of harm to the health and safety or the fundamental rights of persons, taking into account both the severity of the possible harm and its probability of occurrence***,*** and they are used in a number of specifically pre-defined areas specified in the Regulation. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems. ***It is also important to clarify that within the high-risk scenarios referred to in Annex III there may be systems that do not lead to a significant risk to the legal interests protected under those scenarios, taking into account the output produced by the***	(32) As regards stand-alone AI systems, meaning high-risk AI systems other than those that are safety components of products, or which are themselves products, it is appropriate to classify them as high-risk if, in the light of their intended purpose, they pose a high risk of harm to the health and safety or the fundamental rights of persons, taking into account both the severity of the possible harm and its probability of occurrence and they are used in a number of specifically pre-defined areas specified in the Regulation. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems ***that the Commission should be empowered to adopt, via delegated acts, to take into account the rapid pace of technological development, as well as the potential changes in the use of AI systems***. G

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		affect an individual, a plurality of persons or a particular group of persons. Such combination could for instance result in a high severity but low probability to affect a natural person, or a high probability to affect a group of persons with a low intensity over a long period of time, depending on the context. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems.	***AI system. Therefore only when such output has a high degree of importance (i.e. is not purely accessory) in respect of the relevant action or decision so as to generate a significant risk to the legal interests protected, the AI system generating such output should be considered as high-risk. For instance, when the information provided by an AI systems to the human consists of the profiling of natural persons within the meaning of of Article 4(4) Regulation (EU) 2016/679 and Article 3(4) of Directive (EU) 2016/680 and Article 3(5) of Regulation (EU) 2018/1725, such information should not typically be considered of accessory nature in the context of high risk AI systems as referred to in Annex III. However, if the output of the AI system has only negligible or minor relevance for human action or decision, it may be considered purely accessory, including for example, AI systems used for translation for informative purposes or for the management of documents.***	
Recital 32a				
G 42a		***(32a) Providers whose AI systems fall under one of the areas and use cases listed in Annex III that***		***(32a) It is also important to clarify that there may be specific cases in which AI systems referred to pre-*** G

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		consider their system does not pose a significant risk of harm to the health, safety, fundamental rights or the environment should inform the national supervisory authorities by submitting a reasoned notification. This could take the form of a one-page summary of the relevant information on the AI system in question, including its intended purpose and why it would not pose a significant risk of harm to the health, safety, fundamental rights or the environment. The Commission should specify criteria to enable companies to assess whether their system would pose such risks, as well as develop an easy to use and standardised template for the notification. Providers should submit the notification as early as possible and in any case prior to the placing of the AI system on the market or its putting into service, ideally at the development stage, and they should be free to place it on the market at any given time after the notification. However, if the authority estimates the AI system in question was misclassified, it should object to the notification within a period of three months. The objection should be substantiated and duly explain why the AI system has been misclassified. The provider should		***defined areas specified in this Regulation do not lead to a significant risk of harm to the legal interests protected under those areas, because they do not materially influence the decision-making or do not harm those interests substantially. For the purpose of this Regulation an AI system not materially influencing the outcome of decision-making should be understood as an AI system that does not impact the substance, and thereby the outcome, of decision-making, whether human or automated. This could be the case if one or more of the following conditions are fulfilled. The first criterion should be that the AI system is intended to perform a narrow procedural task, such as an AI system that transforms unstructured data into structured data, an AI system that classifies incoming documents into categories or an AI system that is used to detect duplicates among a large number of applications. These tasks are of such narrow and limited nature that they pose only limited risks which are not increased through the use in a context listed in Annex III. The second criterion should be that the task performed by the AI system is intended to improve the result of a previously completed human***

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		retain the right to appeal by providing further arguments. If after the three months there has been no objection to the notification, national supervisory authorities could still intervene if the AI system presents a risk at national level, as for any other AI system on the market. National supervisory authorities should submit annual reports to the AI Office detailing the notifications received and the decisions taken.		***activity that may be relevant for the purpose of the use case listed in Annex III. Considering these characteristics, the AI system only provides an additional layer to a human activity with consequently lowered risk. For example, this criterion would apply to AI systems that are intended to improve the language used in previously drafted documents, for instance in relation to professional tone, academic style of language or by aligning text to a certain brand messaging. The third criterion should be that the AI system is intended to detect decision-making patterns or deviations from prior decision-making patterns. The risk would be lowered because the use of the AI system follows a previously completed human assessment which it is not meant to replace or influence, without proper human review. Such AI systems include for instance those that, given a certain grading pattern of a teacher, can be used to check ex post whether the teacher may have deviated from the grading pattern so as to flag potential inconsistencies or anomalies. The fourth criterion should be that the AI system is intended to perform a task that is only preparatory to an assessment relevant for the purpose of the use case listed in Annex III, thus***

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				making the possible impact of the output of the system very low in terms of representing a risk for the assessment to follow. For example, this criterion covers smart solutions for file handling, which include various functions from indexing, searching, text and speech processing or linking data to other data sources, or AI systems used for translation of initial documents. In any case, AI systems referred to in Annex III should be considered to pose signficant risks of harm to the health, safety or fundamental rights of natural persons if the AI system implies profiling within the meaning of Article 4(4) of Regulation (EU) 2016/679 and Article 3(4) of Directive (EU) 2016/680 and Article 3(5) of Regulation 2018/1725. To ensure traceability and transparency, a provider who considers that an AI system referred to in Annex III is not high-risk on the basis of the aforementioned criteria should draw up documentation of the assessment before that system is placed on the market or put into service and should provide this documentation to national competent authorities upon request. Such provider should be obliged to register the system in the EU database established under this Regulation. With a view to provide

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				further guidance for the practical implementation of the criteria under which AI systems referred to in Annex III are exceptionally not high-risk, the Commission should, after consulting the AI Board, provide guidelines specifying this practical implementation completed by a comprehensive list of practical examples of high risk and non-high risk use cases of AI systems.
Recital 33				
G 43	(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, 'real-time' and 'post' remote biometric identification systems should be classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.	*deleted*	(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, ***race,*** sex or disabilities. Therefore, 'real-time' and 'post' remote biometric identification systems should be classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.	(33) ~~*Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, 'real-time' and 'post' remote biometric identification systems should be classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.*~~ G
Recital 33a				
G 43a		***(33a) As biometric data constitute a special category of sensitive***		***(33a) As biometric data constitutes a special category of sensitive*** G

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		personal data in accordance with Regulation 2016/679, it is appropriate to classify as high-risk several critical use-cases of biometric and biometrics-based systems. AI systems intended to be used for biometric identification of natural persons and AI systems intended to be used to make inferences about personal characteristics of natural persons on the basis of biometric or biometrics-based data, including emotion recognition systems, with the exception of those which are prohibited under this Regulation should therefore be classified as high-risk. This should not include AI systems intended to be used for biometric verification, which includes authentication, whose sole purpose is to confirm that a specific natural person is the person he or she claims to be and to confirm the identity of a natural person for the sole purpose of having access to a service, a device or premises (one-to-one verification). Biometric and biometrics-based systems which are provided for under Union law to enable cybersecurity and personal data protection measures should not be considered as posing a significant risk of harm to the health, safety and fundamental rights.		***personal data, it is appropriate to classify as high-risk several critical use-cases of biometric systems, insofar as their use is permitted under relevant Union and national law.*** ***Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, race, sex or disabilities. Therefore, remote biometric identification systems should be classified as high-risk in view of the risks that they pose. This excludes AI systems intended to be used for biometric verification, which includes authentication, whose sole purpose is to confirm that a specific natural person is the person he or she claims to be and to confirm the identity of a natural person for the sole purpose of having access to a service, unlocking a device or having secure access to premises.*** ***In addition, AI systems intended to be used for biometric categorisation according to sensitive attributes or characteristics protected under Article 9(1) of Regulation (EU) 2016/679 based on biometric data, in so far as these are not prohibited under this Regulation, and emotion***

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				recognition systems that are not prohibited under this Regulation, should be classified as high-risk. Biometric systems which are intended to be used solely for the purpose of enabling cybersecurity and personal data protection measures should not be considered as high risk systems.
Recital 34				
G 44	(34) As regards the management and operation of critical infrastructure, it is appropriate to classify as high-risk the AI systems intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity, since their failure or malfunctioning may put at risk the life and health of persons at large scale and lead to appreciable disruptions in the ordinary conduct of social and economic activities.	(34) As regards the management and operation of critical infrastructure, it is appropriate to classify as high-risk the AI systems intended to be used as safety components in the management and operation of ~~road traffic and~~ the supply of water, gas, heating ***electricity and critical digital infrastructure*** ~~and electricity~~, since their failure or malfunctioning may ***infringe the security and integrity of such critical infrastructure or*** put at risk the life and health of persons at large scale and lead to appreciable disruptions in the ordinary conduct of social and economic activities. ***Safety components of critical infrastructure, including critical digital infrastructure, are systems used to directly protect the physical integrity of critical infrastructure or health and safety of persons and property. Failure or malfunctioning***	(34) As regards the management and operation of critical infrastructure, it is appropriate to classify as high-risk the AI systems intended to be used as safety components in the management and operation of ***critical digital infrastructure as listed in Annex I point 8 of the Directive on the resilience of critical entities,*** road traffic and the supply of water, gas, heating and electricity, since their failure or malfunctioning may put at risk the life and health of persons at large scale and lead to appreciable disruptions in the ordinary conduct of social and economic activities. ***Safety components of critical infrastructure, including critical digital infrastrucure, are systems used to directly protect the physical integrity of critical infrastructure or health and safety of persons and property but which are not***	(34) As regards the management and operation of critical infrastructure, it is appropriate to classify as high-risk the AI systems intended to be used as safety components in the management and operation of ***critical digital infrastructure as listed in Annex I point 8 of the Directive on the resilience of critical entities,*** road traffic and the supply of water, gas, heating and electricity, since their failure or malfunctioning may put at risk the life and health of persons at large scale and lead to appreciable disruptions in the ordinary conduct of social and economic activities. ***Safety components of critical infrastructure, including critical digital infrastrucure, are systems used to directly protect the physical integrity of critical infrastructure or health and safety of persons and property but which are not*** G

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		of such components might directly lead to risks to the physical integrity of critical infrastructure and thus to risks to the health and safety of persons and property. Components intended to be used solely for cybersecurity purposes should not qualify as safety components. Examples of such safety components may include systems for monitoring water pressure or fire alarm controlling systems in cloud computing centres.	***necessary in order for the system to function. Failure or malfunctioning of such components might directly lead to risks to the physical integrity of critical infrastructure and thus to risks to health and safety of persons and property. Components intended to be used solely for cybersecurity purposes should not qualify as safety components. Examples of safety components of such critical infrastructure may include systems for monitoring water pressure or fire alarm controlling systems in cloud computing centres.***	***necessary in order for the system to function. Failure or malfunctioning of such components might directly lead to risks to the physical integrity of critical infrastructure and thus to risks to health and safety of persons and property. Components intended to be used solely for cybersecurity purposes should not qualify as safety components. Examples of safety components of such critical infrastructure may include systems for monitoring water pressure or fire alarm controlling systems in cloud computing centres.***
Recital 35				
G 45	(35) AI systems used in education or vocational training, notably for determining access or assigning persons to educational and vocational training institutions or to evaluate persons on tests as part of or as a precondition for their education should be considered high-risk, since they may determine the educational and professional course of a person's life and therefore affect their ability to secure their livelihood. When improperly designed and used, such systems may violate the right to education and training as well as the right not to be discriminated against and perpetuate historical patterns of	(35) ***Deployment of AI systems in education is important in order to help modernise entire education systems, to increase educational quality, both offline and online and to accelerate digital education, thus also making it available to a broader audience.*** AI systems used in education or vocational training, notably for determining access or ***materially influence decisions on admission or*** assigning persons to educational and vocational training institutions or to evaluate persons on tests as part of or as a precondition for their education ***or to assess the appropriate level of education for an individual and materially***	(35) AI systems used in education or vocational training, notably for determining access***, admission*** or assigning persons to educational and vocational training institutions or ~~to evaluate persons on tests as part of or as a precondition for their education~~***programmes at all levels or to evaluate learning outcomes of persons*** should be considered high-risk, since they may determine the educational and professional course of a person's life and therefore affect their ability to secure their livelihood. When improperly designed and used, such systems may violate the right to education and training as well as the right not	(35) ***Deployment of AI systems in education is important to promote high-quality digital education and training and to allow all learners and teachers to acquire and share the necessary digital skills and competences, including media literacy, and critical thinking, to take an active part in the economy, society, and in democratic processes. However,*** AI systems used in education or vocational training, notably for determining access or ***admission, for*** assigning persons to educational and vocational training institutions or ***programmes at all levels, for evaluating learning outcomes of*** ~~to~~ G

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	discrimination.	***influence the level of education and training that individuals will receive or be able to access or to monitor and detect prohibited behaviour of students during tests*** should be ~~considered high-risk~~***classified as high-risk AI systems***, since they may determine the educational and professional course of a person's life and therefore affect their ability to secure their livelihood. When improperly designed and used, such systems ***can be particularly intrusive and*** may violate the right to education and training as well as the right not to be discriminated against and perpetuate historical patterns of discrimination***, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation***.	to be discriminated against and perpetuate historical patterns of discrimination.	~~evaluate~~ persons***, for assessing the appropriate level of education for an individual and materially influencing the level of education and training that individuals will receive or be able to access or for monitoring and detecting prohibited behaviour of students during tests*** ~~on tests as part of or as a precondition for their education~~ should be ~~considered high-risk~~***classified as high-risk AI systems***, since they may determine the educational and professional course of a person's life and therefore affect their ability to secure their livelihood. When improperly designed and used, such systems ***can be particularly intrusive and*** may violate the right to education and training as well as the right not to be discriminated against and perpetuate historical patterns of discrimination***, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation***.
Recital 36				
G 46	(36) AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making	(36) AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making	(36) AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making	(36) AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making G

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	decisions on promotion and termination and for task allocation, monitoring or evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems may appreciably impact future career prospects and livelihoods of these persons. Relevant work-related contractual relationships should involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. Such persons should in principle not be considered users within the meaning of this Regulation. Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may perpetuate historical patterns of discrimination, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation. AI systems used to monitor the performance and behaviour of these persons may also impact their rights to data protection and privacy.	decisions ***or materially influence decisions on initiation,*** ~~on~~ promotion and termination and for ***personalised*** task allocation ***based on individual behaviour, personal traits or biometric data***, monitoring or evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems may appreciably impact future career prospects ~~and~~***,*** livelihoods of these persons ***and workers' rights***. Relevant work-related contractual relationships should ***meaningfully*** involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. ~~Such persons should in principle not be considered users within the meaning of this Regulation.~~ Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may perpetuate historical patterns of discrimination, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation. AI systems used to monitor the performance and behaviour of these persons may also ~~impact~~***undermine the essence of*** their ***fundamental*** rights to data protection and privacy.	decisions on promotion and termination and for task allocation ***based on individual behavior or personal traits or characteristics***, monitoring or evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems may appreciably impact future career prospects and livelihoods of these persons. Relevant work-related contractual relationships should involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. Such persons should in principle not be considered users within the meaning of this Regulation. Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may perpetuate historical patterns of discrimination, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation. AI systems used to monitor the performance and behaviour of these persons may also impact their rights to data protection and privacy.	decisions ~~on~~ ***affecting terms of the work related relationship*** promotion and termination ~~and for task allocation,~~ ***of work-related contractual relationships for allocating tasks based on individual behaviour, personal traits or characteristics and for*** monitoring or evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems may appreciably impact future career prospects ~~and~~***,*** livelihoods of these persons ***and workers' rights***. Relevant work-related contractual relationships should ***meaningfully*** involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. ~~Such persons should in principle not be considered users within the meaning of this Regulation.~~ Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may perpetuate historical patterns of discrimination, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation. AI systems used to monitor the performance and behaviour of these persons may also ~~impact~~***undermine***

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		This Regulation applies without prejudice to Union and Member State competences to provide for more specific rules for the use of AI-systems in the employment context.		their ***fundamental*** rights to data protection and privacy.
Recital 37				
47	(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the	(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services***, including healthcare services, and essential services, including but not limited to housing, electricity, heating/cooling and internet,*** and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, ***gender,*** disabilities, age,	(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the	(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular,~~ AI systems used to evaluate the credit score or creditworthiness of~~ natural persons ~~should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential~~***applying for or receiving essential public assistance benefits and services from public authorities namely healthcare*** services***, social security benefits, social***~~ such as housing, electricity, and telecommunication~~ services~~. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age,~~

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	market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use. Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they	sexual orientation, or create new forms of discriminatory impacts. ~~Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems~~***However, AI systems provided for by Union law*** for the purpose of ~~creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use~~***detecting fraud in the offering of financial services should not be considered as high-risk under this Regulation***. Natural persons applying for or receiving public assistance benefits and services from public authorities***, including healthcare services and essential services, including but not limited to housing, electricity, heating/cooling and internet,*** are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. ***Similarly, AI systems intended to be used to make***	market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by ~~small-scale providers~~***micro or small entreprises, as defined in the Annex of Commission Recommendation 2003/361/EC*** for their own use. Natural persons applying for or receiving ***essential*** public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, ~~they~~***including whether beneficiaries are legitimately entitled to such benefits or services, those systems*** may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems,	~~sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use. Natural persons applying for or receiving public~~ ***providing protection in cases such as maternity, illness, industrial accidents, dependency or old age and loss of employment and social and housing*** assistance~~ benefits and services from public authorities~~, are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services~~-~~ should be ***granted,*** denied, reduced, revoked or reclaimed by authorities, ~~they~~***including whether beneficiaries are legitimately entitled to such benefits or services, those systems*** may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy~~. Those systems~~ ***and*** should therefore be classified as high-risk. Nonetheless, this Regulation should not hamper the

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	make decisions in very critical situations for the life and health of persons and their property.	***decisions or materially influence decisions on the eligibility of natural persons for health and life insurance may also have a significant impact on persons' livelihood and may infringe their fundamental rights such as by limiting access to healthcare or by perpetuating discrimination based on personal characteristics.*** Those systems should therefore be classified as high-risk. Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used ***to evaluate and classify emergency calls by natural persons or*** to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.	provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property. ***AI systems are also increasingly used for risk assessment in relation to natural persons and pricing in the case of life and health insurance which, if not duly designed, developed and used, can lead to serious consequences for people's life and health, including financial exclusion and discrimination. To ensure a consistent approach within the financial services sector, the above mentioned exception for micro or small enterprises for their own use should apply, insofar as they themselves provide and put into service an AI system for the purpose of selling their own insurance products.***	development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. ***In addition, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, gender, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. However, AI systems provided for by Union law for the purpose of detecting fraud in the offering of financial services and for prudential purposes to calculate credit institutions' and insurances undertakings' capital requirements should not be considered as high-risk under this Regulation. Moreover, AI systems intended to be used for risk assessment and pricing in relation to natural***

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				persons for health and life insurance can also have a significant impact on persons' livelihood and if not duly designed, developed and used, can infringe their fundamental rights and can lead to serious consequences for people's life and health, including financial exclusion and discrimination. -Finally, AI systems used to ***evaluate and classify emergency calls by natural persons or to*** dispatch or establish priority in the dispatching of emergency first response services***, including by police, firefighters and medical aid, as well as of emergency healthcare patient triage systems,*** should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.
Recital 37a				
G 47a		***(37a) Given the role and responsibility of police and judicial authorities, and the impact of decisions they take for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, some specific use-cases of AI applications in law enforcement has to be classified as***		G

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		high-risk, in particular in instances where there is the potential to significantly affect the lives or the fundamental rights of individuals.		
Recital 38				
G 48	(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and documented. It is therefore appropriate to classify as high-risk a	(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its ***performance, its*** accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and documented. It is therefore	(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and documented. It is therefore appropriate to classify as high-risk a	(38) ***Given their role and responsibility,*** actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its ***performance, its*** accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable

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	number of AI systems intended to be used in the law enforcement context where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress. In view of the nature of the activities in question and the risks relating thereto, those high-risk AI systems should include in particular AI systems intended to be used by law enforcement authorities for individual risk assessments, polygraphs and similar tools or to detect the emotional state of natural person, to detect 'deep fakes', for the evaluation of the reliability of evidence in criminal proceedings, for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons, or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups, for profiling in the course of detection, investigation or prosecution of criminal offences, as well as for crime analytics regarding natural persons. AI systems specifically intended to be used for administrative proceedings by tax and customs authorities should not be considered high-risk AI systems used by law enforcement authorities for the purposes of prevention,	appropriate to classify as high-risk a number of AI systems intended to be used in the law enforcement context where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress. In view of the nature of the activities in question and the risks relating thereto, those high-risk AI systems should include in particular AI systems intended to be used by ~~law enforcement authorities for individual risk assessments, polygraphs and similar tools or to detect the emotional state of natural person, to detect 'deep fakes', for the evaluation of the reliability of evidence in criminal proceedings, for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons, or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups~~***or on behalf of law enforcement authorities or by Union agencies, offices or bodies in support of law enforcement authorities, as polygraphs and similar tools insofar as their use is permitted under relevant Union and national law, for the evaluation of the reliability of evidence in criminal proceedings***, for profiling	number of AI systems intended to be used in the law enforcement context where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress. In view of the nature of the activities in question and the risks relating thereto, those high-risk AI systems should include in particular AI systems intended to be used by law enforcement authorities for individual risk assessments, polygraphs and similar tools or to detect the emotional state of natural person, ~~to detect 'deep fakes',~~ for the evaluation of the reliability of evidence in criminal proceedings, for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons, or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups, for profiling in the course of detection, investigation or prosecution of criminal offences~~, as well as for crime analytics regarding natural persons~~. AI systems specifically intended to be used for administrative proceedings by tax and customs authorities ***as well as by financial intelligence units carrying out adminstrative tasks analysing information pursuant to Union***	and documented. It is therefore appropriate to classify as high-risk***, insofar as their use is permitted under relevant Union and national law,*** a number of AI systems intended to be used in the law enforcement context where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress. In view of the nature of the activities in question and the risks relating thereto, those high-risk AI systems should include in particular AI systems intended to be used by ***or on behalf of*** law enforcement authorities ~~for individual risk assessments, polygraphs and similar tools or to detect the emotional state of~~ ***or by Union agencies, offices or bodies in support of law enforcement authorities for assessing the risk of a*** natural person~~, to detect 'deep fakes'~~ ***to become a victim of criminal offences, as polygraphs and similar tools***, for the evaluation of the reliability of evidence in ***in the course of investigation or prosecution of*** criminal ~~proceedings, for predicting the occurrence or reoccurrence of an actual or potential criminal offence~~***offences, and, insofar not prohibited under this regulation, for assessing the***

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	detection, investigation and prosecution of criminal offences.	in the course of detection, investigation or prosecution of criminal offences, as well as for crime analytics regarding natural persons. AI systems specifically intended to be used for administrative proceedings by tax and customs authorities should not be ~~considered~~***classified as*** high-risk AI systems used by law enforcement authorities for the purposes of prevention, detection, investigation and prosecution of criminal offences. ***The use of AI tools by law enforcement and judicial authorities should not become a factor of inequality, social fracture or exclusion. The impact of the use of AI tools on the defence rights of suspects should not be ignored, notably the difficulty in obtaining meaningful information on their functioning and the consequent difficulty in challenging their results in court, in particular by individuals under investigation.***	***anti-money laundering legislation*** should not be considered high-risk AI systems used by law enforcement authorities for the purposes of prevention, detection, investigation and prosecution of criminal offences.	***risk of a natural person of offending or reoffending not solely*** based on profiling of natural persons~~, or~~ ***nor based on*** assessing personality traits and characteristics or past criminal behaviour of natural persons or groups, for profiling in the course of detection, investigation or prosecution of criminal offences, ~~*as well as for crime analytics regarding natural persons*~~. AI systems specifically intended to be used for administrative proceedings by tax and customs authorities ***as well as by financial intelligence units carrying out adminstrative tasks analysing information pursuant to Union anti-money laundering legislation*** should not be ~~considered~~***classified as*** high-risk AI systems used by law enforcement authorities for the purposes of prevention, detection, investigation and prosecution of criminal offences. ***The use of AI tools by law enforcement and authorities should not become a factor of inequality, or exclusion. The impact of the use of AI tools on the defence rights of suspects should not be ignored, notably the difficulty in obtaining meaningful information on the functioning of these systems and the consequent difficulty in challenging their results in court, in particular by individuals under investigation.***

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Recital 39				
G 49	(39) AI systems used in migration, asylum and border control management affect people who are often in particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. It is therefore appropriate to classify as high-risk AI systems intended to be used by the competent public authorities charged with tasks in the fields of migration, asylum and border control management as polygraphs and similar tools or to detect the emotional state of a natural person; for assessing certain risks posed by natural persons entering the territory of a Member State or applying for visa or asylum; for verifying the authenticity of the relevant documents of natural persons; for assisting competent public authorities for the	(39) AI systems used in migration, asylum and border control management affect people who are often in particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. It is therefore appropriate to classify as high-risk AI systems intended to be used by ~~the~~***or on behalf of*** competent public authorities ***or by Union agencies, offices or bodies*** charged with tasks in the fields of migration, asylum and border control management as polygraphs and similar tools ~~or to detect the emotional state of a natural person;~~***insofar as their use is permitted under relevant Union and national law,*** for assessing certain risks posed by natural persons entering the territory of a Member State or applying for visa or asylum;	(39) AI systems used in migration, asylum and border control management affect people who are often in particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. It is therefore appropriate to classify as high-risk AI systems intended to be used by the competent public authorities charged with tasks in the fields of migration, asylum and border control management as polygraphs and similar tools or to detect the emotional state of a natural person; for assessing certain risks posed by natural persons entering the territory of a Member State or applying for visa or asylum; ~~for verifying the authenticity of the relevant documents of natural persons;~~ for assisting competent public authorities for the	(39) AI systems used in migration, asylum and border control management affect people who are often in particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. It is therefore appropriate to classify as high-risk***, insofar as their use is permitted under relevant Union and national law*** AI systems intended to be used by ~~the~~***or on behalf of*** competent public authorities ***or by Union agencies, offices or bodies*** charged with tasks in the fields of migration, asylum and border control management as polygraphs and similar tools ~~or to detect the emotional state of a natural person;~~***,*** for assessing certain risks posed by natural persons entering the territory of a Member State or applying for visa or asylum~~; for verifying the~~ G

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	examination of applications for asylum, visa and residence permits and associated complaints with regard to the objective to establish the eligibility of the natural persons applying for a status. AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council[1], the Regulation (EC) No 810/2009 of the European Parliament and of the Council[2] and other relevant legislation. _____ 1. Directive 2013/32/EU of the European Parliament and of the Council of 26 June 2013 on common procedures for granting and withdrawing international protection (OJ L 180, 29.6.2013, p. 60). 2. Regulation (EC) No 810/2009 of the European Parliament and of the Council of 13 July 2009 establishing a Community Code on Visas (Visa Code) (OJ L 243, 15.9.2009, p. 1).	for verifying the authenticity of the relevant documents of natural persons; for assisting competent public authorities for the examination ***and assessment of the veracity of evidence in relation to*** ~~of~~ applications for asylum, visa and residence permits and associated complaints with regard to the objective to establish the eligibility of the natural persons applying for a status***; for monitoring, surveilling or processing personal data in the context of border management activities, for the purpose of detecting, recognising or identifying natural persons; for the forecasting or prediction of trends related to migration movements and border crossings***. AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council[1], the Regulation (EC) No 810/2009 of the European Parliament and of the Council[2] and other relevant legislation. ***The use of AI systems in migration, asylum and border control management should in no circumstances be used by Member States or Union institutions, agencies or bodies as a means to circumvent their international obligations under the***	examination of applications for asylum, visa and residence permits and associated complaints with regard to the objective to establish the eligibility of the natural persons applying for a status. AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council[1], the Regulation (EC) No 810/2009 of the European Parliament and of the Council[2] and other relevant legislation. _____ 1. Directive 2013/32/EU of the European Parliament and of the Council of 26 June 2013 on common procedures for granting and withdrawing international protection (OJ L 180, 29.6.2013, p. 60). 2. Regulation (EC) No 810/2009 of the European Parliament and of the Council of 13 July 2009 establishing a Community Code on Visas (Visa Code) (OJ L 243, 15.9.2009, p. 1).	~~*authenticity of the relevant documents of natural persons;*~~***,*** for assisting competent public authorities for the examination***, including related assessment of the reliability of evidence, of*** ~~of~~ applications for asylum, visa and residence permits and associated complaints with regard to the objective to establish the eligibility of the natural persons applying for a status***, for the purpose of detecting, recognising or identifying natural persons in the context of migration, asylum and border control management with the exception of travel documents***. AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council[1], the Regulation (EC) No 810/2009 of the European Parliament and of the Council[2] and other relevant legislation. ***The use of AI systems in migration, asylum and border control management should in no circumstances be used by Member States or Union institutions, agencies or bodies as a means to circumvent their international obligations under the Convention of 28 July 1951 relating to the Status of Refugees as amended by the Protocol of 31***

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		Convention of 28 July 1951 relating to the Status of Refugees as amended by the Protocol of 31 January 1967, nor should they be used to in any way infringe on the principle of non-refoulement, or or deny safe and effective legal avenues into the territory of the Union, including the right to international protection. _____ 1. -Directive 2013/32/EU of the European Parliament and of the Council of 26 June 2013 on common procedures for granting and withdrawing international protection (OJ L 180, 29.6.2013, p. 60). 2. -Regulation (EC) No 810/2009 of the European Parliament and of the Council of 13 July 2009 establishing a Community Code on Visas (Visa Code) (OJ L 243, 15.9.2009, p. 1).		***January 1967, nor should they be used to in any way infringe on the principle of non-refoulement, or deny safe and effective legal avenues into the territory of the Union, including the right to international protection.*** _____ 1. -Directive 2013/32/EU of the European Parliament and of the Council of 26 June 2013 on common procedures for granting and withdrawing international protection (OJ L 180, 29.6.2013, p. 60). 2. -Regulation (EC) No 810/2009 of the European Parliament and of the Council of 13 July 2009 establishing a Community Code on Visas (Visa Code) (OJ L 243, 15.9.2009, p. 1).
Recital 40				
G 50	(40) Certain AI systems intended for the administration of justice and democratic processes should be classified as high-risk, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. In particular, to address the risks of potential biases, errors and opacity, it is appropriate to qualify as high-risk AI systems intended to assist judicial authorities in researching and interpreting facts	(40) Certain AI systems intended for the administration of justice and democratic processes should be classified as high-risk, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. In particular, to address the risks of potential biases, errors and opacity, it is appropriate to qualify as high-risk AI systems intended to ***be used by a judicial authority or administrative body or on their***	(40) Certain AI systems intended for the administration of justice and democratic processes should be classified as high-risk, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. In particular, to address the risks of potential biases, errors and opacity, it is appropriate to qualify as high-risk AI systems intended to assist judicial authorities in ~~researching and~~ interpreting facts	(40) Certain AI systems intended for the administration of justice and democratic processes should be classified as high-risk, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. In particular, to address the risks of potential biases, errors and opacity, it is appropriate to qualify as high-risk AI systems intended to ***be used by a judicial authority or on its behalf to*** assist judicial G

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	and the law and in applying the law to a concrete set of facts. Such qualification should not extend, however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks or allocation of resources.	***behalf to*** assist judicial authorities ***or administrative bodies*** in researching and interpreting facts and the law and in applying the law to a concrete set of facts ***or used in a similar way in alternative dispute resolution. The use of artificial intelligence tools can support, but should not replace the decision-making power of judges or judicial independence, as the final decision-making must remain a human-driven activity and decision***. Such qualification should not extend, however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks or allocation of resources.	and the law and in applying the law to a concrete set of facts. Such qualification should not extend, however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks ~~or allocation of resources~~.	authorities- in researching and interpreting facts and the law and in applying the law to a concrete set of facts. ***AI systems intended to be used by alternative dispute resolution bodies for those purposes should also be considered high-risk when the outcomes of the alternative dispute resolution proceedings produce legal effects for the parties. The use of artificial intelligence tools can supportthe decision-making power of judges or judicial independence, but should not replace it, as the final decision-making must remain a human-driven activity and decision.*** Such qualification should not extend, however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks ~~or allocation of resources~~.
Recital 40a				
G 50a		***(40a) In order to address the risks of undue external interference to the right to vote enshrined in Article 39 of the Charter, and of disproportionate effects on***		***(40a) Without prejudice to the rules provided for in [Regulation xxx on the transparency and targeting of political advertising], and in order to address the risks of*** G

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		democratic processes, democracy, and the rule of law, AI systems intended to be used to influence the outcome of an election or referendum or the voting behaviour of natural persons in the exercise of their vote in elections or referenda should be classified as high-risk AI systems. with the exception of AI systems whose output natural persons are not directly exposed to, such as tools used to organise, optimise and structure political campaigns from an administrative and logistical point of view.		***undue external interference to the right to vote enshrined in Article 39 of the Charter, and of adverse effects on democracy, and the rule of law, AI systems intended to be used to influence the outcome of an election or referendum or the voting behaviour of natural persons in the exercise of their vote in elections or referenda should be classified as high-risk AI systems with the exception of AI systems whose output natural persons are not directly exposed to, such as tools used to organise, optimise and structure political campaigns from an administrative and logistical point of view.***
Recital 40b				
G 50b		***(40b) Considering the scale of natural persons using the services provided by social media platforms designated as very large online platforms, such online platforms can be used in a way that strongly influences safety online, the shaping of public opinion and discourse, election and democratic processes and societal concerns. It is therefore appropriate that AI systems used by those online platforms in their recommender systems are subject to this Regulation so as to ensure that the***		G

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		AI systems comply with the requirements laid down under this Regulation, including the technical requirements on data governance, technical documentation and traceability, transparency, human oversight, accuracy and robustness. Compliance with this Regulation should enable such very large online platforms to comply with their broader risk assessment and risk-mitigation obligations in Article 34 and 35 of Regulation EU 2022/2065. The obligations in this Regulation are without prejudice to Regulation (EU) 2022/2065 and should complement the obligations required under the Regulation (EU) 2022/2065 when the social media platform has been designated as a very large online platform. Given the European-wide impact of social media platforms designated as very large online platforms, the authorities designated under Regulation (EU) 2022/2065 should act as enforcement authorities for the purposes of enforcing this provision.		
Recital 41				
G 51	(41) The fact that an AI system is classified as high risk under this Regulation should not be interpreted as indicating that the use of the	(41) The fact that an AI system is classified as ***a*** high risk ***AI system*** under this Regulation should not be interpreted as indicating that the use	(41) The fact that an AI system is classified as high risk under this Regulation should not be interpreted as indicating that the use of the	(41) The fact that an AI system is classified as ***a*** high risk ***AI system*** under this Regulation should not be interpreted as indicating that the use G

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	system is necessarily lawful under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data, on the use of polygraphs and similar tools or other systems to detect the emotional state of natural persons. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of secondary Union law and national law. This Regulation should not be understood as providing for the legal ground for processing of personal data, including special categories of personal data, where relevant.	of the system is necessarily lawful ***or unlawful*** under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data, ~~*on the use of polygraphs and similar tools or other systems to detect the emotional state of natural persons.*~~ Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of secondary Union law and national law. ~~*This Regulation should not be understood as providing for the legal ground for processing of personal data, including special categories of personal data, where relevant.*~~	system is ~~*necessarily*~~ lawful under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data, on the use of polygraphs and similar tools or other systems to detect the emotional state of natural persons. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of secondary Union law and national law. This Regulation should not be understood as providing for the legal ground for processing of personal data, including special categories of personal data, where relevant***, unless it is specifically provided for otherwise in this Regulation***.	of the system is ~~*necessarily*~~ lawful under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data, on the use of polygraphs and similar tools or other systems to detect the emotional state of natural persons. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of secondary Union law and national law. This Regulation should not be understood as providing for the legal ground for processing of personal data, including special categories of personal data, where relevant***, unless it is specifically provided for otherwise in this Regulation***.
Recital 41a				
G 51a		***(41a) A number of legally binding rules at European, national and international level already apply or are relevant to AI systems today, including but not limited to EU primary law (the Treaties of the European Union and its Charter of Fundamental Rights), EU secondary law (such as the General Data Protection Regulation, the Product Liability Directive, the Regulation on the Free Flow of Non-Personal Data, anti-***		G

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		discrimination Directives, consumer law and Safety and Health at Work Directives), the UN Human Rights treaties and the Council of Europe conventions (such as the European Convention on Human Rights), and national law. Besides horizontally applicable rules, various domain-specific rules exist that apply to particular AI applications (such as for instance the Medical Device Regulation in the healthcare sector).		
Recital 42				
G 52	(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory requirements should apply, taking into account the intended purpose of the use of the system and according to the risk management system to be established by the provider.	(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for ~~users~~***deployers*** and affected persons, certain mandatory requirements should apply, taking into account the intended purpose~~ of the use~~***, the reasonably foreseeable misuse*** of the system and according to the risk management system to be established by the provider***. These requirements should be objective-driven, fit for purpose, reasonable and effective, without adding undue regulatory burdens or costs on operators.***	(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market~~ for users and affected persons~~, certain mandatory requirements should apply, taking into account the intended purpose of the use of the system and according to the risk management system to be established by the provider***. In particular, the risk management system should consist of a continuous iterative process planned and run throughout the entire lifecycle of a high-risk AI system. This process should ensure that the provider identifies and analyses the risks to the health, safety and fundamental rights of the persons who may be affected by***	(42) To mitigate the risks from high-risk AI systems placed ~~or otherwise~~***on the market or*** put into service ~~on the Union market for users and affected persons~~***and to ensure a high level of trustworthiness***, certain mandatory requirements should apply***to high risk AI systems***, taking into account the intended purpose ~~of the~~***and the context of*** use of the ***AI*** system and according to the risk management system to be established by the provider***. The measures adopted by the providers to comply with the mandatory requirements of this Regulation should take into account the generally acknowledge state of the art on artificial intelligence, be proportionate and*** G

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			the system in light of its intended purpose, including the possible risks arising from the interaction between the AI system and the environment within which it operates, and accordingly adopts suitable risk management measures in the light of state of the art.	*effective to meet the objectives of this Regulation.* *Following the New Legislative Framework approach, as clarified in Commission notice the 'Blue Guide' on the implementation of EU product rules 2022 (C/2022/3637), the general rule is that several pieces of the EU legislation may have to be taken into consideration for one product, since the making available or putting into service can only take place when the product complies with all applicable Union harmonisation legislation. Hazards of AI systems covered by the requirements of this Regulation concern different aspects than the existing Union harmonisation acts and therefore the requirements of this Regulation would complement the existing body of the Union harmonisation acts. For example, machinery or medical devices products incorporating an AI system might present risks not addressed by the essential health and safety requirements set out in the relevant Union harmonised legislation, as this sectoral legislation does not deal with risks specific to AI systems. This calls for a simultaneous and complementary application of the various legislative acts. To ensure consistency and avoid unnecessary administrative*

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				burden or costs, providers of a product that contains one or more high-risk artificial intelligence system, to which the requirements of this Regulation as well as requirements of the Union harmonisation legislation listed in Annex II, Section A apply, should have a flexibility on operational decisions on how to ensure compliance of a product that contains one or more artificial intelligence systems with all applicable requirements of the Union harmonised legislation in a best way. This flexibility could mean, for example a decision by the provider to integrate a part of the necessary testing and reporting processes, information and documentation required under this Regulation into already existing documentation and procedures required under the existing Union harmonisation legislation listed in Annex II, Section A. This however should not in any way undermine the obligation of the provider to comply with all the applicable requirements.
Recital 42a				
G 52a				***(42a) The risk management system should consist of a continuous, iterative process that is planned and*** G

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				run throughout the entire lifecycle of a high-risk AI system. This process should be aimed at identifying and mitigating the relevant risks of artificial intelligence systems on health, safety and fundamental rights. The risk management system should be regularly reviewed and updated to ensure its continuing effectiveness, as well as justification and documentation of any significant decisions and actions taken subject to this Regulation. This process should ensure that the provider identifies risks or adverse impacts and implements mitigation measures for the known and reasonably foreseeable risks of artificial intelligence systems to the health, safety and fundamental rights in light of its intended purpose and reasonably foreseeable misuse, including the possible risks arising from the interaction between the AI system and the environment within which it operates. The risk management system should adopt the most appropriate risk management measures in the light of the state of the art in AI. When identifying the most appropriate risk management measures, the provider should document and explain the choices made and, when relevant, involve experts and external stakeholders.

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				In identifying reasonably foreseeable misuse of high risk AI systems the provider should cover uses of the AI systems which, while not directly covered by the intended purpose and provided for in the instruction for use may nevertheless be reasonably expected to result from readily predictable human behaviour in the context of the specific characteristics and use of the particular AI system. Any known or foreseeable circumstances, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health and safety or fundamental rights should be included in the instructions for use provided by the provider. This is to ensure that the deployer is aware and takes them into account when using the high-risk AI system. Identifying and implementing risk mitigation measures for foreseeable misuse under this Regulation should not require specific additional training measures for the high-risk AI system by the provider to address them. The providers however are encouraged to consider such additional training measures to mitigate reasonable foreseeable misuses as necessary and

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				appropriate.
Recital 43				
G 53	(43) Requirements should apply to high-risk AI systems as regards the quality of data sets used, technical documentation and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and cybersecurity. Those requirements are necessary to effectively mitigate the risks for health, safety and fundamental rights, as applicable in the light of the intended purpose of the system, and no other less trade restrictive measures are reasonably available, thus avoiding unjustified restrictions to trade.	(43) Requirements should apply to high-risk AI systems as regards the quality ***and relevance*** of data sets used, technical documentation and record-keeping, transparency and the provision of information to ~~users~~***deployers***, human oversight, and robustness, accuracy and cybersecurity. Those requirements are necessary to effectively mitigate the risks for health, safety and fundamental rights, as ***well as the environment, democracy and rule of law, as*** applicable in the light of the intended purpose ***or reasonably foreseeable misuse*** of the system, and no other less trade restrictive measures are reasonably available, thus avoiding unjustified restrictions to trade.	(43) Requirements should apply to high-risk AI systems as regards the quality of data sets used, technical documentation and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and cybersecurity. Those requirements are necessary to effectively mitigate the risks for health, safety and fundamental rights, as applicable in the light of the intended purpose of the system, and no other less trade restrictive measures are reasonably available, thus avoiding unjustified restrictions to trade.	(43) Requirements should apply to high-risk AI systems as regards ***risk management,*** the quality ***and relevance*** of data sets used, technical documentation and record-keeping, transparency and the provision of information to ~~users~~***deployers***, human oversight, and robustness, accuracy and cybersecurity. Those requirements are necessary to effectively mitigate the risks for health, safety and fundamental rights, ~~as applicable in the light of the intended purpose of the system~~, and no other less trade restrictive measures are reasonably available, thus avoiding unjustified restrictions to trade. G
Recital 44				
G 54	(44) High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination	(44) ~~High data~~***Access to data of high*** quality ~~is essential for~~***plays a vital role in providing structure and in ensuring*** the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system	(44) High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination	(44) ***High quality data and access to high*** ~~High data~~ quality ~~is essential for~~***data plays a vital role in providing structure and in ensuring*** the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the G

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	prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant, representative and free of errors and complete in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers shouldbe able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems.	performs as intended and safely and it does not become ~~the~~***a*** source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, ***and where applicable,*** validation and testing data sets***, including the labels,*** should be sufficiently relevant, representative***, appropriately vetted for*** ~~and free of~~ errors and ***as*** complete ***as possible*** in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons ~~on which~~***in relation to whom*** the high-risk AI system is intended to be used***, with specific attention to the mitigation of possible biases in the datasets, that might lead to risks to fundamental rights or discriminatory outcomes for the persons affected by the high-risk AI system. Biases can for example be inherent in underlying datasets, especially when historical data is being used, introduced by the developers of the algorithms, or generated when the systems are implemented in real world settings. Results provided by AI systems are influenced by such inherent biases that are inclined to gradually***	prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant, representative and ***have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These datasets should also be as*** free of errors and complete ***as possible*** in view of the intended purpose of the ~~system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended~~***AI system, taking into account, in a proportionate manner, technical feasibility and state of the art, the availability of data and the implementation of appropriate risk management measures so that possible shortcomings of the datasets are duly addressed. The requirement for the datasets*** to be ~~used. In particular,~~***complete and free of errors should not affect the use of privacy-preserving techniques in the context of the the development and testing of AI systems.*** Training, validation and testing data sets should take into account, to the	high-risk AI system performs as intended and safely and it does not become ~~the~~ ***a*** source of discrimination prohibited by Union law. High quality ***datasets for training, validation and testing require the implementation of appropriate data governance and management practices. Datasets for training, validation and testing, including the labels, should be relevant, sufficiently representative, and to the best extent possible*** ~~training, validation and testing data sets require the implementation of appropriate data governance and management practices. training, validation and testing data sets should be sufficiently relevant, representative and~~ free of errors and complete in view of the intended purpose of the system. ~~They~~***In order to facilitate compliance with EU data protection law, such as Regulation (EU) 2016/679, data governance and management practices should include, in the case of personal data, transparency about the original purpose of the data collection,*** ***The datasets*** should also have the appropriate statistical properties, including as regards the persons or groups of persons ***in relation to whom*** ~~on which~~ the high-risk AI system is intended to be used~~. In particular, training, validation and~~

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		increase and thereby perpetuate and amplify existing discrimination, in particular for persons belonging to certain vulnerable or ethnic groups, or racialised communities. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical***, contextal***, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers ~~shouldbe~~***should, exceptionally and following the application of all applicable conditions laid down under this Regulation and in Regulation (EU) 2016/679, Directive (EU) 2016/680 and Regulation (EU) 2018/1725, be*** able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the ~~bias monitoring,~~***negative bias*** detection and correction in relation to high-risk AI systems. ***Negative bias should be understood as bias that create direct or indirect discriminatory effect against a natural person The requirements related to data governance can be complied with by having recourse to***	extent required ~~in the light of~~***by*** their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers ~~shouldbe~~***should be*** able to process also special categories of personal data, as a matter of substantial public interest ***within the meaning of Article 9(2)(g) of Regulation (EU) 2016/679 and Article 10(2)g) of Regulation (EU) 2018/1725***, in order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems.	~~testing data sets should take into account, to the~~ ***, with specific attention to the mitigation of possible biases in the datasets, that are likely to affect the health and safety of persons, negatively impact fundamental rights or lead to discrimination prohibited under Union law, especially where data outputs influence inputs for future operations ('feedback loops') . Biases can for example be inherent in underlying datasets, especially when historical data is being used, or generated when the systems are implemented in real world settings. Results provided by AI systems could be influenced by such inherent biases that are inclined to gradually increase and thereby perpetuate and amplify existing discrimination, in particular for persons belonging to certain vulnerable groups including racial or ethnic groups. The requirement for the datasets to be to the best extent possible complete and free of errors should not affect the use of privacy-preserving techniques in the context of the development and testing of AI systems. In particular, datasets should take into account, to the extent required by*** ~~extent required in the light of~~ their intended purpose, the features, characteristics or elements that are particular to the specific geographical, ***contextual,***

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		third-parties that offer certified compliance services including verification of data governance, data set integrity, and data training, validation and testing practices.		behavioural or functional setting ~~or context within~~ which the AI system is intended to be used. ~~*In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers shouldbe able to process also special categories of personal*~~***The requirements related to data governance can be complied with by having recourse to third-parties that offer certified compliance services including verification of data governance, data set integrity, and data training, validation and testing practices, as far as compliance with the data requirements of this Regulation are ensured.*** ~~*data, as a matter of substantial public interest, in order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems.*~~
Recital 44a				
G 54a			***(44a) When applying the principles referred to in Article 5(1)(c) of Regulation 2016/679 and Article 4(1)(c) of Regulation 2018/1725, in particular the principle of data minimisation, in regard to training, validation and testing data sets under this Regulation, due regard should be had to the full life cycle***	G

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			of the AI system.	
Recital 45				
55	(45) For the development of high-risk AI systems, certain actors, such as providers, notified bodies and other relevant entities, such as digital innovation hubs, testing experimentation facilities and researchers, should be able to access and use high quality datasets within their respective fields of activities which are related to this Regulation. European common data spaces established by the Commission and the facilitation of data sharing between businesses and with government in the public interest will be instrumental to provide trustful, accountable and non-discriminatory access to high quality data for the training, validation and testing of AI systems. For example, in health, the European health data space will facilitate non-discriminatory access to health data and the training of artificial intelligence algorithms on those datasets, in a privacy-preserving, secure, timely, transparent and trustworthy manner, and with an appropriate institutional governance. Relevant competent authorities, including sectoral ones, providing or supporting the access to data may	(45) For the development ***and assessment*** of high-risk AI systems, certain actors, such as providers, notified bodies and other relevant entities, such as digital innovation hubs, testing experimentation facilities and researchers, should be able to access and use high quality datasets within their respective fields of activities which are related to this Regulation. European common data spaces established by the Commission and the facilitation of data sharing between businesses and with government in the public interest will be instrumental to provide trustful, accountable and non-discriminatory access to high quality data for the training, validation and testing of AI systems. For example, in health, the European health data space will facilitate non-discriminatory access to health data and the training of artificial intelligence algorithms on those datasets, in a privacy-preserving, secure, timely, transparent and trustworthy manner, and with an appropriate institutional governance. Relevant competent authorities, including sectoral ones, providing or supporting the access to data may	(45) For the development of high-risk AI systems, certain actors, such as providers, notified bodies and other relevant entities, such as digital innovation hubs, testing experimentation facilities and researchers, should be able to access and use high quality datasets within their respective fields of activities which are related to this Regulation. European common data spaces established by the Commission and the facilitation of data sharing between businesses and with government in the public interest will be instrumental to provide trustful, accountable and non-discriminatory access to high quality data for the training, validation and testing of AI systems. For example, in health, the European health data space will facilitate non-discriminatory access to health data and the training of artificial intelligence algorithms on those datasets, in a privacy-preserving, secure, timely, transparent and trustworthy manner, and with an appropriate institutional governance. Relevant competent authorities, including sectoral ones, providing or supporting the access to data may	(45) For the development ***and assessment*** of high-risk AI systems, certain actors, such as providers, notified bodies and other relevant entities, such as digital innovation hubs, testing experimentation facilities and researchers, should be able to access and use high quality datasets within their respective fields of activities which are related to this Regulation. European common data spaces established by the Commission and the facilitation of data sharing between businesses and with government in the public interest will be instrumental to provide trustful, accountable and non-discriminatory access to high quality data for the training, validation and testing of AI systems. For example, in health, the European health data space will facilitate non-discriminatory access to health data and the training of artificial intelligence algorithms on those datasets, in a privacy-preserving, secure, timely, transparent and trustworthy manner, and with an appropriate institutional governance. Relevant competent authorities, including sectoral ones, providing or supporting the access to data may

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	also support the provision of high-quality data for the training, validation and testing of AI systems.	also support the provision of high-quality data for the training, validation and testing of AI systems.	also support the provision of high-quality data for the training, validation and testing of AI systems.	also support the provision of high-quality data for the training, validation and testing of AI systems.
Recital 45a				
55a		***(45a) The right to privacy and to protection of personal data must be guaranteed throughout the entire lifecycle of the AI system. In this regard, the principles of data minimisation and data protection by design and by default, as set out in Union data protection law, are essential when the processing of data involves significant risks to the fundamental rights of individuals. Providers and users of AI systems should implement state-of-the-art technical and organisational measures in order to protect those rights. Such measures should include not only anonymisation and encryption, but also the use of increasingly available technology that permits algorithms to be brought to the data and allows valuable insights to be derived without the transmission between parties or unnecessary copying of the raw or structured data themselves.***		***(45a) The right to privacy and to protection of personal data must be guaranteed throughout the entire lifecycle of the AI system. In this regard, the principles of data minimisation and data protection by design and by default, as set out in Union data protection law, are applicable when personal data are processed. Measures taken by providers to ensure compliance with those principles may include not only anonymisation and encryption, but also the use of technology that permits algorithms to be brought to the data and allows training of AI systems without the transmission between parties or copying of the raw or structured data themselves, without prejudice to the requirements on data governance provided for in this Regulation.***
Recital 45b				
55b				

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				44c In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers should, exceptionally, to the extent that it is strictly necessary for the purposes of ensuring bias detection and correction in relation to the high-risk AI systems, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons and following the application of all applicable conditions laid down under this Regulation in addition to the conditions laid down in Regulation (EU) 2016/679, Directive (EU) 2016/680 and Regulation (EU) 2018/1725,be able to process also special categories of personal data, as a matter of substantial public interest within the meaning of Article 9(2)(g) of Regulation (EU) 2016/679 and Article 10(2)g) of Regulation (EU) 2018/1725.
Recital 46				
G 56	(46) Having information on how high-risk AI systems have been developed and how they perform throughout their lifecycle is essential to verify compliance with the requirements under this Regulation. This requires keeping records and the availability of a technical	(46) Having ***comprehensible*** information on how high-risk AI systems have been developed and how they perform throughout their ~~lifecycle~~***lifetime*** is essential to verify compliance with the requirements under this Regulation. This requires keeping records and the availability	(46) Having information on how high-risk AI systems have been developed and how they perform throughout their lifecycle is essential to verify compliance with the requirements under this Regulation. This requires keeping records and the availability of a technical	(46) Having ***comprehensible*** information on how high-risk AI systems have been developed and how they perform throughout their ~~lifecycle~~ ***lifetime*** is essential to ***enable traceability of those systems,*** verify compliance with the requirements under this Regulation, G

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	documentation, containing information which is necessary to assess the compliance of the AI system with the relevant requirements. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date.	of a technical documentation, containing information which is necessary to assess the compliance of the AI system with the relevant requirements. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date ***appropriately throughout the lifecycle of the AI system***. ***AI systems can have a large important environmental impact and high energy consumption during their lifecyle. In order to better apprehend the impact of AI systems on the environment, the technical documentation drafted by providers should include information on the energy consumption of the AI system, including the consumption during development and expected consumption during use. Such information should take into account the relevant Union and national legislation. This reported information should be comprehensible, comparable and verifiable and to that end, the Commission should develop guidelines on a harmonised metholodogy for calculation and reporting of this information. To***	documentation, containing information which is necessary to assess the compliance of the AI system with the relevant requirements. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date. ***Furthermore, providers or users should keep logs automatically generated by the high-risk AI system, including for instance output data, start date and time etc., to the extent that such a system and the related logs are under their control, for a period that is appropriate to enable them to fulfil their obligations.***	***as well as monitoring of their operations and post market monitoring***. This requires keeping records and the availability of a technical documentation, containing information which is necessary to assess the compliance of the AI system with the relevant requirements ***and facilitate post market monitoring***. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used as well as documentation on the relevant risk management system ***and drawn in a clear and comprehensive form.*** The technical documentation should be kept up to date***, appropriately throughout the lifetime of the AI system***. ***Furthermore, high risk AI systems should technically allow for automatic recording of events (logs) over the duration of the lifetime of the system.***

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		ensure that a single documentation is possible, terms and definitions related to the required documentation and any required documentation in the relevant Union legislation should be aligned as much as possible.		
Recital 46a				
G 56a		***(46a) AI systems should take into account state-of-the art methods and relevant applicable standards to reduce the energy use, resource use and waste, as well as to increase their energy efficiency and the overall efficiency of the system. The environmental aspects of AI systems that are significant for the purposes of this Regulation are the energy consumption of the AI system in the development, training and deployment phase as well as the recording and reporting and storing of this data. The design of AI systems should enable the measurement and logging of the consumption of energy and resources at each stage of development, training and deployment. The monitoring and reporting of the emissions of AI systems must be robust, transparent, consistent and accurate. In order to ensure the uniform application of this***		G

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		Regulation and stable legal ecosystem for providers and deployers in the Single Market, the Commission should develop a common specification for the methodology to fulfil the reporting and documentation requirement on the consumption of energy and resources during development, training and deployment. Such common specifications on measurement methodology can develop a baseline upon which the Commission can better decide if future regulatory interventions are needed, upon conducting an impact assessment that takes into account existing law.		
Recital 46b				
G 56b		***(46b) In order to achieve the objectives of this Regulation, and contribute to the Union's environmental objectives while ensuring the smooth functioning of the internal market, it may be necessary to establish recommendations and guidelines and, eventually, targets for sustainability. For that purpose the Commission is entitled to develop a methodology to contribute towards having Key Performance Indicators (KPIs) and a reference for the Sustainable Development Goals***		G

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		(SDGs). The goal should be in the first instance to enable fair comparison between AI implementation choices providing incentives to promote using more efficient AI technologies addressing energy and resource concerns. To meet this objective this Regulation should provide the means to establish a baseline collection of data reported on the emissions from development and training and for deployment.		
Recital 47				
G 57	(47) To address the opacity that may make certain AI systems incomprehensible to or too complex for natural persons, a certain degree of transparency should be required for high-risk AI systems. Users should be able to interpret the system output and use it appropriately. High-risk AI systems should therefore be accompanied by relevant documentation and instructions of use and include concise and clear information, including in relation to possible risks to fundamental rights and discrimination, where appropriate.	(47) To address the opacity that may make certain AI systems incomprehensible to or too complex for natural persons, a certain degree of transparency should be required for high-risk AI systems. Users should be able to interpret the system output and use it appropriately. High-risk AI systems should therefore be accompanied by relevant documentation and instructions of use and include concise and clear information, including in relation to possible risks to fundamental rights and discrimination, where appropriate.	(47) To address the opacity that may make certain AI systems incomprehensible to or too complex for natural persons, a certain degree of transparency should be required for high-risk AI systems. Users should be able to interpret the system output and use it appropriately. High-risk AI systems should therefore be accompanied by relevant documentation and instructions of use and include concise and clear information, including in relation to possible risks to fundamental rights and discrimination ***of the persons who may be affected by the system in light of its intended purpose***, where appropriate. ***To facilitate the understanding of the instructions of***	(47) To address ~~the~~***concerns related to*** opacity ~~that may make~~***and complexity of*** certain AI systems ~~incomprehensible to or too complex for natural persons, a certain degree of~~ ***and help deployers to fulfil their obligations under this Regulation,*** transparency should be required for high-risk AI systems ***before they are placed on the market or put it into service. High-risk AI systems***~~. Users~~ should be ~~able to interpret the~~***designed in a manner to enable deployers to understand how the AI*** system ~~output and use it appropriately. High-risk~~***works, evaluate its functionality, and comprehend its strengths and limitations. High risk*** AI systems***,*** should ~~therefore~~ be accompanied by G

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			use by users, they should contain illustrative examples, as appropriate.	~~*relevant documentation and*~~***appropriate information in the form of*** instructions of use***. Such information should*** ~~*and*~~ include ~~*concise and clear*~~***the characteristics, capabilities and limitations of performance of the AI system. These would cover*** information ***on possible known and foreseeable circumstances related to the use of the high-risk AI system***, including ~~*in relation to possible*~~***deployer action that may influence system behaviour and performance, under which the AI system can lead to*** risks to ***health, safety, and*** fundamental rights***, on the changes that have been pre-determined and assessed for conformity by the provider and on the relevant human oversight measures, including the measures to facilitate the interpretation of the outputs of the AI system by the deployers. Transparency, including the accompanying instructions for use, should assist deployers in the use of the system and support informed decision making by them. Among others, deployers should be in a better position to make the correct choice of the system they intend to use in the light of the obligations applicable to them, be educated about the intended and precluded uses, and use the AI system correctly and as appropriate. In***

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				order to enhance legibility and accessibility of the information included in the instructions of use ~~*and discrimination*~~, where appropriate***, illustrative examples, for instance on the limitations and on the intended and precluded uses of the AI system, should be included. Providers should ensure that all documentation, including the instructions for use, contains meaningful, comprehensive, accessible and understandable information, taking into account the needs and foreseeable knowledge of the target deployers. Instructions for use should be made available in a language which can be easily understood by target deployers, as determined by the Member State concerned.***
Recital 47a				
G 57a		***(47a) Such requirements on transparency and on the explicability of AI decision-making should also help to counter the deterrent effects of digital asymmetry and so-called 'dark patterns' targeting individuals and their informed consent.***		G
Recital 48				
G 58				G

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	(48) High-risk AI systems should be designed and developed in such a way that natural persons can oversee their functioning. For this purpose, appropriate human oversight measures should be identified by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints that cannot be overridden by the system itself and is responsive to the human operator, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role.	(48) High-risk AI systems should be designed and developed in such a way that natural persons can oversee their functioning. For this purpose, appropriate human oversight measures should be identified by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints that cannot be overridden by the system itself and is responsive to the human operator, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role.	(48) High-risk AI systems should be designed and developed in such a way that natural persons can oversee their functioning. For this purpose, appropriate human oversight measures should be identified by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints that cannot be overridden by the system itself and is responsive to the human operator, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role. ***Considering the significant consequences for persons in case of incorrect matches by certain biometric identification systems, it is appropriate to provide for an enhanced human oversight requirement for those systems so that no action or decision may be taken by the user on the basis of the identification resulting from the system unless this has been separately verified and confirmed by at least two natural persons. Those persons could be from one or more entities and include the person operating or using the system. This requirement should not pose unnecessary burden or***	(48) High-risk AI systems should be designed and developed in such a way that natural persons can oversee their functioning***, ensure that they are used as intended and that their impacts are addressed over the system's lifecycle***. For this purpose, appropriate human oversight measures should be identified by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints that cannot be overridden by the system itself and is responsive to the human operator, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role. ***It is also essential, as appropriate, to ensure that high-risk AI systems include mechanisms to guide and inform a natural person to whom human oversight has been assigned to make informed decisions if, when and how to intervene in order to avoid negative consequences or risks, or stop the system if it does not perform as intended. Considering the significant consequences for persons in case of incorrect matches by certain biometric identification systems, it is appropriate to provide for an***

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			delays and it could be sufficient that the separate verifications by the different persons are automatically recorded in the logs generated by the system.	***enhanced human oversight requirement for those systems so that no action or decision may be taken by the deployer on the basis of the identification resulting from the system unless this has been separately verified and confirmed by at least two natural persons. Those persons could be from one or more entities and include the person operating or using the system. This requirement should not pose unnecessary burden or delays and it could be sufficient that the separate verifications by the different persons are automatically recorded in the logs generated by the system. Given the specificities of the areas of law enforcement, migration, border control and asylum, this requirement should not apply in cases where Union or national law considers the application of this requirement to be disproportionate.***
Recital 49				
G 59	(49) High-risk AI systems should perform consistently throughout their lifecycle and meet an appropriate level of accuracy, robustness and cybersecurity in accordance with the generally acknowledged state of the art. The level of accuracy and accuracy	(49) High-risk AI systems should perform consistently throughout their lifecycle and meet an appropriate level of accuracy, robustness and cybersecurity in accordance with the generally acknowledged state of the art. ***Performance metrics and their***	(49) High-risk AI systems should perform consistently throughout their lifecycle and meet an appropriate level of accuracy, robustness and cybersecurity in accordance with the generally acknowledged state of the art. The level of accuracy and accuracy	(49) High-risk AI systems should perform consistently throughout their lifecycle and meet an appropriate level of accuracy, robustness and cybersecurity***, in the light of their intended purpose and*** in accordance with the generally acknowledged state of the art. ***The*** G

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	metrics should be communicated to the users.	***expected level should be defined with the primary objective to mitigate risks and negative impact of the AI system. The expected*** ~~*The*~~ level of ~~*accuracy and accuracy*~~***performance metrics should be communicated in a clear, transparent, easily understandable and intelligible way to the deployers. The declaration of performance*** metrics ***cannot be considered proof of future levels, but relevant methods need to be applied to ensure consistent levels during use While standardisation organisations exist to establish standards, coordination on benchmarking is needed to establish how these standardised requirements and characteristics of AI systems*** should be ~~*communicated to the users*~~***measured. The European Artificial Intelligence Office should bring together national and international metrology and benchmarking authorities and provide non-binding guidance to address the technical aspects of how to measure the appropriate levels of performance and robustness***.	metrics should be communicated to the users.	***Commission and relevant organisations and stakeholders are encouraged to take due consideration of mitigation of risks and negative impacts of the AI system. The expected*** ~~*The*~~ level of ***performance metrics should be declared in the accompanying instructions of use. Providers are urged to communicate this information to deployers in a clear and easily understandable way, free of misunderstandings or misleading statements.*** ***The EU legislation on legal metrology, including on Measuring Instruments Directive (MID) and Non-automatic weighing instruments (NAWI) Directive, aims to ensure the accuracy of measurements and to help the transparency and fairness of commercial transactions. In this context, in cooperation with relevant stakeholders and organisation, such as metrology and benchmarking authorities, the Commission should encourage, as appropriate, the development of benchmarks and measurement methodologies for AI systems. In doing so, the Commission should take note and collaborate with international partners working on metrology and relevant measurement indicators relating to***

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				Artificial Intelligence.~~*accuracy and accuracy metrics should be communicated to the users.*~~
Recital 50				
60	(50) The technical robustness is a key requirement for high-risk AI systems. They should be resilient against risks connected to the limitations of the system (e.g. errors, faults, inconsistencies, unexpected situations) as well as against malicious actions that may compromise the security of the AI system and result in harmful or otherwise undesirable behaviour. Failure to protect against these risks could lead to safety impacts or negatively affect the fundamental rights, for example due to erroneous decisions or wrong or biased outputs generated by the AI system.	(50) The technical robustness is a key requirement for high-risk AI systems. They should be resilient against risks connected to the limitations of the system (e.g. errors, faults, inconsistencies, unexpected situations) as well as against malicious actions that may compromise the security of the AI system and result in harmful or otherwise undesirable behaviour. Failure to protect against these risks could lead to safety impacts or negatively affect the fundamental rights, for example due to erroneous decisions or wrong or biased outputs generated by the AI system. ***Users of the AI system should take steps to ensure that the possible trade-off between robustness and accuracy does not lead to discriminatory or negative outcomes for minority subgroups.***	(50) The technical robustness is a key requirement for high-risk AI systems. They should be resilient ~~against risks connected to the~~***in relation to harmful or otherwise undesirable behaviour that may result from*** limitations ~~*of the system*~~***within the systems or the environment in which the systems operate*** (e.g. errors, faults, inconsistencies, unexpected situations)***. High-risk AI systems should therefore be designed and developed with appropriate technical solutions to prevent or minimize that***~~*as well as against malicious actions that may compromise the security of the AI system and result in*~~ harmful or otherwise undesirable behaviour***, such as for instance mechanisms enabling the system to safely interrupt its operation (fail-safe plans) in the presence of certain anomalies or when operation takes place outside certain predetermined boundaries***. Failure to protect against these risks could lead to safety impacts or negatively affect the fundamental rights, for example	(50) The technical robustness is a key requirement for high-risk AI systems. They should be resilient ~~against risks connected to the~~***in relation to harmful or otherwise undesirable behaviour that may result from*** limitations ~~*of the system*~~***within the systems or the environment in which the systems operate*** (e.g. errors, faults, inconsistencies, unexpected situations)***. Therefore, technical and organisational measures should be taken to ensure robustness of high-risk AI systems, for example by designing and developing appropriate technical solutions to prevent or minimize***~~*as well as against malicious actions that may compromise the security of the AI system and result in*~~ harmful or otherwise undesirable behaviour. ***Those technical solution may include for instance mechanisms enabling the system to safely interrupt its operation (fail-safe plans) in the presence of certain anomalies or when operation takes place outside certain predetermined boundaries.*** Failure to protect

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			due to erroneous decisions or wrong or biased outputs generated by the AI system.	against these risks could lead to safety impacts or negatively affect the fundamental rights, for example due to erroneous decisions or wrong or biased outputs generated by the AI system.
Recital 51				
G 61	(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can leverage AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, suitable measures should therefore be taken by the providers of high-risk AI systems, also taking into account as appropriate the underlying ICT infrastructure.	(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can leverage AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks ***or confidentiality attacks***), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, suitable measures should therefore be taken by the providers of high-risk AI systems, ***as well as the notified bodies, competent national authorities and market surveillance authorities,*** also taking into account as appropriate the underlying ICT infrastructure. ***High-risk AI should be accompanied by security solutions and patches for the***	(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can leverage AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, suitable measures should therefore be taken by the providers of high-risk AI systems, also taking into account as appropriate the underlying ICT infrastructure.	(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can leverage AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks ***or membership inference***), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, suitable measures***, such as security controls,*** should therefore be taken by the providers of high-risk AI systems, also taking into account as appropriate the underlying ICT infrastructure. G

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		lifetime of the product, or in case of the absence of dependence on a specific product, for a time that needs to be stated by the manufacturer.		
Recital 51a				
G 61a				***(51a) Without prejudice to the requirements related to robustness and accuracy set out in this Regulation, high-risk AI systems which fall within the scope of the Regulation 2022/0272, in accordance with Article 8 of the the Regulation 2022/0272 may demonstrate compliance with the cybersecurity requirement of this Regulation by fulfilling the essential cybersecurity requirements set out in Article 10 and Annex I of the Regulation 2022/0272.When high-risk AI systems fulfil the essential requirements of Regulation 2022/0272, they should be deemed compliant with the cybersecurity requirements set out in this Regulation in so far as the achievement of those requirements is demonstrated in the EU declaration of conformity or parts thereof issued under Regulation 2022/0272.*** ***For this purpose, the assessment of the cybersecurity risks, associated*** G

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				to a product with digital elements classified as high-risk AI system according to this Regulation, carried out under Regulation 2022/0272, should consider risks to the cyber resilience of an AI system as regards attempts by unauthorised third parties to alter its use, behaviour or performance, including AI specific vulnerabilities such as data poisoning or adversarial attacks, as well as, as relevant, risks to fundamental rights as required by this Regulation. ***The conformity assessment procedure provided by this Regulation should apply in relation to the essential cybersecurity requirements of a product with digital elements covered by Regulation 2022/0272 and classified as a high-risk AI system under this Regulation. However, this rule should not result in reducing the necessary level of assurance for critical products with digital elements covered by Regulation 2022/0272. Therefore, by way of derogation from this rule, high-risk AI systems that fall within the scope of this Regulation and are also qualified as important and critical products with digital elements pursuant to Regulation 2022/0272 and to which the***

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				conformity assessment procedure based on internal control referred to in Annex VI of this Regulation applies, are subject to the conformity assessment provisions of Regulation 2022/0272 insofar as the essential cybersecurity requirements of Regulation 2022/0272 are concerned. In this case, for all the other aspects covered by this Regulation the respective provisions on conformity assessment based on internal control set out in Annex VI of this Regulation should apply. Building on the knowledge and expertise of ENISA on the cybersecurity policy and tasks assigned to ENISA under the Regulation 2019/1020 the European Commission should cooperate with ENISA on issues related to cybersecurity of AI systems.
Recital 52				
G 62	(52) As part of Union harmonisation legislation, rules applicable to the placing on the market, putting into service and use of high-risk AI systems should be laid down consistently with Regulation (EC) No 765/2008 of the European Parliament and of the Council[1] setting out the requirements for	(52) As part of Union harmonisation legislation, rules applicable to the placing on the market, putting into service and use of high-risk AI systems should be laid down consistently with Regulation (EC) No 765/2008 of the European Parliament and of the Council[1] setting out the requirements for	(52) As part of Union harmonisation legislation, rules applicable to the placing on the market, putting into service and use of high-risk AI systems should be laid down consistently with Regulation (EC) No 765/2008 of the European Parliament and of the Council[1] setting out the requirements for	(52) As part of Union harmonisation legislation, rules applicable to the placing on the market, putting into service and use of high-risk AI systems should be laid down consistently with Regulation (EC) No 765/2008 of the European Parliament and of the Council[1] setting out the requirements for G

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	accreditation and the market surveillance of products, Decision No 768/2008/EC of the European Parliament and of the Council[2] on a common framework for the marketing of products and Regulation (EU) 2019/1020 of the European Parliament and of the Council[3] on market surveillance and compliance of products ('New Legislative Framework for the marketing of products'). _____ 1. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30). 2. Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82). 3. 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 (Text with EEA relevance) (OJ L 169, 25.6.2019, p. 1–44).	accreditation and the market surveillance of products, Decision No 768/2008/EC of the European Parliament and of the Council[2] on a common framework for the marketing of products and Regulation (EU) 2019/1020 of the European Parliament and of the Council[3] on market surveillance and compliance of products ('New Legislative Framework for the marketing of products'). _____ 1. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30). 2. Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82). 3. 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 (Text with EEA relevance) (OJ L 169, 25.6.2019, p. 1–44).	accreditation and the market surveillance of products, Decision No 768/2008/EC of the European Parliament and of the Council[2] on a common framework for the marketing of products and Regulation (EU) 2019/1020 of the European Parliament and of the Council[3] on market surveillance and compliance of products ('New Legislative Framework for the marketing of products'). _____ 1. [1] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30). 2. [2] Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82). 3. [3] 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 (Text with EEA relevance) (OJ L 169, 25.6.2019, p. 1–44).	accreditation and the market surveillance of products, Decision No 768/2008/EC of the European Parliament and of the Council[2] on a common framework for the marketing of products and Regulation (EU) 2019/1020 of the European Parliament and of the Council[3] on market surveillance and compliance of products ('New Legislative Framework for the marketing of products'). _____ 1. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30). 2. Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82). 3. 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 (Text with EEA relevance) (OJ L 169, 25.6.2019, p. 1–44). Text Origin: Commission Proposal
Recital 52a				
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			(52a) In line with New Legislative Framework principles, specific obligations for relevant operators within the AI value chain should be set to ensure legal certainty and facilitate compliance with this Regulation. In certain situations those operators could act in more than one role at the same time and should therefore fufil cumulatively all relevant obligations associated with those roles. For example, an operator could act as a distributor and an importer at the same time.	
Recital 53				
G 63	(53) It is appropriate that a specific natural or legal person, defined as the provider, takes the responsibility for the placing on the market or putting into service of a high-risk AI system, regardless of whether that natural or legal person is the person who designed or developed the system.	(53) It is appropriate that a specific natural or legal person, defined as the provider, takes the responsibility for the placing on the market or putting into service of a high-risk AI system, regardless of whether that natural or legal person is the person who designed or developed the system.	(53) It is appropriate that a specific natural or legal person, defined as the provider, takes the responsibility for the placing on the market or putting into service of a high-risk AI system, regardless of whether that natural or legal person is the person who designed or developed the system.	(53) It is appropriate that a specific natural or legal person, defined as the provider, takes the responsibility for the placing on the market or putting into service of a high-risk AI system, regardless of whether that natural or legal person is the person who designed or developed the system. G
Recital 53a				
G 63a		***(53a) As signatories to the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD), the Union and the Member States are legally obliged to protect persons with disabilities***		***(53a) As signatories to the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD), the Union and the Member States are legally obliged to protect persons with disabilities*** G

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		from discrilmination and promote their equality, to ensure that persons with disabilities have access, on an equal basis wirh others, to information and communications technologies and systems, and to ensure respect for privacy for persons with disabilities. Given the growing importance and use of AI systems, the application of universal design principles to all new technologies and services should ensure full, equal, and unrestricted access for everyone potentially affected by or using AI technologies, including persons with disabilities, in a way that takes full account of their inherent dignity and diversity. It is therefore essential that Providers ensure full compliance with accessibility requirements, including Directive (EU) 2016/2102 and Directive (EU) 2019/882. Providers should ensure compliance with these requirements by design. Therefore, the necessary measures should be integrated as much as possible into the design of the high-risk AI system.		***from discrimination and promote their equality, to ensure that persons with disabilities have access, on an equal basis with others, to information and communications technologies and systems, and to ensure respect for privacy for persons with disabilities. Given the growing importance and use of AI systems, the application of universal design principles to all new technologies and services should ensure full and equal access for everyone potentially affected by or using AI technologies, including persons with disabilities, in a way that takes full account of their inherent dignity and diversity. It is therefore essential that Providers ensure full compliance with accessibility requirements, including Directive (EU) 2016/2102 and Directive (EU) 2019/882. Providers should ensure compliance with these requirements by design. Therefore, the necessary measures should be integrated as much as possible into the design of the high-risk AI system.***
Recital 54				
G 64	(54) The provider should establish a sound quality management system, ensure the accomplishment of the required conformity assessment	(54) The provider should establish a sound quality management system, ensure the accomplishment of the required conformity assessment	(54) The provider should establish a sound quality management system, ensure the accomplishment of the required conformity assessment	(54) The provider should establish a sound quality management system, ensure the accomplishment of the required conformity assessment G

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	procedure, draw up the relevant documentation and establish a robust post-market monitoring system. Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in question.	procedure, draw up the relevant documentation and establish a robust post-market monitoring system. ***For providers that have already in place quality management systems based on standards such as ISO 9001 or other relevant standards, no duplicative quality management system in full should be expected but rather an adaptation of their existing systems to certain aspects linked to compliance with specific requirements of this Regulation. This should also be reflected in future standardization activities or guidance adopted by the Commission in this respect.*** Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in question.	procedure, draw up the relevant documentation and establish a robust post-market monitoring system. Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in question.	procedure, draw up the relevant documentation and establish a robust post-market monitoring system. ***Providers of high risk AI systems that are subject to obligations regarding quality management systems under relevant sectorial Union law should have the possibility to include the elements of the quality management system provided for in this Regulation as part of the existing quality management system provided for in that other sectorial Union legislation. The complementarity between this Regulation and existing sectorial Union law should also be taken into account in future standardization activities or guidance adopted by the Commission.*** Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in question.
Recital 54a				
G 64a			***(54a) To ensure legal certainty, it is***	G

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			necessary to clarify that, under certain specific conditions, any natural or legal person should be considered a provider of a new high-risk AI system and therefore assume all the relevant obligations. For example, this would be the case if that person puts its name or trademark on a high-risk AI system already placed on the market or put into service, or if that person modifies the intended purpose of an AI system which is not high-risk and is already placed on the market or put into service, in a way that makes the modified system a high-risk AI system. These provisions should apply without prejudice to more specific provisions established in certain New Legislative Framework sectorial legislation with which this Regulation should apply jointly. For example, Article 16, paragraph 2 of Regulation 745/2017, establishing that certain changes should not be considered modifications of a device that could affect its compliance with the applicable requirements, should continue to apply to high-risk AI systems that are medical devices within the meaning of that Regulation.	
Recital 54a				
G 64b				G

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Recital 55				
G 65	(55) Where a high-risk AI system that is a safety component of a product which is covered by a relevant New Legislative Framework sectorial legislation is not placed on the market or put into service independently from the product, the manufacturer of the final product as defined under the relevant New Legislative Framework legislation should comply with the obligations of the provider established in this Regulation and notably ensure that the AI system embedded in the final product complies with the requirements of this Regulation.	(55) Where a high-risk AI system that is a safety component of a product which is covered by a relevant New Legislative Framework sectorial legislation is not placed on the market or put into service independently from the product, the manufacturer of the final product as defined under the relevant New Legislative Framework legislation should comply with the obligations of the provider established in this Regulation and notably ensure that the AI system embedded in the final product complies with the requirements of this Regulation.	(55) Where a high-risk AI system that is a safety component of a product which is covered by a relevant New Legislative Framework sectorial legislation is not placed on the market or put into service independently from the product, the ~~manufacturer of the final product~~***product manufacturer*** as defined under the relevant New Legislative Framework legislation should comply with the obligations of the provider established in this Regulation and notably ensure that the AI system embedded in the final product complies with the requirements of this Regulation.		G
Recital 56				
G 66	(56) To enable enforcement of this Regulation and create a level-playing field for operators, and taking into account the different forms of making available of digital products, it is important to ensure that, under all circumstances, a person established in the Union can provide authorities with all the necessary information on the compliance of an AI system.	(56) To enable enforcement of this Regulation and create a level-playing field for operators, and taking into account the different forms of making available of digital products, it is important to ensure that, under all circumstances, a person established in the Union can provide authorities with all the necessary information on the compliance of an AI system.	(56) To enable enforcement of this Regulation and create a level-playing field for operators, and taking into account the different forms of making available of digital products, it is important to ensure that, under all circumstances, a person established in the Union can provide authorities with all the necessary information on the compliance of an AI system.	(56) To enable enforcement of this Regulation and create a level-playing field for operators, and taking into account the different forms of making available of digital products, it is important to ensure that, under all circumstances, a person established in the Union can provide authorities with all the necessary information on the compliance of an AI system. G

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	Therefore, prior to making their AI systems available in the Union, where an importer cannot be identified, providers established outside the Union shall, by written mandate, appoint an authorised representative established in the Union.	Therefore, prior to making their AI systems available in the Union, ~~*where an importer cannot be identified,*~~ providers established outside the Union shall, by written mandate, appoint an authorised representative established in the Union.	Therefore, prior to making their AI systems available in the Union, where an importer cannot be identified, providers established outside the Union shall, by written mandate, appoint an authorised representative established in the Union.	Therefore, prior to making their AI systems available in the Union, ~~*where an importer cannot be identified,*~~ providers established outside the Union shall, by written mandate, appoint an authorised representative established in the Union. ***This authorised representative plays a pivotal role in ensuring the compliance of the high-risk AI systems placed on the market or put into service in the Union by those providers who are not established in the Union and in serving as their contact person established in the Union.***
Recital 56a				
G 66a			***(56a) For providers who are not established in the Union, the authorised representative plays a pivotal role in ensuring the compliance of the high-risk AI systems placed on the market or put into service in the Union by those providers and in serving as their contact person established in the Union. Given that pivotal role, and in order to ensure that responsibility is assumed for the purposes of enforcement of this Regulation, it is appropriate to make the authorised representative jointly and severally liable with the provider for defective high-risk AI***	G

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			systems. The liability of the authorised representative provided for in this Regulation is without prejudice to the provisions of Directive 85/374/EEC on liability for defective products.	
Recital 56a				
G 66b				***(56a) In the light of the nature and complexity of the value chain for AI systems and in line with New Legislative Framework principles, it is essential to ensure legal certainty and facilitate the compliance with this Regulation. Therefore, it is necessary to clarify the role and the specific obligations of relevant operators along the value chain, such as importers and distributors who may contribute to the development of AI systems. In certain situations those operators could act in more than one role at the same time and should therefore fulfil cumulatively all relevant obligations associated with those roles. For example, an operator could act as a distributor and an importer at the same time.*** G
Recital 57				
G 67	(57) In line with New Legislative Framework principles, specific	(57) In line with New Legislative Framework principles, specific	*deleted*	(57) ~~*In line with New Legislative Framework principles,*~~ ***To ensure*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	obligations for relevant economic operators, such as importers and distributors, should be set to ensure legal certainty and facilitate regulatory compliance by those relevant operators.	obligations for relevant economic operators, such as importers and distributors, should be set to ensure legal certainty and facilitate regulatory compliance by those relevant operators.		***legal certainty, it is necessary to clarify that, under certain*** specific ***conditions, any distributor, importer, deployer or other third-party should be considered a provider of a high-risk AI system and therefore assume all the relevant*** obligations***. This would be the case if that party puts its name or trademark on a high-risk AI system already placed on the market or put into service, without prejudice to contractual arrangements stipulating that the obligations are allocated otherwise, or if that party make a substantial modification to a high-risk AI system that has already been placed on the market or has already been put into service and in a way that it remains a high-risk AI system in accordance with Article 6, or if it modifies the intended purpose of an AI system, including a general purpose AI system, which has not been classified as high-risk and has already been placed on the market or put into service, in a way that the AI system becomes a high-risk AI system in accordance with Article 6. These provisions should apply without prejudice to more specific provisions established in certain New Legislative Framework sectorial legislation with which this Regulation should apply jointly. For example, Article 16, paragraph***

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				2 of Regulation 745/2017, establishing that certain changes ~~*for relevant economic operators, such as importers and distributors,*~~ should ***not be considered modifications of a device that could affect its compliance with the applicable requirements, should continue to apply to high-risk AI systems that are medical devices within the meaning of that Regulation***~~*be set to ensure legal certainty and facilitate regulatory compliance by those relevant operators*~~.
Recital 57a				
G 67a				***(57a) General purpose AI systems may be used as high-risk AI systems by themselves or be components of other high risk AI systems. Therefore, due to their particular nature and in order to ensure a fair sharing of responsibilities along the AI value chain, the providers of such systems should, irrespective of whether they may be used as high-risk AI systems as such by other providers or as components of high-risk AI systems and unless provided otherwise under this Regulation, closely cooperate with the providers of the respective high-risk AI systems to enable their compliance with the relevant obligations under*** G

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				this Regulation and with the competent authorities established under this Regulation.
Recital 57b				
G 67b				***(57b) Where, under the conditions laid down in this Regulation, the provider that initially placed the AI system on the market or put it into service should no longer be considered the provider for the purposes of this Regulation, and when that provider has not expressly excluded the change of the AI system into a high-risk AI system, the former provider should nonetheless closely cooperate and 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.*** G
Recital 57c				
G 67c				***(57c) In addition, where a high-risk AI system that is a safety component of a product which is covered by a relevant New Legislative Framework sectorial*** G

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				legislation is not placed on the market or put into service independently from the product, the product manufacturer as defined under the relevant New Legislative Framework legislation should comply with the obligations of the provider established in this Regulation and notably ensure that the AI system embedded in the final product complies with the requirements of this Regulation.
Recital 57d				
G 67d				***(57d) Within the AI value chain multiple parties often supply AI systems, tools and services but also components or processes that are incorporated by the provider into the AI system with various objectives , including the model training, model retraining, model testing and evaluation, integration into software, or other aspects of model development. These parties have an important role in the value chain towards the provider of the high-risk AI system into which their AI systems, tools, services, components or processes are integrated, and should provide by written agreement this provider with the necessary information, capabilities, technical access and other*** G

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				assistance based on the generally acknowledged state of the art, in order to enable the provider to fully comply with the obligations set out in this Regulation, without compromising their own intellectual property rights or trade secrets.
Recital 57e				
G 67e				***(57e) Third parties making accessible to the public tools, services, processes, or AI components other than general-purpose AI models, shall not be mandated to comply with requirements targeting the responsibilities along the AI value chain, in particuliar towards the provider that has used or integrated them, when those tools, services, processes, or AI components are made accessible under a free and open licence. Developers of free and open-source tools, services, processes, or AI components other than general-purpose AI models should be encouraged to implement widely adopted documentation practices, such as model cards and data sheets, as a way to accelerate information sharing along the AI value chain, allowing the promotion of trustworthy AI systems in the Union.*** G

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Recital 57f				
G 67f				***(57f) The Commission could develop and recommend voluntary model contractual terms between providers of high-risk AI systems and third parties that supply tools, services, components or processes that are used or integrated in high-risk AI systems, to facilitate the cooperation along the value chain. When developing voluntary model contractual terms, the Commission should also take into account possible contractual requirements applicable in specific sectors or business cases.***
Recital 58				
G 68	(58) Given the nature of AI systems and the risks to safety and fundamental rights possibly associated with their use, including as regard the need to ensure proper monitoring of the performance of an AI system in a real-life setting, it is appropriate to set specific responsibilities for users. Users should in particular use high-risk AI systems in accordance with the instructions of use and certain other obligations should be provided for with regard to monitoring of the	(58) Given the nature of AI systems and the risks to safety and fundamental rights possibly associated with their use, including as ~~regard~~***regards*** the need to ensure proper monitoring of the performance of an AI system in a real-life setting, it is appropriate to set specific responsibilities for ~~users. Users~~***deployers. Deployers*** should in particular use high-risk AI systems in accordance with the instructions of use and certain other obligations should be provided for with regard	(58) Given the nature of AI systems and the risks to safety and fundamental rights possibly associated with their use, including as regard the need to ensure proper monitoring of the performance of an AI system in a real-life setting, it is appropriate to set specific responsibilities for users. Users should in particular use high-risk AI systems in accordance with the instructions of use and certain other obligations should be provided for with regard to monitoring of the	(58) Given the nature of AI systems and the risks to safety and fundamental rights possibly associated with their use, including as ~~regard~~***regards*** the need to ensure proper monitoring of the performance of an AI system in a real-life setting, it is appropriate to set specific responsibilities for ~~users. Users~~ ***deployers . Deployers*** should in particular ***take appropriate technical and organisational measures to ensure they*** use high-risk AI systems in accordance with

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	functioning of the AI systems and with regard to record-keeping, as appropriate.	to monitoring of the functioning of the AI systems and with regard to record-keeping, as appropriate.	functioning of the AI systems and with regard to record-keeping, as appropriate. ***These obligations should be without prejudice to other user obligations in relation to high-risk AI systems under Union or national law, and should not apply where the use is made in the course of a personal non-professional activity.***	the instructions of use and certain other obligations should be provided for with regard to monitoring of the functioning of the AI systems and with regard to record-keeping, as appropriate. ***Furthermore, deployers should ensure that the persons assigned to implement the instructions for use and human oversight as set out in this Regulation have the necessary competence, in particular an adequate level of AI literacy, training and authority to properly fulfil those tasks. These obligations should be without prejudice to other deployer obligations in relation to high-risk AI systems under Union or national law.***
Recital 58a				
G 68a			***(58a) It is appropriate to clarify that this Regulation does not affect the obligations of providers and users of AI systems in their role as data controllers or processors stemming from Union law on the protection of personal data in so far as the design, the development or the use of AI systems involves the processing of personal data. It is also appropriate to clarify that data subjects continue to enjoy all the rights and guarantees awarded to them by such Union law, including***	G

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			the rights related to solely automated individual decision-making, including profiling. Harmonised rules for the placing on the market, the putting into service and the use of AI systems established under this Regulation should facilitate the effective implementation and enable the exercise of the data subjects' rights and other remedies guaranteed under Union law on the protection of personal data and of other fundamental rights.	
Recital 58b				
G 68b				***(58b) This Regulation is without prejudice to obligations for employers to inform or to inform and consult workers or their representatives under Union or national law and practice, including directive 2002/14/EC on a general framework for informing and consulting employees, on decisions to put into service or use AI systems. It remains necessary to ensure information of workers and their representatives on the planned deployment of high-risk AI systems at the workplace in cases where the conditions for those information or information and consultation obligations in other legal instruments are not fulfilled.*** G

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				Moreover, such information right is ancillary and necessary to the objective of protecting fundamental rights that underlies this Regulation. Therefore, an information requirement to that effect should be laid down in this regulation, without affecting any existing rights of workers.
Recital 58c				
G 68c		***(58a) Whilst risks related to AI systems can result from the way such systems are designed, risks can as well stem from how such AI systems are used. Deployers of high-risk AI system therefore play a critical role in ensuring that fundamental rights are protected, complementing the obligations of the provider when developing the AI system. Deployers are best placed to understand how the high-risk AI system will be used concretely and can therefore identify potential significant risks that were not foreseen in the development phase, due to a more precise knowledge of the context of use, the people or groups of people likely to be affected, including marginalised and vulnerable groups. Deployers should identify appropriate governance structures in that specific context of use, such***		***(58b) Whilst risks related to AI systems can result from the way such systems are designed, risks can as well stem from how such AI systems are used. Deployers of high-risk AI system therefore play a critical role in ensuring that fundamental rights are protected, complementing the obligations of the provider when developing the AI system. Deployers are best placed to understand how the high-risk AI system will be used concretely and can therefore identify potential significant risks that were not foreseen in the development phase, due to a more precise knowledge of the context of use, the people or groups of people likely to be affected, including vulnerable groups. Deployers of high risk AI systems referred to in Annex III also play a critical role in informing natural persons and*** G

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		as arrangements for human oversight, complaint-handling procedures and redress procedures, because choices in the governance structures can be instrumental in mitigating risks to fundamental rights in concrete use-cases. In order to efficiently ensure that fundamental rights are protected, the deployer of high-risk AI systems should therefore carry out a fundamental rights impact assessment prior to putting it into use. The impact assessment should be accompanied by a detailed plan describing the measures or tools that will help mitigating the risks to fundamental rights identified at the latest from the time of putting it into use. If such plan cannot be identified, the deployer should refrain from putting the system into use. When performing this impact assessment, the deployer should notify the national supervisory authority and, to the best extent possible relevant stakeholders as well as representatives of groups of persons likely to be affected by the AI system in order to collect relevant information which is deemed necessary to perform the impact assessment and are encouraged to make the summary of their fundamental rights impact assessment publicly available on their online website. This		*should, when they make decisions or assist in making decisions related to natural persons , where applicable, inform the natural persons that they are subject to the use of the high risk AI system. This information should include the intended purpose and the type of decisions it makes. The deployer should also inform the natural person about its right to an explanation provided under this Regulation. With regard to high risk AI systems used for law enforcement purposes, this obligation should be implemented in accordance with Article 13 of Directive 2016/680.*

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		obligations should not apply to SMEs which, given the lack of resrouces, might find it difficult to perform such consultation. Nevertheless, they should also strive to invole such representatives when carrying out their fundamental rights impact assessment.In addition, given the potential impact and the need for democratic oversight and scrutiny, deployers of high-risk AI systems that are public authorities or Union institutions, bodies, offices and agencies, as well deployers who are undertakings designated as a gatekeeper under Regulation (EU) 2022/1925 should be required to register the use of any high-risk AI system in a public database. Other deployers may voluntarily register.		
Recital 58d				
G 68d				G
Recital 58e				
G 68e				***(58d) Any processing of biometric data involved in the use of AI systems for biometric identification for the purpose of law enforcement needs to comply with Article 10 of Directive (EU) 2016/680, that allows such processing only where strictly necessary, subject to*** G

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				appropriate safeguards for the rights and freedoms of the data subject, and where authorised by Union or Member State law. Such use, when authorized, also needs to respect the principles laid down in Article 4 paragraph 1 of Directive (EU) 2016/680 including lawfulness, fairness and transparency, purpose limitation, accuracy and storage limitation.
Recital 58f				
G 68f				***(58e) Without prejudice to applicable Union law, notably the GDPR and Directive (EU) 2016/680 (the Law Enforcement Directive), considering the intrusive nature of post remote biometric identification systems, the use of post remote biometric identification systems shall be subject to safeguards. Post biometric identification systems should always be used in a way that is proportionate, legitimate and strictly necessary, and thus targeted, in terms of the individuals to be identified, the location, temporal scope and based on a closed dataset of legally acquired video footage. In any case, post remote biometric identification systems should not be used in the framework of law enforcement to lead to indiscriminate surveillance.*** G

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				The conditions for post remote biometric identification should in any case not provide a basis to circumvent the conditions of the prohibition and strict exceptions for real time remote biometric identification
Recital 58g				
G 68g				***(58g) In order to efficiently ensure that fundamental rights are protected, deployers of high-risk AI systems that are bodies governed by public law, or private operators providing public services and operators deploying certain high-risk AI system referred to in Annex III, such as banking or insurance entities, should carry out a fundamental rights impact assessment prior to putting it into use . Services important for individuals that are of public nature may also be provided by private entities. Private operators providing such services of public nature are linked to tasks in the public interest such as in the area of education, healthcare, social services, housing, administration of justice. The aim of the fundamental rights impact assessment is for the deployer to identify the specific risks to the rights of individuals or groups of individuals likely to be affected,*** G

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				identify measures to be taken in case of the materialisation of these risk.The impact assessment should apply to the first use of the high-risk AI system, and should be updated when the deployer considers that any of the relevant factors have changed. The impact assessment should identify the deployer's relevant processes in which the high-risk AI system will be used in line with its intended purpose, and should include a description of the period of time and frequency in which the system is intended to be used as well as of specific categories of natural persons and groups who are likely to be affected in the specific context of use. The assessment should also include the identification of specific risks of harm likely to impact the fundamental rights of these persons or groups. While performing this assessment, the deployer should take into account information relevant to a proper assessment of impact, including but not limited to the information given by the provider of the high-risk AI system in the instructions for use. In light of the risks identified, deployers should determine measures to be taken in case of the materialization of these risks, including for example governance arrangements in that specific context of use, such

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				as arrangements for human oversight according to the instructions of use or, complaint handling and redress procedures, as they could be instrumental in mitigating risks to fundamental rights in concrete use-cases. After performing this impact assessment, the deployer should notify the relevant market surveillance authority. Where appropriate, to collect relevant information necessary to perform the impact assessment, deployers of high-risk AI system, in particular when AI systems are used in the public sector, could involve relevant stakeholders, including the representatives of groups of persons likely to be affected by the AI system, independent experts, and civil society organisations in conducting such impact assessments and designing measures to be taken in the case of materialization of the risks. The AI Office should develop a template for a questionnaire in order to facilitate compliance and reduce the administrative burden for deployers.
Recital 59				
G 69	(59) It is appropriate to envisage that the user of the AI system should	(59) It is appropriate to envisage that the ~~user~~***deployer*** of the AI	*deleted*	

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	be the natural or legal person, public authority, agency or other body under whose authority the AI system is operated except where the use is made in the course of a personal non-professional activity.	system should be the natural or legal person, public authority, agency or other body under whose authority the AI system is operated except where the use is made in the course of a personal non-professional activity.		
Recital 60				
G *70*	*(60)* In the light of the complexity of the artificial intelligence value chain, relevant third parties, notably the ones involved in the sale and the supply of software, software tools and components, pre-trained models and data, or providers of network services, should cooperate, as appropriate, with providers and users to enable their compliance with the obligations under this Regulation and with competent authorities established under this Regulation.	(60) ***Within the AI value chain multiple entities often supply tools and services but also components or processes that are then incorporated by the provider into the AI system, including in relation to data collection and pre-processing, model training, model retraining, model testing and evaluation, integration into software, or other aspects of model development. The involved entities may make their offering commercially available directly or indirectly, through interfaces, such as Application Programming Interfaces (API), and distributed under free and open source licenses but also more and more by AI workforce platforms, trained parameters resale, DIY kits to build models or the offering of paying access to a model serving architecture to develop and train models.*** In the light of ~~*the*~~***this*** complexity of the ~~*artificial*~~	*deleted*	G

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		~~intelligence~~***AI*** value chain, ***all*** relevant third parties, ~~notably the ones~~***in particular those that are*** involved in the ***development,*** sale and the ***commercial*** supply of software~~, software~~ tools~~ and~~***,*** components, pre-trained models ~~and data~~***or data incorporated into the AI system***, or providers of network services, should ***without compromising their own intellectual property rights or trade secrets, make available the required information, training or expertise and*** cooperate, as appropriate, with providers ~~and users~~ to enable their ***control over all*** compliance ~~with the obligations~~***relevant aspects of the AI system that falls*** under this Regulation***. To allow a cost-effective AI value chain governance, the level of control shall be explicitly disclosed by each third party that supplies the provider with a tool, service, component or process that is later incorporated by the provider into the AI system*** ~~and with competent authorities established under this Regulation~~.		
Recital 60ea				
70a		***(60a) Software and data that are openly shared and where users can freely access, use, modify and redistribute them or modified***		

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		versions thereof, can contribute to research and innovation in the market. Research by the Commission also shows that free and open-source software can contribute between EUR 65 billion to EUR 95 billion to the European Union's GDP and that it can provide significant growth opportunities for the European economy. Users are allowed to run, copy, distribute, study, change and improve software and data, including models by way of free and open-source licences. To foster the development and deployment of AI, especially by SMEs, start-ups, academic research but also by individuals, this Regulation should not apply to such free and open-source AI components except to the extent that they are placed on the market or put into service by a provider as part of a high-risk AI system or of an AI system that falls under Title II or IV of this Regulation.		
Recital 60eb				
G 70b		***(60b) Neither the collaborative development of free and open-source AI components nor making them available on open repositories should constitute a placing on the market or putting into service. A***		G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		commercial activity, within the understanding of making available on the market, might however be characterised by charging a price, with the exception of transactions between micro enterprises, for a free and open-source AI component but also by charging a price for technical support services, by providing a software platform through which the provider monetises other services, or by the use of personal data for reasons other than exclusively for improving the security, compatibility or interoperability of the software.		
Recital 60c				
G 70c		***(60c) Where one party is in a stronger bargaining position, there is a risk that that party could leverage such position to the detriment of the other contracting party when negotiating the supply of tools, services, components or processes that are used or integrated in a high risk AI system or the remedies for the breach or the termination of related obligations. Such contractual imbalances particularly harm micro, small and medium-sized enterprises as well as start-ups, unless they are owned or sub-***		G

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		contracted by an enterprise which is able to compensate the sub-contractor appropriately, as they are without a meaningful ability to negotiate the conditions of the contractual agreement, and may have no other choice than to accept 'take-it-or-leave-it' contractual terms. Therefore, unfair contract terms regulating the supply of tools, services, components or processes that are used or integrated in a high risk AI system or the remedies for the breach or the termination of related obligations should not be binding to such micro, small or medium-sized enterprises and start-ups when they have been unilaterally imposed on them.		
Recital 60d				
G 70d		***(60d) Rules on contractual terms should take into account the principle of contractual freedom as an essential concept in business-to-business relationships. Therefore, not all contractual terms should be subject to an unfairness test, but only to those terms that are unilaterally imposed on micro, small and medium-sized enterprises and start-ups. This concerns 'take-it-or-leave-it' situations where one party supplies a certain contractual term and the micro, small or***		G

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		medium-sized enterprise and start-up cannot influence the content of that term despite an attempt to negotiate it. A contractual term that is simply provided by one party and accepted by the micro, small, medium-sized enterprise or a start-up or a term that is negotiated and subsequently agreed in an amended way between contracting parties should not be considered as unilaterally imposed.		
Recital 60e				
G 70e		***(60e) Furthermore, the rules on unfair contractual terms should only apply to those elements of a contract that are related to supply of tools, services, components or processes that are used or integrated in a high risk AI system or the remedies for the breach or the termination of related obligations. Other parts of the same contract, unrelated to these elements, should not be subject to the unfairness test laid down in this Regulation.***		
Recital 60f				
G 70f		***(60f) Criteria to identify unfair contractual terms should be applied only to excessive contractual terms,***		

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		where a stronger bargaining position is abused. The vast majority of contractual terms that are commercially more favourable to one party than to the other, including those that are normal in business-to-business contracts, are a normal expression of the principle of contractual freedom and continue to apply. If a contractual term is not included in the list of terms that are always considered unfair, the general unfairness provision applies. In this regard, the terms listed as unfair terms should serve as a yardstick to interpret the general unfairness provision.		
Recital 60g				
G 70g		***(60g) Foundation models are a recent development, in which AI models are developed from algorithms designed to optimize for generality and versatility of output. Those models are often trained on a broad range of data sources and large amounts of data to accomplish a wide range of downstream tasks, including some for which they were not specifically developed and trained. The foundation model can be unimodal or multimodal, trained through various methods such as supervised***		G

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		learning or reinforced learning. AI systems with specific intended purpose or general purpose AI systems can be an implementation of a foundation model, which means that each foundation model can be reused in countless downstream AI or general purpose AI systems. These models hold growing importance to many downstream applications and systems.		
Recital 60h				
G 70h		***(60h) In the case of foundation models provided as a service such as through API access, the cooperation with downstream providers should extend throughout the time during which that service is provided and supported, in order to enable appropriate risk mitigation, unless the provider of the foundation model transfers the training model as well as extensive and appropriate information on the datasets and the development process of the system or restricts the service, such as the API access, in such a way that the downstream provider is able to fully comply with this Regulation without further support from the original provider of the foundation model.***		G

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Recital 60i				
70i		***(60i) In light of the nature and complexity of the value chain for AI system, it is essential to clarify the role of actors contributing to the development of AI systems. There is significant uncertainty as to the way foundation models will evolve, both in terms of typology of models and in terms of self-governance. Therefore, it is essential to clarify the legal situation of providers of foundation models. Combined with their complexity and unexpected impact, the downstream AI provider's lack of control over the foundation model's development and the consequent power imbalance and in order to ensure a fair sharing of responsibilities along the AI value chain, such models should be subject to proportionate and more specific requirements and obligations under this Regulation, namely foundation models should assess and mitigate possible risks and harms through appropriate design, testing and analysis, should implement data governance measures, including assessment of biases, and should comply with technical design requirements to ensure appropriate levels of performance, predictability, interpretability, corrigibility, safety and***		

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		cybersecurity and should comply with environmental standards. These obligations should be accompanied by standards. Also, foundation models should have information obligations and prepare all necessary technical documentation for potential downstream providers to be able to comply with their obligations under this Regulation. Generative foundation models should ensure transparency about the fact the content is generated by an AI system, not by humans. These specific requirements and obligations do not amount to considering foundation models as high risk AI systems, but should guarantee that the objectives of this Regulation to ensure a high level of protection of fundamental rights, health and safety, environment, democracy and rule of law are achieved. Pre-trained models developed for a narrower, less general, more limited set of applications that cannot be adapted for a wide range of tasks such as simple multi-purpose AI systems should not be considered foundation models for the purposes of this Regulation, because of their greater interpretability which makes their behaviour less unpredictable.		

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Recital 60j				
70j		*(60j) Given the nature of foundation models, expertise in conformity assessment is lacking and third-party auditing methods are still under development . The sector itself is therefore developing new ways to assess fundamental models that fulfil in part the objective of auditing (such as model evaluation, red-teaming or machine learning verification and validation techniques). Those internal assessments for foundation models should be should be broadly applicable (e.g. independent of distribution channels, modality, development methods), to address risks specific to such models taking into account industry state-of-the-art practices and focus on developing sufficient technical understanding and control over the model, the management of reasonably foreseeable risks, and extensive analysis and testing of the model through appropriate measures, such as by the involvement of independent evaluators. As foundation models are a new and fast-evolving development in the field of artificial intelligence, it is appropriate for the Commission and the AI Office to monitor and periodically asses the legislative and governance*		

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		framework of such models and in particular of generative AI systems based on such models, which raise significant questions related to the generation of content in breach of Union law, copyright rules, and potential misuse. It should be clarified that this Regulation should be without prejudice to Union law on copyright and related rights, including Directives 2001/29/EC, 2004/48/ECR and (EU) 2019/790 of the European Parliament and of the Council.		
Recital 60c				
G 70k				***(60a) The notion of general-purpose AI models should be clearly defined and set apart from the notion of AI systems to enable legal certainty. The definition should be based on the key functional characteristics of a general-purpose AI model, in particular the generality and the capability to competently perform a wide range of distinct tasks. These models are typically trained on large amounts of data, through various methods, such as self-supervised, unsupervised or reinforcement learning. General-purpose AI models may be placed on the market in various ways, including through libraries,*** G

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				application programming interfaces (APIs), as direct download, or as physical copy. These models may be further modified or fine-tuned into new models. Although AI models are essential components of AI systems, they do not constitute AI systems on their own. AI models require the addition of further components, such as for example a user interface, to become AI systems. AI models are typically integrated into and form part of AI systems. This Regulation provides specific rules for general purpose AI models and for general purpose AI models that pose systemic risks, which should apply also when these models are integrated or form part of an AI system. It should be understood that the obligations for the providers of general-purpose AI models should apply once the general-purpose AI models are placed on the market. When the provider of a general-purpose AI model integrates an own model into its own AI system that is made available on the market or put into service, that model should be considered as being placed on the market and, therefore, the obligations in this Regulation for models should continue to apply in addition to those for AI systems. The obligations foreseen for models should in any case not apply when

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				an own model is used for purely internal processes that are not essential for providing a product or a service to third parties and the rights of natural persons are not affected. Considering their potential significantly negative effects, the general-purpose AI models with systemic risk should always be subject to the relevant obligations under this Regulation. The definition should not cover AI models used before their placing on the market for the sole purpose of research, development and prototyping activities. This is without prejudice to the obligation to comply with this Regulation when, following such activities, a model is placed on the market. Text Origin: GSC
Recital 60d				
70l				***(60b) Whereas the generality of a model could, among other criteria, also be determined by a number of parameters, models with at least a billion of parameters and trained with a large amount of data using self-supervision at scale should be considered as displaying significant generality and competently performing a wide range of distinctive tasks.***

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				Text Origin: GSC
Recital 60e				
G 70m				***(60c) Large generative AI models are a typical example for a general-purpose AI model, given that they allow for flexible generation of content (such as in the form of text, audio, images or video) that can readily accommodate a wide range of distinctive tasks.*** Text Origin: GSC
Recital 60f				
G 70n				
Recital 60g				
G 70o				***(60d) When a general-purpose AI model is integrated into or forms part of an AI system, this system should be considered a general-purpose AI system when, due to this integration, this system has the capability to serve a variety of purposes. A general-purpose AI system can be used directly, or it may be integrated into other AI systems.*** Text Origin: GSC

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Recital 60h				
G 70p				*(60e) Providers of general-purpose AI models have a particular role and responsibility in the AI value chain, as the models they provide may form the basis for a range of downstream systems, often provided by downstream providers that necessitate a good understanding of the models and their capabilities, both to enable the integration of such models into their products, and to fulfil their obligations under this or other regulations. Therefore, proportionate transparency measures should be foreseen, including the drawing up and keeping up to date of documentation, and the provision of information on the general purpose AI model for its usage by the downstream providers. Technical documentation should be prepared and kept up to date by the general purpose AI model provider for the purpose of making it available, upon request, to the AI Office and the national competent authorities. The minimal set of elements contained in such documentations should be outlined, respectively, in Annex (XY) and Annex (XX). The Commission should be enabled to amend the Annexes by delegated acts in the light of the evolving technological* G

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				developments. Text Origin: GSC
Recital 60i				
G 70q				***(60i) Software and data, including models, released under a free and open-source licence that allows them to be openly shared and where users can freely access, use, modify and redistribute them or modified versions thereof, can contribute to research and innovation in the market and can provide significant growth opportunities for the Union economy. General purpose AI models released under free and open-source licences should be considered to ensure high levels of transparency and openness if their parameters, including the weights, the information on the model architecture, and the information on model usage are made publicly available. The licence should be considered free and open-source also when it allows users to run, copy, distribute, study, change and improve software and data, including models under the condition that the original provider of the model is credited, the identical or comparable terms of distribution are respected.*** G

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				(60i+1) Free and open-source AI components covers the software and data, including models and general purpose AI models, tools, services or processes of an AI system. Free and open-source AI components can be provided through different channels, including their development on open repositories. For the purpose of this Regulation, AI components that are provided against a price or otherwise monetised, including through the provision of technical support or other services, including through a software platform, related to the AI component, or the use of personal data for reasons other than exclusively for improving the security, compatibility or interoperability of the software, with the exception of transactions between micro enterprises, should not benefit from the exceptions provided to free and open source AI components. The fact of making AI components available through open repositories should not, in itself, constitute a monetisation.
Recital 60f				
G 70r				***(60f) The providers of general purpose AI models that are released under a free and open source license, and whose parameters,*** G

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				including the weights, the information on the model architecture, and the information on model usage, are made publicly available should be subject to exceptions as regards the transparency-related requirements imposed on general purpose AI models, unless they can be considered to present a systemic risk, in which case the circumstance that the model is transparent and accompanied by an open source license should not be considered a sufficient reason to exclude compliance with the obligations under this Regulation. ***In any case, given that the release of general purpose AI models under free and open source licence does not necessarily reveal substantial information on the dataset used for the training or fine-tuning of the model and on how thereby the respect of copyright law was ensured, the exception provided for general purpose AI models from compliance with the tranparency-related requirements should not concern the obligation to produce a summary about the content used for model training and the obligation to put in place a policy to respect Union copyright law in particular to identify and respect the reservations of rights expressed***

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				pursuant to Article 4(3) of Directive (EU) 2019/790. Text Origin: GSC
Recital 60g				
G 70s				***(60g) Compliance with the obligations foreseen for the providers of general-purpose AI models should be commensurate and proportionate to the type of model provider, excluding the need for compliance for persons who develop or use models for non-professional or scientific research purposes, who should nevertheless be encouraged to voluntarily comply with these requirements. Without prejudice to Union Copyright law, compliance with these obligations should take due account of the size of the provider and allow simplified ways of compliance for SMEs including start-ups, that should not represent an excessive cost and not discourage the use of such models. In case of a modification or fine-tuning of a model, the obligations for providers should be limited to that modification or fine-tuning, for example by complementing the already existing technical documentation with information on the modifications, including new*** G

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				training data sources, as a means to comply with the value chain obligations provided in this Regulation. Text Origin: GSC
Recital 60l				
G 70t				
Recital 60i				
G 70u				***(60i) General-purpose models, in particular large generative models, capable of generating text, images, and other content, present unique innovation opportunities but also challenges to artists, authors, and other creators and the way their creative content is created, distributed, used and consumed. The development and training of such models require access to vast amounts of text, images, videos, and other data. Text and data mining techniques may be used extensively in this context for the retrieval and analysis of such content, which may be protected by copyright and related rights. Any use of copyright protected content requires the authorization of the rightholder concerned unless relevant copyright exceptions and limitations apply.***

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				Directive (EU) 2019/790 introduced exceptions and limitations allowing reproductions and extractions of works or other subject matter, for the purposes of text and data mining, under certain conditions. Under these rules, rightholders may choose to reserve their rights over their works or other subject matter to prevent text and data mining, unless this is done for the purposes of scientific research. Where the rights to opt out has been expressly reserved in an appropriate manner, providers of general-purpose AI models need to obtain an authorisation from rightholders if they want to carry out text and data mining over such works. Text Origin: GSC
Recital 60j				
G 70v				***(60j) Providers that place general purpose AI models on the EU market should ensure compliance with the relevant obligations in this Regulation. For this purpose, providers of general purpose AI models should put in place a policy to respect Union law on copyright and related rights, in particular to identify and respect the reservations of rights expressed by rightholders pursuant to Article 4(3) of Directive*** G

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				(EU) 2019/790. Any provider placing a general purpose AI model on the EU market should comply with this obligation, regardless of the jurisdiction in which the copyright-relevant acts underpinning the training of these general purpose AI models take place. This is necessary to ensure a level playing field among providers of general purpose AI models where no provider should be able to gain a competitive advantage in the EU market by applying lower copyright standards than those provided in the Union. Text Origin: GSC
Recital 60k				
G 70w				***(60k) In order to increase transparency on the data that is used in the pre-training and training of general purpose AI models, including text and data protected by copyright law, it is adequate that providers of such models draw up and make publicly available a sufficiently detailed summary of the content used for training the general purpose model. While taking into due account the need to protect trade secrets and confidential business information, this summary should be generally*** G

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				comprehensive in its scope instead of technically detailed to facilitate parties with legitimate interests, including copyright holders, to exercise and enforce their rights under Union law, for example by listing the main data collections or sets that went into training the model, such as large private or public databases or data archives, and by providing a narrative explanation about other data sources used. It is appropriate for the AI Office to provide a template for the summary, which should be simple, effective, and allow the provider to provide the required summary in narrative form. Text Origin: GSC
Recital 60ka				
G 70x				***(60ka) With regard to the obligations imposed on providers of general-purpose AI models to put in place a policy to respect Union copyright law and make publicly available a summary of the content used for the training, the AI Office should monitor whether the provider has fulfilled those obligations without verifying or proceeding to a work-by-work assessment of the training data in terms of copyright compliance. This*** G

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				Regulation does not affect the enforcement of copyright rules as provided for under Union law.
Recital 60l				
G 70y				Text Origin: GSC
Recital 60m				
G 70z				***(60m) General-purpose AI models could pose systemic risks which include, but are not limited to, any actual or reasonably foreseeable negative effects in relation to major accidents, disruptions of critical sectors and serious consequences to public health and safety; any actual or reasonably foreseeable negative effects on democratic processes, public and economic security; the dissemination of illegal, false, or discriminatory content. Systemic risks should be understood to increase with model capabilities and model reach, can arise along the entire lifecycle of the model, and are influenced by conditions of misuse, model reliability, model fairness and model security, the degree of autonomy of the model, its access to tools, novel or combined modalities, release and distribution strategies, the potential***

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				to remove guardrails and other factors. In particular, international approaches have so far identified the need to devote attention to risks from potential intentional misuse or unintended issues of control relating to alignment with human intent; chemical, biological, radiological, and nuclear risks, such as the ways in which barriers to entry can be lowered, including for weapons development, design acquisition, or use; offensive cyber capabilities, such as the ways in vulnerability discovery, exploitation, or operational use can be enabled; the effects of interaction and tool use, including for example the capacity to control physical systems and interfere with critical infrastructure; risks from models of making copies of themselves or "self-replicating" or training other models; the ways in which models can give rise to harmful bias and discrimination with risks to individuals, communities or societies; the facilitation of disinformation or harming privacy with threats to democratic values and human rights; risk that a particular event could lead to a chain reaction with considerable negative effects that could affect up to an entire city, an entire domain activity or an entire community.

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				Text Origin: GSC
Recital 60n				
G 70aa				***(60n) It is appropriate to establish a methodology for the classification of general-purpose AI models as general-purpose AI model with systemic risks. Since systemic risks result from particularly high capabilities, a general-purpose AI models should be considered to present systemic risks if it has high-impact capabilities, evaluated on the basis of appropriate technical tools and methodologies, or significant impact on the internal market due to its reach. High-impact capabilities in general purpose AI models means capabilities that match or exceed the capabilities recorded in the most advanced general-purpose AI models. The full range of capabilities in a model could be better understood after its release on the market or when users interact with the model. According to the state of the art at the time of entry into force of this Regulation, the cumulative amount of compute used for the training of the general-purpose AI model measured in floating point operations (FLOPs) is one of the relevant*** G

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				approximations for model capabilities. The amount of compute used for training cumulates the compute used across the activities and methods that are intended to enhance the capabilities of the model prior to deployment, such as pre-training, synthetic data generation and fine-tuning. Therefore, an initial threshold of FLOPs should be set, which, if met by a general-purpose AI model, leads to a presumption that the model is a general-purpose AI model with systemic risks. This threshold should be adjusted over time to reflect technological and industrial changes, such as algorithmic improvements or increased hardware efficiency, and should be supplemented with benchmarks and indicators for model capability. To inform this, the AI Office should engage with the scientific community, industry, civil society and other experts. Thresholds, as well as tools and benchmarks for the assessment of high-impact capabilities, should be strong predictors of generality, its capabilities and associated systemic risk of general-purpose AI models, and could take into taking into account the way the model will be placed on the market or the number of users it may affect. To complement this system, there

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				should be a possibility for the Commission to take individual decisions designating a general-purpose AI model as a general-purpose AI model with systemic risk if it is found that such model has capabilities or impact equivalent to those captured by the set threshold. This decision should be taken on the basis of an overall assessment of the criteria set out in Annex YY, such as quality or size of the training data set, number of business and end users, its input and output modalities, its degree of autonomy and scalability, or the tools it has access to. Upon a reasoned request of a provider whose model has been designated as a general-purpose AI model with systemic risk, the Commission should take the request into account and may decide to reassess whether the general-purpose AI model can still be considered to present systemic risks. Text Origin: GSC
Recital 60o				
G 70ab				***(60o) It is also necessary to clarify a procedure for the classification of a general purpose AI model with systemic risks. A general purpose AI model that meets the applicable*** G

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				threshold for high-impact capabilities should be presumed to be a general purpose AI models with systemic risk. The provider should notify the AI Office at the latest two weeks after the requirements are met or it becomes known that a general purpose AI model will meet the requirements that lead to the presumption. This is especially relevant in relation to the FLOP threshold because training of general purpose AI models takes considerable planning which includes the upfront allocation of compute resources and, therefore, providers of general purpose AI models are able to know if their model would meet the threshold before the training is completed. In the context of this notification, the provider should be able to demonstrate that because of its specific characteristics, a general purpose AI model exceptionally does not present systemic risks, and that it thus should not be classified as a general purpose AI model with systemic risks. This information is valuable for the AI Office to anticipate the placing on the market of general purpose AI models with systemic risks and the providers can start to engage with the AI Office early on. This is especially important with regard to general-purpose AI models that are planned

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				to be released as open-source, given that, after open-source model release, necessary measures to ensure compliance with the obligations under this Regulation may be more difficult to implement. Text Origin: GSC
Recital 60p				
G 70ac				***(60p) If the Commission becomes aware of the fact that a general-purpose AI model meets the requirements to classify as a general-purpose model with systemic risk, which previously had either not been known or of which the relevant provider has failed to notify the Commission, the Commission should be empowered to designate it so. A system of qualified alerts should ensure that the AI Office is made aware by the scientific panel of general-purpose AI models that should possibly be classified as general-purpose AI models with systemic risk, in addition to the monitoring activities of the AI Office.*** Text Origin: GSC
Recital 60q				
G 70ad				***(60q) The providers of general-***

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				purpose AI models presenting systemic risks should be subject, in addition to the obligations provided for providers of general-purpose AI models, to obligations aimed at identifying and mitigating those risks and ensuring an adequate level of cybersecurity protection, regardless of whether it is provided as a standalone model or embedded in an AI system or a product. To achieve these objectives, the Regulation should require providers to perform the necessary model evaluations, in particular prior to its first placing on the market, including conducting and documenting adversarial testing of models, also, as appropriate, through internal or independent external testing. In addition, providers of general-purpose AI models with systemic risks should continuously assess and mitigate systemic risks, including for example by putting in place risk management policies, such as accountability and governance processes, implementing post-market monitoring, taking appropriate measures along the entire model's lifecycle and cooperating with relevant actors across the AI value chain. Text Origin: GSC

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Recital 60r				
G 70ae				***(60r) Providers of general purpose AI models with systemic risks should assess and mitigate possible systemic risks. If, despite efforts to identify and prevent risks related to a general-purpose AI model that may present systemic risks, the development or use of the model causes a serious incident, the general purpose AI model provider should without undue delay keep track of the incident and report any relevant information and possible corrective measures to the Commission and national competent authorities. Furthermore, providers should ensure an adequate level of cybersecurity protection for the model and its physical infrastructure, if appropriate, along the entire model lifecycle. Cybersecurity protection related to systemic risks associated with malicious use of or attacks should duly consider accidental model leakage, unsanctioned releases, circumvention of safety measures, and defence against cyberattacks, unauthorised access or model theft. This protection could be facilitated by securing model weights, algorithms, servers, and datasets, such as through operational security measures for information*** G

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				security, specific cybersecurity policies, adequate technical and established solutions, and cyber and physical access controls, appropriate to the relevant circumstances and the risks involved. Text Origin: GSC
Recital 60x				
G 70af				***(60s) The AI Office should encourage and facilitate the drawing up, review and adaptation of Codes of Practice, taking into account international approaches. All providers of general-purpose AI models could be invited to participate. To ensure that the Codes of Practice reflect the state of the art and duly take into account a diverse set of perspectives, the AI Office should collaborate with relevant national competent authorities, and could, where appropriate, consult with civil society organisations and other relevant stakeholders and experts, including the Scientific Panel, for the drawing up of the Codes. Codes of Practice should cover obligations for providers of general-purpose AI models and of general-purpose models presenting systemic risks. In addition, as regards systemic risks,*** G

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				Codes of Practice should help to establish a risk taxonomy of the type and nature of the systemic risks at Union level, including their sources. Codes of practice should also be focused on specific risk assessment and mitigation measures. Text Origin: GSC
Recital 60t				
G 70ag				***(60t) The Codes of Practice should represent a central tool for the proper compliance with the obligations foreseen under this Regulation for providers of general-purpose AI models. Providers should be able to rely on Codes of Practice to demonstrate compliance with the obligations. By means of implementing acts, the Commission may decide to approve a code of practice and give it a general validity within the Union, or, alternatively, to provide common rules for the implementation of the relevant obligations, if, by the time the Regulation becomes applicable, a Code of Practice cannot be finalised or is not deemed adequate by the AI Office. Once a harmonised standard is published and assessed as suitable to cover the relevant obligations by the AI*** G

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				Office, the compliance with a European harmonised standard should grant providers the presumption of conformity. Providers of general-purpose AI models should furthermore be able to demonstrate compliance using alternative adequate means, if codes of practice or harmonized standards are not available, or they choose not to rely on those. Text Origin: GSC
Recital 60u				
G 70ah				***(60u) This Regulation regulates AI systems and models by imposing certain requirements and obligations for relevant market actors that are placing them on the market, putting into service or use in the Union, thereby complementing obligations for providers of intermediary services that embed such systems or models into their services regulated by Regulation (EU) 2022/2065. To the extent that such systems or models are embedded into designated very large online platforms or very large online search engines, they are subject to the risk management framework provided for in Regulation (EU) 2022/2065. Consequently, the corresponding*** G

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				obligations of the AI Act should be presumed to be fulfilled, unless significant systemic risks not covered by Regulation (EU) 2022/2065 emerge and are identified in such models. Within this framework, providers of very large online platforms and very large search engines are obliged to assess potential systemic risks stemming from the design, functioning and use of their services, including how the design of algorithmic systems used in the service may contribute to such risks, as well as systemic risks stemming from potential misuses. Those providers are also obliged to take appropriate mitigating measures in observance of fundamental rights. Text Origin: GSC
Recital 60aa				
G 70ai				***(60aa) Considering the quick pace of innovation and the technological evolution of digital services in scope of different instruments of Union law in particular having in mind the usage and the perception of their recipients, the AI systems subject to this Regulation may be provided as intermediary services or parts thereof within the meaning of*** G

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				Regulation (EU) 2022/2065, which should be interpreted in a technology-neutral manner. For example, AI systems may be used to provide online search engines, in particular, to the extent that an AI system such as an online chatbot performs searches of, in principle, all websites, then incorporates the results into its existing knowledge and uses the updated knowledge to generate a single output that combines different sources of information.
Recital 60v				
G 70aj				***(60v) Furthermore, obligations placed on providers and deployers of certain AI systems in this Regulation to enable the detection and disclosure that the outputs of those systems are artificially generated or manipulated are particularly relevant to facilitate the effective implementation of Regulation (EU) 2022/2065. This applies in particular as regards the obligations of providers of very large online platforms or very large online search engines to identify and mitigate systemic risks that may arise from the dissemination of content that has been artificially generated or manipulated, in particular risk of the actual or*** G

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				foreseeable negative effects on democratic processes, civic discourse and electoral processes, including through disinformation. Text Origin: GSC
Recital 61				
71	(61) Standardisation should play a key role to provide technical solutions to providers to ensure compliance with this Regulation. Compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council[1] should be a means for providers to demonstrate conformity with the requirements of this Regulation. However, the Commission could adopt common technical specifications in areas where no harmonised standards exist or where they are insufficient. 1. Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the	(61) Standardisation should play a key role to provide technical solutions to providers to ensure compliance with this Regulation. Compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council[1] should be a means for providers to demonstrate conformity with the requirements of this Regulation. ~~*However, the Commission could adopt common technical specifications in areas where no harmonised standards exist or where they are insufficient*~~***To ensure the effectiveness of standards as policy tool for the Union and considering the importance of standards for ensuring conformity with the requirements of this Regulation and for the competitiveness of undertakings, it is necessary to ensure a balanced representation of interests by involving all relevant stakeholders in the development of standards. The standardisation***	(61) Standardisation should play a key role to provide technical solutions to providers to ensure compliance with this Regulation***, in line with the state of the art***. Compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council[1]***, which are normally expected to reflect the state of the art,*** should be a means for providers to demonstrate conformity with the requirements of this Regulation. However, ***in the absence of relevant references to harmonised standards,*** the Commission ~~*could adopt*~~***should be able to establish, via implementing acts,*** common ~~*technical specifications in areas where no*~~***specifications for certain requirements under this Regulation as an exceptional fall back solution to facilitate the provider's obligation to comply with the requirements of this Regulation, when the standardisation process is***	(61) Standardisation should play a key role to provide technical solutions to providers to ensure compliance with this Regulation***, in line with the state of the art, to promote innovation as well as competitiveness and growth in the single market***. Compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council[1]***, which are normally expected to reflect the state of the art,*** should be a means for providers to demonstrate conformity with the requirements of this Regulation. ***A balanced representation of interests involving all relevant stakeholders in the development of standards, in particular SME's, consumer organisations and environmental and social stakeholders in accordance with Article 5 and 6 of Regulation 1025/2012 should therefore be encouraged.*** ***In order to facilitate compliance, the standardisation requests should***

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	Council (OJ L 316, 14.11.2012, p. 12).	***process should be transparent in terms of legal and natural persons participating in the standardisation activities***. _____ 1. Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).	***blocked or when there are delays in the establishment of an appropriate*** harmonised ***standard. If such delay is due to the technical complexity of the standard in question, this should be considered by the Commission before contemplating the establishment of common specifications. An appropriate involvement of small and medium enterprises in the elaboration of*** standards ~~exist or where they are insufficient~~***supporting the implementation of this Regulation is essential to promote innovation and competitiveness in the field of artificial intelligence within the Union. Such involvement should be appropriately ensured in accordance with Article 5 and 6 of Regulation 1025/2012***. _____ 1. ***[1]*** Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).	***be issued by the Commission without undue delay. When preparing the standardisation request, the Commission should consult the AI advisory Forum and the Board in order to collect relevant expertise.*** However, ***In the absence of relevant references to harmonised standards,*** the Commission ~~could adopt~~***should be able to establish, via implementing acts, and after consultation of the AI Advisory forum, common specifications for certain requirements under this Regulation. The*** common ~~technical specifications in areas where no~~***specification should be an exceptional fall back solution to facilitate the provider's obligation to comply with the requirements of this Regulation, when the standardisation request has not been accepted by any of the European standardisation organisations, or when the relevant harmonized standards insufficiently address fundamental rights concerns, or when the*** harmonised ~~standards exist or where they are insufficient~~***standarts do not comply with the request, or when there are delays in the adoption of an appropriate harmonised standard***. ***If such delay in the adoption of a harmonised standard is due to the***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				technical complexity of the standard in question, this should be considered by the Commission before contemplating the establishment of common specifications. When developing common specifications, the Commission is encouraged to cooperate with international partners and international standardisation bodies. _____ 1. Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).
Recital 61a				
G 71a			***(61a) It is appropriate that, without prejudice to the use of harmonised standards and common specifications, providers benefit from a presumption of conformity with the relevant requirement on data when their high-risk AI system has been trained and tested on data reflecting the specific geographical, behavioural or functional setting***	***(61a) It is appropriate that, without prejudice to the use of harmonised standards and common specifications, providers of of high-risk AI system that has been trained and tested on data reflecting the specific geographical, behavioural, contextual or functional setting within which the AI system is intended to be used, should be*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			within which the AI system is intended to be used. Similarly, in line with Article 54(3) of Regulation (EU) 2019/881 of the European Parliament and of the Council, high-risk AI systems that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to that Regulation and the references of which have been published in the Official Journal of the European Union should be presumed to be in compliance with the cybersecurity requirement of this Regulation. This remains without prejudice to the voluntary nature of that cybersecurity scheme.	***presumed to be in compliance with the respective measure provided for under the requirement on data governance set out in this Regulation.*** ***Without prejudice to the requirements related to robustness and accuracy set out in this Regulation, in line with Article 54(3) of Regulation (EU) 2019/881 of the European Parliament and of the Council, high-risk AI systems that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to that Regulation and the references of which have been published in the Official Journal of the European Union should be presumed to be in compliance with the cybersecurity requirement of this Regulation in so far as the cybersecurity certificate or statement of conformity or parts thereof cover the cybersecurity requirement of this Regulation This remains without prejudice to the voluntary nature of that cybersecurity scheme.***
Recital 61a				
G 71b		***(61a) In order to facilitate compliance, the first***		G

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		standardisation requests should be issued by the Commission two months after the entry into force of this Regulation at the latest. This should serve to improve legal certainty, thereby promoting investment and innovation in AI, as well as competitiveness and growth of the Union market, while enhancing multistakeholder governance representing all relevant European stakeholders such as the AI Office, European standardisation organisations and bodies or experts groups established under relevant sectorial Union law as well as industry, SMEs, start-ups, civil society, researchers and social partners, and should ultimately facilitate global cooperation on standardisation in the field of AI in a manner consistent with Union values. When preparing the standardisation request, the Commission should consult the AI Office and the AI advisory Forum in order to collect relevant expertise.		
Recital 61b				
G 71c		***(61b) When AI systems are intended to be used at the workplace, harmonised standards should be limited to technical specifications and procedures.***		G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 61c				
G 71d		***(61c) The Commission should be able to adopt common specifications under certain conditions, when no relevant harmonised standard exists or to address specific fundamental rights concerns. Through the whole drafting process, the Commission should regularly consult the AI Office and its advisory forum, the European standardisation organisations and bodies or expert groups established under relevant sectorial Union law as well as relevant stakeholders, such as industry, SMEs, start-ups, civil society, researchers and social partners.***		G
Recital 61d				
G 71e		***(61d) When adopting common specifications, the Commission should strive for regulatory alignment of AI with likeminded global partners, which is key to fostering innovation and cross-border partnerships within the field of AI, as coordination with likeminded partners in international standardisation bodies is of great importance.***		G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 62				
G 72	(62) In order to ensure a high level of trustworthiness of high-risk AI systems, those systems should be subject to a conformity assessment prior to their placing on the market or putting into service.	(62) In order to ensure a high level of trustworthiness of high-risk AI systems, those systems should be subject to a conformity assessment prior to their placing on the market or putting into service. ***To increase the trust in the value chain and to give certainty to businesses about the performance of their systems, third-parties that supply AI components may voluntarily apply for a third-party conformity assessment.***	(62) In order to ensure a high level of trustworthiness of high-risk AI systems, those systems should be subject to a conformity assessment prior to their placing on the market or putting into service.	(62) In order to ensure a high level of trustworthiness of high-risk AI systems, those systems should be subject to a conformity assessment prior to their placing on the market or putting into service.
Recital 63				
G 73	(63) It is appropriate that, in order to minimise the burden on operators and avoid any possible duplication, for high-risk AI systems related to products which are covered by existing Union harmonisation legislation following the New Legislative Framework approach, the compliance of those AI systems with the requirements of this Regulation should be assessed as part of the conformity assessment already foreseen under that legislation. The applicability of the requirements of this Regulation should thus not affect the specific	(63) It is appropriate that, in order to minimise the burden on operators and avoid any possible duplication, for high-risk AI systems related to products which are covered by existing Union harmonisation legislation following the New Legislative Framework approach, the compliance of those AI systems with the requirements of this Regulation should be assessed as part of the conformity assessment already foreseen under that legislation. The applicability of the requirements of this Regulation should thus not affect the specific	(63) It is appropriate that, in order to minimise the burden on operators and avoid any possible duplication, for high-risk AI systems related to products which are covered by existing Union harmonisation legislation following the New Legislative Framework approach, the compliance of those AI systems with the requirements of this Regulation should be assessed as part of the conformity assessment already foreseen under that legislation. The applicability of the requirements of this Regulation should thus not affect the specific	(63) It is appropriate that, in order to minimise the burden on operators and avoid any possible duplication, for high-risk AI systems related to products which are covered by existing Union harmonisation legislation following the New Legislative Framework approach, the compliance of those AI systems with the requirements of this Regulation should be assessed as part of the conformity assessment already foreseen under that legislation. The applicability of the requirements of this Regulation should thus not affect the specific

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	logic, methodology or general structure of conformity assessment under the relevant specific New Legislative Framework legislation. This approach is fully reflected in the interplay between this Regulation and the [Machinery Regulation]. While safety risks of AI systems ensuring safety functions in machinery are addressed by the requirements of this Regulation, certain specific requirements in the [Machinery Regulation] will ensure the safe integration of the AI system into the overall machinery, so as not to compromise the safety of the machinery as a whole. The [Machinery Regulation] applies the same definition of AI system as this Regulation.	logic, methodology or general structure of conformity assessment under the relevant specific New Legislative Framework legislation. This approach is fully reflected in the interplay between this Regulation and the [Machinery Regulation]. While safety risks of AI systems ensuring safety functions in machinery are addressed by the requirements of this Regulation, certain specific requirements in the [Machinery Regulation] will ensure the safe integration of the AI system into the overall machinery, so as not to compromise the safety of the machinery as a whole. The [Machinery Regulation] applies the same definition of AI system as this Regulation.	logic, methodology or general structure of conformity assessment under the relevant specific New Legislative Framework legislation. This approach is fully reflected in the interplay between this Regulation and the [Machinery Regulation]. While safety risks of AI systems ensuring safety functions in machinery are addressed by the requirements of this Regulation, certain specific requirements in the [Machinery Regulation] will ensure the safe integration of the AI system into the overall machinery, so as not to compromise the safety of the machinery as a whole. The [Machinery Regulation] applies the same definition of AI system as this Regulation. ***With regard to high-risk AI systems related to products covered by Regulations 745/2017 and 746/2017 on medical devices, the applicability of the requirements of this Regulation should be without prejudice and take into account the risk management logic and benefit-risk assessment performed under the medical device framework.***	logic, methodology or general structure of conformity assessment under the relevant specific New Legislative Framework legislation. ~~*This approach is fully reflected in the interplay between this Regulation and the [Machinery Regulation]. While safety risks of AI systems ensuring safety functions in machinery are addressed by the requirements of this Regulation, certain specific requirements in the [Machinery Regulation] will ensure the safe integration of the AI system into the overall machinery, so as not to compromise the safety of the machinery as a whole. The [Machinery Regulation] applies the same definition of AI system as this Regulation.*~~
Recital 64				
G 74	(64) Given the more extensive experience of professional pre-market certifiers in the field of	(64) Given the ***complexity of high-risk AI systems and the risks that are associated to them, it is***	(64) Given the more extensive experience of professional pre-market certifiers in the field of	(64) Given the ~~*more extensive*~~***complexity of high-risk AI systems and the risks that are*** G

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	product safety and the different nature of risks involved, it is appropriate to limit, at least in an initial phase of application of this Regulation, the scope of application of third-party conformity assessment for high-risk AI systems other than those related to products. Therefore, the conformity assessment of such systems should be carried out as a general rule by the provider under its own responsibility, with the only exception of AI systems intended to be used for the remote biometric identification of persons, for which the involvement of a notified body in the conformity assessment should be foreseen, to the extent they are not prohibited.	***essential to develop a more adequate capacity for the application of third party conformity assessment for high-risk AI systems. However, given the current***~~more extensive~~ experience of professional pre-market certifiers in the field of product safety and the different nature of risks involved, it is appropriate to limit, at least in an initial phase of application of this Regulation, the scope of application of third-party conformity assessment for high-risk AI systems other than those related to products. Therefore, the conformity assessment of such systems should be carried out as a general rule by the provider under its own responsibility, with the only exception of AI systems intended to be used for the remote biometric identification of persons, ***or AI systems intended to be used to make inferences about personal characteristics of natural persons on the basis of biometric or biometrics-based data, including emotion recognition systems*** for which the involvement of a notified body in the conformity assessment should be foreseen, to the extent they are not prohibited.	product safety and the different nature of risks involved, it is appropriate to limit, at least in an initial phase of application of this Regulation, the scope of application of third-party conformity assessment for high-risk AI systems other than those related to products. Therefore, the conformity assessment of such systems should be carried out as a general rule by the provider under its own responsibility, with the only exception of AI systems intended to be used for the remote biometric identification of persons, for which the involvement of a notified body in the conformity assessment should be foreseen, to the extent they are not prohibited.	***associated to them, it is important to develop an adequate system of conformity assessment procedure for high risk AI systems involving notified bodies, so called third party conformity assessment. However, given the current*** experience of professional pre-market certifiers in the field of product safety and the different nature of risks involved, it is appropriate to limit, at least in an initial phase of application of this Regulation, the scope of application of third-party conformity assessment for high-risk AI systems other than those related to products. Therefore, the conformity assessment of such systems should be carried out as a general rule by the provider under its own responsibility, with the only exception of AI systems intended to be used for ~~*the remote biometric identification of persons, for which the involvement of a notified body in the conformity assessment should be foreseen, to the extent they are not prohibited*~~***biometrics***.
Recital 65				
75	(65) In order to carry out third-party	(65) In order to carry out third-party	(65) In order to carry out third-party	(65) In order to carry out third-party

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	conformity assessment for AI systems intended to be used for the remote biometric identification of persons, notified bodies should be designated under this Regulation by the national competent authorities, provided they are compliant with a set of requirements, notably on independence, competence and absence of conflicts of interests.	conformity ~~assessment for AI systems intended to be used for the remote biometric identification of persons~~***assessments when so required***, notified bodies should be designated under this Regulation by the national competent authorities, provided they are compliant with a set of requirements, notably on independence, competence ~~and~~, absence of conflicts of interests ***and minimum cybersecurity requirements***. ***Member States should encourage the designation of a sufficient number of conformity assessment bodies, in order to make the certification feasible in a timely manner. The procedures of assessment, designation, notification and monitoring of conformity assessment bodies should be implemented as uniformly as possible in Member States, with a view to removing administrative border barriers and ensuring that the potential of the internal market is realised.***	conformity assessment for AI systems intended to be used for the remote biometric identification of persons, notified bodies should be ~~designated~~***notified*** under this Regulation by the national competent authorities, provided they are compliant with a set of requirements, notably on independence, competence and absence of conflicts of interests. ***Notification of those bodies should be sent by national competent authorities to the Commission and the other Member States by means of the electronic notification tool developed and managed by the Commission pursuant to Article R23 of Decision 768/2008.***	conformity ~~assessment for AI systems intended to be used for the remote biometric identification of persons~~***assessments when so required***, notified bodies should be ~~designated~~ ***notified*** under this Regulation by the national competent authorities, provided they are compliant with a set of requirements, notably on independence, competence ~~and~~, absence of conflicts of interests ***and suitable cybersecurity requirements***. ***Notification of those bodies should be sent by national competent authorities to the Commission and the other Member States by means of the electronic notification tool developed and managed by the Commission pursuant to Article R23 of Decision 768/2008.***
Recital 65a				
G 75a		***(65a) In line with Union commitments under the World Trade Organization Agreement on Technical Barriers to Trade, it is adequate to maximise the***		***(65a) In line with Union commitments under the World Trade Organization Agreement on Technical Barriers to Trade, it is adequate to facilitate the mutual*** G

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		acceptance of test results produced by competent conformity assessment bodies, independent of the territory in which they are established, where necessary to demonstrate conformity with the applicable requirements of the Regulation. The Commission should actively explore possible international instruments for that purpose and in particular pursue the possible establishment of mutual recognition agreements with countries which are on a comparable level of technical development, and have compatible approach concerning AI and conformity assessment.		***recognition of conformity assessment results produced by competent conformity assessment bodies, independent of the territory in which they are established, provided that those conformity assessment bodies established under the law of a third country meet the applicable requirements of the Regulation and the Union has concluded an agreement to that extent. In this context, the Commission should actively explore possible international instruments for that purpose and in particular pursue the conclusion of mutual recognition agreements with third countries.***
Recital 66				
G 76	(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may affect the compliance of the system with this Regulation or when the intended purpose of the system changes. In addition, as regards AI systems which continue to 'learn' after being placed on the market or put into service (i.e. they automatically adapt	(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an ***high-risk*** AI system undergoes a new conformity assessment whenever ~~a~~***an unplanned*** change occurs which ***goes beyond controlled or predetermined changes by the provider including continuous learning and which may create a new unacceptable risk and significantly***~~may~~ affect the compliance of the ***high-risk AI***	(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that ~~an AI system undergoes a new conformity assessment~~ whenever a change occurs which may affect the compliance of ~~the~~***a high risk AI*** system with this Regulation ***(e.g. change of operating system or software architecture),*** or when the intended purpose of the system changes~~. In addition, as regards~~***, that AI system should be considered***	(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that ~~an AI system undergoes a new conformity assessment~~ whenever a change occurs which may affect the compliance of ~~the~~***a high risk AI*** system with this Regulation ***(e.g. change of operating system or software architecture),*** or when the intended purpose of the system changes***, that AI system should be considered a new AI system which*** G

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	how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been pre-determined by the provider and assessed at the moment of the conformity assessment should not constitute a substantial modification.	system with this Regulation or when the intended purpose of the system changes. In addition, as regards AI systems which continue to 'learn' after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been pre-determined by the provider and assessed at the moment of the conformity assessment should not constitute a substantial modification. ***The same should apply to updates of the AI system for security reasons in general and to protect against evolving threats of manipulation of the system, provided that they do not amount to a substantial modification.***	***a new AI system which should undergo a new conformity assessment. However, changes occuring to the algorithm and the performance of*** AI systems which continue to 'learn' after being placed on the market or put into service (i.e. ~~they~~ automatically ~~adapt~~***adapting*** how functions are carried out)~~, it is necessary to provide rules establishing that~~ ***should not constitute a substantial modification, provided that those*** changes ~~to the algorithm and its performance that~~ have been pre-determined by the provider and assessed at the moment of the conformity assessment~~ should not constitute a substantial modification.~~.	***should undergo a new conformity assessment. However, changes occuring to the algorithm and the performance of***~~. In addition, as regards~~ AI systems which continue to 'learn' after being placed on the market or put into service (i.e.~~ they~~ automatically ~~adapt~~***adapting*** how functions are carried out)~~, it is necessary to provide rules establishing that changes to the algorithm and its performance that~~ ***should not constitute a substantial modification, provided that those changes*** have been pre-determined by the provider and assessed at the moment of the conformity assessment~~ should not constitute a substantial modification~~.
Recital 67				
G 77	(67) High-risk AI systems should bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the internal market. Member States should not create unjustified obstacles to the placing on the market or putting into service of high-risk AI systems that comply with the requirements laid down in this Regulation and bear the CE	(67) High-risk AI systems should bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the internal market. ***For physical high-risk AI systems, a physical CE marking should be affixed, and may be complemented by a digital CE marking. For digital only high-risk AI systems, a digital CE marking should be used.*** Member States	(67) High-risk AI systems should bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the internal market. Member States should not create unjustified obstacles to the placing on the market or putting into service of high-risk AI systems that comply with the requirements laid down in this Regulation and bear the CE	(67) High-risk AI systems should bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the internal market. ***For high-risk AI systems embedded in a product, a physical CE marking should be affixed, and may be complemented by a digital CE marking. For high-risk AI systems only provided digitally, a digital CE marking*** G

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	marking.	should not create unjustified obstacles to the placing on the market or putting into service of high-risk AI systems that comply with the requirements laid down in this Regulation and bear the CE marking.	marking.	***should be used.*** Member States should not create unjustified obstacles to the placing on the market or putting into service of high-risk AI systems that comply with the requirements laid down in this Regulation and bear the CE marking.
Recital 68				
G 78	(68) Under certain conditions, rapid availability of innovative technologies may be crucial for health and safety of persons and for society as a whole. It is thus appropriate that under exceptional reasons of public security or protection of life and health of natural persons and the protection of industrial and commercial property, Member States could authorise the placing on the market or putting into service of AI systems which have not undergone a conformity assessment.	(68) Under certain conditions, rapid availability of innovative technologies may be crucial for health and safety of persons***, the environment and climate change*** and for society as a whole. It is thus appropriate that under exceptional reasons of ~~public security or~~ protection of life and health of natural persons***, environmental protection*** and the protection of ~~industrial and commercial property~~***critical infrastructure***, Member States could authorise the placing on the market or putting into service of AI systems which have not undergone a conformity assessment.	(68) Under certain conditions, rapid availability of innovative technologies may be crucial for health and safety of persons and for society as a whole. It is thus appropriate that under exceptional reasons of public security or protection of life and health of natural persons and the protection of industrial and commercial property, Member States could authorise the placing on the market or putting into service of AI systems which have not undergone a conformity assessment.	(68) Under certain conditions, rapid availability of innovative technologies may be crucial for health and safety of persons***, the protection of the environment and climate change*** and for society as a whole. It is thus appropriate that under exceptional reasons of ***public security or*** ~~public security or~~ protection of life and health of natural persons***, environmental protection*** and the protection of ***key industrial and infrastructural assets*** ~~industrial and commercial property~~, ***Market Surveillance Authorities*** ~~Member States~~ could authorise the placing on the market or putting into service of AI systems which have not undergone a conformity assessment***. In a duly justified situations as provided under this regulations, law enforcement authorities or civil protection authorities may put a specific high-risk AI system into service without*** G

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				the authorisation of the market surveillance authority, provided that such authorisation is requested during or after the use without undue delay.
Recital 69				
G 79	(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system in a EU database, to be established and managed by the Commission. The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council[1]. In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report. _____ 1. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural	(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system ***and foundation models*** in a EU database, to be established and managed by the Commission. ***This database should be freely and publicly accessible, easily understandable and machine-readable. The database should also be user-friendly and easily navigable, with search functionalities at minimum allowing the general public to search the database for specific high-risk systems, locations, categories of risk under Annex IV and keywords. Deployers who are public authorities or Union institutions, bodies, offices and***	(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register ***themselves and information about*** their high-risk AI system in a EU database, to be established and managed by the Commission. ***Before using a high-risk AI system listed in Annex III, users of high-risk AI systems that are public authorities, agencies or bodies, with the exception of law enforcement, border control, immigration or asylum authorities, and authorities that are users of high-risk AI systems in the area of critical infrastructure shall also register themselves in such database and select the system that they envisage to use.*** The Commission should be the controller of that database, in	(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, ***as well as providers who consider that an AI system referred to in annex III is by derogation not high-risk,*** should be required to register ~~their high-risk~~ ***themselves and information about their*** AI system~~-~~ in a EU database, to be established and managed by the Commission. ***Before using a high-risk AI system listed in Annex III, deployers of high-risk AI systems that are public authorities, agencies or bodies, shall register themselves in such database and select the system that they envisage to use.. Other deployers should be entitled to do so voluntarily. This section of the database should be publicly accessible, free of charge, the*** G

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	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).	***agencies or deployers acting on their behalf and deployers who are undertakings designated as a gatekeeper under Regulation (EU)2022/1925 should also register in the EU database before putting into service or using a high-risk AI system for the first time and following each substantial modification. Other deployers should be entitled to do so voluntarily. Any substantial modification of high-risk AI systems shall also be registered in the EU database.*** The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council[1]. In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report. ***The Commission should take into account cybersecurity and hazard-related risks when carrying out its tasks as data controller on the EU database. In order to maximise the availability and use of the database by the public, the database, including the information made available through it, should comply with requirements under the Directive 2019/882.***	accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council[1]. In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report. _____ 1. ***[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).	***information should be easily navigatable, understandable and machine-readable. The database should also be user-friendly, for example by providing search functionalities, including through keywords, allowing the general public to find relevant information included in Annex VIII and on the areas of risk under Annex III to which the high-risk AI systems correspond. . Any substantial modification of high-risk AI systems should also be registered in the EU database. For high risk AI systems in the area of law enforcement, migration, asylum and border control management, the registration obligations should be fulfilled in a secure non-public section of the database. Access to the secure non-public section should be strictly limited to the Commission as well as to market surveillance authorities with regard to their national section of that database. High risk AI systems in the area of critical infrastructure should only be registered at national level.*** The Commission should be the controller of ***the EU*** ~~that~~ database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council[1]. In order to ensure the full functionality of the database, when deployed, the procedure for setting

	Commission Proposal	EP Mandate	Council Mandate	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).		the database should include the elaboration of functional specifications by the Commission and an independent audit report. ***The Commission should take into account cybersecurity and hazard-related risks when carrying out its tasks as data controller on the EU database. In order to maximise the availability and use of the database by the public, the database, including the information made available through it, should comply with requirements under the Directive 2019/882.*** _____ 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).
Recital 70				
G 80	(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the	(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the	(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the	(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the G

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	requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.	requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.	requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the ***point of view of a natural person who is reasonably well-informed, observant and circumspect taking into account the*** circumstances and the context of use. ***When implementing such obligation, the characteristics of individuals belonging to vulnerable groups due to their age or disability should be taken into account to the extent the AI system is intended to interact with those groups as well.*** Moreover, natural persons should be notified when they are exposed to ~~*an emotion recognition system or a biometric categorisation system*~~***systems that, by processing their biometric data, can identify or infer the emotions or intentions of those persons or assign them to specific categories. Such specific categories can relate to aspects such as sex, age, hair colour, eye colour, tatoos, personal traits, ethnic origin, personal preferences and interests or to other aspects such as sexual or political orientation***. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or	requirements and obligations for high-risk AI systems ***and subject to targeted exceptions to take into account the special need of law enforcement***. In particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the ***point of view of a natural person who is reasonably well-informed, observant and circumspect taking into account the*** circumstances and the context of use. ~~*Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing*~~***When implementing such obligation, the characteristics of individuals belonging to vulnerable groups due to their age or disability should be taken into account to the extent the AI system is intended to interact with those groups as well. Moreover, natural persons should be notified when they are exposed to systems that, by processing their biometric data, can identify or infer the emotions or intentions of those*** persons~~*, places or events and would*~~

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin. ***The compliance with the information obligations referred to above should not be interpreted as indicating that the use of the system or its output is lawful under this Regulation or other Union and Member State law and should be without prejudice to other transparency obligations for users of AI systems laid down in Union or national law. Furthermore it should also not be interpreted as indicating that the use of the system or its output impedes the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Funadamental Rights of the EU, in particular where the content is part of an evidently creative, satirical, artistic or fictional work or programme, subject to appropriate safeguards for the rights and freedoms of third parties.***	~~*falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin*~~ ***or assign them to specific categories. Such specific categories can relate to aspects such as sex, age, hair colour, eye colour, tattoos, personal traits, ethnic origin, personal preferences and interests. Such information and notifications should be provided in accessible formats for persons with disabilities***.
Recital 70a				

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G 80a				*(70a) A variety of AI systems can generate large quantities of synthetic content that becomes increasingly hard for humans to distinguish from human-generated and authentic content. The wide availability and increasing capabilities of those systems have a significant impact on the integrity and trust in the information ecosystem, raising new risks of misinformation and manipulation at scale, fraud, impersonation and consumer deception. In the light of those impacts, the fast technological pace and the need for new methods and techniques to trace origin of information, it is appropriate to require providers of those systems to embed technical solutions that enable marking in a machine readable format and detection that the output has been generated or manipulated by an AI system and not a human. Such techniques and methods should be sufficiently reliable, interoperable, effective and robust as far as this is technically feasible, taking into account available techniques or a combination of such techniques, such as watermarks, metadata identifications, cryptographic methods for proving provenance and authenticity of content, logging methods, fingerprints or other* G

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				techniques, as may be appropriate. When implementing this obligation, providers should also take into account the specificities and the limitations of the different types of content and the relevant technological and market developments in the field, as reflected in the generally acknowledged state-of-the-art. Such techniques and methods can be implemented at the level of the system or at the level of the model, including general-purpose AI models generating content, thereby facilitating fulfilment of this obligation by the downstream provider of the AI system. To remain proportionate, it is appropriate to envisage that this marking obligation should not cover AI systems performing primarily an assistive function for standard editing or AI systems not substantially altering the input data provided by the deployer or the semantics thereof.
Recital 70b				
G 80b				***(70b) Further to the technical solutions employed by the providers of the system, deployers , who use an AI system to generate or manipulate image, audio or video content that appreciably resembles*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				existing persons, places or events and would falsely appear to a person to be authentic ('deep fakes'), should also clearly and distinguishably disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin The compliance with this transparency obligation should not be interpreted as indicating that the use of the system or its output impedes the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, in particular where the content is part of an evidently creative, satirical, artistic or fictional work or programme, subject to appropriate safeguards for the rights and freedoms of third parties. In those cases, the transparency obligation for deep fakes set out in this Regulation is limited to disclosure of the existence of such generated or manipulated content in an appropriate manner that does not hamper the display or enjoyment of the work, including its normal exploitation and use, while maintaining the utility and quality of the work. In addition, it is also appropriate to envisage a similar disclosure obligation in relation to

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				AI-generated or manipulated text to the extent it is published with the purpose of informing the public on matters of public interest unless the AI-generated content has undergone a process of human review or editorial control and a natural or legal person holds editorial responsibility for the publication of the content.
Recital 70c				
G 80c				***(70c) To ensure consistent implementation, it is appropriate to empower the Commission to adopt implementing acts on the application of the provisions on the labelling and detection of artificially generated or manipulated content. Without prejudice to the mandatory nature and full applicability of these obligations, the Commission may also encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the obligations regarding the detection and labelling of artificially generated or manipulated content, including to support practical arrangements for making, as appropriate, the detection mechanisms accessible and facilitating cooperation with other actors in the value chain,*** G

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				disseminating content or checking its authenticity and provenance to enable the public to effectively distinguish AI-generated content.
Recital 70d				
G 80d				***(70d) The obligations placed on providers and deployers of certain AI systems in this Regulation to enable the detection and disclosure that the outputs of those systems are artificially generated or manipulated are particularly relevant to facilitate the effective implementation of Regulation (EU) 2022/2065. This applies in particular as regards the obligations of providers of very large online platforms or very large online search engines to identify and mitigate systemic risks that may arise from the dissemination of content that has been artificially generated or manipulated, in particular risk of the actual or foreseeable negative effects on democratic processes, civic discourse and electoral processes, including through disinformation. The requirement to label content generated by AI systems under this Regulation is without prejudice to the obligation in Article 16(6) of Regulation 2022/2065 for providers of hosting services to process*** G

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				notices on illegal content received pursuant to Article 16(1) and should not influence the assessment and the decision on the illegality of the specific content. That assessment should be performed solely with reference to the rules governing the legality of the content.
Recital 70e				
G 80e				***(70e) The compliance with the transparency obligations for the AI systems coved by this Regulation should not be interpreted as indicating that the use of the system or its output is lawful under this Regulation or other Union and Member State law and should be without prejudice to other transparency obligations for deployers of AI systems laid down in Union or national law.***
Recital 71				
G 81	(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk	(71) Artificial intelligence is a rapidly developing family of technologies that requires ~~novel forms of~~ regulatory oversight and a safe ***and controlled*** space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards	(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk	(71) Artificial intelligence is a rapidly developing family of technologies that requires ~~novel forms of~~ regulatory oversight and a safe ***and controlled*** space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards

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	mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, national competent authorities from one or more Member States should be encouraged to establish artificial intelligence regulatory sandboxes to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service.	and risk mitigation measures. To ensure a legal framework that ~~is innovation-friendly~~***promotes innovation***, ***is*** future-proof***,*** and resilient to disruption, ~~national competent authorities from one or more~~ Member States should ~~be encouraged to establish~~***establish at least one*** artificial intelligence regulatory ~~sandboxes~~***sandbox*** to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service. ***It is indeed desirable for the establishment of regulatory sandboxes, whose establishment is currently left at the discretion of Member States, as a next step to be made mandatory with established criteria. That mandatory sandbox could also be established jointly with one or several other Member States, as long as that sandbox would cover the respective national level of the involved Member States. Additional sandboxes may also be established at different levels, including cross Member States, in order to facilitate cross-border cooperation and synergies. With the exception of the mandatory sandbox at national level, Member States should also be able to establish virtual or hybrid sandboxes. All regulatory***	mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, national competent authorities from one or more Member States should be encouraged to establish artificial intelligence regulatory sandboxes to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service.	and risk mitigation measures. To ensure a legal framework that ~~is innovation-friendly,~~ ***promotes innovation, is*** future-proof and resilient to disruption, ~~national competent authorities from one or more Member States should be encouraged to establish~~***Member States should ensure that their national competent authorities establish at least one*** artificial intelligence regulatory sandboxes ***at national level*** to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service. ***Member States could also fulfill this obligation through participating in already existing regulatory sandboxes or establishing jointly a sandbox with one or several Member States' competent authorities, insofar as this participation provides equivalent level of national coverage for the participating Member States. Regulatory sandboxes could be established in physical, digital or hybrid form and may accommodate physical as well as digital products. Establishing authorities should also ensure that the regulatory sandboxes have the adequate resources for their functioning, including financial and human***

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		sandboxes should be able to accommodate both physical and virtual products. Establishing authorities should also ensure that the regulatory sandboxes have the adequate financial and human resources for their functioning.		***resources.***
Recital 72				
G 82	(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in	(72) The objectives of the regulatory sandboxes should be ~~to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems~~ ***: for the establishing authorities to increase their understanding of technical developments, improve supervisory methods and provide guidance to AI systems developers and providers to achieve regulatory compliance*** with this Regulation ~~and other~~***or where*** relevant***, other applicable*** Union and Member States legislation~~; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium~~	(72) The objectives of the ***AI*** regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems~~–~~ with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs)***, including*** ~~and~~ start-ups. ***The participation in the AI regulatory sandbox should focus on issues that raise legal uncertainty for providers and prospective providers to innovate, experiment with AI in*** ~~To ensure uniform implementation across~~ the	(72) The objectives of the ***AI*** regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems~~–~~ with this Regulation and other relevant Union and Member States legislation~~;~~, to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, ***to facilitate regulatory learning for authorities and companies, including with a view to future adaptions of the legal framework, to support cooperation and the sharing of best practices with the authorities involved in the AI regulatory sandbox,*** and to accelerate access to markets, including by removing barriers for small and medium enterprises G

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	the supervision of the sandboxes. This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680. Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.	~~enterprises (SMEs) and start-ups. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680. Participants in the sandbox~~***, as well as with the Charter of Fundamental Rights; for the prospective providers to allow and facilitate the testing and development of innovative solutions related to AI systems in the pre-marketing phase to enhance legal certainty, to allow for more regulatory learning by establishing authorities in a controlled environment to develop better guidance and to identify possible future improvements of the legal framework through the ordinary legislative procedure. Any significant risks identified during the development and testing of such***	Union and ~~economies of scale, it is appropriate to establish common rules for the~~***contribute to evidence-based regulatory learning. The supervision of the AI systems in the AI*** regulatory ~~sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. This Regulation should provide the legal basis for the use of personal data collected for~~***sandbox should therefore cover their development, training, testing and validation before the systems are placed on the market or put into service, as well as the notion and occurrence of substantial modification that may require a new conformity assessment procedure. Where appropriate, national competent authorities establishing AI regulatory sandboxes should cooperate with*** other ~~purposes for developing certain AI systems in the public interest~~***relevant authorities, including those supervising the protection of fundamental rights, and could allow for the involvement of other actors*** within the AI ~~regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679~~***ecosystem such as national or European standardisation organisations, notified bodies, testing and***	(SMEs)***, including*** ~~and~~ start-ups. ~~To ensure uniform implementation across~~***Regulatory sandboxes should be widely available throughout*** the Union***, and particular attention should be given to their accessibility for SMEs, including startups. The participation in the AI*** ~~and economies of scale, it is appropriate to establish common rules for the~~ regulatory ~~sandboxes' implementation and a framework for cooperation between the relevant authorities involved in~~***sandbox should focus on issues that raise legal uncertainty for providers and prospective providers to innovate, experiment with AI in the Union and contribute to evidence-based regulatory learning.*** The supervision of the ~~sandboxes. This Regulation~~***AI systems in the AI regulatory sandbox*** should ~~provide the legal basis for the use of personal data collected for other purposes for developing certain~~***therefore cover their development, training, testing and validation before the systems are placed on the market or put into service, as well as the notion and occurrence of substantial modification that may require a new conformity assessment procedure. Any significant risks identified during the development and testing of such*** AI systems

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		AI systems should result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. Member States should ensure ~~*appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation*~~***that regulatory sandboxes are widely available throughout the Union, while the participation should remain voluntary. It is especially important to ensure that SMEs and startups can easily access these sandboxes, are actively involved and participate*** in the ~~*sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57*~~	***experimentation facilities, research and experimentation labs, innovation hubs and relevant stakeholder and civil society organisations. To ensure uniform implementation across the Union and economies of scale, it is*** ~~*and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680. Participants in the sandbox should ensure*~~ appropriate ~~*safeguards and cooperate with the competent*~~***to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant*** authorities~~*, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when*~~ ***involved in the supervision of the sandboxes. AI regulatory sandboxes established under this Regulation should be without prejudice to other legislation allowing for the establishment of other sandboxes aiming at ensuring compliance with legislation other that this Regulation. Where appropriate, relevant competent authorities in***	***should result in adequate mitigation and, failing that,*** in the ~~*public interest within the*~~ ***suspension of the development and testing process Where appropriate, national competent authorities establishing*** AI regulatory ~~*sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680. Participants in the sandbox should ensure*~~***sandboxes should cooperate with other relevant authorities, including those supervising the protection of fundamental rights,, and could allow for the involvement of other actors within the AI ecosystem such as national or European standardisation organisations, notified bodies, testing and experimentation facilities, research and experimentation labs, European Digital innovation hubs and relevant stakeholder and civil society organisations. To ensure uniform implementation across the Union and economies of scale, it is*** appropriate ~~*safeguards and cooperate with the competent*~~***to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant*** authorities~~*, including by*~~

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		~~of Directive 2016/680~~***development and testing of innovative AI systems, in order to be able to contribute with their knowhow and experience***.	***charge of those other regulatory sandboxes should consider the benefits of using those sandboxes also for the purpose of ensuring compliance of AI systems with this Regulation. Upon agreement between the national*** competent authorities ~~decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680~~***and the participants in the AI regulatory sandbox, testing in real world conditions may also be operated and supervised in the framework of the AI regulatory sandbox***.	~~following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when~~ ***involved in the supervision of the sandboxes. AI regulatory sandboxes established under this Regulation should be without prejudice to other legislation allowing for the establishment of other sandboxes aiming at ensuring compliance with legislation other that this Regulation. Where appropriate, relevant competent authorities in charge of those other regulatory sandboxes should consider the benefits of using those sandboxes also for the purpose of ensuring compliance of AI systems with this Regulation. Upon agreement between the national*** competent authorities ~~decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680~~***and the participants in the AI regulatory sandbox, testing in real world conditions may also be operated and supervised in the framework of the AI regulatory sandbox***.
Recital 72a				

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G 82a			*(72a) This Regulation should provide the legal basis for the participants in the AI regulatory sandbox to use personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox, in line with Article 6(4) and 9(2)(g) of Regulation (EU) 2016/679, and Article 5 and 10 of Regulation (EU) 2018/1725, and without prejudice to Articles 4(2) and 10 of Directive (EU) 2016/680. All other obligations of data controllers and rights of data subjects under Regulation (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU) 2016/680 remain applicable. In particular, this Regulation should not provide a legal basis in the meaning of Article 22(2)(b) of Regulation (EU) 2016/679 and Article 24(2)(b) of Regulation (EU) 2018/1725. Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in*	*(72a) This Regulation should provide the legal basis for the providers and prospective providers in the AI regulatory sandbox to use personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox, only under specified conditions, in line with Article 6(4) and 9(2)(g) of Regulation (EU) 2016/679, and Article 5, 6 and 10 of Regulation (EU) 2018/1725, and without prejudice to Articles 4(2) and 10 of Directive (EU) 2016/680. All other obligations of data controllers and rights of data subjects under Regulation (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU) 2016/680 remain applicable. In particular, this Regulation should not provide a legal basis in the meaning of Article 22(2)(b) of Regulation (EU) 2016/679 and Article 24(2)(b) of Regulation (EU) 2018/1725. Providers and prospective providers in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to adequately mitigate any identified - significant risks to safety, health, and fundamental rights that may* G

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			the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.	***arise during the development, testing and experimentation in the sandbox.***
Recital 72a				
G 82b		***(72a) This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox only under specified conditions in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680. Prospective providers in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety, health and the environment and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the prospective providers in the sandbox should be taken into account when competent***		G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		authorities decide over the temporary or permanent suspension of their participation in the sandbox whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.		
Recital 72b				
G 82c			***(72b) In order to accelerate the process of development and placing on the market of high-risk AI systems listed in Annex III, it is important that providers or prospective providers of such systems may also benefit from a specific regime for testing those systems in real world conditions, without participating in an AI regulatory sandbox. However, in such cases and taking into account the possible consequences of such testing on individuals, it should be ensured that appropriate and sufficient guarantees and conditions are introduced by the Regulation for providers or prospective providers. Such guarantees should include, among others, requesting informed consent of natural persons to participate in testing in real world conditions, with the exception of law enforcement in cases where the seeking of informed consent would***	***(72b) In order to accelerate the process of development and placing on the market of high-risk AI systems listed in Annex III, it is important that providers or prospective providers of such systems may also benefit from a specific regime for testing those systems in real world conditions, without participating in an AI regulatory sandbox. However, in such cases and taking into account the possible consequences of such testing on individuals, it should be ensured that appropriate and sufficient guarantees and conditions are introduced by the Regulation for providers or prospective providers. Such guarantees should include, among others, requesting informed consent of natural persons to participate in testing in real world conditions, with the exception of law enforcement in cases where the seeking of informed consent would*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			prevent the AI system from being tested. Consent of subjects to participate in such testing under this Regulation is distinct from and without prejudice to consent of data subjects for the processing of their personal data under the relevant data protection law.	***prevent the AI system from being tested. Consent of subjects to participate in such testing under this Regulation is distinct from and without prejudice to consent of data subjects for the processing of their personal data under the relevant data protection law. It is also important to minimise the risks and enable oversight by competent authorities and therefore require prospective providers to have a real-world testing plan submitted to competent market surveillance authority, register the testing in dedicated sections in the EU-wide database subject to some limited exceptions, set limitations on the period for which the testing can be done and require additional safeguards for persons belonging to certain vulnerable groups as well as a written agreement defining the roles and responsibilities of prospective providers and deployers and effective oversight by competent personnel involved in the real world testing. Furthermore, it is appropriate to envisage additional safeguards to ensure that the predictions, recommendations or decisions of the AI system can be effectively reversed and disregarded and that personal data is protected and is deleted when the subjects have withdrawn their consent to participate in the testing without***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				prejudice to their rights as data subjects under the EU data protection law. As regards transfer of data, it is also appropriate to envisage that data collected and processed for the purpose of the testing in real world conditions should only be transferred to third countries outside the Union provided appropriate and applicable safeguards under Union law are implemented, notably in accordance with bases for transfer of personal data under Union law on data protection, while for non-personal data appropriate safeguards are put in place in accordance with Union law, such as the Data Governance Act and the Data Act.
Recital 72c				
G 82d		***(72b) To ensure that Artificial Intelligence leads to socially and environmentally beneficial outcomes, Member States should support and promote research and development of AI in support of socially and environmentally beneficial outcomes by allocating sufficient resources, including public and Union funding, and giving priority access to regulatory sandboxes to projects led by civil society. Such projects should be based on the principle of***		***(72c) To ensure that Artificial Intelligence leads to socially and environmentally beneficial outcomes, Member States are encouraged to support and promote research and development of AI solutions in support of socially and environmentally beneficial outcomes, such as AI-based solutions to increase accessibility for persons with disabilities, tackle socio-economic inequalities, or meet environmental targets, by allocating sufficient resources,*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		interdisciplinary cooperation between AI developers, experts on inequality and non-discrimination, accessibility, consumer, environmental, and digital rights, as well as academics.		***including public and Union funding, and, where appropriate and provided that the eligibility and selection criteria are fulfilled, considering in particular projects which pursue such objectives. Such projects should be based on the principle of interdisciplinary cooperation between AI developers, experts on inequality and non-discrimination, accessibility, consumer, environmental, and digital rights, as well as academics.***
Recital 73				
G 83	(73) In order to promote and protect innovation, it is important that the interests of small-scale providers and users of AI systems are taken into particular account. To this objective, Member States should develop initiatives, which are targeted at those operators, including on awareness raising and information communication. Moreover, the specific interests and needs of small-scale providers shall be taken into account when Notified Bodies set conformity assessment fees. Translation costs related to mandatory documentation and communication with authorities may constitute a significant cost for providers and other operators, notably those of a smaller scale.	(73) In order to promote and protect innovation, it is important that the interests of small-scale providers and users of AI systems are taken into particular account. To this objective, Member States should develop initiatives, which are targeted at those operators, including on ***AI literacy,*** awareness raising and information communication. ***Member States shall utilise existing channels and where appropriate, establish new dedicated channels for communication with SMEs, start-ups, user and other innovators to provide guidance and respond to queries about the implementation of this Regulation. Such existing channels could include but are not limited to ENISA's Computer***	(73) In order to promote and protect innovation, it is important that the interests of ~~small-scale~~***SME*** providers and users of AI systems are taken into particular account. To this objective, Member States should develop initiatives, which are targeted at those operators, including on awareness raising and information communication. Moreover, the specific interests and needs of ~~small-scale~~***SME*** providers shall be taken into account when notified bodies set conformity assessment fees. Translation costs related to mandatory documentation and communication with authorities may constitute a significant cost for providers and other operators, notably those of a smaller scale.	(73) In order to promote and protect innovation, it is important that the interests of ~~small-scale providers and users~~***SMEs, including start-ups, that are providers or deployers*** of AI systems are taken into particular account. To this objective, Member States should develop initiatives, which are targeted at those operators, including on***,*** awareness raising and information communication. ***Member States shall provide SME's, including start-ups, having a registered office or a branch in the Union, with priority access to the AI regulatory sandboxes provided that they fulfil the eligibility conditions and selection criteria and without precluding*** G

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	Member States should possibly ensure that one of the languages determined and accepted by them for relevant providers' documentation and for communication with operators is one which is broadly understood by the largest possible number of cross-border users.	***Security Incident Response Teams, National Data Protection Agencies, the AI-on demand platform, the European Digital Innovation Hubs and other relevant instruments funded by EU programmes as well as the Testing and Experimentation Facilities established by the Commission and the Member States at national or Union level. Where appropriate, these channels shall work together to create synergies and ensure homogeneity in their guidance to start-ups, SMEs and users.*** Moreover, the specific interests and needs of small-scale providers shall be taken into account when Notified Bodies set conformity assessment fees. ***The Commission shall regularly assess the certification and compliance costs for SMEs and start-ups, including through transparent consultations with SMEs, start-ups and users and shall work with Member States to lower such costs. For example,*** translation costs related to mandatory documentation and communication with authorities may constitute a significant cost for providers and other operators, notably those of a smaller scale. Member States should possibly ensure that one of the languages determined and accepted by them for relevant providers' documentation and for communication with	Member States should possibly ensure that one of the languages determined and accepted by them for relevant providers' documentation and for communication with operators is one which is broadly understood by the largest possible number of cross-border users.	***other providers and prospective providers to access the sandboxes provided the same conditions and criteria are fulfilled. Member States shall utilise existing channels and where appropriate, establish new dedicated channels for communication with SMEs, start-ups, deployers other innovators and, as appropriate, local public authorities, to support SMEs throughout their development path by providing guidance and responding to queries about the implementation of this Regulation. Where appropriate, these channels shall work together to create synergies and ensure homogeneity in their guidance to SMEs including start-ups and deployers. Additionally, Member States should facilitate the participation of SMEs and other relevant stakeholders in the standardisation development processes.*** Moreover, the specific interests and needs of ~~small-scale~~ ***SMEs including start-up*** providers ~~shall~~***should*** be taken into account when Notified Bodies set conformity assessment fees. ***The Commission should regularly assess the certification and compliance costs for SMEs including start-ups, through transparent consultations deployers and should work with Member States to lower such costs.***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		operators is one which is broadly understood by the largest possible number of cross-border users. ***Medium-sized enterprises which recently changed from the small to medium-size category within the meaning of the Annex to Recommendation 2003/361/EC (Article 16) shall have access to these initiatives and guidance for a period of time deemed appropriate by the Member States, as these new medium-sized enterprises may sometimes lack the legal resources and training necessary to ensure proper understanding and compliance with provisions.***		***For example,*** translation costs related to mandatory documentation and communication with authorities may constitute a significant cost for providers and other operators, notably those of a smaller scale. Member States should possibly ensure that one of the languages determined and accepted by them for relevant providers' documentation and for communication with operators is one which is broadly understood by the largest possible number of cross-border ~~users~~***deployers. In order to address the specific needs of SMEs including start-ups, the Commission should provide standardised templates for the areas covered by this Regulation upon request of the AI Board. Additionally, the Commission should complement Member States' efforts by providing a single information platform with easy-to-use information with regards to this Regulation for all providers and deployers, by organising appropriate communication campaigns to raise awareness about the obligations arising from this Regulation, and by evaluating and promoting the convergence of best practices in public procurement procedures in relation to AI systems. Medium-sized enterprises which recently changed from the***

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				small to medium-size category within the meaning of the Annex to Recommendation 2003/361/EC (Article 16) should have access to these support measures , as these new medium-sized enterprises may sometimes lack the legal resources and training necessary to ensure proper understanding and compliance with provisions.
Recital 73a				
G 83a			***(73a) In order to promote and protect innovation, the AI-on demand platform, all relevant EU funding programmes and projects, such as Digital Europe Programme, Horizon Europe, implemented by the Commission and the Member States at national or EU level should contribute to the achievement of the objectives of this Regulation.***	***(73a) In order to promote and protect innovation, the AI-on demand platform, all relevant EU funding programmes and projects, such as Digital Europe Programme, Horizon Europe, implemented by the Commission and the Member States at national or Union level should, as appropriate, contribute to the achievement of the objectives of this Regulation.***
Recital 74				
G 84	(74) In order to minimise the risks to implementation resulting from lack of knowledge and expertise in the market as well as to facilitate compliance of providers and notified bodies with their obligations under this Regulation, the AI-on demand platform, the European Digital	(74) In order to minimise the risks to implementation resulting from lack of knowledge and expertise in the market as well as to facilitate compliance of providers and notified bodies with their obligations under this Regulation, the AI-on demand platform, the European Digital	(74) ***In particular,*** in order to minimise the risks to implementation resulting from lack of knowledge and expertise in the market as well as to facilitate compliance of providers***, notably SMEs,*** and notified bodies with their obligations under this Regulation, the AI-on	(74) ***In particular,*** in order to minimise the risks to implementation resulting from lack of knowledge and expertise in the market as well as to facilitate compliance of providers***, notably SMEs, including start-ups,*** and notified bodies with their obligations under this

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	Innovation Hubs and the Testing and Experimentation Facilities established by the Commission and the Member States at national or EU level should possibly contribute to the implementation of this Regulation. Within their respective mission and fields of competence, they may provide in particular technical and scientific support to providers and notified bodies.	Innovation Hubs and the Testing and Experimentation Facilities established by the Commission and the Member States at national or EU level should ~~possibly~~ contribute to the implementation of this Regulation. Within their respective mission and fields of competence, they may provide in particular technical and scientific support to providers and notified bodies.	demand platform, the European Digital Innovation Hubs and the Testing and Experimentation Facilities established by the Commission and the Member States at national or EU level should possibly contribute to the implementation of this Regulation. Within their respective mission and fields of competence, they may provide in particular technical and scientific support to providers and notified bodies.	Regulation, the AI-on demand platform, the European Digital Innovation Hubs and the Testing and Experimentation Facilities established by the Commission and the Member States at national or EU level should ~~possibly~~ contribute to the implementation of this Regulation. Within their respective mission and fields of competence, they may provide in particular technical and scientific support to providers and notified bodies.
Recital 74a				
G 84a			***(74a) Moreover, in order to ensure proportionality considering the very small size of some operators regarding costs of innovation, it is appropriate to exempt microenterprises from the most costly obligations, such as to establish a quality management system which would reduce the administrative burden and the costs for those enterprises without affecting the level of protection and the need for compliance with the requirements for high-risk AI systems.***	***(74a) Moreover, in order to ensure proportionality considering the very small size of some operators regarding costs of innovation, it is appropriate to allow microenterprises to fulfill one of the most costly obligations, namely to establish a quality management system, in a simplified manner which would reduce the administrative burden and the costs for those enterprises without affecting the level of protection and the need for compliance with the requirements for high-risk AI systems. The Commission should develop guidelines to specify the elements of the quality management system to be fulfilled in this simplified manner by*** G

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				microentreprises.
Recital 75				
G 85	(75) It is appropriate that the Commission facilitates, to the extent possible, access to Testing and Experimentation Facilities to bodies, groups or laboratories established or accredited pursuant to any relevant Union harmonisation legislation and which fulfil tasks in the context of conformity assessment of products or devices covered by that Union harmonisation legislation. This is notably the case for expert panels, expert laboratories and reference laboratories in the field of medical devices pursuant to Regulation (EU) 2017/745 and Regulation (EU) 2017/746.	(75) It is appropriate that the Commission facilitates, to the extent possible, access to Testing and Experimentation Facilities to bodies, groups or laboratories established or accredited pursuant to any relevant Union harmonisation legislation and which fulfil tasks in the context of conformity assessment of products or devices covered by that Union harmonisation legislation. This is notably the case for expert panels, expert laboratories and reference laboratories in the field of medical devices pursuant to Regulation (EU) 2017/745 and Regulation (EU) 2017/746.	(75) It is appropriate that the Commission facilitates, to the extent possible, access to Testing and Experimentation Facilities to bodies, groups or laboratories established or accredited pursuant to any relevant Union harmonisation legislation and which fulfil tasks in the context of conformity assessment of products or devices covered by that Union harmonisation legislation. This is notably the case for expert panels, expert laboratories and reference laboratories in the field of medical devices pursuant to Regulation (EU) 2017/745 and Regulation (EU) 2017/746.	(75) It is appropriate that the Commission facilitates, to the extent possible, access to Testing and Experimentation Facilities to bodies, groups or laboratories established or accredited pursuant to any relevant Union harmonisation legislation and which fulfil tasks in the context of conformity assessment of products or devices covered by that Union harmonisation legislation. This is notably the case for expert panels, expert laboratories and reference laboratories in the field of medical devices pursuant to Regulation (EU) 2017/745 and Regulation (EU) 2017/746. Text Origin: Commission Proposal
Recital 75a				
G 85a				***(75a) This Regulation should establish a governance framework that both allows to coordinate and support the application of this Regulation at national level, as well as build capabilities at Union level and integrate stakeholders in the field of artificial intelligence. The***

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				effective implementation and enforcement of this Regulation require a governance framework that allows to coordinate and build up central expertise at Union level. The Commission has established the AI Office by Commission decision of […], which has as its mission to develop Union expertise and capabilities in the field of artificial intelligence and to contribute to the implementation of Union legislation on artificial intelligence. Member States should facilitate the tasks of the AI Office with a view to support the development of Union expertise and capabilities at Union level and to strengthen the functioning of the digital single market. Furthermore, a European Artificial Intelligence Board composed of representatives of the Member States, a scientific panel to integrate the scientific community and an advisory forum to contribute stakeholder input to the implementation of this Regulation, both at national and Union level, should be established. The development of Union expertise and capabilities should also include making use of existing resources and expertise, notably through synergies with structures built up in the context of the Union level enforcement of other legislation and synergies with related

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				initiatives at Union level, such as the EuroHPC Joint Undertaking and the AI Testing and Experimentation Facilities under the Digital Europe Programme.
Recital 76				
G 86	(76) In order to facilitate a smooth, effective and harmonised implementation of this Regulation a European Artificial Intelligence Board should be established. The Board should be responsible for a number of advisory tasks, including issuing opinions, recommendations, advice or guidance on matters related to the implementation of this Regulation, including on technical specifications or existing standards regarding the requirements established in this Regulation and providing advice to and assisting the Commission on specific questions related to artificial intelligence.	(76) In order to ~~*facilitate a smooth,*~~ ***avoid fragmentation, to ensure the optimal functioning of the Single market, to ensure*** effective and harmonised implementation of this Regulation***, to achieve a high level of trustworthiness and of protection of health and safety, fundamental rights, the environment, democracy and the rule of law across the Union with regards to AI systems, to actively support national supervisory authorities, Union institutions, bodies, offices and agencies in matters pertaining to this Regulation, and to increase the uptake of artificial intelligence throughout the Union, an*** ~~*a*~~ European ***Union*** Artificial Intelligence ~~*Board*~~***Office*** should be established. The ~~*Board*~~***AI Office should have legal personality, should act in full independence,*** should be responsible for a number of advisory ***and coordination*** tasks, including issuing opinions, recommendations, advice or guidance on matters related to the	(76) In order to facilitate a smooth, effective and harmonised implementation of this Regulation a European Artificial Intelligence Board should be established. The Board should ***reflect the various interests of the AI eco-system and be composed of representatives of the Member States. In order to ensure the involvement of relevant stakeholders, a standing subgroup of the Board should be created. The Board should*** be responsible for a number of advisory tasks, including issuing opinions, recommendations, advice or ***contributing to*** guidance on matters related to the implementation of this Regulation, including on ***enforcement matters,*** technical specifications or existing standards regarding the requirements established in this Regulation and providing advice to ~~*and assisting the Commission*~~***the Commission and the Member States and their national competent authorities*** on specific questions related to artificial intelligence. ***In order to give some***	(76) In order to facilitate a smooth, effective and harmonised implementation of this Regulation a European Artificial Intelligence Board should be established. The Board should ***reflect the various interests of the AI eco-system and be composed of representatives of the Member States. The Board should*** be responsible for a number of advisory tasks, including issuing opinions, recommendations, advice or ***contributing to*** guidance on matters related to the implementation of this Regulation, including on ***enforcement matters,*** technical specifications or existing standards regarding the requirements established in this Regulation and providing advice to ***the Commission and the Member States and their national competent authorities***~~*and assisting the Commission*~~ on specific questions related to artificial intelligence. ***In order to give some flexibility to Member States in the designation of their representatives in the AI Board, such*** G

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		implementation of this Regulation ***and should be adequately funded and staffed. Member States should provide the strategic direction and control of the AI Office through the management board of the AI Office, alongside the Commission, the EDPS, the FRA, and ENISA. An executive director should be responsible for managing the activities of the secretariat of the AI office and for representing the AI office. Stakeholders should formally participate in the work of the AI Office through an advisory forum that should ensure varied and balanced stakeholder representation and should advise the AI Office on matters pertaining to this Regulation. In case the establishment of the AI Office prove not to be sufficient to ensure a fully consistent application of this Regulation at Union level as well as efficient cross-border enforcement measures, the creation of an AI agency should be considered***~~, including on technical specifications or existing standards regarding the requirements established in this Regulation and providing advice to and assisting the Commission on specific questions related to artificial intelligence~~.	***flexibility to Member States in the designation of their representatives in the AI Board, such representatives may be any persons belonging to public entities who should have the relevant competences and powers to facilitate coordination at national level and contribute to the achievement of the Board's tasks. The Board should establish two standing sub-groups to provide a platform for cooperation and exchange among market surveillance authorities and notifying authorities on issues related respectively to market surveillance and notified bodies. The standing subgroup for market surveillance should act as the Administrative Cooperation Group (ADCO) for this Regulation in the meaning of Article 30 of Regulation (EU) 2019/1020. In line with the role and tasks of the Commission pursuant to Article 33 of Regulation (EU) 2019/1020, the Commission should support the activities of the standing subgroup for market surveillance by undertaking market evaluations or studies, notably with a view to identifying aspects of this Regulation requiring specific and urgent coordination among market surveillance authorities. The Board may establish other standing or***	***representatives may be any persons belonging to public entities who should have the relevant competences and powers to facilitate coordination at national level and contribute to the achievement of the Board's tasks. The Board should establish two standing sub-groups to provide a platform for cooperation and exchange among market surveillance authorities and notifying authorities on issues related respectively to market surveillance and notified bodies. The standing subgroup for market surveillance should act as the Administrative Cooperation Group (ADCO) for this Regulation in the meaning of Article 30 of Regulation (EU) 2019/1020. In line with the role and tasks of the Commission pursuant to Article 33 of Regulation (EU) 2019/1020, the Commission should support the activities of the standing subgroup for market surveillance by undertaking market evaluations or studies, notably with a view to identifying aspects of this Regulation requiring specific and urgent coordination among market surveillance authorities. The Board may establish other standing or temporary sub-groups as appropriate for the purpose of examining specific issues. The***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			temporary sub-groups as appropriate for the purpose of examining specific issues. The Board should also cooperate, as appropriate, with relevant EU bodies, experts groups and networks active in the context of relevant EU legislation, including in particular those active under relevant EU regulation on data, digital products and services.	***Board should also cooperate, as appropriate, with relevant EU bodies, experts groups and networks active in the context of relevant EU legislation, including in particular those active under relevant EU regulation on data, digital products and services.*** ***(76x) With a view to ensure the involvement of stakeholders in the implementation and application of this Regulation, an advisory forum should be established to advise and provide technical expertise to the Board and the Commission. To ensure a varied and balanced stakeholder representation between commercial and non-commercial interest and, within the category of commercial interests, with regards to SMEs and other undertakings, the advisory forum should comprise inter alia industry, start-ups, SMEs, academia, civil society, including social partners, as well as the Fundamental Rights Agency, European Union Agency for Cybersecurity, the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI).*** ***(76y) To support the***

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				implementation and enforcement of this Regulation, in particular the monitoring activities of the AI Office as regards general-purpose AI models, a scientific panel of independent experts should be established. The independent experts constituting the scientific panel should be selected on the basis of up-to-date scientific or technical expertise in the field of artificial intelligence and should perform their tasks with impartiality, objectivity and ensure the confidentiality of information and data obtained in carrying out their tasks and activities. To allow reinforcing national capacities necessary for the effective enforcement of this Regulation, Member States should be able to request support from the pool of experts constituting the scientific panel for their enforcement activities.
Recital 76a				
G 86a			***(76a) The Commission should actively support the Member States and operators in the implementation and enforcement of this Regulation. In this regard it should develop guidelines on particular topics aiming at facilitating the application of this***	***(76a) In order to support adequate enforcement as regards AI systems and reinforce the capacities of the Member States, EU AI testing support structures should be established and made available to the Member States.*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Regulation, while paying particular attention to the needs of SMEs and start-us in sectors most likely to be affected. In order to support adequate enforcement and the capacities of the Member States, Union testing facilities on AI and a pool of relevant experts should be established and made available to the Member States.	
Recital 77				
G 87	(77) Member States hold a key role in the application and enforcement of this Regulation. In this respect, each Member State should designate one or more national competent authorities for the purpose of supervising the application and implementation of this Regulation. In order to increase organisation efficiency on the side of Member States and to set an official point of contact vis-à-vis the public and other counterparts at Member State and Union levels, in each Member State one national authority should be designated as national supervisory authority.	(77) ***Each*** Member ~~*States hold a key role in*~~***State should designate a national supervisory authority for the purpose of supervising*** the application and ~~*enforcement*~~***implementation*** of this Regulation. ~~*In this respect, each Member State*~~***It*** should ~~*designate one or more national competent authorities for the purpose of supervising the application and implementation of this Regulation*~~***also represent its Member State at the management board of the AI Office***. In order to increase organisation efficiency on the side of Member States and to set an official point of contact vis-à-vis the public and other counterparts at Member State and Union levels~~*, in each Member State one national authority should be designated as national supervisory authority*~~***. Each***	(77) Member States hold a key role in the application and enforcement of this Regulation. In this respect, each Member State should designate one or more national competent authorities for the purpose of supervising the application and implementation of this Regulation. ~~*In order to increase organisation efficiency on the side of Member States and to set an official point of contact vis-à-vis the public and other counterparts at Member State and Union levels, in each Member State one*~~***Member States may decide to appoint any kind of public entity to perform the tasks of the national competent authorities within the meaning of this Regulation, in accordance with their specific*** national ~~*authority should be designated as national supervisory authority*~~***organisational***	(77) Member States hold a key role in the application and enforcement of this Regulation. In this respect, each Member State should designate ***at least one notifying authority and at least one market surveillance authority as***~~*one or more*~~ national competent authorities for the purpose of supervising the application and implementation of this Regulation. ***Member States may decide to appoint any kind of public entity to perform the tasks of the national competent authorities within the meaning of this Regulation, in accordance with their specific national organisational characteristics and needs.*** In order to increase organisation efficiency on the side of Member States and to set ~~*an official*~~***a single*** point of contact vis-à-vis the public and other G

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		national supervisory authority should act with complete independence in performing its tasks and exercising its powers in accordance with this Regulation.	***characteristics and needs***.	counterparts at Member State and Union levels, ~~in~~ each Member State ~~one national authority should be designated as national supervisory authority~~***should designate a market surveillance authority to act as single point of contact***.
Recital 77a				
G 87a		***(77a) The national supervisory authorities should monitor the application of the provisions pursuant to this Regulation and contribute to its consistent application throughout the Union. For that purpose, the national supervisory authorities should cooperate with each other, with the relevant national competent authorities, the Commission, and with the AI Office.***		G
Recital 77a				
G 87b		***(77b) The member or the staff of each national supervisory authority should, in accordance with Union or national law, be subject to a duty of professional secrecy both during and after their term of office, with regard to any confidential information which has come to their knowledge in the course of the performance of their tasks or***		***(77a) The national competent authorities should exercise their powers independently, impartially and without bias, so as to safeguard the principles of objectivity of their activities and tasks and to ensure the application and implementation of this Regulation. The members of these authorities should refrain from any action incompatible with*** G

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		exercise of their powers. During their term of office, that duty of professional secrecy should in particular apply to trade secrets and to reporting by natural persons of infringements of this Regulation.		***their duties and should be subject to confidentiality rules under this Regulation.***
Recital 78				
G 88	(78) In order to ensure that providers of high-risk AI systems can take into account the experience on the use of high-risk AI systems for improving their systems and the design and development process or can take any possible corrective action in a timely manner, all providers should have a post-market monitoring system in place. This system is also key to ensure that the possible risks emerging from AI systems which continue to 'learn' after being placed on the market or put into service can be more efficiently and timely addressed. In this context, providers should also be required to have a system in place to report to the relevant authorities any serious incidents or any breaches to national and Union law protecting fundamental rights resulting from the use of their AI systems.	(78) In order to ensure that providers of high-risk AI systems can take into account the experience on the use of high-risk AI systems for improving their systems and the design and development process or can take any possible corrective action in a timely manner, all providers should have a post-market monitoring system in place. This system is also key to ensure that the possible risks emerging from AI systems which continue to 'learn' ***or evolve*** after being placed on the market or put into service can be more efficiently and timely addressed. In this context, providers should also be required to have a system in place to report to the relevant authorities any serious incidents or any breaches to national and Union law***, including those*** protecting fundamental rights ***and consumer rights*** resulting from the use of their AI systems ***and take appropriate corrective actions. Deployers should also report to the***	(78) In order to ensure that providers of high-risk AI systems can take into account the experience on the use of high-risk AI systems for improving their systems and the design and development process or can take any possible corrective action in a timely manner, all providers should have a post-market monitoring system in place. This system is also key to ensure that the possible risks emerging from AI systems which continue to 'learn' after being placed on the market or put into service can be more efficiently and timely addressed. In this context, providers should also be required to have a system in place to report to the relevant authorities any serious incidents ~~or any breaches to national and Union law protecting fundamental rights~~ resulting from the use of their AI systems.	(78) In order to ensure that providers of high-risk AI systems can take into account the experience on the use of high-risk AI systems for improving their systems and the design and development process or can take any possible corrective action in a timely manner, all providers should have a post-market monitoring system in place. ***Where relevant, post-market monitoring should include an analysis of the interaction with other AI systems including other devices and software. Post-market monitoring should not cover sensitive operational data of deployers which are law enforcement authorities.*** This system is also key to ensure that the possible risks emerging from AI systems which continue to 'learn' after being placed on the market or put into service can be more efficiently and timely addressed. In this context, providers should also be required to have a system in place to report to the relevant authorities any

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		relevant authorities, any serious incidents or breaches to national and Union law resulting from the use of their AI system when they become aware of such serious incidents or breaches.		serious incidents ***resulting from the use of their AI systems, meaning incident or malfunctioning leading to death or serious damage to health, serious and irreversible disruption of the management and operation of critical infrastructure, breaches of obligations under*** ~~or any breaches to national and~~ Union law ~~protecting~~***intended to protect*** fundamental rights ~~resulting from the use of their AI systems~~***or serious damage to property or the environment***.
Recital 79				
G 89	(79) In order to ensure an appropriate and effective enforcement of the requirements and obligations set out by this Regulation, which is Union harmonisation legislation, the system of market surveillance and compliance of products established by Regulation (EU) 2019/1020 should apply in its entirety. Where necessary for their mandate, national public authorities or bodies, which supervise the application of Union law protecting fundamental rights, including equality bodies, should also have access to any documentation created under this Regulation.	(79) In order to ensure an appropriate and effective enforcement of the requirements and obligations set out by this Regulation, which is Union harmonisation legislation, the system of market surveillance and compliance of products established by Regulation (EU) 2019/1020 should apply in its entirety. ***For the purpose of this Regulation, national supervisory authorities should act as market surveillance authorities for AI systems covered by this Regulation except for AI systems covered by Annex II of this Regulation. For AI systems covered by legal acts listed in the Annex II, the competent authorites under***	(79) In order to ensure an appropriate and effective enforcement of the requirements and obligations set out by this Regulation, which is Union harmonisation legislation, the system of market surveillance and compliance of products established by Regulation (EU) 2019/1020 should apply in its entirety. ~~Where necessary for~~***Market surveillance authorities designated pursuant to this Regulation should have all enforcement powers under this Regulation and Regulation (EU) 2019/1020 and should exercise*** their ~~mandate, national public~~***powers and carry out their duties independently, impartially and***	(79) In order to ensure an appropriate and effective enforcement of the requirements and obligations set out by this Regulation, which is Union harmonisation legislation, the system of market surveillance and compliance of products established by Regulation (EU) 2019/1020 should apply in its entirety. ***Market surveillance authorities designated pursuant to this Regulation should have all enforcement powers under this Regulation and Regulation (EU) 2019/1020 and should exercise*** ~~Where necessary for~~ their ~~mandate, national public~~***powers and carry out their duties independently,*** G

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		those legal acts should remain the lead authority. National supervisory authorities and competent authorities in the legal acts listed in Annex II should work together whenever necessary. When appropriate, the competent authorities in the legal acts listed in Annex II should send competent staff to the national supervisory authority in order to assist in the performance of its tasks. For the purpose of this Regulation, national supervisory authorities should have the same powers and obligations as market surveillance authorities under Regulation (EU) 2019/1020. Where necessary for their mandate, national public authorities or bodies, which supervise the application of Union law protecting fundamental rights, including equality bodies, should also have access to any documentation created under this Regulation. ***After having exhausted all other reasonable ways to assess/verify the conformity and upon a reasoned request, the national supervisory authority should be granted access to the training, validation and testing datasets, the trained and training model of the high-risk AI system, including its relevant model parameters and their execution /run environment. In cases of simpler software systems falling under this***	***without bias. Although the majority of AI systems are not subject to specific requirements and obligations under this Requaltion, market surveillance*** authorities ~~or~~***may take measures in relation to all AI systems when they present a risk in accordance with this Regulation. Due to the specific nature of Union institutions, agencies and*** bodies ***falling within the scope of this Regulation, it is appropriate to designate the European Data Protection Supervisor as a competent market surveillance authority for them. This should be without prejudice to the designation of national competent authorities by the Member States. Market surveillance activities***~~, which supervise the application of Union law protecting fundamental rights, including equality bodies,~~ should ~~also have access to any documentation created under this Regulation~~***not affect the ability of the supervised entities to carry out their tasks independently, when such independence is required by Union law***.	***impartially and without bias. Although the majority of AI systems are not subject to specific requirements and obligations under this Regulation, market surveillance*** authorities ~~or~~***may take measures in relation to all AI systems when they present a risk in accordance with this Regulation. Due to the specific nature of Union institutions, agencies and*** bodies ***falling within the scope of this Regulation, it is appropriate to designate the European Data Protection Supervisor as a competent market surveillance authority for them. This should be without prejudice to the designation of national competent authorities by the Member States. Market surveillance activities***~~, which supervise the application of Union law protecting fundamental rights, including equality bodies,~~ should ~~also have access to any documentation created under this Regulation~~***not affect the ability of the supervised entities to carry out their tasks independently, when such independence is required by Union law***.

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		Regulation that are not based on trained models, and where all other ways to verify conformity have been exhausted, the national supervisory authority may exceptionally have access to the source code, upon a reasoned request. Where the national supervisory authority has been granted access to the training, validation and testing datasets in accordance with this Regulation, such access should be achieved through appropriate technical means and tools, including on site access and in exceptional circumstances, remote access. The national supervisory authority should treat any information, including source code, software, and data as applicable, obtained as confidential information and respect relevant Union law on the protection of intellectual property and trade secrets. The national supervisory authority should delete any information obtained upon the completion of the investigation.		
Recital 79a				
G 89a			***(79a) This Regulation is without prejudice to the competences, tasks, powers and independence of relevant national public authorities or bodies which supervise the application of Union law protecting***	***(79a) This Regulation is without prejudice to the competences, tasks, powers and independence of relevant national public authorities or bodies which supervise the application of Union law protecting*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			fundamental rights, including equality bodies and data protection authorities. Where necessary for their mandate, those national public authorities or bodies should also have access to any documentation created under this Regulation. A specific safeguard procedure should be set for ensuring adequate and timely enforcement against AI systems presenting a risk to health, safety and fundamental rights. The procedure for such AI systems presenting a risk should be applied to high-risk AI systems presenting a risk, prohibited systems which have been placed on the market, put into service or used in violation of the prohibited practices laid down in this Regulation and AI systems which have been made available in violation of the transparency requirements laid down in this Regulation and present a risk.	***fundamental rights, including equality bodies and data protection authorities. Where necessary for their mandate, those national public authorities or bodies should also have access to any documentation created under this Regulation. A specific safeguard procedure should be set for ensuring adequate and timely enforcement against AI systems presenting a risk to health, safety and fundamental rights. The procedure for such AI systems presenting a risk should be applied to high-risk AI systems presenting a risk, prohibited systems which have been placed on the market, put into service or used in violation of the prohibited practices laid down in this Regulation and AI systems which have been made available in violation of the transparency requirements laid down in this Regulation and present a risk.***
Recital 80				
G 90	(80) Union legislation on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI	(80) Union ~~legislation~~***law*** on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI	(80) Union legislation on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI	(80) Union legislation on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI G

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	systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the authorities responsible for the supervision and enforcement of the financial services legislation, including where applicable the European Central Bank, should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, including for market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council[1], it is also appropriate to integrate the conformity assessment procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive 2013/36/EU. In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality management system of providers and the monitoring	systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services ~~legislation, the~~ ***law, the competent*** authorities responsible for the supervision and enforcement of the financial services ~~legislation~~***law***, including where applicable the European Central Bank, should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, including for market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council[1], it is also appropriate to integrate the conformity assessment procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive 2013/36/EU. In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality management system of providers and the monitoring	systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the authorities responsible for the supervision and enforcement of the financial services legislation~~, including where applicable the European Central Bank,~~ should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, including for market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions ***unless Member States decide to designate another authority to fulfill these market surveillance tasks. Those competent authorities should have all powers under this Regulation and Regulation (EU) 2019/1020 on market surveillance to enforce the requirements and obligations of this Regulation, including powers to carry our ex post market surveillance activities that can be integrated, as appropriate, into their existing supervisory mechanisms and procedures under the relevant Union financial services legislation. It is appropriate to envisage that, when acting as market surveillance authorities under this Regulation,***	systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the ~~authorities responsible~~***competent authorities*** for the supervision and enforcement of the financial services legislation, ~~including where applicable~~***notably competent authorities as defined in Directive 2009/138/EC, Directive (EU) 2016/97, Directive 2013/36/EU Regulation (EU) No 575/2013, Directive 2008/48/EC and Directive 2014/17/EU of*** the European ~~Central Bank~~***Parliament and of the Council***, should be designated***, within their respective competences,*** as competent authorities for the purpose of supervising the implementation of this Regulation, including for market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions ***unless Member States decide to designate another authority to fulfil these market surveillance tasks. Those competent authorities should have all powers under this Regulation and Regulation (EU) 2019/1020 on market surveillance to enforce the requirements and obligations of this Regulation, including powers to carry our ex post market***

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	obligation placed on users of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU. _____ 1. Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).	obligation placed on ~~users~~***deployers*** of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU. _____ 1. Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).	***the national authorities responsible for the supervision of credit institutions regulated under Directive 2013/36/EU, which are participating in the Single Supervisory Mechanism (SSM) established by Council Regulation No 1024/2013, should report, without delay, to the European Central Bank any information identified in the course of their market surveillance activities that may be of potential interest for the European Central Bank's prudential supervisory tasks as specified in that Regulation***. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council[1], it is also appropriate to integrate ~~*the conformity assessment procedure and*~~ some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive 2013/36/EU. In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality management system of providers and the monitoring obligation placed on users of high-risk AI systems to the extent that	***surveillance activities that can be integrated, as appropriate, into their existing supervisory mechanisms and procedures under the relevant Union financial services legislation. It is appropriate to envisage that, when acting as market surveillance authorities under this Regulation, the national authorities responsible for the supervision of credit institutions regulated under Directive 2013/36/EU, which are participating in the Single Supervisory Mechanism (SSM) established by Council Regulation No 1024/2013, should report, without delay, to the European Central Bank any information identified in the course of their market surveillance activities that may be of potential interest for the European Central Bank's prudential supervisory tasks as specified in that Regulation***. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council[1], it is also appropriate to integrate ~~*the conformity assessment procedure and*~~ some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			these apply to credit institutions regulated by Directive 2013/36/EU. ***The same regime should apply to insurance and re-insurance undertakings and insurance holding companies under Directive 2009/138/EU (Solvency II) and the insurance intermediaries under Directive 2016/97/EU and other types of financial institutions subject to requirements regarding internal governance, arrangements or processes established pursuant to the relevant Union financial services legislation to ensure consistency and equal treatment in the financial sector.*** _____ 1. *[1]* Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).	procedures under Directive 2013/36/EU. In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality management system of providers and the monitoring obligation placed on ~~users~~***deployers*** of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU. ***The same regime should apply to insurance and re-insurance undertakings and insurance holding companies under Directive 2009/138/EU (Solvency II) and the insurance intermediaries under Directive 2016/97/EU and other types of financial institutions subject to requirements regarding internal governance, arrangements or processes established pursuant to the relevant Union financial services legislation to ensure consistency and equal treatment in the financial sector.*** ***(80-x) Each market surveillance authority for high-risk AI systems listed in point 1 of Annex III insofar as these systems are used for law enforcement purposes and for purposes listed in points 6, 7 and 8 of Annex III should have effective investigative and corrective powers, including at least the power to obtain access to all personal data that are being***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				processed and to all information necessary for the performance of its tasks. The market surveillance authorities should be able to exercise their powers by acting with complete independence. Any limitations of their access to sensitive operational data under this Regulation should be without prejudice to the powers conferred to them by Directive 2016/680. No exclusion on disclosing data to national data protection authorities under this Regulation should affect the current or future powers of those authorities beyond the scope of this Regulation. ***(80x) The market surveillance authorities of the Member States and the Commission should be able to propose joint activities, including joint investigations, to be conducted by market surveillance authorities or market surveillance authorities jointly with the Commission, that have the aim of promoting compliance, identifying non-compliance, raising awareness and providing guidance in relation to this Regulation with respect to specific categories of high-risk AI systems that are found to present a serious risk across several Member States. Joint activities to promote compliance should be carried out in accordance with Article 9 of the***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				2019/1020. The AI Office should provide coordination support for joint investigations. ***(80y) It is necessary to clarify the responsibilities and competences on national and Union level as regards AI systems that are built on general-purpose AI models. To avoid overlapping competences, where an AI system is based on a general-purpose AI model and the model and system are provided by the same provider, the supervision should take place at Union level through the AI Office, which should have the powers of a market surveillance authority within the meaning of Regulation (EU) 2019/1020 for this purpose. In all other cases, national market surveillance authorities remain responsible for the supervision of AI systems. However, for general-purpose AI systems that can be used directly by deployers for at least one purpose that is classified as high-risk, market surveillance authorities should cooperate with the AI Office to carry out evaluations of compliance and inform the Board and other market surveillance authorities accordingly. Furthermore, market surveillance authorities should be able to request assistance from the AI Office where the market***

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				surveillance authority is unable to conclude an investigation on a high-risk AI system because of its inability to access certain information related to the general-purpose AI model on which the high-risk AI system is built. In such cases, the procedure regarding mutual assistance in cross-border cases in Chapter VI of Regulation (EU) 2019/1020 should apply by analogy. ***(80z) To make best use of the centralised Union expertise and synergies at Union level, the powers of supervision and enforcement of the obligations on providers of general-purpose AI models should be a competence of the Commission. The Commission should entrust the implementation of these tasks to the AI Office, without prejudice to the powers of organisation of the Commission and the division of competences between member States and the Union based on the Treaties. The AI Office should be able to carry out all necessary actions to monitor the effective implementation of this Regulation as regards general-purpose AI models. It should be able to investigate possible infringements of the rules on providers of general-purpose AI models both on its own initiative,***

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				following the results of its monitoring activities, or upon request from market surveillance authorities in line with the conditions set out in this Regulation. To support effective monitoring of the AI Office, it should provide for the possibility that downstream providers lodge complaints about possible infringements of the rules on providers of general-purpose AI systems. ***(80z+1) With a view to complement the governance systems for general-purpose AI models, the scientific panel should support the monitoring activities of the AI Office and may, in certain cases, provide qualified alerts to the AI Office which trigger follow-ups such as investigations. This should be the case where the scientific panel has reason to suspect that a general-purpose AI model poses a concrete and identifiable risk at Union level. Furthermore, this should be the case where the scientific panel has reason to suspect that a general-purpose AI model meets the criteria that would lead to a classification as general-purpose AI model with systemic risk. To equip the scientific panel with the information necessary for the performance of these tasks,***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				there should be a mechanism whereby the scientific panel can request the Commission to require documentation or information from a provider. ***(80z+2) The AI Office should be able to take the necessary actions to monitor the effective implementation of and compliance with the obligations for providers of general purpose AI models laid down in this Regulation. The AI Office should be able to investigate possible infringements in accordance with the powers provided for in this Regulation, including by requesting documentation and information, by conducting evaluations, as well as by requesting measures from providers of general purpose AI models. In the conduct of evaluations, in order to make use of independent expertise, the AI Office should be able to involve independent experts to carry out the evaluations on its behalf. Compliance with the obligations should be enforceable, inter alia, through requests to take appropriate measures, including risk mitigation measures in case of identified systemic risks as well as restricting the making available on the market, withdrawing or recalling the model. As a safeguard***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				in case needed beyond the procedural rights provided for in this Regulation, providers of general-purpose AI models should have the procedural rights provided for in Article 18 of Regulation (EU) 2019/1020, which should apply by analogy, without prejudice to more specific procedural rights provided for by this Regulation. _____ 1. Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338). Text Origin: GSC
Recital 80a				
G 90a		***(80a) Given the objectives of this Regulation, namely to ensure an equivalent level of protection of health, safety and fundamental rights of natural persons, to ensure the protection of the rule of law and democracy, and taking into account that the mitigation of the risks of AI system against such rights may not be sufficiently achieved at national level or may be subject to diverging interpretation which could ultimately lead to an uneven level of protection of natural persons and***		G

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		create market fragmentation, the national supervisory authorities should be empowered to conduct joint investigations or rely on the union safeguard procedure provided for in this Regulation for effective enforcement. Joint investigations should be initiated where the national supervisory authority have sufficient reasons to believe that an infringement of this Regulation amount to a widespread infringement or a widespread infringement with a Union dimension, or where the AI system or foundation model presents a risk which affects or is likely to affect at least 45 million individuals in more than one Member State.		
Recital 80a				
G 90b				G
Recital 81				
G 91	(81) The development of AI systems other than high-risk AI systems in accordance with the requirements of this Regulation may lead to a larger uptake of trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should be encouraged to create codes of conduct intended to foster the voluntary application of	(81) The development of AI systems other than high-risk AI systems in accordance with the requirements of this Regulation may lead to a larger uptake of trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should be encouraged to create codes of conduct intended to foster the voluntary application of	(81) The development of AI systems other than high-risk AI systems in accordance with the requirements of this Regulation may lead to a larger uptake of trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should be encouraged to create codes of conduct intended to foster the voluntary application of	(81) The development of AI systems other than high-risk AI systems in accordance with the requirements of this Regulation may lead to a larger uptake of ***ethical and*** trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should be encouraged to create codes of conduct***, including related*** G

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	the mandatory requirements applicable to high-risk AI systems. Providers should also be encouraged to apply on a voluntary basis additional requirements related, for example, to environmental sustainability, accessibility to persons with disability, stakeholders' participation in the design and development of AI systems, and diversity of the development teams. The Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI development, including on data access infrastructure, semantic and technical interoperability of different types of data.	the mandatory requirements applicable to high-risk AI systems. Providers should also be encouraged to apply on a voluntary basis additional requirements related, for example, to environmental sustainability, accessibility to persons with disability, stakeholders' participation in the design and development of AI systems, and diversity of the development teams. The Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI development, including on data access infrastructure, semantic and technical interoperability of different types of data.	the ~~mandatory~~ requirements applicable to high-risk AI systems***, adapted in light of the intended purpose of the systems and the lower risk involved***. Providers should also be encouraged to apply on a voluntary basis additional requirements related, for example, to environmental sustainability, accessibility to persons with disability, stakeholders' participation in the design and development of AI systems, and diversity of the development teams. The Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI development, including on data access infrastructure, semantic and technical interoperability of different types of data.	***governance mechanisms,*** intended to foster the voluntary application of ***some or all of*** the mandatory requirements applicable to high-risk AI systems***, adapted in light of the intended purpose of the systems and the lower risk involved and taking into account the available technical solutions and industry best practices such as model and data cards***. Providers ***and, as appropriate, deployers of all AI systems, high-risk or not, and models*** should also be encouraged to apply on a voluntary basis additional requirements related, for example, to ***the elements of the European ethic guidelines for trustworthy AI,*** environmental sustainability, ***AI literacy measures, inclusive and diverse design and development of AI systems, including attention to vulnerable persons and*** accessibility to persons with disability, stakeholders' participation ***with the involvement as appropriate, of relevant stakeholders such as business and civil society organisations, academia and research organisations, trade unions and consumer protection organisation*** in the design and development of AI systems, and diversity of the development teams***, including gender balance. To ensure that the voluntary codes of conduct are effective, they should***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				be based on clear objectives and key performance indicators to measure the achievement of those objectives. They should be also developed in an inclusive way, as appropriate, with the involvement of relevant stakeholders such as business and civil society organisations, academia and research organisations, trade unions and consumer protection organisation. The Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI development, including on data access infrastructure, semantic and technical interoperability of different types of data.
Recital 82				
G 92	(82) It is important that AI systems related to products that are not high-risk in accordance with this Regulation and thus are not required to comply with the requirements set out herein are nevertheless safe when placed on the market or put into service. To contribute to this objective, the Directive 2001/95/EC of the European Parliament and of the Council[1] would apply as a safety net. _____	(82) It is important that AI systems related to products that are not high-risk in accordance with this Regulation and thus are not required to comply with the requirements set out ~~herein~~***for high-risk AI systems*** are nevertheless safe when placed on the market or put into service. To contribute to this objective, the Directive 2001/95/EC of the European Parliament and of the Council[1]~~–~~ would apply as a safety net.	(82) It is important that AI systems related to products that are not high-risk in accordance with this Regulation and thus are not required to comply with the requirements set out herein are nevertheless safe when placed on the market or put into service. To contribute to this objective, the Directive 2001/95/EC of the European Parliament and of the Council[1]~~–~~ would apply as a safety net. _____	(82) It is important that AI systems related to products that are not high-risk in accordance with this Regulation and thus are not required to comply with the requirements set out ~~herein~~***for high-risk AI systems*** are nevertheless safe when placed on the market or put into service. To contribute to this objective, ~~the Directive 2001/95/EC~~ ***Regulation (EU) 2023/988*** of the European Parliament and of the Council[1] would apply as a safety net. G

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	1. Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).	_____ 1. -Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).	1. -Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).	_____ 1. ***Regulation (EU) 2023/988*** ~~Directive 2001/95/EC~~ of the European Parliament and of the Council of ~~3 December 2001~~***of 10 May 2023*** on general product safety***, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (Text with EEA relevance) (OJ L 135, 23.5.2023, p. 1–51)*** ~~(OJ L 11, 15.1.2002, p. 4)~~.
Recital 83				
G 93	(83) In order to ensure trustful and constructive cooperation of competent authorities on Union and national level, all parties involved in the application of this Regulation should respect the confidentiality of information and data obtained in carrying out their tasks.	(83) In order to ensure trustful and constructive cooperation of competent authorities on Union and national level, all parties involved in the application of this Regulation should ~~respect~~***aim for transparency and openness while respecting*** the confidentiality of information and data obtained in carrying out their tasks ***by putting in place technical and organisational measures to protect the security and confidentiality of the information obtained carrying out their activities including for intellectual property rights and public and national security interests. Where the activities of the Commission, national competent authorities and notified bodies pursuant to this Regulation results in a breach of***	(83) In order to ensure trustful and constructive cooperation of competent authorities on Union and national level, all parties involved in the application of this Regulation should respect the confidentiality of information and data obtained in carrying out their tasks***, in accordance with Union or national law***.	(83) In order to ensure trustful and constructive cooperation of competent authorities on Union and national level, all parties involved in the application of this Regulation should respect the confidentiality of information and data obtained in carrying out their tasks***, in accordance with Union or national law. They should carry out their tasks and activities in such a manner as to protect, in particular, intellectual property rights, confidential business information and trade secrets, the effective implementation of this Regulation, public and national security interests, the integrity of criminal or administrative proceedings, and the integrity of classified information.*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		intellectual property rights, Member States should provide for adequate measures and remedies to ensure the enforcement of intellectual property rights in application of Directive 2004/48/EC.		
Recital 84				
G 94	(84) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement. For certain specific infringements, Member States should take into account the margins and criteria set out in this Regulation. The European Data Protection Supervisor should have the power to impose fines on Union institutions, agencies and bodies falling within the scope of this Regulation.	(84) ***Compliance with this Regulation should be enforceable by means of the imposition of fines by the national supervisory authority when carrying out proceedings under the procedure laid down in this Regulation.*** Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement. ***In order to strengthen and harmonise administrative penalties for infringement of this Regulation, the upper limits for setting the administrative fines*** for certain specific infringements ***should be laid down. When assessing the amount of the fines, national competent authorities***~~,~~ ~~*Member States*~~ should***, in each individual case,*** take into account ***all relevant circumstances of the specific situation, with due regard in particular to the nature, gravity***	(84) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement***, and in respect of the ne bis in idem principle***. For certain specific infringements, Member States should take into account the margins and criteria set out in this Regulation. The European Data Protection Supervisor should have the power to impose fines on Union institutions, agencies and bodies falling within the scope of this Regulation.	(84) ***Compliance with this Regulation should be enforceable by means of the imposition of penalties and other enforcement measures.*** Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement***, and in respect of the ne bis in idem principle. In order to strengthen and harmonise administrative penalties for infringement of this Regulation, the upper limits for setting the administrative fines*** ~~.~~ for certain specific infringements ***should be laid down. When assessing the amount of the fines***, Member States should***, in each individual case,*** take into account ***all relevant circumstances of the specific situation, with due regard in particular to the nature, gravity and duration of the infringement and of its consequences and to the*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		and duration of the infringement and of its consequences and to the provider's size, in particular if the provider is a SME or a start-up~~the margins and criteria set out in this Regulation~~. The European Data Protection Supervisor should have the power to impose fines on Union institutions, agencies and bodies falling within the scope of this Regulation. ***The penalties and litigation costs under this Regulation should not be subject to contractual clauses or any other arrangements.***		***provider's size, in particular if the provider is an SME including a start-up***~~the margins and criteria set out in this Regulation~~. The European Data Protection Supervisor should have the power to impose fines on Union institutions, agencies and bodies falling within the scope of this Regulation. ***(84a) Compliance with the obligations on providers of general-purpose AI models imposed under this Regulation should be enforceable among others by means of fines. To that end, appropriate levels of fines should also be laid down for infringement of those obligations, including the failure to comply with measures requested by the Commission in accordance with this Regulation, subject to appropriate limitation periods in accordance with the principle of proportionality. All decisions taken by the Commission under this Regulation are subject to review by the Court of Justice of the European Union in accordance with the TFEU.***
Recital 84a				
G 94a		***(84a) As the rights and freedoms of natural and legal persons and groups of natural persons can be***		***(84aa) Union and national law already provides effective remedies to natural and legal persons whose*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		seriously undermined by AI systems, it is essential that natural and legal persons or groups of natural persons have meaningful access to reporting and redress mechanisms and to be entitled to access proportionate and effective remedies. They should be able to report infringments of this Regulation to their national supervisory authority and have the right to lodge a complaint against the providers or deployers of AI systems. Where applicable, deployers should provide internal complaints mechanisms to be used by natural and legal persons or groups of natural persons. Without prejudice to any other administrative or non-judicial remedy, natural and legal persons and groups of natural persons should also have the right to an effective judicial remedy with regard to a legally binding decision of a national supervisory authority concerning them or, where the national supervisory authority does not handle a complaint, does not inform the complainant of the progress or preliminary outcome of the complaint lodged or does not comply with its obligation to reach a final decision, with regard to the complaint.		***rights and freedoms are adversely affected by the use of AI systems. Without prejudice to those remedies, any natural or legal person having grounds to consider that there has been an infringement of the provisions of this Regulation should be entitled to lodge a complaint to the relevant market surveillance authority.*** Text Origin: EP Mandate
Recital 84b				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 94b		*(84b) Affected persons should always be informed that they are subject to the use of a high-risk AI system, when deployers use a high-risk AI system to assist in decision-making or make decisions related to natural persons. This information can provide a basis for affected persons to exercise their right to an explanation under this Regulation.When deployers provide an explanation to affected persons under this Regulation, they should take into account the level of expertise and knowledge of the average consumer or individual.*		*(84b) Affected persons should have the right to request an explanation when a decision is taken by the deployer with the output from certain high-risk systems as provided for in this Regulation as the main basis and which produces legal effects or similarly significantly affects him or her in a way that they consider to adversely impact their health, safety or fundamental rights. This explanation should be a clear and meaningful and should provide a basis for affected persons to exercise their rights. This should not apply to the use of AI systems for which exceptions or restrictions follow from Union or national law and should apply only to the extent this right is not already provided for under Union legislation.* G
Recital 84c				
G 94c		*(84c) Union law on the protection of whistleblowers (Directive (EU) 2019/1937) has full application to academics, designers, developers, project contributors, auditors, product managers, engineers and economic operators acquiring information on breaches of Union law by a provider of AI system or its AI system.*		*(84c) Persons acting as 'whisteblowers' on the breaches of this Regulation should be afforded the protection guaranteed by Union legislation on the protection of persons who report breaches of law. Therefore, Directive (EU) 2019/1937 should apply to the reporting of breaches of this Regulation and the protection of* G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				persons reporting such breaches.
Recital 85				
G 95	(85) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the techniques and approaches referred to in Annex I to define AI systems, the Union harmonisation legislation listed in Annex II, the high-risk AI systems listed in Annex III, the provisions regarding technical documentation listed in Annex IV, the content of the EU declaration of conformity in Annex V, the provisions regarding the conformity assessment procedures in Annex VI and VII and the provisions establishing the high-risk AI systems to which the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation should apply. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional	(85) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the ~~*techniques and approaches referred to in Annex I to define AI systems, the*~~ Union harmonisation legislation listed in Annex II, the high-risk AI systems listed in Annex III, the provisions regarding technical documentation listed in Annex IV, the content of the EU declaration of conformity in Annex V, the provisions regarding the conformity assessment procedures in Annex VI and VII and the provisions establishing the high-risk AI systems to which the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation should apply. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional	(85) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the ~~*techniques and approaches referred to in Annex I to define AI systems, the*~~ Union harmonisation legislation listed in Annex II, the high-risk AI systems listed in Annex III, the provisions regarding technical documentation listed in Annex IV, the content of the EU declaration of conformity in Annex V, the provisions regarding the conformity assessment procedures in Annex VI and VII and the provisions establishing the high-risk AI systems to which the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation should apply. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional	(85) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the ~~*techniques and approaches referred to in Annex I to define AI systems, the*~~ Union harmonisation legislation listed in Annex II, the high-risk AI systems listed in Annex III, the provisions regarding technical documentation listed in Annex IV, the content of the EU declaration of conformity in Annex V, the provisions regarding the conformity assessment procedures in Annex VI and VII ~~*and*~~***,*** the provisions establishing the high-risk AI systems to which the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation should apply***, the threshold as well as to supplement benchmarks and indicators in the rules for classification of general-purpose AI models with systemic risk, the criteria for the designation of general-purpose AI models with systemic risk in Annex YY, the*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Agreement of 13 April 2016 on Better Law-Making[1]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. _____ 1. OJ L 123, 12.5.2016, p. 1.	Agreement of 13 April 2016 on Better Law-Making[1]. ***These consultations should involve the participation of a balanced selection of stakeholders, including consumer organisations, civil society, associations representing affected persons, businesses representatives from different sectors and sizes, as well as researchers and scientists***. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. _____ 1. OJ L 123, 12.5.2016, p. 1.	Agreement of 13 April 2016 on Better Law-Making[1]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. ***Such consultations and advisory support should also be carried out in the framework of the activities of the AI Board and its subgroups.*** _____ 1. ***[1]*** OJ L 123, 12.5.2016, p. 1.	***technical documentation for providers of general-purpose AI models in Annex VIIIb and the transparency information for providers of general-purpose AI models in Annex VIIIc***. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[~~1~~1]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. _____ ~~1. OJ L 123, 12.5.2016, p. 1.~~
Recital 85a				
G 95a		***(85a) Given the rapid technological developments and the required technical expertise in conducting the assessment of high-risk AI systems, the Commission should regularly review the***		***(85a) Given the rapid technological developments and the required technical expertise in the effective application of this Regulation, the Commission should evaluate and review this Regulation by three*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		implementation of this Regulation, in particular the prohibited AI systems, the transparency obligations and the list of high-risk areas and use cases, at least every year, while consulting the AI office and the relevant stakeholders.		***years after the date of entry into application and every four years thereafter and report to the European Parliament and the Council. In addition, taking into account the implications for the scope of this Regulation, the Commission should carry out an assessment of the need to amend the list in Annex III and the list of prohibited practices once a year. Moreover, by two years after entry into application and every four years thereafter, the Commission should evaluate and report to the European Parliament and to the Council on the need to amend the high-risk areas in Annex III, the AI systems within the scope of the transparency obligations in Title IV, the effectiveness of the supervision and governance system and the progress on the development of standardisation deliverables on energy efficient development of general-purpose AI models, including the need for further measures or actions. Finally, within two years after the entry into application and every three years thereafter, the Commission should evaluate the impact and effectiveness of voluntary codes of conducts to foster the application of the requirements set out in Title III, Chapter 2, for systems other than***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				high-risk AI systems and possibly other additional requirements for such AI systems.
Recital 86				
96	(86) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1]. _____ 1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p.13).	(86) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1]. _____ 1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p.13).	(86) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1]. ***It is of particular importance that, in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making, whenever broader expertise is needed in the early preparation of draft implementing acts, the Commission makes use of expert groups, consults targeted stakeholders or carries out public consultations, as appropriate. Such consultations and advisory support should also be carried out in the framework of the activities of the AI Board and its subgroups, including the preparation of implementing acts in relation to Articles 4, 4b and 6.*** _____ 1. ***[1]*** Regulation (EU) No 182/2011 of the European Parliament and of the	(86) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[~~1~~***1***]. _____ ~~1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p.13).~~

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p.13).	
Recital 87				
G 97	(87) Since the objective of this Regulation cannot be sufficiently achieved by the Member States and can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 TEU. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.	(87) Since the objective of this Regulation cannot be sufficiently achieved by the Member States and can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 TEU. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.	(87) Since the objective of this Regulation cannot be sufficiently achieved by the Member States and can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 TEU. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.	(87) Since the objective of this Regulation cannot be sufficiently achieved by the Member States and can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 TEU. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective. Text Origin: Commission Proposal
Recital 87a				
G 97a			***(87a) In order to ensure legal certainty, ensure an appropriate adaptation period for operators and avoid disruption to the market, including by ensuring continuity of the use of AI systems, it is appropriate that this Regulation***	***(87a) In order to ensure legal certainty, ensure an appropriate adaptation period for operators and avoid disruption to the market, including by ensuring continuity of the use of AI systems, it is appropriate that this Regulation***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			applies to the high-risk AI systems that have been placed on the market or put into service before the general date of application thereof, only if, from that date, those systems are subject to significant changes in their design or intended purpose. It is appropriate to clarify that, in this respect, the concept of significant change should be understood as equivalent in substance to the notion of substantial modification, which is used with regard only to high-risk AI systems as defined in this Regulation.	***applies to the high-risk AI systems that have been placed on the market or put into service before the general date of application thereof, only if, from that date, those systems are subject to significant changes in their design or intended purpose. It is appropriate to clarify that, in this respect, the concept of significant change should be understood as equivalent in substance to the notion of substantial modification, which is used with regard only to high-risk AI systems as defined in this Regulation. By way of exception and in light of public accountability, operators of AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX and operators of high-risk AI systems that are intended to be used by public authorities should take the necessary steps to comply with the requirements of this Regulation by end of 2030 and by four years after the entry into application respectively.***
Recital 87a				
G 97b		***(87a) As reliable information on the resource and energy use, waste production and other environmental impact of AI systems***		G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		and related ICT technology, including software, hardware and in particular data centres, is limited, the Commission should introduce of an adequate methodology to measure the environmental impact and effectiveness of this Regulation in light of the Union environmental and climate objectives.		
Recital 87b				
97c				***(87b) Providers of high-risk AI systems are encouraged to start to comply, on voluntary basis, with the relevant obligations foreseen under this Regulation already during the transitional period.***
Recital 88				
98	(88) This Regulation should apply from … [OP – please insert the date established in Art. 85]. However, the infrastructure related to the governance and the conformity assessment system should be operational before that date, therefore the provisions on notified bodies and governance structure should apply from … [OP – please insert the date – three months following the entry into force of this Regulation]. In addition, Member	(88) This Regulation should apply from … [OP – please insert the date established in Art. 85]. However, the infrastructure related to the governance and the conformity assessment system should be operational before that date, therefore the provisions on notified bodies and governance structure should apply from … [OP – please insert the date – three months following the entry into force of this Regulation]. In addition, Member	(88) This Regulation should apply from … [***OP – please insert the date established in Art. 85***~~OP – please insert the date established in Art. 85~~]. However, the infrastructure related to the governance and the conformity assessment system should be operational before that date, therefore the provisions on notified bodies and governance structure should apply from … [***OP – please insert the date – three months following the entry into***	(88) This Regulation should apply from … [OP – please insert the date established in Art. 85]. However, ***taking into account the unacceptable risk associated with the use of AI in certain ways, the prohibitions should apply already from … [OP – please insert the date – 6 months after entry into force of this Regulation]. While the full effect of these prohibitions follows with the establishment of the governance and enforcement of this***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	States should lay down and notify to the Commission the rules on penalties, including administrative fines, and ensure that they are properly and effectively implemented by the date of application of this Regulation. Therefore the provisions on penalties should apply from [OP – please insert the date – twelve months following the entry into force of this Regulation].	States should lay down and notify to the Commission the rules on penalties, including administrative fines, and ensure that they are properly and effectively implemented by the date of application of this Regulation. Therefore the provisions on penalties should apply from [OP – please insert the date – twelve months following the entry into force of this Regulation].	***force of this Regulation***~~*OP – please insert the date – three months following the entry into force of this Regulation*~~]. In addition, Member States should lay down and notify to the Commission the rules on penalties, including administrative fines, and ensure that they are properly and effectively implemented by the date of application of this Regulation. Therefore the provisions on penalties should apply from [***OP – please insert the date – twelve months following the entry into force of this Regulation***~~*OP – please insert the date – twelve months following the entry into force of this Regulation*~~].	***Regulation, anticipating the application of the prohibitions is important to take account of unacceptable risk and has effect on other procedures, such as in civil law. Moreover,*** the infrastructure related to the governance and the conformity assessment system should be operational before that date, therefore the provisions on notified bodies and governance structure should apply from … [OP – please insert the date – ~~*three*~~ ***twelve*** months following the entry into force of this Regulation]. ***Given the rapid pace of technological advancements and adoption of general-purpose AI models, obligations for providers of general purpose AI models should apply within 12 months from the date of entry into force. Codes of Practice should be ready at the latest 3 months before the entry into application of the relevant provisions, to enable providers to demonstrate compliance in time. The AI Office should ensure that classification rules and procedures are up to date in light of technological developments.*** In addition, Member States should lay down and notify to the Commission the rules on penalties, including administrative fines, and ensure that they are properly and effectively implemented by the date

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				of application of this Regulation. Therefore the provisions on penalties should apply from [OP – please insert the date – twelve months following the entry into force of this Regulation].
Recital 89				
99	(89) The European Data Protection Supervisor and the European Data Protection Board were consulted in accordance with Article 42(2) of Regulation (EU) 2018/1725 and delivered an opinion on […]”.	(89) The European Data Protection Supervisor and the European Data Protection Board were consulted in accordance with Article 42(2) of Regulation (EU) 2018/1725 and delivered an opinion on ~~[…]”~~***18 June 2021***.	(89) The European Data Protection Supervisor and the European Data Protection Board were consulted in accordance with Article 42(2) of Regulation (EU) 2018/1725 and delivered an opinion on […]”.	(89) The European Data Protection Supervisor and the European Data Protection Board were consulted in accordance with Article 42(2) of Regulation (EU) 2018/1725 and delivered an opinion on ~~[…]~~”***18 June 2021***.
Formula				
100	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	
TITLE I				
101	TITLE I GENERAL PROVISIONS	TITLE I GENERAL PROVISIONS	TITLE I GENERAL PROVISIONS	TITLE I GENERAL PROVISIONS Text Origin: Commission Proposal
Article 1				
102	Article 1	Article 1	Article 1	Article 1

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Subject matter	Subject matter	Subject matter	Subject matter Text Origin: Commission Proposal
Article 1, first paragraph -a				
G 102a		***The purpose of this Regulation is to promote the uptake of human-centric and trustworthy artificial intelligence and to ensure a high level of protection of health, safety, fundamental rights, democracy and the rule of law, and the environment from harmful effects of artificial intelligence systems in the Union while supporting innovation;***		***(1) The purpose of this Regulation is to improve the functioning of the internal market and promoting the uptake of human centric and trustworthy artificial intelligence, while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, rule of law and environmental protection against harmful effects of artificial intelligence systems in the Union and supporting innovation.*** G
Article 1, first paragraph				
G 103	This Regulation lays down:	This Regulation lays down:	This Regulation lays down:	This Regulation lays down: Text Origin: Commission Proposal G
Article 1, first paragraph, point (a)				
G 104	(a) harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems')	(a) harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems')	(a) harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems')	(a) harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems') G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	in the Union;	in the Union;	in the Union;	in the Union; Text Origin: Commission Proposal
Article 1, first paragraph, point (b)				
105	(b) prohibitions of certain artificial intelligence practices;	(b) prohibitions of certain artificial intelligence practices;	(b) prohibitions of certain artificial intelligence practices;	(b) prohibitions of certain artificial intelligence practices; Text Origin: Commission Proposal
Article 1, first paragraph, point (c)				
106	(c) specific requirements for high-risk AI systems and obligations for operators of such systems;	(c) specific requirements for high-risk AI systems and obligations for operators of such systems;	(c) specific requirements for high-risk AI systems and obligations for operators of such systems;	(c) specific requirements for high-risk AI systems and obligations for operators of such systems; Text Origin: Commission Proposal
Article 1, first paragraph, point (d)				
107	(d) harmonised transparency rules for AI systems intended to interact with natural persons, emotion recognition systems and biometric categorisation systems, and AI systems used to generate or manipulate image, audio or video content;	(d) harmonised transparency rules for ~~*AI systems intended to interact with natural persons, emotion recognition systems and biometric categorisation systems, and*~~***certain*** AI systems~~*used to generate or manipulate image, audio or video content*~~;	(d) harmonised transparency rules for ~~*AI systems intended to interact with natural persons, emotion recognition systems and biometric categorisation systems, and*~~***certain*** AI systems~~*used to generate or manipulate image, audio or video content*~~;	(d) harmonised transparency rules for ***certain*** AI systems***;*** ***(da) harmonised rules for the placing on the market of general-purpose AI models***~~*intended to interact with natural persons, emotion recognition systems and biometric categorisation systems, and AI systems used to generate or manipulate image, audio or video content*~~;

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: EP Mandate
Article 1, first paragraph, point (e)				
108	(e) rules on market monitoring and surveillance.	(e) rules on market monitoring, ***market surveillance governance and enforcement;*** ~~and surveillance.~~	(e) rules on market monitoring, ***market surveillance and governance;*** ~~and surveillance.~~	(e) rules on market monitoring, ***market surveillance governance and enforcement;*** ~~and surveillance.~~ Text Origin: EP Mandate
Article 1, first paragraph, point (ea)				
108a			***(ea) measures in support of innovation.***	
Article 1, first paragraph, point (ea)				
108b		***(ea) measures to support innovation, with a particular focus on SMEs and start-ups, including on setting up regulatory sandboxes and targeted measures to reduce the regulatory burden on SMEs's and start-ups;***		***(ea) measures to support innovation, with a particular focus on SMEs, including start-ups;*** Text Origin: EP Mandate
Article 1, first paragraph a, point (eb new)				
108c		***(eb) rules for the establishment and functioning of the Union's Artificial Intelligence Office (AI Office).***		
Article 2				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 109	Article 2 Scope	Article 2 Scope	Article 2 Scope	Article 2 Scope Text Origin: Commission Proposal G
Article 2(1)				
G 110	1. This Regulation applies to:	1. This Regulation applies to:	1. This Regulation applies to:	1. This Regulation applies to: Text Origin: Commission Proposal G
Article 2(1), point (a)				
G 111	(a) providers placing on the market or putting into service AI systems in the Union, irrespective of whether those providers are established within the Union or in a third country;	(a) providers placing on the market or putting into service AI systems in the Union, irrespective of whether those providers are established within the Union or in a third country;	(a) providers placing on the market or putting into service AI systems in the Union, irrespective of whether those providers are ***physically present or*** established within the Union or in a third country;	(a) providers placing on the market or putting into service AI systems ***or placing on the market general-purpose AI models*** in the Union, irrespective of whether those providers are established ***or who are located*** within the Union or in a third country; Text Origin: Council Mandate G
Article 2(1), point (b)				
G 112	(b) users of AI systems located within the Union;	(b) ~~users~~***deployers*** of AI systems ***that have their place of establishment or who are*** located within the Union;	(b) users of AI systems ~~located~~***who are physically present or established*** within the Union;	(b) ~~users~~***deployers*** of AI systems ***that have their place of establishment or who are*** located within the Union; Text Origin: EP Mandate G

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Article 2(1), point (c)				
113	(c) providers and users of AI systems that are located in a third country, where the output produced by the system is used in the Union;	(c) providers and ~~users~~***deployers*** of AI systems that ***have their place of establishment or who*** are located in a third country, where ***either Member State law applies by virtue of a public international law or*** the output produced by the system is ***intended to be*** used in the Union;	(c) providers and users of AI systems ~~that are located~~***who are physically present or established*** in a third country, where the output produced by the system is used in the Union;	(c) providers and ~~users~~***deployers*** of AI systems that ***have their place of establishment or who*** are located in a third country, where the output produced by the system is used in the Union; Text Origin: EP Mandate
Article 2(1), point (ca)				
113a			***(ca) importers and distributors of AI systems;***	***(ca) importers and distributors of AI systems;*** Text Origin: Council Mandate
Article 2(1), point (ca new)				
113b		***(ca) providers placing on the market or putting into service AI systems referred to in Article 5 outside the Union where the provider or distributor of such systems is located within the Union;***		
Article 2(1), point (cb)				
113c			***(cb) product manufacturers placing on the market or putting into service an AI system together with their product and under their own name or trademark;***	***(cb) product manufacturers placing on the market or putting into service an AI system together with their product and under their own name or trademark;***

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				Text Origin: Council Mandate
Article 2(1), point (cb new)				
113d		***(cb) importers and distributors of AI systems as well as authorised representatives of providers of AI systems, where such importers, distributors or authorised representatives have their establishment or are located in the Union;***		
Article 2(1), point (cc)				
113e			***(cc) authorised representatives of providers, which are established in the Union.***	***(cc) authorised representatives of providers, which are not established in the Union.*** Text Origin: Council Mandate
Article 2(1), point (cd)				
113f		***(cc) affected persons as defined in Article 3(8a) that are located in the Union and whose health, safety or fundamental rights are adversely impacted by the use of an AI system that is placed on the market or put into service within the Union.***		***(cc) affected persons that are located in the Union.*** Text Origin: EP Mandate
Article 2(2)				
114				

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	2. For high-risk AI systems that are safety components of products or systems, or which are themselves products or systems, falling within the scope of the following acts, only Article 84 of this Regulation shall apply:	2. For high-risk AI systems that are safety components of products or systems, or which are themselves products or systems~~, falling~~ ***and that fall,*** within the scope of ~~the following acts~~***harmonisation legislation listed in Annex II - Section B***, only Article 84 of this Regulation shall apply~~:~~***;***	2. For ~~high-risk~~ AI systems ~~that are safety components of products or systems, or which are themselves~~***classified as high-risk AI systems in accordance with Articles 6(1) and 6(2) related to*** products ~~or systems, falling within the scope of the following acts,~~***covered by Union harmonisation legislation listed in Annex II, section B*** only Article 84 of this Regulation shall apply~~:~~***.*** ***Article 53 shall apply only insofar as the requirements for high-risk AI systems under this Regulation have been integrated under that Union harmonisation legislation.***	2. ***2.*** For ~~high-risk~~ AI systems ~~that are safety components of products or systems, or which are themselves~~***classified as high-risk AI systems in accordance with Articles 6(1) and 6(2) related to*** products ~~or systems, falling within the scope of the following acts,~~ ***covered by Union harmonisation legislation listed in Annex II, section B*** only Article 84 of this Regulation shall apply~~:~~***.*** ***Article 53 shall apply only insofar as the requirements for high-risk AI systems under this Regulation have been integrated under that Union harmonisation legislation.***
Article 2(2), point (a)				
G 115	(a) Regulation (EC) 300/2008;	*deleted*	*deleted*	G
Article 2(2), point (b)				
G *116*	*(b)* Regulation (EU) No 167/2013;	*deleted*	*deleted*	G
Article 2(2), point (c)				
G *117*	*(c)* Regulation (EU) No 168/2013;	*deleted*	*deleted*	G
Article 2(2), point (d)				

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G 118	*(d)* Directive 2014/90/EU;	*deleted*	*deleted*	(d) ~~*Directive 2014/90/EU;*~~***deleted*** G
Article 2(2), point (e)				
G 119	(e) Directive (EU) 2016/797;	*deleted*	*deleted*	(e) ~~*Directive (EU) 2016/797;*~~***deleted*** G
Article 2(2), point (f)				
G 120	(f) Regulation (EU) 2018/858;	*deleted*	*deleted*	(f) ~~*Regulation (EU) 2018/858;*~~***deleted*** G
Article 2(2), point (g)				
G 121	(g) Regulation (EU) 2018/1139;	*deleted*	*deleted*	(g) ~~*Regulation (EU) 2018/1139;*~~***deleted*** G
Article 2(2), point (h)				
G 122	(h) Regulation (EU) 2019/2144.	*deleted*	*deleted*	(h) ~~*Regulation (EU) 2019/2144.*~~***deleted*** G
Article 2(3)				
G 123	3. This Regulation shall not apply to AI systems developed or used exclusively for military purposes.		3. This Regulation shall not apply to AI systems ~~*developed*~~***if and insofar placed on the market, put into service,*** or used ~~*exclusively for*~~ ***with or without modification of such systems for the purpose of activities***	3. ***This Regulation shall not apply to areas outside the scope of EU law and in any event shall not affect the competences of the Member States concerning national security, regardless of the type of*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			which fall outside the scope of Union law, and in any event activities concerning military***, defence or national security, regardless of the type of entity carrying out those activities.*** ***In addition, this Regulation shall not apply to AI systems which are not placed on the market or put into service in the Union, where the output is used in the Union for the purpose of activities which fall outside the scope of Union law, and in any event activities concerning military, defence or national security, regardless of the type of entity carrying out those activities*** ~~*purposes*~~.	***entity entrusted by the Member States to carry out the tasks in relation to those competences.*** This Regulation shall not apply to AI systems ~~*developed or used*~~ ***if and insofar placed on the market, put into service, or used with or without modification of such systems exclusively for military, defence or national security purposes, regardless of the type of entity carrying out those activities.*** ***This Regulation shall not apply to AI systems which are not placed on the market or put into service in the Union, where the output is used in the Union*** exclusively for military***, defence or national security*** purposes***, regardless of the type of entity carrying out those activities***.
Article 2(4)				
G 124	4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States.	4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international ***cooperation or*** agreements for law enforcement and judicial cooperation with the Union or with	4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States.	4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international ***cooperation or*** agreements for law enforcement and judicial cooperation with the Union or with

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		one or more Member States~~.~~ ***and are subject of a decision of the Commission adopted in accordance with Article 36 of Directive (EU) 2016/680 or Article 45 of Regulation 2016/679 (adequacy decision) or are part of an international agreement concluded between the Union and that third country or international organisation pursuant to Article 218 TFUE providing adequate safeguards with respect to the protection of privacy and fundamental rights and freedoms of individuals;***		one or more Member States~~.~~***, under the condition that this third country or international organisations provide adequate safeguards with respect to the protection of fundamental rights and freedoms of individuals;*** Text Origin: EP Mandate
Article 2(5)				
G 125	5. This Regulation shall not affect the application of the provisions on the liability of intermediary service providers set out in Chapter II, Section IV of Directive 2000/31/EC of the European Parliament and of the Council[1] [as to be replaced by the corresponding provisions of the Digital Services Act]. 1. Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') (OJ L 178, 17.7.2000, p. 1).	5. This Regulation shall not affect the application of the provisions on the liability of intermediary service providers set out in Chapter II, Section IV of Directive 2000/31/EC of the European Parliament and of the Council[1] [as to be replaced by the corresponding provisions of the Digital Services Act]. 1. Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') (OJ L 178, 17.7.2000, p. 1).	5. This Regulation shall not affect the application of the provisions on the liability of intermediary service providers set out in Chapter II, Section ~~IV~~***4*** of Directive 2000/31/EC of the European Parliament and of the Council[1] [***as to be replaced by the corresponding provisions of the Digital Services Act***~~as to be replaced by the corresponding provisions of the Digital Services Act~~]. 1. ***[1]*** Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market	5. This Regulation shall not affect the application of the provisions on the liability of intermediary service providers set out in Chapter II, Section ~~IV~~***4*** of Directive 2000/31/EC of the European Parliament and of the Council[1] [***as to be replaced by the corresponding provisions of the Digital Services Act***~~as to be replaced by the corresponding provisions of the Digital Services Act~~]. 1. ***[1]*** Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			('Directive on electronic commerce') (OJ L 178, 17.7.2000, p. 1).	('Directive on electronic commerce') (OJ L 178, 17.7.2000, p. 1). Text Origin: Council Mandate
Article 2(5a)				
G 125a			***5a. This Regulation shall not apply to AI systems, including their output, specifically developed and put into service for the sole purpose of scientific research and development.***	***5a. This Regulation shall not apply to AI systems and models, including their output, specifically developed and put into service for the sole purpose of scientific research and development.*** Text Origin: Council Mandate
Article 2(5b)				
G 125b		***5a. Union law on the protection of personal data, privacy and the confidentiality of communications applies to personal data processes in connection with the rights and obligations laid down in this Regulation. This Regulation shall not affect Regulations (EU) 2016/679 and (EU) 2018/1725 and Directives 2002/58/EC and (EU) 2016/680, without prejudice to arrangements provided for in Article 10(5) and Article 54 of this Regulation.;***		***5a. 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 Regulations (EU) 2016/679 and (EU) 2018/1725 and Directives 2002/58/EC and (EU) 2016/680, without prejudice to arrangements provided for in Article 10(5) and Article 54 of this Regulation;*** Text Origin: EP Mandate
Article 2(5c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 125c			***5b. This Regulation shall not apply to any research and development activity regarding AI systems.***	***5b. This Regulation shall not apply to any research, testing and development activity regarding AI systems or models prior to being placed on the market or put into service; those activities shall be conducted respecting applicable Union law. The testing in real world conditions shall not be covered by this exemption.*** Text Origin: Council Mandate
Article 2(5d)				
G 125d		***5b. This Regulation is without prejudice to the rules laid down by other Union legal acts related to consumer protection and product safety;***		***5b. This Regulation is without prejudice to the rules laid down by other Union legal acts related to consumer protection and product safety.*** Text Origin: EP Mandate
Article 2(5e)				
G 125e			***5c. This Regulation shall not apply to obligations of users who are natural persons using AI systems in the course of a purely personal non-professional activity, except Article 52.***	***5c. This Regulation shall not apply to obligations of deployers who are natural persons using AI systems in the course of a purely personal non-professional activity.*** Text Origin: Council Mandate
Article 2(5f)				

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G 125f		***5c. This regulation shall not preclude Member States or the Union from maintaining or introducing laws, regulations or administrative provisions which are more favourable to workers in terms of protecting their rights in respect of the use of AI systems by employers, or to encourage or allow the application of collective agreements which are more favourable to workers.***		***5e. This Regulation shall not preclude Member States or the Union from maintaining or introducing laws, regulations or administrative provisions which are more favourable to workers in terms of protecting their rights in respect of the use of AI systems by employers, or to encourage or allow the application of collective agreements which are more favourable to workers.*** Text Origin: Presidency2
Article 2(5d) new				
G 125g		***5d. This Regulation shall not apply to research, testing and development activities regarding an AI system prior to this system being placed on the market or put into service, provided that these activities are conducted respecting fundamental rights and the applicable Union law. The testing in real world conditions shall not be covered by this exemption.The Commission is empowered to may adopt delegated acts in accordance with Article 73 that clarify the application of this paragraph to specify this exemption to prevent its existing and potential abuse. The AI Office shall provide guidance on***		

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		the governance of research and development pursuant to Article 56, also aiming to coordinate its application by the national supervisory authorities;		
Article 2(5g)				
125h				***5g. The obligations laid down in this Regulation shall not apply to AI systems released under free and open source licences unless they are placed on the market or put into service as high-risk AI systems or an AI system that falls under Title II and IV.***
Article 2(5h)				
125i		***5e. This Regulation shall not apply to AI components provided under free and open-source licences except to the extent they are placed on the market or put into service by a provider as part of a high-risk AI system or of an AI system that falls under Title II or IV. This exemption shall not apply to foundation models as defined in Art 3.***		***5f.*** Text Origin: Presidency2
Article 3				
126	Article 3	Article 3	Article 3	

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	Definitions	Definitions	Definitions	
Article 3, first paragraph				
127	For the purpose of this Regulation, the following definitions apply:	For the purpose of this Regulation, the following definitions apply:	For the purpose of this Regulation, the following definitions apply:	
Article 3, first paragraph, point (1)				
128	(1) 'artificial intelligence system' (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;	(1) 'artificial intelligence system' (AI system) means ~~software~~***a machine-based system*** that is ~~developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined~~***designed to operate with varying levels of autonomy and that can, for explicit or implicit*** objectives, generate outputs such as ~~content,~~ predictions, recommendations, or decisions***, that influence physical or virtual environments*** ~~influencing the environments they interact with~~;	(1) 'artificial intelligence system' (AI system) means ~~software~~***a system*** that is ~~developed with one or more of the techniques and approaches listed in Annex I and can, for~~***designed to operate with elements of autonomy and that, based on machine and/or human-provided data and inputs, infers how to achieve*** a given set of ~~human-defined objectives, generate~~***objectives using machine learning and/or logic- and knowledge based approaches, and produces system-generated*** outputs such as content ***(generative AI systems)***, predictions, recommendations~~,~~ or decisions***,*** influencing the environments ~~they interact with~~***with which the AI system interacts***;	(1) ~~'artificial intelligence~~***An AI*** system~~' (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives~~ ***is a machine-based system designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment and that, for explicit or implicit objectives, infers, from the input it receives, how to*** generate outputs such as ~~content, predictions~~***predictions, content***, recommendations, or decisions ~~influencing the~~***that can influence physical or virtual*** environments***. .*** ~~they interact with;~~
Article 3, first paragraph, point (1a)				
128a			***(1a) 'life cycle of an AI system' means the duration of an AI***	

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			system, from design through retirement. Without prejudice to the powers of the market surveillance authorities, such retirement may happen at any point in time during the post-market monitoring phase upon the decision of the provider and implies that the system may not be used further. An AI system lifecycle is also ended by a substantial modification to the AI system made by the provider or any other natural or legal person, in which case the substantially modified AI system shall be considered as a new AI system.	
Article 3, first paragraph, point (1a)				
G 128b		***(1a) 'risk' means the combination of the probability of an occurrence of harm and the severity of that harm;***		***(1a) 'risk' means the combination of the probability of an occurrence of harm and the severity of that harm;*** G
Article 3, first paragraph, point (1b)				
G 128c			***(1b) 'general purpose AI system' means an AI system that - irrespective of how it is placed on the market or put into service, including as open source software - is intended by the provider to perform generally applicable functions such as image and speech recognition, audio and video***	G

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			generation, pattern detection, question answering, translation and others; a general purpose AI system may be used in a plurality of contexts and be integrated in a plurality of other AI systems;	
Article 3, first paragraph, point (1b new)				
G 128d		***(1b) 'significant risk' means a risk that is significant as a result of the combination of its severity, intensity, probability of occurrence, and duration of its effects, and its the ability to affect an individual, a plurality of persons or to affect a particular group of persons;***		G
Article 3, first paragraph, point (1c new)				
G 128e		***(1c) 'foundation model' means an AI system model that is trained on broad data at scale, is designed for generality of output, and can be adapted to a wide range of distinctive tasks;***		G
Article 3, first paragraph, point (1d new)				
G 128f		***(1d) 'general purpose AI system' means an AI system that can be used in and adapted to a wide range of applications for which it was not intentionally and specifically***		G

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		designed;		
Article 3, first paragraph, point (1e new)				
G 128g		***(1e) 'large training runs' means the production process of a powerful AI model that require computing resources above a very high threshold;***		
Article 3, first paragraph, point (2)				
G 129	(2) 'provider' means a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed with a view to placing it on the market or putting it into service under its own name or trademark, whether for payment or free of charge;	(2) 'provider' means a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed with a view to placing it on the market or putting it into service under its own name or trademark, whether for payment or free of charge;	(2) 'provider' means a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed ~~*with a view to placing it*~~***and places that system*** on the market or ~~*putting*~~***puts*** it into service under its own name or trademark, whether for payment or free of charge;	(2) 'provider' means a natural or legal person, public authority, agency or other body that develops an AI system or ***a general purpose AI model or*** that has an AI system ~~*developed with a view to placing it*~~***or a general purpose AI model developed and places them*** on the market or ~~*putting it*~~***puts the system*** into service under its own name or trademark, whether for payment or free of charge; Text Origin: Council Mandate
Article 3, first paragraph, point (3)				
G 130	(3) 'small-scale provider' means a provider that is a micro or small enterprise within the meaning of Commission Recommendation 2003/361/EC[1];	*deleted*	*deleted*	

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	_____ 1. Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).			
Article 3, first paragraph, point (3a)				
G *130a*			***(3a) 'small and medium-sized enterprise' (SMEs) means an enterprise as defined in the Annex of Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises;***	
Article 3, first paragraph, point (4)				
G 131	(4) 'user' means any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity;	(4) '~~*user'*~~ ***deployer*** means any natural or legal person, public authority, agency or other body using an AI system under its authority~~,~~ except where the AI system is used in the course of a personal non-professional activity;	(4) 'user' means any natural or legal person, ***including a*** public authority, agency or other body ~~*using an AI system*~~***,*** under ~~*its*~~***whose*** authority~~*, except where the AI*~~ ***the*** system is used ~~*in the course of a personal non-professional activity*~~;	(4) '~~*user'*~~***deployer*** means any natural or legal person, public authority, agency or other body using an AI system under its authority~~,~~ except where the AI system is used in the course of a personal non-professional activity;
Article 3, first paragraph, point (5)				
G 132	(5) 'authorised representative' means any natural or legal person established in the Union who has received a written mandate from a provider of an AI system to, respectively, perform and carry out on its behalf the obligations and	(5) 'authorised representative' means any natural or legal person established in the Union who has received a written mandate from a provider of an AI system to, respectively, perform and carry out on its behalf the obligations and	(5) 'authorised representative' means any natural or legal person ***physically present or*** established in the Union who has received ***and accepted*** a written mandate from a provider of an AI system to, respectively, perform and carry out	(5) 'authorised representative' means any natural or legal person ***located or*** established in the Union who has received ***and accepted*** a written mandate from a provider of an AI system ***or a general-purpose AI model*** to, respectively, perform

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	procedures established by this Regulation;	procedures established by this Regulation;	on its behalf the obligations and procedures established by this Regulation;	and carry out on its behalf the obligations and procedures established by this Regulation; Text Origin: Council Mandate
Article 3, first paragraph, point (5a)				
G 132a			***(5a) 'product manufacturer' means a manufacturer within the meaning of any of the Union harmonisation legislation listed in Annex II;***	G
Article 3, first paragraph, point (6)				
G 133	(6) 'importer' means any natural or legal person established in the Union that places on the market or puts into service an AI system that bears the name or trademark of a natural or legal person established outside the Union;	(6) 'importer' means any natural or legal person established in the Union that places on the market or puts into service an AI system that bears the name or trademark of a natural or legal person established outside the Union;	(6) 'importer' means any natural or legal person ***physically present or*** established in the Union that places on the market ~~*or puts into service*~~ an AI system that bears the name or trademark of a natural or legal person established outside the Union;	(6) 'importer' means any natural or legal person ***located or*** established in the Union that places on the market ~~*or puts into service*~~ an AI system that bears the name or trademark of a natural or legal person established outside the Union; Text Origin: Council Mandate G
Article 3, first paragraph, point (7)				
G 134	(7) 'distributor' means any natural or legal person in the supply chain, other than the provider or the importer, that makes an AI system available on the Union market without affecting its properties;	(7) 'distributor' means any natural or legal person in the supply chain, other than the provider or the importer, that makes an AI system available on the Union market without affecting its properties;	(7) 'distributor' means any natural or legal person in the supply chain, other than the provider or the importer, that makes an AI system available on the Union market ~~*without affecting its properties*~~;	(7) 'distributor' means any natural or legal person in the supply chain, other than the provider or the importer, that makes an AI system available on the Union market ~~*without affecting its properties*~~; G

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				Text Origin: Council Mandate
Article 3, first paragraph, point (8)				
G 135	(8) 'operator' means the provider, the user, the authorised representative, the importer and the distributor;	(8) 'operator' means the provider, the ~~user~~***deployer***, the authorised representative, the importer and the distributor;	(8) 'operator' means the provider, the ***product manufacturer, the*** user, the authorised representative, the importer ~~and~~***or*** the distributor;	(8) 'operator' means the provider, the ~~user~~***product manufacturer, the deployer***, the authorised representative, the importer ~~and~~***or*** the distributor; Text Origin: Council Mandate
Article 3, first paragraph, point (8a new)				
G 135a		***(8a) 'affected person' means any natural person or group of persons who are subject to or otherwise affected by an AI system;***		
Article 3, first paragraph, point (9)				
G 136	(9) 'placing on the market' means the first making available of an AI system on the Union market;	(9) 'placing on the market' means the first making available of an AI system on the Union market;	(9) 'placing on the market' means the first making available of an AI system on the Union market;	(9) 'placing on the market' means the first making available of an AI system ***or a general purpose AI model*** on the Union market; Text Origin: Commission Proposal
Article 3, first paragraph, point (10)				
G 137	(10) 'making available on the market' means any supply of an AI system for distribution or use on the	(10) 'making available on the market' means any supply of an AI system for distribution or use on the	(10) 'making available on the market' means any supply of an AI system for distribution or use on the	(10) 'making available on the market' means any supply of an AI system ***or a general purpose AI***

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	Union market in the course of a commercial activity, whether in return for payment or free of charge;	Union market in the course of a commercial activity, whether in return for payment or free of charge;	Union market in the course of a commercial activity, whether in return for payment or free of charge;	***model*** for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge; Text Origin: Commission Proposal
Article 3, first paragraph, point (11)				
G 138	(11) 'putting into service' means the supply of an AI system for first use directly to the user or for own use on the Union market for its intended purpose;	(11) 'putting into service' means the supply of an AI system for first use directly to the ~~*user*~~***deployer*** or for own use on the Union market for its intended purpose;	(11) 'putting into service' means the supply of an AI system for first use directly to the user or for own use ~~*on*~~***in*** the Union ~~*market*~~ for its intended purpose;	(11) 'putting into service' means the supply of an AI system for first use directly to the ~~*user*~~***deployer*** or for own use ~~*on*~~***in*** the Union ~~*market*~~ for its intended purpose; Text Origin: Council Mandate
Article 3, first paragraph, point (12)				
G 139	(12) 'intended purpose' means the use for which an AI system is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation;	(12) 'intended purpose' means the use for which an AI system is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation;	(12) 'intended purpose' means the use for which an AI system is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation;	(12) 'intended purpose' means the use for which an AI system is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation; Text Origin: Commission Proposal
Article 3, first paragraph, point (13)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 140	(13) 'reasonably foreseeable misuse' means the use of an AI system in a way that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems;	(13) 'reasonably foreseeable misuse' means the use of an AI system in a way that is not in accordance with its intended purpose ***as indicated in instructions for use established by the provider***, but which may result from reasonably foreseeable human behaviour or interaction with other ***systems, including other AI*** systems;	(13) 'reasonably foreseeable misuse' means the use of an AI system in a way that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems;	(13) 'reasonably foreseeable misuse' means the use of an AI system in a way that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems***, including other AI systems***; Text Origin: EP Mandate
Article 3, first paragraph, point (14)				
G 141	(14) 'safety component of a product or system' means a component of a product or of a system which fulfils a safety function for that product or system or the failure or malfunctioning of which endangers the health and safety of persons or property;	(14) 'safety component of a product or system' means***, in line with Union harmonisation law listed in Annex II,*** a component of a product or of a system which fulfils a safety function for that product or system***,*** or the failure or malfunctioning of which endangers the health and safety of persons~~ or property~~;	(14) 'safety component of a product or system' means a component of a product or of a system which fulfils a safety function for that product or system or the failure or malfunctioning of which endangers the health and safety of persons or property;	(14) 'safety component of a product or system' means a component of a product or of a system which fulfils a safety function for that product or system***,*** or the failure or malfunctioning of which endangers the health and safety of persons or property; Text Origin: EP Mandate
Article 3, first paragraph, point (15)				
G 142	(15) 'instructions for use' means the information provided by the provider to inform the user of in particular an AI system's intended purpose and proper use, inclusive of the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be	(15) 'instructions for use' means the information provided by the provider to inform the ~~user~~***deployer*** of in particular an AI system's intended purpose and proper use, ***as well as information on any precautions to be taken;*** inclusive of the specific geographical, behavioural or	(15) 'instructions for use' means the information provided by the provider to inform the user of in particular an AI system's intended purpose and proper use~~, inclusive of the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be~~	(15) 'instructions for use' means the information provided by the provider to inform the user of in particular an AI system's intended purpose and proper use~~, inclusive of the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be~~

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	used;	functional setting within which the high-risk AI system is intended to be used;	~~used~~;	~~used~~; Text Origin: Council Mandate
Article 3, first paragraph, point (16)				
143	(16) 'recall of an AI system' means any measure aimed at achieving the return to the provider of an AI system made available to users;	(16) 'recall of an AI system' means any measure aimed at achieving the return to the provider of an AI system ***that has been*** made available to ~~users~~***deployers***;	(16) 'recall of an AI system' means any measure aimed at achieving the return to the provider ***or taking it out of service or disabling the use*** of an AI system made available to users;	(16) 'recall of an AI system' means any measure aimed at achieving the return to the provider ***or taking it out of service or disabling the use*** of an AI system made available to ~~users~~***deployers***; Text Origin: Council Mandate
Article 3, first paragraph, point (17)				
144	(17) 'withdrawal of an AI system' means any measure aimed at preventing the distribution, display and offer of an AI system;	(17) 'withdrawal of an AI system' means any measure aimed at preventing the distribution, display and offer of an AI system;	(17) 'withdrawal of an AI system' means any measure aimed at preventing ***an AI system in the supply chain being made available on the market***~~the distribution, display and offer of an AI system~~;	(17) 'withdrawal of an AI system' means any measure aimed at preventing ***an AI system in the supply chain being made available on the market***~~the distribution, display and offer of an AI system~~; Text Origin: Council Mandate
Article 3, first paragraph, point (18)				
145	(18) 'performance of an AI system' means the ability of an AI system to achieve its intended purpose;	(18) 'performance of an AI system' means the ability of an AI system to achieve its intended purpose;	(18) 'performance of an AI system' means the ability of an AI system to achieve its intended purpose;	(18) 'performance of an AI system' means the ability of an AI system to achieve its intended purpose; Text Origin: Commission Proposal

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (19)				
G 146	(19) 'notifying authority' means the national authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring;	(19) 'notifying authority' means the national authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring;	(19) 'notifying authority' means the national authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring;	(19) 'notifying authority' means the national authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring; Text Origin: Commission Proposal
Article 3, first paragraph, point (20)				
G 147	(20) 'conformity assessment' means the process of verifying whether the requirements set out in Title III, Chapter 2 of this Regulation relating to an AI system have been fulfilled;	(20) 'conformity assessment' means the process of ~~verifying~~***demonstrating*** whether the requirements set out in Title III, Chapter 2 of this Regulation relating to an AI system have been fulfilled;	(20) 'conformity assessment' means the process of verifying whether the requirements set out in Title III, Chapter 2 of this Regulation relating to ~~an~~***a high-risk*** AI system have been fulfilled;	(20) 'conformity assessment' means the process of ~~verifying~~***demonstrating*** whether the requirements set out in Title III, Chapter 2 of this Regulation relating to ~~an~~***a high-risk*** AI system have been fulfilled; Text Origin: Council Mandate
Article 3, first paragraph, point (21)				
G 148	(21) 'conformity assessment body' means a body that performs third-party conformity assessment activities, including testing, certification and inspection;	(21) 'conformity assessment body' means a body that performs third-party conformity assessment activities, including testing, certification and inspection;	(21) 'conformity assessment body' means a body that performs third-party conformity assessment activities, including testing, certification and inspection;	(21) 'conformity assessment body' means a body that performs third-party conformity assessment activities, including testing, certification and inspection; Text Origin: Commission Proposal

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (22)				
149	(22) 'notified body' means a conformity assessment body designated in accordance with this Regulation and other relevant Union harmonisation legislation;	(22) 'notified body' means a conformity assessment body ~~designated~~***notified*** in accordance with this Regulation and other relevant Union harmonisation legislation;	(22) 'notified body' means a conformity assessment body designated in accordance with this Regulation and other relevant Union harmonisation legislation;	(22) 'notified body' means a conformity assessment body ~~designated~~***notified*** in accordance with this Regulation and other relevant Union harmonisation legislation; Text Origin: EP Mandate
Article 3, first paragraph, point (23)				
150	(23) 'substantial modification' means a change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed;	(23) 'substantial modification' means a ~~change to~~***modification or a series of modifications of*** the AI system ~~following~~***after*** its placing on the market or putting into service which ~~affects~~***is not foreseen or planned in the initial risk assessment by the provider and as a result of which*** the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation ***is affected*** or results in a modification to the intended purpose for which the AI system has been assessed;	(23) 'substantial modification' means a change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation, or ~~results in~~ a modification to the intended purpose for which the AI system has been assessed***. For high-risk AI systems that continue to learn after being placed on the market or put into service, changes to the high-risk AI system and its performance that have been pre-determined by the provider at the moment of the initial conformity assessment and are part of the information contained in the technical documentation referred to in point 2(f) of Annex IV, shall not***	(23) 'substantial modification' means a change to the AI system ~~following~~***after*** its placing on the market or putting into service which ~~affects~~***is not foreseen or planned in the initial conformity assessment by the provider and as a result of which*** the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation ***is affected*** or results in a modification to the intended purpose for which the AI system has been assessed; Text Origin: EP Mandate

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			constitute a substantial modification;	
Article 3, first paragraph, point (24)				
G 151	(24) 'CE marking of conformity' (CE marking) means a marking by which a provider indicates that an AI system is in conformity with the requirements set out in Title III, Chapter 2 of this Regulation and other applicable Union legislation harmonising the conditions for the marketing of products ('Union harmonisation legislation') providing for its affixing;	(24) 'CE marking of conformity' (CE marking) means a ***physical or digital*** marking by which a provider indicates that an ***AI system or a product with an embedded*** AI system is in conformity with the requirements set out in Title III, Chapter 2 of this Regulation and other applicable Union legislation harmonising the conditions for the marketing of products ('Union harmonisation legislation') providing for its affixing;	(24) 'CE marking of conformity' (CE marking) means a marking by which a provider indicates that an AI system is in conformity with the requirements set out in Title III, Chapter 2 ***or in Article 4b*** of this Regulation and other applicable Union ~~legislation~~***legal act*** harmonising the conditions for the marketing of products ('Union harmonisation legislation') providing for its affixing;	(24) 'CE marking of conformity' (CE marking) means a marking by which a provider indicates that an AI system is in conformity with the requirements set out in Title III, Chapter 2 of this Regulation and other applicable Union legislation harmonising the conditions for the marketing of products ('Union harmonisation legislation') providing for its affixing; Text Origin: Commission Proposal G
Article 3, first paragraph, point (25)				
G 152	(25) 'post-market monitoring' means all activities carried out by providers of AI systems to proactively collect and review experience gained from the use of AI systems they place on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;	(25) 'post-market monitoring' means all activities carried out by providers of AI systems to proactively collect and review experience gained from the use of AI systems they place on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;	(25) 'post-market monitoring ***system***' means all activities carried out by providers of AI systems to ~~proactively~~ collect and review experience gained from the use of AI systems they place on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;	(25) 'post-market monitoring ***system***' means all activities carried out by providers of AI systems to ~~proactively~~ collect and review experience gained from the use of AI systems they place on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions; Text Origin: Council Mandate G
Article 3, first paragraph, point (26)				

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G 153	(26) 'market surveillance authority' means the national authority carrying out the activities and taking the measures pursuant to Regulation (EU) 2019/1020;	(26) 'market surveillance authority' means the national authority carrying out the activities and taking the measures pursuant to Regulation (EU) 2019/1020;	(26) 'market surveillance authority' means the national authority carrying out the activities and taking the measures pursuant to Regulation (EU) 2019/1020;	(26) 'market surveillance authority' means the national authority carrying out the activities and taking the measures pursuant to Regulation (EU) 2019/1020; Text Origin: Commission Proposal
Article 3, first paragraph, point (27)				
G 154	(27) 'harmonised standard' means a European standard as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012;	(27) 'harmonised standard' means a European standard as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012;	(27) 'harmonised standard' means a European standard as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012;	(27) 'harmonised standard' means a European standard as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012; Text Origin: Commission Proposal
Article 3, first paragraph, point (28)				
G 155	(28) 'common specifications' means a document, other than a standard, containing technical solutions providing a means to, comply with certain requirements and obligations established under this Regulation;	(28) 'common specifications' means a document, other than a standard, containing technical solutions providing a means to, comply with certain requirements and obligations established under this Regulation;	(28) 'common ~~specifications~~***specification***' means a ~~document, other than a standard, containing technical solutions providing a~~***set of technical specifications, as defined in point 4 of Article 2 of Regulation (EU) No 1025/2012 providing*** means to~~,~~ comply with certain requirements ~~and obligations~~ established under this Regulation;	(28) 'common ~~specifications~~***specification***' means a ~~document, other than a standard, containing technical solutions providing a~~***set of technical specifications, as defined in point 4 of Article 2 of Regulation (EU) No 1025/2012 providing*** means to~~,~~ comply with certain requirements ~~and obligations~~ established under this Regulation; Text Origin: Council Mandate

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Article 3, first paragraph, point (29)				
156	(29) 'training data' means data used for training an AI system through fitting its learnable parameters, including the weights of a neural network;	(29) 'training data' means data used for training an AI system through fitting its learnable parameters~~, including the weights of a neural network~~;	(29) 'training data' means data used for training an AI system through fitting its learnable parameters~~, including the weights of a neural network~~;	(29) 'training data' means data used for training an AI system through fitting its learnable parameters~~, including the weights of a neural network~~; Text Origin: Council Mandate
Article 3, first paragraph, point (30)				
157	(30) 'validation data' means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process, among other things, in order to prevent overfitting; whereas the validation dataset can be a separate dataset or part of the training dataset, either as a fixed or variable split;	(30) 'validation data' means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process, among other things, in order to prevent ***underfitting or*** overfitting; whereas the validation dataset ~~can be~~***is*** a separate dataset or part of the training dataset, either as a fixed or variable split;	(30) 'validation data' means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process, among other things, in order to prevent overfitting; whereas the validation dataset can be a separate dataset or part of the training dataset, either as a fixed or variable split;	(30) 'validation data' means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process, among other things, in order to prevent ***underfitting or*** overfitting; whereas the validation dataset ~~can be~~***is*** a separate dataset or part of the training dataset, either as a fixed or variable split; Text Origin: EP Mandate
Article 3, first paragraph, point (31)				
158	(31) 'testing data' means data used for providing an independent evaluation of the trained and validated AI system in order to confirm the expected performance of that system before its placing on the market or putting into service;	(31) 'testing data' means data used for providing an independent evaluation of the trained and validated AI system in order to confirm the expected performance of that system before its placing on the market or putting into service;	(31) 'testing data' means data used for providing an independent evaluation of the trained and validated AI system in order to confirm the expected performance of that system before its placing on the market or putting into service;	(31) 'testing data' means data used for providing an independent evaluation of the ~~trained and validated~~ AI system in order to confirm the expected performance of that system before its placing on the market or putting into service;

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				Text Origin: Commission Proposal
Article 3, first paragraph, point (32)				
G 159	(32) 'input data' means data provided to or directly acquired by an AI system on the basis of which the system produces an output;	(32) 'input data' means data provided to or directly acquired by an AI system on the basis of which the system produces an output;	(32) 'input data' means data provided to or directly acquired by an AI system on the basis of which the system produces an output;	(32) 'input data' means data provided to or directly acquired by an AI system on the basis of which the system produces an output; Text Origin: Commission Proposal G
Article 3, first paragraph, point (33)				
G 160	(33) 'biometric data' means personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images or dactyloscopic data;	(33) 'biometric data' means ~~personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images or dactyloscopic data~~***biometric data as defined in Article 4, point (14) of Regulation (EU) 2016/679***;	(33) 'biometric data' means personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, ~~which allow or confirm the unique identification of that natural person,~~ such as facial images or dactyloscopic data;	(33) 'biometric data' means personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, ~~which allow or confirm the unique identification of that natural person,~~ such as facial images or dactyloscopic data; Text Origin: EP Mandate G
Article 3, first paragraph, point (33a new)				
G 160a		***(33a) 'biometric-based data' means data resulting from specific technical processing relating to physical, physiological or behavioural signals of a natural***		G

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		person;		
Article 3, first paragraph, point (33a)				
G 160b		***(33b) 'biometric identification' means the automated recognition of physical, physiological, behavioural, and psychological human features for the purpose of establishing an individual's identity by comparing biometric data of that individual to stored biometric data of individuals in a database (one-to-many identification);***		***(33a) 'biometric identification' means the automated recognition of physical, physiological, behavioural, and psychological human features for the purpose of establishing an individual's identity by comparing biometric data of that individual to stored biometric data of individuals in a database;*** G
Article 3, first paragraph, point (33b)				
G 160c		***(33c) 'biometric verification' means the automated verification of the identity of natural persons by comparing biometric data of an individual to previously provided biometric data (one-to-one verification, including authentication);***		***(33c) 'biometric verification' means the automated verification of the identity of natural persons by comparing biometric data of an individual to previously provided biometric data (one-to-one verification, including authentication);*** G Text Origin: EP Mandate
Article 3, first paragraph, point (33c)				
G 160d		***(33d) 'special categories of personal data' means the categories of personal data referred to in Article 9(1) of Regulation (EU)***		***(33d) 'special categories of personal data' means the categories of personal data referred to in Article 9(1) of Regulation (EU)*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		2016/679;		***2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725;*** ***33e) 'sensitive operational data' means operational data related to activities of prevention, detection, investigation and prosecution of criminal offences, the disclosure of which can jeopardise the integrity of criminal proceedings.*** Text Origin: EP Mandate
Article 3, first paragraph, point (34)				
G 161	(34) 'emotion recognition system' means an AI system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric data;	(34) 'emotion recognition system' means an AI system for the purpose of identifying or inferring emotions***, thoughts, states of mind*** or intentions of ~~natural persons~~***individuals or groups*** on the basis of their biometric ***and biometric-based*** data;	(34) 'emotion recognition system' means an AI system for the purpose of identifying or inferring ***psychological states,*** emotions or intentions of natural persons on the basis of their biometric data;	(34) 'emotion recognition system' means an AI system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric data; Text Origin: Commission Proposal
Article 3, first paragraph, point (35)				
G 162	(35) 'biometric categorisation system' means an AI system for the purpose of assigning natural persons to specific categories, such as sex, age, hair colour, eye colour, tattoos, ethnic origin or sexual or political orientation, on the basis of their	(35) 'biometric categorisation ~~system'~~ means ~~an AI system for the purpose of~~ assigning natural persons to specific categories, ~~such as sex, age, hair colour, eye colour, tattoos, ethnic origin or sexual or political orientation, on the basis of their~~	(35) 'biometric categorisation system' means an AI system for the purpose of assigning natural persons to specific categories~~, such as sex, age, hair colour, eye colour, tattoos, ethnic origin or sexual or political orientation,~~ on the basis of their	(35) 'biometric categorisation system' means an AI system for the purpose of assigning natural persons to specific categories~~, such as sex, age, hair colour, eye colour, tattoos, ethnic origin or sexual or political orientation, on the basis of their~~

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	biometric data;	~~biometric~~***or inferring their characteristics and attributes on the basis of their biometric or biometric-based data, or which can be inferred from such*** data;	biometric data;	~~biometric data~~ ***on the basis of their biometric data unless ancillary to another commercial service and strictly necessary for objective technical reasons***; Text Origin: Council Mandate
Article 3, first paragraph, point (36)				
G 163	(36) 'remote biometric identification system' means an AI system for the purpose of identifying natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database, and without prior knowledge of the user of the AI system whether the person will be present and can be identified ;	(36) 'remote biometric identification system' means an AI system for the purpose of identifying natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database, and without prior knowledge of the ~~user~~***deployer*** of the AI system whether the person will be present and can be identified***,*** ***excluding verification systems*** ~~-~~;	(36) 'remote biometric identification system' means an AI system for the purpose of identifying natural persons ***typically*** at a distance***, without their active involvement,*** through the comparison of a person's biometric data with the biometric data contained in a reference ~~database, and without prior knowledge of the user of the AI system whether the person will be present and can be identified~~ ***data repository***;	(36) 'remote biometric identification system' means an AI system for the purpose of identifying natural persons***, without their active involvement, typically*** at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database~~, and without prior knowledge of the user of the AI system whether the person will be present and can be identified~~ ~~-~~; G Text Origin: Commission Proposal
Article 3, first paragraph, point (37)				
G 164	(37) ''real-time' remote biometric identification system' means a remote biometric identification system whereby the capturing of biometric data, the comparison and the identification all occur without a significant delay. This comprises not only instant identification, but also	(37) ''real-time' remote biometric identification system' means a remote biometric identification system whereby the capturing of biometric data, the comparison and the identification all occur without a significant delay. This comprises not only instant identification, but also	(37) ''real-time' remote biometric identification system' means a remote biometric identification system whereby the capturing of biometric data, the comparison and the identification all occur ~~without a significant delay. This comprises not only instant identification, but also~~	(37) ''real-time' remote biometric identification system' means a remote biometric identification system whereby the capturing of biometric data, the comparison and the identification all occur without a significant delay. This comprises not only instant identification, but also G

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	limited short delays in order to avoid circumvention.	limited ~~short~~ delays in order to avoid circumvention~~.~~**;**	~~limited short delays in order to avoid circumvention.~~***instantaneously or near instantaneously;***	limited short delays in order to avoid circumvention. Text Origin: Commission Proposal
Article 3, first paragraph, point (38)				
G 165	(38) ''post' remote biometric identification system' means a remote biometric identification system other than a 'real-time' remote biometric identification system;	(38) ''post' remote biometric identification system' means a remote biometric identification system other than a 'real-time' remote biometric identification system;	*deleted*	*(38)* ''post' remote biometric identification system' means a remote biometric identification system other than a 'real-time' remote biometric identification system; Text Origin: EP Mandate
Article 3, first paragraph, point (39)				
G 166	(39) 'publicly accessible space' means any physical place accessible to the public, regardless of whether certain conditions for access may apply;	(39) 'publicly accessible space' means any ***publicly or privately owned*** physical place accessible to the public, regardless of whether certain conditions for access may apply***, and regardless of the potential capacity restrictions***;	(39) 'publicly accessible space' means any ***publicly or privately owned*** physical place accessible to ~~the public,~~***an undetermined number of natural persons*** regardless of whether certain conditions ***or circumstances*** for access ~~may apply~~***have been predetermined, and regardless of the potential capacity restrictions***;	(39) 'publicly accessible space' means any ***publicly or privately owned*** physical place accessible to ~~the public~~***an undetermined number of natural persons***, regardless of whether certain conditions for access may apply***, and regardless of the potential capacity restrictions***; Text Origin: Commission Proposal
Article 3, first paragraph, point (40)				
G 167	(40) 'law enforcement authority' means:	(40) 'law enforcement authority' means:	(40) 'law enforcement authority' means:	(40) 'law enforcement authority' means:

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Article 3, first paragraph, point (40)(a)				
G 168	(a) any public authority competent for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security; or	(a) any public authority competent for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security; or	(a) any public authority competent for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security; or	(a) any public authority competent for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security; or Text Origin: Commission Proposal
Article 3, first paragraph, point (40)(b)				
G 169	(b) any other body or entity entrusted by Member State law to exercise public authority and public powers for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;	(b) any other body or entity entrusted by Member State law to exercise public authority and public powers for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;	(b) any other body or entity entrusted by Member State law to exercise public authority and public powers for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;	(b) any other body or entity entrusted by Member State law to exercise public authority and public powers for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security; Text Origin: Commission Proposal
Article 3, first paragraph, point (41)				
G 170	(41) ‘law enforcement’ means	(41) ‘law enforcement’ means	(41) ‘law enforcement’ means	(41) ‘law enforcement’ means

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	activities carried out by law enforcement authorities for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;	activities carried out by law enforcement authorities ***or on their behalf*** for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;	activities carried out by law enforcement authorities ***or on their behalf*** for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;	activities carried out by law enforcement authorities ***or on their behalf*** for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security; Text Origin: Council Mandate
Article 3, first paragraph, point (42)				
G 171	(42) 'national supervisory authority' means the authority to which a Member State assigns the responsibility for the implementation and application of this Regulation, for coordinating the activities entrusted to that Member State, for acting as the single contact point for the Commission, and for representing the Member State at the European Artificial Intelligence Board;	(42) 'national supervisory authority' means ~~the~~***a public*** authority to which a Member State assigns the responsibility for the implementation and application of this Regulation, for coordinating the activities entrusted to that Member State, for acting as the single contact point for the Commission, and for representing the Member State ~~at the European Artificial Intelligence Board~~***in the management Board of the AI Office***;	*deleted*	(42) ~~'national supervisory authority'~~***Artificial Intelligence office means the Commission's function of contributing to the implementation, monitoring and supervision of AI systems and AI governance. References in this Regulation to the Artificial Intelligence office shall be understood as references to the Commission.*** ~~means the authority to which a Member State assigns the responsibility for the implementation and application of this Regulation, for coordinating the activities entrusted to that Member State, for acting as the single contact point for the Commission, and for representing the Member State at the European Artificial Intelligence Board;~~ G

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Article 3, first paragraph, point (43)				
172	(43) 'national competent authority' means the national supervisory authority, the notifying authority and the market surveillance authority;	(43) 'national competent authority' means ***any of*** the national ~~supervisory authority, the notifying authority and the market surveillance authority~~***authorities which are responsible for the enforcement of this Regulation***;	(43) 'national competent authority' means ~~the national supervisory authority~~,***any of the following:*** the notifying authority and the market surveillance authority***. As regards AI systems put into service or used by EU institutions, agencies, offices and bodies, the European Data Protection Supervisor shall fulfil the responsibilities that in the Member States are entrusted to the national competent authority and, as relevant, any reference to national competent authorities or market surveillance authorities in this Regulation shall be understood as referring to the European Data Protection Supervisor***;	(43) 'national competent authority' means ~~the national supervisory authority~~,***any of the following:*** the notifying authority and the market surveillance authority***. As regards AI systems put into service or used by EU institutions, agencies, offices and bodies, any reference to national competent authorities or market surveillance authorities in this Regulation shall be understood as referring to the European Data Protection Supervisor***; Text Origin: Council Mandate
Article 3, first paragraph, point (44)				
173	(44) 'serious incident' means any incident that directly or indirectly leads, might have led or might lead to any of the following:	(44) 'serious incident' means any incident ***or malfunctioning of an AI system*** that directly or indirectly leads, might have led or might lead to any of the following:	(44) 'serious incident' means any incident ~~that directly or indirectly leads, might have led or might lead~~***or malfunctioning of an AI system that directly or indirectly leads*** to any of the following:	(44) 'serious incident' means any incident ~~that directly or indirectly leads, might have led or might lead~~***or malfunctioning of an AI system that directly or indirectly leads*** to any of the following: Text Origin: Council Mandate
Article 3, first paragraph, point (44)(a)				
174	(a) the death of a person or serious	(a) the death of a person or serious	(a) the death of a person or serious	(a) the death of a person or serious

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	damage to a person's health, to property or the environment,	damage to a person's health, ~~to property or the environment,~~	damage to a person's health~~, to property or the environment,~~;	damage to a person's health~~, to property or the environment,~~; Text Origin: Council Mandate
Article 3, first paragraph, point (44)(b)				
175	(b) a serious and irreversible disruption of the management and operation of critical infrastructure.	(b) a serious ~~and irreversible~~ disruption of the management and operation of critical infrastructure~~.~~;	(b) a serious and irreversible disruption of the management and operation of critical infrastructure~~.~~;	(b) a serious and irreversible disruption of the management and operation of critical infrastructure. Text Origin: Commission Proposal
Article 3, first paragraph, point (44)(ba)				
175a			***(ba) breach of obligations under Union law intended to protect fundamental rights;***	***(ba) breach of obligations under Union law intended to protect fundamental rights;*** Text Origin: Council Mandate
Article 3, first paragraph, point (44)(ba new)				
175b		***(ba) a breach of fundamental rights protected under Union law,***		
Article 3, first paragraph, point (44)(bb)				
175c			***(bb) serious damage to property or the environment.***	***(bb) serious damage to property or the environment.*** Text Origin: Council Mandate
Article 3, first paragraph, point (44)(bb new)				

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G 175d		*(bb) serious damage to property or the environment.*		G
Article 3, first paragraph, point (44)(bc)				
G 175e		*(44a) 'personal data' means personal data as defined in Article 4, point (1) of Regulation (EU) 2016/679;*		*(44a) 'personal data' means personal data as defined in Article 4, point (1) of Regulation (EU) 2016/679 ;* Text Origin: EP Mandate G
Article 3, first paragraph, point (44)(bd)				
G 175f			*(44a) 'non-personal data' means data other than personal data as defined in point (1) of Article 4 of Regulation (EU) 2016/679;*	*(44c) 'non-personal data' means data other than personal data as defined in point (1) of Article 4 of Regulation (EU) 2016/679;* Text Origin: Council Mandate G
Article 3, first paragraph, point (44)(be)				
G 175g		*(44b) 'profiling' means any form of automated processing of personal data as defined in point (4) of Article 4 of Regulation (EU) 2016/679; or in the case of law enforcement authorities – in point 4 of Article 3 of Directive (EU) 2016/680 or, in the case of Union institutions, bodies, offices or agencies, in point 5 Article 3 of Regulation (EU) 2018/1725;*		*(be) 'profiling' means any form of automated processing of personal data as defined in point (4) of Article 4 of Regulation (EU) 2016/679; or in the case of law enforcement authorities – in point 4 of Article 3 of Directive (EU) 2016/680 or, in the case of Union institutions, bodies, offices or agencies, in point 5 Article 3 of Regulation (EU) 2018/1725;* G

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Article 3, first paragraph, point (44)(bf)				
G 175h			*(44b) 'real world testing plan' means a document that describes the objectives, methodology, geographical, population and temporal scope, monitoring, organisation and conduct of testing in real world conditions;*	*(bf) 'real world testing plan' means a document that describes the objectives, methodology, geographical, population and temporal scope, monitoring, organisation and conduct of testing in real world conditions;* *(44 eb)'Sandbox plan' means a document agreed between the participating provider and the competent authority describing the objectives, conditions, timeframe, methodology and requirements for the activities carried out within the sandbox.* G
Article 3, first paragraph, point (44)(bg)				
G 175i			*(44c) 'AI regulatory sandbox' means a concrete framework set up by a national competent authority which offers providers or prospective providers of AI systems the possibility to develop, train, validate and test, where appropriate in real world conditions, an innovative AI system, pursuant to a specific plan for a limited time under regulatory supervision.*	*(bg) 'AI regulatory sandbox' means a concrete and controlled framework set up by a competent authority which offers providers or prospective providers of AI systems the possibility to develop, train, validate and test, where appropriate in real world conditions, an innovative AI system, pursuant to a sandbox plan for a limited time under regulatory supervision.* G
Article 3, first paragraph, point (44)(bh)				

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G 175j				*(bh) 'AI literacy' refers to skills, knowledge and understanding that allows providers, users and affected persons, taking into account their respective rights and obligations in the context of this Regulation, to make an informed deployment of AI systems, as well as to gain awareness about the opportunities and risks of AI and possible harm it can cause.* G
Article 3, first paragraph, point (44)(bi)				
G 175k			*(44e) 'testing in real world conditions' means the temporary testing of an AI system for its intended purpose in real world conditions outside of 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 requirements of this Regulation; testing in real world conditions shall not be considered as placing the AI system on the market or putting it into service within the meaning of this Regulation, provided that all conditions under Article 53 or Article 54a are fulfilled;*	*'testing in real world conditions' means the temporary testing of an AI system for its intended purpose in real world conditions outside of 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 requirements of this Regulation; testing in real world conditions shall not be considered as placing the AI system on the market or putting it into service within the meaning of this Regulation, provided that all conditions under Article 53 or Article 54a are fulfilled;* G
Article 3, first paragraph, point (44)(bj)				

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G 175l			*(44f) 'subject' for the purpose of real world testing means a natural person who participates in testing in real world conditions;*	*(bj) 'subject' for the purpose of real world testing means a natural person who participates in testing in real world conditions;*
Article 3, first paragraph, point (44)(bk)				
G 175m			*(44g) 'informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular testing in real world conditions, after having been informed of all aspects of the testing that are relevant to the subject's decision to participate; in the case of minors and of incapacitated subjects, the informed consent shall be given by their legally designated representative;*	*(bk) 'informed consent' means a subject's freely given, specific, unambiguous and voluntary expression of his or her willingness to participate in a particular testing in real world conditions, after having been informed of all aspects of the testing that are relevant to the subject's decision to participate;*
Article 3, first paragraph, point (44)(bl)				
G 175n		*(44c) "deep fake" means manipulated or synthetic audio, image or video content that would falsely appear to be authentic or truthful, and which features depictions of persons appearing to say or do things they did not say or do, produced using AI techniques, including machine learning and deep learning;*		*(bl) "deep fake" means AI generated or manipulated image, audio or video content that resembles existing persons, objects, places or other entities or events and would falsely appear to a person to be authentic or truthful*
Article 3, first paragraph, point (44)(bm)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 175o		***(44d) 'widespread infringement' means any act or omission contrary to Union law that protects the interest of individuals:***		***(44e) 'widespread infringement' means any act or omission contrary to Union law that protects the interest of individuals:*** Text Origin: EP Mandate G
Article 3, first paragraph, point (44)(bn)				
G 175p		***(a) which has harmed or is likely to harm the collective interests of individuals residing in at least two Member States other than the Member State, in which:***		***(a) which has harmed or is likely to harm the collective interests of individuals residing in at least two Member States other than the Member State, in which:*** Text Origin: EP Mandate G
Article 3, first paragraph, point (44e)(a)(i new)				
G 175q		***(i) the act or omission originated or took place;***		***(i) the act or omission originated or took place;*** Text Origin: EP Mandate G
Article 3, first paragraph, point (44e)(a)(i new)				
G 175r		***(ii) the provider concerned, or, where applicable, its authorised representative is established; or,***		***(ii) the provider concerned, or, where applicable, its authorised representative is established; or,*** Text Origin: EP Mandate G
Article 3, first paragraph, point (44e)(a)(i new)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 175s		***(iii) the deployer is established, when the infringement is committed by the deployer;***		***(iii) the deployer is established, when the infringement is committed by the deployer;*** Text Origin: EP Mandate
Article 3, first paragraph, point (44e)(a)(i new)				
G 175t		***(b) which protects the interests of individuals, that have caused, cause or are likely to cause harm to the collective interests of individuals and that have common features, including the same unlawful practice, the same interest being infringed and that are occurring concurrently, committed by the same operator, in at least three Member States;***		***(b) which protects the interests of individuals, that have caused, cause or are likely to cause harm to the collective interests of individuals and that have common features, including the same unlawful practice, the same interest being infringed and that are occurring concurrently, committed by the same operator, in at least three Member States;*** Text Origin: EP Mandate
Article 3, first paragraph, point (44h)				
G 175u			***(44h) 'critical infrastructure' means an asset, system or part thereof which is necessary for the delivery of a service that is essential for the maintenance of vital societal functions or economic activities within the meaning of Article 2(4) and (5) of Directive …../….. on the resilience of critical entities;***	

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Article 3, first paragraph, point (44i)				
G 175v			***(44i) 'personal data' means data as defined in point (1) of Article 4 of Regulation (EU) 2016/679;***	G
Article 3, first paragraph, point (44b new)				
G 175w		***(44e) 'non-personal data' means data other than personal data;***		G
Article 3, first paragraph, point (44f new)				
G 175x		***(44f) 'widespread infringement with a Union dimension' means a widespread infringement that has harmed or is likely to harm the collective interests of individuals in at least two-thirds of the Member States, accounting, together, for at least two-thirds of the population of the Union;***		G
Article 3, first paragraph, point (44g new)				
G 175y		***(44g) 'regulatory sandbox' means a controlled environment established by a public authority that facilitates the safe development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan***		G

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		under regulatory supervision;		
Article 3, first paragraph, point (44a)				
175z		***(44h) 'critical infrastructure' means an asset, a facility, equipment, a network or a system, or a part of an asset, a facility, equipment, a network or a system, which is necessary for the provision of an essential service within the meaning of Article 2(4) of Directive (EU) 2022/2557;***		***(44h) 'critical infrastructure' means an asset, a facility, equipment, a network or a system, or a part of thereof, which is necessary for the provision of an essential service within the meaning of Article 2(4) of Directive (EU) 2022/2557;*** Text Origin: EP Mandate
Article 3, first paragraph, point (44k new)				
175aa		***(44k) 'social scoring' means evaluating or classifying natural persons based on their social behaviour, socio-economic status or known or predicted personal or personality characteristics;***		
Article 3, first paragraph, point (44l new)				
175ab		***(44l) 'social behaviour' means the way a natural person interacts with and influences other natural persons or society;***		
Article 3, first paragraph, point (44m new)				
175ac				

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		(44m) 'state of the art' means the developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience;		
Article 3, first paragraph, point (44n new)				
G 175ad		*(44n) 'testing in real world conditions' means the temporary testing of an AI system for its intended purpose in real world conditions outside of a laboratory or otherwise simulated environment;*		G
Article 3, first paragraph, point (44b)				
G 175ae				*(44b) 'general purpose AI model' means an AI model, including when trained with a large amount of data using self-supervision at scale, that displays significant generality and is capable to competently perform a wide range of distinct tasks regardless of the way the model is placed on the market and that can be integrated into a variety of downstream systems or applications. This does not cover AI models that are used before release on the market for research, development and* G

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				prototyping activities.
Article 3, first paragraph, point (44c)				
G 175af				***(44c) 'high-impact capabilities' in general purpose AI models means capabilities that match or exceed the capabilities recorded in the most advanced general purpose AI models.*** G
Article 3, first paragraph, point (44d)				
G 175ag				***(44d) 'systemic risk at Union level' means a risk that is specific to the high-impact capabilities of general-purpose AI models, having a significant impact on the internal market due to its reach, and with actual or reasonably foreseeable negative effects on public health, safety, public security, fundamental rights, or the society as a whole, that can be propagated at scale across the value chain.*** G
Article 3, first paragraph, point (44e)				
G 175ah				***(44e) 'general-purpose AI system' means an AI system which is based on a general-purpose AI model , that has the capability to serve a variety of purposes, both for direct use as well as for integration in*** G

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				other AI systems;
Article 3, first paragraph, point (44f)				
G 175ai				***(44f) 'floating-point operation' means any mathematical operation or assignment involving floating-point numbers, which are a subset of the real numbers typically represented on computers by an integer of fixed precision scaled by an integer exponent of a fixed base.*** G
Article 3, first paragraph, point (44g)				
G 175aj				***(44g) 'downstream provider' means a provider of an AI system, including a general-purpose AI system, which integrates an AI model, regardless of whether the model is provided by themselves and vertically integrated or provided by another entity based on contractual relations.*** G
Article 4				
G 176	Article 4 Amendments to Annex I	*deleted*	Article 4 ~~*Amendments to Annex I*~~ ***Implementing acts***	G
Article 4, first paragraph				
G 177				G

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	The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and approaches listed in Annex I, in order to update that list to market and technological developments on the basis of characteristics that are similar to the techniques and approaches listed therein.	*deleted*	~~*The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and*~~ ***In order to ensure uniform conditions for the implementation of this Regulation as regards machine learning approaches and logic- and knowledged based*** approaches ~~*listed in Annex I, in order to update that list to*~~***referred to in Article 3(1), the Commission may adopt implementing acts to specify the technical elements of those approaches, taking into account*** market and technological developments***. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2)*** ~~*on the basis of characteristics that are similar to the techniques and approaches listed therein*~~.	
Title Ia				
G 177a			***Title Ia GENERAL PURPOSE AI SYSTEMS***	G
Article 4a new				
G 177b		***Article 4a General principles applicable to all AI systems***		G

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Article 4a, first paragraph new				
G 177c		***1. All operators falling under this Regulation shall make their best efforts to develop and use AI systems or foundation models in accordance with the following general principles establishing a high-level framework that promotes a coherent human-centric European approach to ethical and trustworthy Artificial Intelligence, which is fully in line with the Charter as well as the values on which the Union is founded:***		G
Article 4a, first paragraph, point (a new)				
G 177d		***(a) 'human agency and oversight' means that AI systems shall be developed and used as a tool that serves people, respects human dignity and personal autonomy, and that is functioning in a way that can be appropriately controlled and overseen by humans;***		G
Article 4a, first paragraph, point (b new)				
G 177e		***(b) 'technical robustness and safety' means that AI systems shall be developed and used in a way to minimize unintended and***		G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		unexpected harm as well as being robust in case of unintended problems and being resilient against attempts to alter the use or performance of the AI system so as to allow unlawful use by malicious third parties;		
Article 4a, first paragraph, point (c new)				
G 177f		***(c) 'privacy and data governance' means that AI systems shall be developed and used in compliance with existing privacy and data protection rules, while processing data that meets high standards in terms of quality and integrity;***		G
Article 4a, first paragraph, point (d new)				
G 177g		***(d) 'transparency' means that AI systems shall be developed and used in a way that allows appropriate traceability and explainability, while making humans aware that they communicate or interact with an AI system as well as duly informing users of the capabilities and limitations of that AI system and affected persons about their rights;***		G
Article 4a, first paragraph, point (e new)				
G 177h				G

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		(e) 'diversity, non-discrimination and fairness' means that AI systems shall be developed and used in a way that includes diverse actors and promotes equal access, gender equality and cultural diversity, while avoiding discriminatory impacts and unfair biases that are prohibited by Union or national law;		
Article 4a, first paragraph, point (f new)				
G 177i		***(f) 'social and environmental well-being' means that AI systems shall be developed and used in a sustainable and environmentally friendly manner as well as in a way to benefit all human beings, while monitoring and assessing the long-term impacts on the individual, society and democracy.***		G
Article 4a, second paragraph new				
G 177j		***2. Paragraph 1 is without prejudice to obligations set up by existing Union and national law. For high-risk AI systems, the general principles are translated into and complied with by providers or deployers by means of the requirements set out in Articles 8 to 15, and the relevant obligations laid down in Chapter 3 of Title III of***		G

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		this Regulation. For foundation models, the general principles are translated into and complied with by providers by means of the requirements set out in Articles 28 to 28b. For all AI systems, the application of the principles referred to in paragraph 1 can be achieved, as applicable, through the provisions of Article 28, Article 52, or the application of harmonised standards, technical specifications, and codes of conduct as referred to in Article 69,without creating new obligations under this Regulation.		
Article 4a, third paragraph new				
G 177k		***3. The Commission and the AI Office shall incorporate these guiding principles in standardisation requests as well as recommendations consisting in technical guidance to assist providers and deployers on how to develop and use AI systems. European Standardisation Organisations shall take the general principles referred to in paragraph 1 of this Article into account as outcome-based objectives when developing the appropriate harmonised standards for high risk AI systems as referred to in Article 40(2b).***		G

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Article 4, first paragraph a				
G 177l		***Article 4b*** ***AI literacy***		***Article 4b*** ***AI literacy*** Text Origin: EP Mandate G
Article 4, third paragraph				
G 177m		***1. When implementing this Regulation, the Union and the Member States shall promote measures for the development of a sufficient level of AI literacy, across sectors and taking into account the different needs of groups of providers, deployers and affected persons concerned, including through education and training, skilling and reskilling programmes and while ensuring proper gender and age balance, in view of allowing a democratic control of AI systems.***		G
Article 4, fourth paragraph				
G 177n		***2. Providers and deployers of AI systems shall take measures to ensure a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the***		***2. Providers and deployers of AI systems shall take measures to ensure, to their best extent, 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, education*** G

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		context the AI systems are to be used in, and considering the persons or groups of persons on which the AI systems are to be used.		***and training and the context the AI systems are to be used in, and considering the persons or groups of persons on which the AI systems are to be used.***
Article 4b, third paragraph new				
G 177o		***3. Such literacy measures shall consist, in particular, of the teaching of basic notions and skills about AI systems and their functioning, including the different types of products and uses, their risks and benefits.***		
Article 4b, fourth paragraph new				
G 177p		***4. A sufficient level of AI literacy is one that contributes, as necessary, to the ability of providers and deployers to ensure compliance and enforcement of this Regulation.***		
Article 4a				
G 177q			***Article 4a Compliance of general purpose AI systems with this Regulation***	
Article 4a(1)				
G 177r			***1. Without prejudice to Articles 5,***	

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			52, 53 and 69 of this Regulation, general purpose AI systems shall only comply with the requirements and obligations set out in Article 4b.	
Article 4a(2)				
G 177s			***2. Such requirements and obligations shall apply irrespective of whether the general purpose AI system is placed on the market or put into service as a pre-trained model and whether further fine-tuning of the model is to be performed by the user of the general purpose AI system.***	G
Article 4b				
G 177t			***Article 4b Requirements for general purpose AI systems and obligations for providers of such systems***	G
Article 4b(1)				
G 177u			***1. General purpose AI systems which may be used as high risk AI systems or as components of high risk AI systems in the meaning of Article 6, shall comply with the requirements established in Title III, Chapter 2 of this Regulation as***	G

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			from the date of application of the implementing acts adopted by the Commission in accordance with the examination procedure referred to in Article 74(2) no later than 18 months after the entry into force of this Regulation. Those implementing acts shall specify and adapt the application of the requirements established in Title III, Chapter 2 to general purpose AI systems in the light of their characteristics, technical feasibility, specificities of the AI value chain and of market and technological developments. When fulfilling those requirements, the generally acknowledged state of the art shall be taken into account.	
Article 4b(2)				
G 177v			***2. Providers of general purpose AI systems referred to in paragraph 1 shall comply, as from the date of application of the implementing acts referred to in paragraph 1, with the obligations set out in Articles 16aa, 16e, 16f, 16g, 16i, 16j, 25, 48 and 61.***	G
Article 4b(3)				
G 177w			***3. For the purpose of complying with the obligations set out in***	G

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			Article 16e, providers shall follow the conformity assessment procedure based on internal control set out in Annex VI, points 3 and 4.	
Article 4b(4)				
G 177x			***4. Providers of such systems shall also keep the technical documentation referred to in Article 11 at the disposal of the national competent authorities for a period ending ten years after the general purpose AI system is placed on the Union market or put into service in the Union.***	G
Article 4b(5)				
G 177y			***5. Providers of general purpose AI systems shall cooperate with and provide the necessary information to other providers intending to put into service or place such systems on the Union market as high-risk AI systems or as components of high-risk AI systems, with a view to enabling the latter to comply with their obligations under this Regulation. Such cooperation between providers shall preserve, as appropriate, intellectual property rights, and confidential business information or trade secrets in accordance with Article 70. In***	G

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			order to ensure uniform conditions for the implementation of this Regulation as regards the information to be shared by the providers of general purpose AI systems, the Commission may adopt implementing acts in accordance with the examination procedure referred to in Article 74(2).	
Article 4b(6)				
G 177z			***6. In complying with the requirements and obligations referred to in paragraphs 1, 2 and 3:*** ***- any reference to the intended purpose shall be understood as referring to possible use of the general purpose AI systems as high risk AI systems or as components of AI high risk systems in the meaning of Article 6;*** ***- any reference to the requirements for high-risk AI systems in Chapter II, Title III shall be understood as referring only to the requirements set out in the present Article.***	G
Article 4c				
G 177aa			***Article 4c*** ***Exceptions to Article 4b***	G
Article 4c(1)				

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G 177ab			***1. Article 4b shall not apply when the provider has explicitly excluded all high-risk uses in the instructions of use or information accompanying the general purpose AI system.***	G
Article 4c(2)				
G 177ac			***2. Such exclusion shall be made in good faith and shall not be deemed justified if the provider has sufficient reasons to consider that the system may be misused.***	G
Article 4c(3)				
G 177ad			***3. When the provider detects or is informed about market misuse they shall take all necessary and proportionate measures to prevent such further misuse, in particular taking into account the scale of the misuse and the seriousness of the associated risks.***	G
TITLE II				
G 178	TITLE II PROHIBITED ARTIFICIAL INTELLIGENCE PRACTICES	TITLE II PROHIBITED ARTIFICIAL INTELLIGENCE PRACTICES	TITLE II PROHIBITED ARTIFICIAL INTELLIGENCE PRACTICES	TITLE II PROHIBITED ARTIFICIAL INTELLIGENCE PRACTICES Text Origin: Commission G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Proposal
Article 5				
G 179	Article 5	Article 5	Article 5	Article 5 ***Prohibited Artificial Intelligence Practices*** Text Origin: Commission Proposal
Article 5(1)				
G 180	1. The following artificial intelligence practices shall be prohibited:	1. The following artificial intelligence practices shall be prohibited:	1. The following artificial intelligence practices shall be prohibited:	1. The following artificial intelligence practices shall be prohibited: Text Origin: Commission Proposal
Article 5(1), point (-a)(a)				
G 181	(a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness in order to materially distort a person's behaviour in a manner that causes or is likely to cause that person or another person physical or psychological harm;	(a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness ~~in order to~~ ***or purposefully manipulative or deceptive techniques, with the objective to or the effect of*** materially ~~distort~~***distorting*** a person's ***or a group of persons'*** behaviour ***by appreciably impairing the person's ability to make an informed decision, thereby causing***	(a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness ~~in order to~~ ***with the objective to or the effect of*** materially ~~distort~~***distorting*** a person's behaviour in a manner that causes or is ***reasonably*** likely to cause that person or another person physical or psychological harm;	(a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness ~~in order to~~ ***or purposefully manipulative or deceptive techniques, with the objective to or the effect of*** materially ~~distort~~***distorting*** a person's ***or a group of persons'*** behaviour ***by appreciably impairing the person's ability to make an informed decision, thereby causing***

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		the person to take a decision that that person would not have otherwise taken in a manner that causes or is likely to cause that person~~ or~~, another person ~~physical or psychological~~***or group of persons significant*** harm;		***the person to take a decision that that person would not have otherwise taken*** in a manner that causes or is likely to cause that person~~ or~~, another person ~~physical or psychological~~***or group of persons significant*** harm; Text Origin: EP Mandate
Article 5(1), point (-a)(a) a				
G 181a		***The prohibition of AI system that deploys subliminal techniques referred to in the first sub-paragraph shall not apply to AI systems intended to be used for approved therapeutical purposes on the basis of specific informed consent of the individuals that are exposed to them or, where applicable, of their legal guardian;***		Text Origin: EP Mandate G
Article 5(1), point (b)				
G 182	(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, physical or mental disability, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person	(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a ***person or a*** specific group of persons***, including characteristics of such person's or a such group's known or predicted personality traits or social or economic situation***~~ due to their~~ age, physical or mental ~~disability, in~~	(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, ~~physical or mental disability, in order to~~ ***disability or a specific social or economic situation, with the objective to or the effect of*** materially ~~distort~~***distorting*** the	(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a ***person or a*** specific group of persons due to their age, ~~physical or mental disability, in order to~~ ***disability or a specific social or economic situation, with the objective to or the effect of*** materially ~~distort~~***distorting*** the G

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	physical or psychological harm;	~~order to~~ ***ability with the objective or to the effect of*** materially ~~distort~~***distorting*** the behaviour of ***that person or*** a person pertaining to that group in a manner that causes or is likely to cause that person or another person ~~physical or psychological~~***significant*** harm;	behaviour of a person pertaining to that group in a manner that causes or is ***reasonably*** likely to cause that person or another person physical or psychological harm;	behaviour of ***that person or*** a person pertaining to that group in a manner that causes or is ***reasonably*** likely to cause that person or another person ~~physical or psychological harm;~~***significant harm***
Article 5(1), point (ba)				
182a		***(ba) the placing on the market, putting into service or use of biometric categorisation systems that categorise natural persons according to sensitive or protected attributes or characteristics or based on the inference of those attributes or characteristics. This prohibition shall not apply to AI systems intended to be used for approved therapeutical purposes on the basis of specific informed consent of the individuals that are exposed to them or, where applicable, of their legal guardian.***		***(ba) the placing on the market or putting into service for this specific purpose, or use of biometric categorisation systems that categorise individually natural persons based on their biometric data to deduce or infer their race, political opinions, trade union membership, religious or philosophical beliefs, sex life or sexual orientation.*** ***This prohibition does not cover any labelling or filtering of lawfully acquired biometric datasets, such as images, based on biometric data or categorizing of biometric data in the area of law enforcement.***
Article 5(1), point (c)				
183	(c) the placing on the market, putting into service or use of AI systems by public authorities or on	(c) the placing on the market, putting into service or use of AI systems ~~by public authorities or on~~	(c) the placing on the market, putting into service or use of AI systems ~~by public authorities or on~~	(c) the placing on the market, putting into service or use of AI systems ~~by public authorities or on~~

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	their behalf for the evaluation or classification of the trustworthiness of natural persons over a certain period of time based on their social behaviour or known or predicted personal or personality characteristics, with the social score leading to either or both of the following:	~~their behalf for the~~***for the social scoring*** evaluation or classification of ~~the trustworthiness of natural persons~~***natural persons or groups thereof*** over a certain period of time based on their social behaviour or known***, inferred*** or predicted personal or personality characteristics, with the social score leading to either or both of the following:	~~their behalf~~ for the evaluation or classification ~~of the trustworthiness~~ of natural persons over a certain period of time based on their social behaviour or known or predicted personal or personality characteristics, with the social score leading to either or both of the following:	~~their behalf~~ for the evaluation or classification of ~~the trustworthiness of natural persons~~***natural persons or groups thereof*** over a certain period of time based on their social behaviour or known***, inferred*** or predicted personal or personality characteristics, with the social score leading to either or both of the following: Text Origin: EP Mandate
Article 5(1), point (c)(i)				
G 184	(i) detrimental or unfavourable treatment of certain natural persons or whole groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected;	(i) detrimental or unfavourable treatment of certain natural persons or whole groups thereof in social contexts ~~which~~***that*** are unrelated to the contexts in which the data was originally generated or collected;	(i) detrimental or unfavourable treatment of certain natural persons or ~~whole~~ groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected;	(i) detrimental or unfavourable treatment of certain natural persons or whole groups thereof in social contexts ~~which~~***that*** are unrelated to the contexts in which the data was originally generated or collected; Text Origin: EP Mandate
Article 5(1), point (c)(ii)				
G 185	(ii) detrimental or unfavourable treatment of certain natural persons or whole groups thereof that is unjustified or disproportionate to their social behaviour or its gravity;	(ii) detrimental or unfavourable treatment of certain natural persons or whole groups thereof that is unjustified or disproportionate to their social behaviour or its gravity;	(ii) detrimental or unfavourable treatment of certain natural persons or ~~whole~~ groups thereof that is unjustified or disproportionate to their social behaviour or its gravity;	(ii) detrimental or unfavourable treatment of certain natural persons or ~~whole~~ groups thereof that is unjustified or disproportionate to their social behaviour or its gravity; Text Origin: Council Mandate
Article 5(1), point (d)				

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G 186	(d) the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement, unless and in as far as such use is strictly necessary for one of the following objectives:	(d) the use of 'real-time' remote biometric identification systems in publicly accessible spaces ~~for the purpose of law enforcement, unless and in as far as such use is strictly necessary for one of the following objectives:~~;	(d) the use of 'real-time' remote biometric identification systems in publicly accessible spaces ***by law enforcement authorities or on their behalf*** for the purpose of law enforcement, unless and in as far as such use is strictly necessary for one of the following objectives:	(d) the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement~~,~~ unless and in as far as such use is strictly necessary for one of the following objectives:
Article 5(1), point (d)(i)				
G 187	(i) the targeted search for specific potential victims of crime, including missing children;	*deleted*	(i) the targeted search for specific potential victims of crime~~, including missing children~~;	(i) the targeted search for specific ~~potential~~ victims of ~~crime, including~~***abduction, trafficking in human beings and sexual exploitation of human beings as well as search for*** missing ~~children;~~***persons***
Article 5(1), point (d)(ii)				
G 188	(ii) the prevention of a specific, substantial and imminent threat to the life or physical safety of natural persons or of a terrorist attack;	*deleted*	(ii) the prevention of a specific~~, substantial and imminent~~ ***and substantial*** threat to the ***critical infrastructure, life, health***~~life~~ or physical safety of natural persons or ~~of a~~***the prevention of*** terrorist ~~attack~~***attacks***;	(ii) the prevention of a specific, substantial and imminent threat to the life or physical safety of natural persons or ***a genuine and present or genuine and foreseeable threat*** of a terrorist attack~~;~~
Article 5(1), point (d)(iii)				
G 189	(iii) the detection, localisation, identification or prosecution of a	*deleted*	(iii) the ~~detection,~~ localisation~~, identification or prosecution of a~~	(iii) the ~~detection,~~ localisation~~,~~ ***or*** identification ~~or prosecution of a~~

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	perpetrator or suspect of a criminal offence referred to in Article 2(2) of Council Framework Decision 2002/584/JHA[1] and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, as determined by the law of that Member State. _____ 1. Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).		~~perpetrator or suspect of~~ ***or identification of a natural person for the purposes of conducting*** a criminal ~~offence~~***investigation, prosecution or executing a criminal penalty for offences,*** referred to in Article 2(2) of Council Framework Decision 2002/584/JHA[1] and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, ***or other specific offences punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least five years,*** as determined by the law of that Member State. _____ 1. ***[1]*** Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).	~~perpetrator or suspect of~~ ***of a person suspected of having committed a criminal offence, for the purposes of conducting*** a criminal ~~offence referred to in Article 2(2) of Council Framework Decision 2002/584/JHA[1]~~***investigation, prosecution or executing a criminal penalty for offences, referred to in Annex IIa*** and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least ~~three~~***four*** years~~, as determined by the law of that Member State~~. ***This paragraph is without prejudice to the provisions in Article 9 of the GDPR for the processing of biometric data for purposes other than law enforcement***. _____ ~~1. Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).~~
Article 5(1), point (d)(iiia)				
G 189a		***(da) the placing on the market, putting into service or use of an AI system for making risk assessments of natural persons or groups thereof in order to assess the risk of a natural person for offending or reoffending or for predicting the***		***(da) the placing on the market, putting into service for this specific purpose, or use of an AI system for making risk assessments of natural persons in order to assess or predict the risk of a natural person to commit a criminal offence, based*** G

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		occurrence or reoccurrence of an actual or potential criminal or administrative offence based on profiling of a natural person or on assessing personality traits and characteristics, including the person's location, or past criminal behaviour of natural persons or groups of natural persons;		***solely on the profiling of a natural person or on assessing their personality traits and characteristics;*** ***This prohibition shall not apply to AI systems used to support the human assessment of the involvement of a person in a criminal activity, which is already based on objective and verifiable facts directly linked to a criminal activity.***
Article 5(1), point (d)(iiib)				
G 189b		***(db) The placing on the market, putting into service or use of AI systems that create or expand facial recognition databases through the untargeted scraping of facial images from the internet or CCTV footage;***		***(db) the placing on the market, putting into service for this specific purpose, or use of AI systems that create or expand facial recognition databases through the untargeted scraping of facial images from the internet or CCTV footage;*** G
Article 5(1), point (d)(iiic)				
G 189c		***(dc) the placing on the market, putting into service or use of AI systems to infer emotions of a natural person in the areas of law enforcement, border management, in workplace and education institutions.***		***dc) the placing on the market, putting into service for this specific purpose, or use of AI systems to infer emotions of a natural person in the areas of workplace and education institutions except in cases where the use of the AI system is intended to be put in place or into the market for medical or*** G

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				safety reasons;
Article 5(1), point (d)(iiid)				
G 189d		***(dd) the putting into service or use of AI systems for the analysis of recorded footage of publicly accessible spaces through 'post' remote biometric identification systems, unless they are subject to a pre-judicial authorisation in accordance with Union law and strictly necessary for the targeted search connected to a specific serious criminal offense as defined in Article 83(1) of TFEU that already took place for the purpose of law enforcement.***		***(iiid) deleted*** G
Article 5(1), point (d)(iiie)				
G 189e		***1a. This Article shall not affect the prohibitions that apply where an artificial intelligence practice infringes another Union law, including Union law on data protection, non discrimination, consumer protection or competition;***		***1a. This Article shall not affect the prohibitions that apply where an artificial intelligence practice infringes other Union law.*** Text Origin: EP Mandate G
Article 5(2), first subparagraph				
G 190	2. The use of 'real-time' remote biometric identification systems in	*deleted*	*2.* The use of 'real-time' remote biometric identification systems in	2. The use of 'real-time' remote biometric identification systems in G

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	publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall take into account the following elements:		publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall take into account the following elements:	publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall ***only be deployed for the purposes under paragraph 1, point d) to confirm the specifically targeted individual's identity and it shall*** take into account the following elements:
Article 5(2), first subparagraph, point (a)				
G 191	(a) the nature of the situation giving rise to the possible use, in particular the seriousness, probability and scale of the harm caused in the absence of the use of the system;	*deleted*	*(a)* the nature of the situation giving rise to the possible use, in particular the seriousness, probability and scale of the harm caused in the absence of the use of the system;	(a) the nature of the situation giving rise to the possible use, in particular the seriousness, probability and scale of the harm caused in the absence of the use of the system; G
Article 5(2), first subparagraph, point (b)				
G 192	(b) the consequences of the use of the system for the rights and freedoms of all persons concerned, in particular the seriousness, probability and scale of those consequences.	*deleted*	*(b)* the consequences of the use of the system for the rights and freedoms of all persons concerned, in particular the seriousness, probability and scale of those consequences.	(b) the consequences of the use of the system for the rights and freedoms of all persons concerned, in particular the seriousness, probability and scale of those consequences. G
Article 5(2), second subparagraph				
G 193	In addition, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to	*deleted*	In addition, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to	In addition, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to G

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	in paragraph 1 point d) shall comply with necessary and proportionate safeguards and conditions in relation to the use, in particular as regards the temporal, geographic and personal limitations.		in paragraph 1 point d) shall comply with necessary and proportionate safeguards and conditions in relation to the use, in particular as regards the temporal, geographic and personal limitations.	in paragraph 1 point d) shall comply with necessary and proportionate safeguards and conditions in relation to the use ***in accordance with national legislations authorizing the use thereof***, in particular as regards the temporal, geographic and personal limitations. ***The use of the 'real-time' remote biometric identification system in publicly accessible spaces shall only be authorised if the law enforcement authority has completed a fundamental rights impact assessment as provided for in Article 29a and has registered the system in the database according to Article 51. However, in duly justified cases of urgency, the use of the system may be commenced without the registration, provided that the registration is completed without undue delay.***
Article 5(3), first subparagraph				
G 194	3. As regards paragraphs 1, point (d) and 2, each individual use for the purpose of law enforcement of a 'real-time' remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent administrative authority	*deleted*	3. As regards paragraphs 1, point (d) and 2, each ~~*individual*~~ use for the purpose of law enforcement of a 'real-time' remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent administrative authority	3. As regards paragraphs 1, point (d) and 2, each ~~*individual*~~ use for the purpose of law enforcement of a 'real-time' remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or ~~*by*~~ an independent administrative authority G

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	of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation and the authorisation may be requested only during or after the use.		of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation ~~and the~~***provided that, such*** authorisation ~~may~~***shall*** be requested ~~only~~***without undue delay*** during ~~or after the use~~***use of the AI system, and if such authorisation is rejected, its use shall be stopped with immediate effect***.	***whose decision is binding*** of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation ~~and the~~***provided that, such*** authorisation ~~may~~***shall*** be requested ~~only during or after the use~~***without undue delay, at the latest within 24 hours. If such authorisation is rejected, its use shall be stopped with immediate effect and all the data, as well as the results and outputs of this use shall be immediately discarded and deleted***.
Article 5(3), second subparagraph				
G 195	The competent judicial or administrative authority shall only grant the authorisation where it is satisfied, based on objective evidence or clear indications presented to it, that the use of the 'real-time' remote biometric identification system at issue is necessary for and proportionate to achieving one of the objectives specified in paragraph 1, point (d), as identified in the request. In deciding on the request, the	*deleted*	The competent judicial or administrative authority shall only grant the authorisation where it is satisfied, based on objective evidence or clear indications presented to it, that the use of the 'real-time' remote biometric identification system at issue is necessary for and proportionate to achieving one of the objectives specified in paragraph 1, point (d), as identified in the request. In deciding on the request, the	The competent judicial ***authority or an independent*** ~~or~~ administrative authority ***whose decision is binding*** shall only grant the authorisation where it is satisfied, based on objective evidence or clear indications presented to it, that the use of the 'real-time' remote biometric identification system at issue is necessary for and proportionate to achieving one of the objectives specified in paragraph 1, point (d), as identified in the request G

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	competent judicial or administrative authority shall take into account the elements referred to in paragraph 2.		competent judicial or administrative authority shall take into account the elements referred to in paragraph 2.	***and, in particular, remains limited to what is strictly necessary concerning the period of time as well as geographic and personal scope.*** ~~.~~ In deciding on the request, the competent judicial ***authority or an independent*** ~~or~~ administrative authority ***whose decision is binding*** shall take into account the elements referred to in paragraph 2***.*** ***It shall be ensured that no decision that produces an adverse legal effect on a person may be taken by the judicial authority or an independent administrative authority whose decision is binding solely based on the output of the remote biometric identification system .*** ~~.~~
Article 5(3a)				
G 195a				***3a. Without prejudice to paragraph 3, each use of a 'real-time' remote biometric identification system in publicly accessible spaces for law enforcement purposes shall be notified to the relevant market surveillance authority and the national data protection authority in accordance with the national rules referred to in paragraph 4. The notification shall as a minimum contain the information specified under paragraph 5 and shall not include sensitive*** G

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				operational data.
Article 5(4)				
G 196	4. A Member State may decide to provide for the possibility to fully or partially authorise the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.	*deleted*	4. A Member State may decide to provide for the possibility to fully or partially authorise the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision ***and reporting*** relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.	4. A Member State may decide to provide for the possibility to fully or partially authorise the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. ~~*That*~~ Member ~~*State*~~***States concerned*** shall lay down in ~~*its*~~***their*** national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision ***and reporting*** relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement. ***Member States shall notify those rules to the Commission at the latest 30 days following the adoption thereof.*** ***Member States may introduce, in accordance with Union law, more restrictive laws on the use of remote*** G

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				biometric identification systems.
Article 5(5)				
G 196a				***5. National market surveillance authorities and the national data protection authorities of Member States that have been notified of the use of 'real-time' remote biometric identification systems in publicly accessible spaces for law enforcement purposes pursuant to paragraph 3a shall submit to the Commission annual reports on such use. For that purpose, the Commission shall provide Member States and national market surveillance and data protection authorities with a template, including information on the number of the decisions taken by competent judicial authorities or an independent administrative authority whose decision is binding upon requests for authorisations in accordance with paragraph 3 and their result;***
Article 5(6)				
G 196b				***6. The Commission shall publish annual reports on the use of 'real-time' remote biometric identification systems in publicly accessible spaces for law***

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				enforcement purposes based on aggregated data in Member States based on the annual reports referred to in paragraph 5, which shall not include sensitive operational data of the related law enforcement activities.
TITLE III				
G 197	TITLE III HIGH-RISK AI SYSTEMS	TITLE III HIGH-RISK AI SYSTEMS	TITLE III HIGH-RISK AI SYSTEMS	TITLE III HIGH-RISK AI SYSTEMS Text Origin: Commission Proposal
Chapter 1				
G 198	Chapter 1 CLASSIFICATION OF AI SYSTEMS AS HIGH-RISK	Chapter 1 CLASSIFICATION OF AI SYSTEMS AS HIGH-RISK	Chapter 1 CLASSIFICATION OF AI SYSTEMS AS HIGH-RISK	
Article 6				
G 199	Article 6 Classification rules for high-risk AI systems	Article 6 Classification rules for high-risk AI systems	Article 6 Classification rules for high-risk AI systems	Article 6 Classification rules for high-risk AI systems Text Origin: Commission Proposal
Article 6(1)				
G 200	1. Irrespective of whether an AI	1. Irrespective of whether an AI	1. ~~*Irrespective of whether*~~ An AI	1. Irrespective of whether an AI

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	system is placed on the market or put into service independently from the products referred to in points (a) and (b), that AI system shall be considered high-risk where both of the following conditions are fulfilled:	system is placed on the market or put into service independently from the products referred to in points (a) and (b), that AI system shall be considered high-risk where both of the following conditions are fulfilled:	system ***that is itself a product covered by the Union harmonisation legislation listed in Annex II shall be considered as high risk if it is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to the above mentioned legislation.***~~*is placed on the market or put into service independently from the products referred to in points (a) and (b), that AI system shall be considered high-risk where both of the following conditions are fulfilled:*~~	system is placed on the market or put into service independently from the products referred to in points (a) and (b), that AI system shall be considered high-risk where both of the following conditions are fulfilled: Text Origin: Commission Proposal
Article 6(1), point (a)				
G 201	(a) the AI system is intended to be used as a safety component of a product, or is itself a product, covered by the Union harmonisation legislation listed in Annex II;	(a) the AI system is intended to be used as a safety component of a product, or ***the AI system*** is itself a product, covered by the Union harmonisation ~~*legislation*~~***law*** listed in Annex II;	*deleted*	(a) the AI system is intended to be used as a safety component of a product, or ***the AI system*** is itself a product, covered by the Union harmonisation legislation listed in Annex II; Text Origin: EP Mandate
Article 6(1), point (b)				
G 202	(b) the product whose safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment with a view	(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	*deleted*	(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

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	to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.	assessment ***related to risks for health and safety,*** with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation ~~legislation~~***law*** listed in Annex II~~.~~***;***		assessment***,*** with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II~~.~~***;*** Text Origin: EP Mandate
Article 6(2)				
G 203	2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk.	~~2~~***1a***. In addition to the high-risk AI systems referred to in paragraph 1, AI systems ***falling under one or more of the critical areas and use cases*** referred to in Annex III shall ~~also~~***be considered high-risk if they pose a significant risk of harm to the health, safety or fundamental rights of natural persons. Where an AI system falls under Annex III point 2, it shall*** be considered ***to be high-risk if it poses a significant risk of harm to the environment***~~high-risk~~.	2. ~~In addition to the high-risk AI systems~~***An AI system intended to be used as a safety component of a product covered by the legislation*** referred to in paragraph 1~~, AI systems referred to in Annex III~~ ***shall be considered as high risk if it is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to above mentioned legislation. This provision*** shall ~~also be considered high-risk~~***apply irrespective of whether the AI system is placed on the market or put into service independently from the product***.	2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk. G
Article 6(2), second subparagraph				
G 203a		***The Commission shall, six months prior to the entry into force of this Regulation, after consulting the AI Office and relevant stakeholders,***		G

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		provide guidelines clearly specifying the circumstances where the output of AI systems referred to in Annex III would pose a significant risk of harm to the health, safety or fundamental rights of natural persons or cases in which it would not.		
Article 6(2a), first subparagraph				
G 203b			***2a. AI systems referred to in Annex III shall be considered high-risk unless the output of the system is purely accessory in respect of the relevant action or decision to be taken and is not therefore likely to lead to a significant risk to the health, safety or fundamental rights.*** ***In order to ensure uniform conditions for the implementation of this Regulation, the Commission shall, no later than one year after the entry into force of this Regulation, adopt implementing acts to specify the circumstances where the output of AI systems referred to in Annex III would be purely accessory in respect of the relevant action or decision to be taken. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74, paragraph 2.***	***2a. By derogation from paragraph 2 AI systems shall not be considered as high risk if they do not pose a significant risk of harm, to the health, safety or fundamental rights of natural persons, including by not materially influencing the outcome of decision making. This shall be the case if one or more of the following criteria are fulfilled:*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 6(2a), first subparagraph, point (a)				
203c				***(a) the AI system is intended to perform a narrow procedural task;***
Article 6(2a), first subparagraph, point (b)				
203d				***(b) the AI system is intended to improve the result of a previously completed human activity;***
Article 6(2a), first subparagraph, point (c)				
203e				***(c) the AI system is intended to detect decision-making patterns or deviations from prior decision-making patterns and is not meant to replace or influence the previously completed human assessment, without proper human review; or***
Article 6(2a), first subparagraph, point (d)				
203f				***(d) the AI system is intended to perform a preparatory task to an assessment relevant for the purpose of the use cases listed in Annex III.***
Article 6(2a), second subparagraph				
203g				***Notwithstanding first subparagraph of this paragraph, an AI system shall always be considered high-***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				risk if the AI system performs profiling of natural persons.
Article 6(2a new)				
G 203h		***2a. Where providers falling under one or more of the critical areas and use cases referred to in Annex III consider that their AI system does not pose a significant risk as described in paragraph 2, they shall submit a reasoned notification to the national supervisory authority that they are not subject to the requirements of Title III Chapter 2 of this Regulation. Where the AI system is intended to be used in two or more Member States, that notification shall be addressed to the AI Office. Without prejudice to Article 65, the national supervisory authority shall review and reply to the notification, directly or via the AI Office, within three months if they deem the AI system to be misclassified.***		G
Article 6(2b new)				
G 203i		***2b. Providers that misclassify their AI system as not subject to the requirements of Title III Chapter 2 of this Regulation and place it on the market before the deadline for objection by national supervisory***		G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		authorities shall be subject to fines pursuant to Article 71.		
Article 6(2c new)				
203j		***2c. National supervisory authorities shall submit a yearly report to the AI Office detailing the number of notifications received, the related high-risk areas at stake and the decisions taken concerning received notifications***		
Article 6(2b)				
203k				***2b. A provider who considers that an AI system referred to in Annex III is not high-risk shall document its assessment before that system is placed on the market or put into service. Such provider shall be subject to the registration obligation set out in Article 51(1a). Upon request of national competent authorities, the provider shall provide the documentation of the assessment.***
Article 6(2c)				
203l				***2c. The Commission shall, after consulting the AI Board, and no later than [18 months] after the entry into force of this Regulation,***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				provide guidelines specifying the practical implementation of this article completed by a comprehensive list of practical examples of high risk and non-high risk use cases on AI systems pursuant to Article 82b.
Article 6(2d), first subparagraph				
G 203m				***2d. The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the criteria laid down in points a) to d) of the first subparagraph of paragraph 2a.***
Article 6(2d), second subparagraph				
G 203n				***The Commission may adopt delegated acts adding new criteria to those laid down in points a) to d) of the first subparagraph of paragraph 2a, or modifying them, only where there is concrete and reliable evidence of the existence of AI systems that fall under the scope of Annex III but that do not pose a significant risk of harm to the health, safety and fundamental rights.***
Article 6(2d), third subparagraph				
G 203o				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				The Commission shall adopt delegated acts deleting any of the criteria laid down in the first subparagraph of paragraph 2a where there is concrete and reliable evidence that this is necessary for the purpose of maintaining the level of protection of health, safety and fundamental rights in the Union.
Article 6(2d), fourth subparagraph				
G 203p				***Any amendment to the criteria laid down in points a) to d) set out in the first subparagraph of paragraph 2a shall not decrease the overall level of protection of health, safety and fundamental rights in the Union.*** G
Article 6(2d), fifth subparagraph				
G 203q				***When adopting the delegated acts, the Commission shall ensure consistency with the delegated acts adopted pursuant to Article 7(1) and shall take account of market and technological developments.*** G
Article 7				
G 204	Article 7 Amendments to Annex III	Article 7 Amendments to Annex III	Article 7 Amendments to Annex III	Article 7 Amendments to Annex III Text Origin: Commission G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Proposal
Article 7(1)				
205	1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by adding high-risk AI systems where both of the following conditions are fulfilled:	1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to ~~update the list in~~***amend*** Annex III by adding ***or modifying areas or use-cases of*** high-risk AI systems where ~~both of the following conditions are fulfilled:~~***these pose a significant risk of harm to health and safety, or an adverse impact on fundamental rights, to the environment, or to democracy and the rule of law, and that risk is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.***	1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to ~~update~~***amend*** the list in Annex III by adding high-risk AI systems where both of the following conditions are fulfilled:	1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to ~~update the list in~~***amend*** Annex III by adding ***or modifying use-cases of*** high-risk AI systems where both of the following conditions are fulfilled: Text Origin: EP Mandate
Article 7(1), point (a)				
206	(a) the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III;	*deleted*	*(a)* the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III;	(a) the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III; Text Origin: Commission Proposal
Article 7(1), point (b)				
207	(b) the AI systems pose a risk of		*(b)* the AI systems pose a risk of	(b) the AI systems pose a risk of

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	harm to the health and safety, or a risk of adverse impact on fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.	*deleted*	harm to the health and safety, or a risk of adverse impact on fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.	harm to ~~the~~ health and safety, or ~~a risk of~~***an*** adverse impact on fundamental rights, ~~that is, in respect of its severity and probability of occurrence,~~***and that risk is*** equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.
Article 7(1a)				
G 207a		***1a. The Commission is also empowered to adopt delegated acts in accordance with Article 73 to remove use-cases of high-risk AI systems from the list in Annex III if the conditions referred to in paragraph 1 no longer apply;***		G
Article 7(2)				
G 208	2. When assessing for the purposes of paragraph 1 whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall take into account the following criteria:	2. When assessing ~~for the purposes of paragraph 1 whether~~ an AI system ~~poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III,~~***for the purposes of paragraph 1 and 1a*** the Commission shall take into account the following criteria:	2. When assessing for the purposes of paragraph 1 whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall take into account the following criteria:	2. When assessing for the purposes of paragraph 1 whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall take into account the following criteria: Text Origin: Commission Proposal G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 7(2), point (a)				
G 209	(a) the intended purpose of the AI system;	(a) the intended purpose of the AI system;	(a) the intended purpose of the AI system;	(a) the intended purpose of the AI system; Text Origin: EP Mandate G
Article 7(2), point (aa)				
G 209a		***(aa) the general capabilities and functionalities of the AI system independent of its intended purpose;***		G
Article 7(2), point (b)				
G 210	(b) the extent to which an AI system has been used or is likely to be used;	(b) the extent to which an AI system has been used or is likely to be used;	(b) the extent to which an AI system has been used or is likely to be used;	(b) the extent to which an AI system has been used or is likely to be used; Text Origin: Commission Proposal G
Article 7(2), point (ba)				
G 210a		***(ba) the nature and amount of the data processed and used by the AI system;***		***(ba) the nature and amount of the data processed and used by the AI system, in particular whether special categories of personal data are processed;*** Text Origin: EP Mandate G
Article 7(2), point (bb)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 210b		***(bb) the extent to which the AI system acts autonomously;***		***(bb) the extent to which the AI system acts autonomously and the possibility for a human to override a decision or recommendations that may lead to potential harm;*** Text Origin: Presidency2
Article 7(2), point (c)				
G 211	(c) the extent to which the use of an AI system has already caused harm to the health and safety or adverse impact on the fundamental rights or has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by reports or documented allegations submitted to national competent authorities;	(c) the extent to which the use of an AI system has already caused harm to ~~the~~ health and safety***, has had an*** ~~or~~ adverse impact on ~~the~~ fundamental rights***, the environment, democracy and the rule of law*** or has given rise to significant concerns in relation to the ~~materialisation~~***likelihood*** of such harm or adverse impact, as demonstrated ***for example*** by reports or documented allegations submitted to national ~~competent~~***supervisory*** authorities***, to the Commission, to the AI Office, to the EDPS, or to the European Union Agency for Fundamental Rights***;	(c) the extent to which the use of an AI system has already caused harm to the health and safety or adverse impact on the fundamental rights or has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by reports or documented allegations submitted to national competent authorities;	(c) the extent to which the use of an AI system has already caused harm to ~~the~~ health and safety***, has had an*** ~~or~~ adverse impact on ~~the~~ fundamental rights or has given rise to significant concerns in relation to the ~~materialisation~~***likelihood*** of such harm or adverse impact, as demonstrated ***for example*** by reports or documented allegations submitted to national competent authorities~~;~~ ***or by other reports, as appropriate.*** Text Origin: Presidency2
Article 7(2), point (d)				
G 212	(d) the potential extent of such harm or such adverse impact, in particular in terms of its intensity and its ability to affect a plurality of	(d) the potential extent of such harm or such adverse impact, in particular in terms of its intensity and its ability to affect a plurality of persons	(d) the potential extent of such harm or such adverse impact, in particular in terms of its intensity and its ability to affect a plurality of	(d) the potential extent of such harm or such adverse impact, in particular in terms of its intensity and its ability to affect a plurality of persons

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	persons;	***or to disproportionately affect a particular group of persons***;	persons;	***or to disproportionately affect a particular group of persons***; Text Origin: EP Mandate
Article 7(2), point (e)				
G 213	(e) the extent to which potentially harmed or adversely impacted persons are dependent on the outcome produced with an AI system, in particular because for practical or legal reasons it is not reasonably possible to opt-out from that outcome;	(e) the extent to which potentially harmed or adversely impacted persons are dependent on the ~~outcome~~***output*** produced ~~with~~***involving*** an AI system, ***and that output is purely accessory in respect of the relevant action or decision to be taken,*** in particular because for practical or legal reasons it is not reasonably possible to opt-out from that ~~outcome~~***output***;	(e) the extent to which potentially harmed or adversely impacted persons are dependent on the outcome produced with an AI system, in particular because for practical or legal reasons it is not reasonably possible to opt-out from that outcome;	(e) the extent to which potentially harmed or adversely impacted persons are dependent on the outcome produced with an AI system, in particular because for practical or legal reasons it is not reasonably possible to opt-out from that outcome; Text Origin: Commission Proposal
Article 7(2), point (ea new)				
G 213a		***(ea) the potential misuse and malicious use of the AI system and of the technology underpinning it;***		
Article 7(2), point (f)				
G 214	(f) the extent to which potentially harmed or adversely impacted persons are in a vulnerable position in relation to the user of an AI system, in particular due to an imbalance of power, knowledge, economic or social circumstances, or	(f) the extent to which ***there is an imbalance of power, or the*** potentially harmed or adversely impacted persons are in a vulnerable position in relation to the user of an AI system, in particular due to ~~an imbalance of power~~***status, authority***,	(f) the extent to which potentially harmed or adversely impacted persons are in a vulnerable position in relation to the user of an AI system, in particular due to an imbalance of power, knowledge, economic or social circumstances, or	(f) the extent to which ***there is an imbalance of power, or the*** potentially harmed or adversely impacted persons are in a vulnerable position in relation to the user of an AI system, in particular due to ~~an imbalance of power~~***status, authority***,

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	age;	knowledge, economic or social circumstances, or age;	age;	knowledge, economic or social circumstances, or age; Text Origin: Presidency2
Article 7(2), point (g)				
G 215	(g) the extent to which the outcome produced with an AI system is easily reversible, whereby outcomes having an impact on the health or safety of persons shall not be considered as easily reversible;	(g) the extent to which the outcome produced ~~with~~***involving*** an AI system is easily reversible ***or remedied***, whereby outcomes having an ***adverse*** impact on ***health, safety, fundamental rights of persons, the environment, or on democracy and rule of law***~~the health or safety of persons~~ shall not be considered as easily reversible;	(g) the extent to which the outcome produced with an AI system is ***not*** easily reversible, whereby outcomes having an impact on the health or safety of persons shall not be considered as easily reversible;	(g) the extent to which the outcome produced ~~with~~***involving*** an AI system is easily ***corrigible or*** reversible, ***taking into account the technical solutions available to correct or reverse,*** whereby outcomes having ~~an~~***and adverse*** impact on ~~the~~ health ~~or~~, safety, ***fundamental rights,*** ~~of persons~~ shall not be considered as easily ***corrigible or*** reversible~~;~~. G
Article 7(2), point (ga)				
G 215a		***(ga) the extent of the availability and use of effective technical solutions and mechanisms for the control, reliability and corrigibility of the AI system;***		G
Article 7(2), point (ga)				
G 215b		***(gb) the magnitude and likelihood of benefit of the deployment of the AI system for individuals, groups, or society at large, including possible improvements in product***		***(gb) the magnitude and likelihood of benefit of the deployment of the AI system for individuals, groups, or society at large, including possible improvements in product*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		safety;		***safety;*** Text Origin: Presidency2
Article 7(2), point (gc new)				
G 215c		***(gc) the extent of human oversight and the possibility for a human to intercede in order to override a decision or recommendations that may lead to potential harm;***		G
Article 7(2), point (h)				
G 216	(h) the extent to which existing Union legislation provides for:	(h) the extent to which existing Union ~~legislation~~***law*** provides for:	(h) the extent to which existing Union legislation provides for:	(h) the extent to which existing Union legislation provides for: Text Origin: Presidency2 G
Article 7(2), point (h)(i)				
G 217	(i) effective measures of redress in relation to the risks posed by an AI system, with the exclusion of claims for damages;	(i) effective measures of redress in relation to the ~~risks posed~~***damage caused*** by an AI system, with the exclusion of claims for ***direct or indirect*** damages;	(i) effective measures of redress in relation to the risks posed by an AI system, with the exclusion of claims for damages;	(i) effective measures of redress in relation to the risks posed by an AI system, with the exclusion of claims for damages; Text Origin: Presidency2 G
Article 7(2), point (h)(ii)				
G 218	(ii) effective measures to prevent or substantially minimise those risks.	(ii) effective measures to prevent or substantially minimise those risks.	(ii) effective measures to prevent or substantially minimise those risks~~.~~***;***	(ii) effective measures to prevent or substantially minimise those risks. Text Origin: Presidency2 G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 7(2), point (ha)				
G 218a			***(ha) the magnitude and likelihood of benefit of the AI use for individuals, groups, or society at large.***	G
Article 7(2a new)				
G 218b		***2a. When assessing an AI system for the purposes of paragraphs 1 or 1a the Commission shall consult the AI Office and, where relevant, representatives of groups on which an AI system has an impact, industry, independent experts, the social partners, and civil society organisations. The Commission shall also organise public consultations in this regard and shall make the results of those consultations and of the final assessment publicly available;***		G
Article 7(2a)				
G 218c			***2a. The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list in Annex III by removing high-risk AI systems where both of the following conditions are fulfilled:***	***2a. The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list in Annex III by removing high-risk AI systems where both of the following conditions are fulfilled:*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Council Mandate
Article 7(2a), point (a)				
G 218d			***(a) the high-risk AI system(s) concerned no longer pose any significant risks to fundamental rights, health or safety, taking into account the criteria listed in paragraph 2;***	***(a) the high-risk AI system(s) concerned no longer pose any significant risks to fundamental rights, health or safety, taking into account the criteria listed in paragraph 2;*** Text Origin: Council Mandate
Article 7(2a), point (b)				
G 218e			***(b) the deletion does not decrease the overall level of protection of health, safety and fundamental rights under Union law.***	***(b) the deletion does not decrease the overall level of protection of health, safety and fundamental rights under Union law.*** Text Origin: Council Mandate
Article 7(2b new)				
G 218f		***2b. The AI Office, national supervisory authorities or the European Parliament may request the Commission to reassess and recategorise the risk categorisation of an AI systemin accordance with paragraphs 1 and 1a. The Commission shall give reasons for its decision and make them public.***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Chapter 2				
219	Chapter 2 requirements for high-risk Ai systems	Chapter 2 requirements for high-risk Ai systems	Chapter 2 Requirements for high-risk ~~Ai~~***AI*** systems	Chapter 2 Requirements for high-risk ~~Ai~~***AI*** systems Text Origin: Council Mandate
Article 8				
220	Article 8 Compliance with the requirements	Article 8 Compliance with the requirements	Article 8 Compliance with the requirements	Article 8 Compliance with the requirements Text Origin: Commission Proposal
Article 8(1)				
221	1. High-risk AI systems shall comply with the requirements established in this Chapter.	1. High-risk AI systems shall comply with the requirements established in this Chapter.	1. High-risk AI systems shall comply with the requirements established in this Chapter***, taking into account the generally acknowledged state of the art***.	1. High-risk AI systems shall comply with the requirements established in this Chapter***, taking into account its intended purpose as well as the generally acknowledged state of the art on AI and AI related technologies.*** ***The risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements***. Text Origin: Council Mandate
Article 8(1a)				
221a				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		1a. In complying with the requirements established in this Chapter, due account shall be taken of guidelines developed as referred to in Article 82b, the generally acknowledged state of the art, including as reflected in the relevant harmonised standards and common specifications as referred to in Articles 40 and 41 or those already set out in Union harmonisation law.		***1a.*** Text Origin: Presidency2
Article 8(2)				
G 222	2. The intended purpose of the high-risk AI system and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.	2. The intended purpose of the high-risk AI system***, the reasonably foreseeable misuses*** and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.	2. The intended purpose of the high-risk AI system and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.	2. ~~*The intended purpose of the high-risk AI system and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.*~~ Text Origin: Auxiliary 1
Article 8(2a)				
G 222a		***2a. As long as the requirements of Title III, Chapters 2 and 3 or Title VIII, Chapters 1, 2 and 3 for high-risk AI systems are addressed by Union harmonisation law listed in Annex II, Section A, the requirements or obligations of those Chapters of this Regulation shall be deemed to be fulfilled, as long as***		***2a. Where a product contains an artificial intelligence system, to which the requirements of this Regulation as well as requirements of the Union harmonisation legislation listed in Annex II, Section A apply, providers shall be responsible for ensuring that their product is fully compliant with all***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		they include the AI component. Requirements of Chapters 2 and 3 of Title III or Title VIII, Chapters 1, 2 and 3 for high-risk AI systems not addressed by Union harmonisation law listed in Annex II Section A, shall be incorporated into that Union harmonisation law, where applicable. The relevant conformity assessment shall be carried out as part of the procedures laid out under Union harmonisation law listed in Annex II, Section A.		***applicable requirements required under the Union harmonisation legislation.*** ***In ensuring the compliance of high-risk AI systems referred in paragraph 1 with the requirements set out in Chapter 2 of this Title, and in order to ensure consistency, avoid duplications and minimise additional burdens, providers shall have a choice to integrate, as appropriate, the necessary testing and reporting processes, information and documentation they provide with regard to their product into already existing documentation and procedures required under the Union harmonisation legislation listed in Annex II, Section A.*** Text Origin: EP Mandate
Article 9				
G 223	Article 9 Risk management system	Article 9 Risk management system	Article 9 Risk management system	Article 9 Risk management system Text Origin: Commission Proposal
Article 9(1)				
G 224	1. A risk management system shall be established, implemented,	1. A risk management system shall be established, implemented,	1. A risk management system shall be established, implemented,	1. A risk management system shall be established, implemented,

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	documented and maintained in relation to high-risk AI systems.	documented and maintained in relation to high-risk AI systems***, throughout the entire lifecycle of the AI system. The risk management system can be integrated into, or a part of, already existing risk management procedures relating to the relevant Union sectoral law insofar as it fulfils the requirements of this article***.	documented and maintained in relation to high-risk AI systems.	documented and maintained in relation to high-risk AI systems. Text Origin: Commission Proposal
Article 9(2)				
G 225	2. The risk management system shall consist of a continuous iterative process run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic updating. It shall comprise the following steps:	2. The risk management system shall consist of a continuous iterative process run throughout the entire lifecycle of a high-risk AI system, requiring regular ~~systematic~~***review and*** updating ***of the risk management process, to ensure its continuing effectiveness, and documentation of any significant decisions and actions taken subject to this Article***. It shall comprise the following steps:	2. The risk management system shall ~~consist of~~***be understood as*** a continuous iterative process ***planned and*** run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic updating. It shall comprise the following steps:	2. The risk management system shall ~~consist of~~***be understood as*** a continuous iterative process ***planned and*** run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic ***review and*** updating. It shall comprise the following steps: Text Origin: Auxiliary 1
Article 9(2), point (a)				
G 226	(a) identification and analysis of the known and foreseeable risks associated with each high-risk AI system;	(a) identification***, estimation and evaluation*** ~~and analysis~~ of the known and ***the reasonably*** foreseeable risks ~~associated with each~~***that the high-risk AI system can pose to the health or safety of***	(a) identification and analysis of the known and foreseeable risks ~~associated with each~~***most likely to occur to health, safety and fundamental rights in view of the intended purpose of the*** high-risk AI	(a) identification and analysis of the known and ***the reasonably*** foreseeable risks ~~associated with each~~***that the high-risk AI system can pose to the health, safety or fundamental rights when the*** high-

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		natural persons, their fundamental rights including equal access and opportunities, democracy and rule of law or the environement when the high-risk AI system ***is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse***;	system;	risk AI system ***is used in accordance with its intended purpose*** ; Text Origin: Auxiliary 1
Article 9(2), point (b)				
G 227	(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse;	*deleted*	*deleted*	*(b)* estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse; G
Article 9(2), point (c)				
G 228	(c) evaluation of other possibly arising risks based on the analysis of data gathered from the post-market monitoring system referred to in Article 61;	(c) evaluation of ~~other possibly arising~~***emerging significant*** risks ***as described in point (a) and identified*** based on the analysis of data gathered from the post-market monitoring system referred to in Article 61;	(c) evaluation of other possibly arising risks based on the analysis of data gathered from the post-market monitoring system referred to in Article 61;	(c) evaluation of other possibly arising risks based on the analysis of data gathered from the post-market monitoring system referred to in Article 61; Text Origin: Auxiliary 1 G
Article 9(2), point (d)				
G 229	(d) adoption of suitable risk management measures in accordance with the provisions of the following paragraphs.	(d) adoption of ~~suitable~~***appropriate and targeted*** risk management measures ***designed to address the risks identified pursuant to points a***	(d) adoption of suitable risk management measures in accordance with the provisions of the following paragraphs.	(d) adoption of ~~suitable~~***appropriate and targeted*** risk management measures ***designed to address the risks identified pursuant to point a*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		and b of this paragraph in accordance with the provisions of the following paragraphs.		***of this paragraph*** in accordance with the provisions of the following paragraphs. Text Origin: Auxiliary 1
Article 9(2), point (da)				
G 229a			***2a. The risks referred to in this paragraph shall concern only those which may be reasonably mitigated or eliminated through the development or design of the high-risk AI system, or the provision of adequate technical information.***	***2a. The risks referred to in this paragraph shall concern only those which may be reasonably mitigated or eliminated through the development or design of the high-risk AI system, or the provision of adequate technical information.*** Text Origin: Auxiliary 1
Article 9(3)				
G 230	3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible interactions resulting from the combined application of the requirements set out in this Chapter 2. They shall take into account the generally acknowledged state of the art, including as reflected in relevant harmonised standards or common specifications.	3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible interactions resulting from the combined application of the requirements set out in this Chapter 2~~. They shall take into account the generally acknowledged state of the art, including as reflected in relevant harmonised standards or common specifications~~***, with a view to mitigate risks effectively while ensuring an appropriate and proportionate implementation of the requirements***.	3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible ~~interactions~~***interaction*** resulting from the combined application of the requirements set out in this Chapter 2~~. They shall take into account the generally acknowledged state of the art, including as reflected in relevant harmonised standards or common specifications~~***, with a view to minimising risks more effectively while achieving an appropriate balance in implementing the measures to fulfil those***	3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible ~~interactions~~***interaction*** resulting from the combined application of the requirements set out in this Chapter 2~~. They shall take into account the generally acknowledged state of the art, including as reflected in relevant harmonised standards or common specifications~~***, with a view to minimising risks more effectively while achieving an appropriate balance in implementing the measures to fulfil those*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			requirements.	***requirements***. Text Origin: Auxiliary 1
Article 9(4), first subparagraph				
231	4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user.	4. The risk management measures referred to in paragraph 2, point (d) shall be such that ~~any~~***relevant*** residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is ***reasonably*** judged ***to be*** acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks ***and the reasoned judgements made*** shall be communicated to the ~~user~~***deployer***.	4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable~~, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user~~.	4. The risk management measures referred to in paragraph 2, point (d) shall be such that ~~any~~***relevant*** residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged ~~acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user~~***to be acceptable***. Text Origin: Auxiliary 1
Article 9(4), second subparagraph				
232	In identifying the most appropriate risk management measures, the following shall be ensured:	In identifying the most appropriate risk management measures, the following shall be ensured:	In identifying the most appropriate risk management measures, the following shall be ensured:	In identifying the most appropriate risk management measures, the following shall be ensured: Text Origin: Commission Proposal
Article 9(4), second subparagraph, point (a)				
233	(a) elimination or reduction of risks	(a) elimination or reduction of	(a) elimination or reduction of risks	(a) elimination or reduction of

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	as far as possible through adequate design and development;	***identified*** risks as far as ~~possible~~***technically feasible*** through adequate design and development ***of the high-risk AI system, involving when relevant, experts and external stakeholders***;	***identified and evaluated pursuant to paragraph 2*** as far as possible through adequate design and development ***of the high risk AI system***;	***identified*** risks ***and evaluated pursuant to paragraph 2*** as far as ~~possible~~***technically feasible*** through adequate design and development~~;~~ ***of the high-risk AI system,*** Text Origin: EP Mandate
Article 9(4), second subparagraph, point (b)				
G 234	(b) where appropriate, implementation of adequate mitigation and control measures in relation to risks that cannot be eliminated;	(b) where appropriate, implementation of adequate mitigation and control measures ~~in relation to~~***addressing significant*** risks that cannot be eliminated;	(b) where appropriate, implementation of adequate mitigation and control measures in relation to risks that cannot be eliminated;	(b) where appropriate, implementation of adequate mitigation and control measures ~~in relation to~~***addressing*** risks that cannot be eliminated; Text Origin: EP Mandate
Article 9(4), second subparagraph, point (c)				
G 235	(c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point (b) of this Article, and, where appropriate, training to users.	(c) provision of ~~adequate~~***the required*** information pursuant to Article 13, ~~in particular as regards the risks referred to in paragraph 2, point (b) of this Article,~~ and, where appropriate, training to ~~users~~***deployers***.	(c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point (b) of this Article, and, where appropriate, training to users.	(c) provision of ~~adequate~~***the required*** information pursuant to Article 13, ~~in particular as regards the risks~~ referred to in paragraph 2, point (b) of this Article, and, where appropriate, training to ~~users~~***deployers***. Text Origin: EP Mandate
Article 9(4), third subparagraph				
G 236	In eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be	In eliminating or reducing risks related to the use of the high-risk AI system, ~~due consideration~~***providers***	~~In~~***With a view to*** eliminating or reducing risks related to the use of the high-risk AI system, due	~~In~~***With a view to*** eliminating or reducing risks related to the use of the high-risk AI system, due

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	given to the technical knowledge, experience, education, training to be expected by the user and the environment in which the system is intended to be used.	shall ~~be given to~~***take into due consideration*** the technical knowledge, experience, education~~, training to be expected by the user and the environment in which the system is intended to be used~~ ***and training the deployer may need, including in relation to the presumable context of use***.	consideration shall be given to the technical knowledge, experience, education, training to be expected by the user and the environment in which the system is intended to be used.	consideration shall be given to the technical knowledge, experience, education, training to be expected by the ~~user~~***deployer*** and the ~~environment~~***presumable context*** in which the system is intended to be used. Text Origin: Council Mandate
Article 9(5)				
G 237	5. High-risk AI systems shall be tested for the purposes of identifying the most appropriate risk management measures. Testing shall ensure that high-risk AI systems perform consistently for their intended purpose and they are in compliance with the requirements set out in this Chapter.	5. High-risk AI systems shall be tested for the purposes of identifying the most appropriate ***and targeted*** risk management measures ***and weighing any such measures against the potential benefits and intended goals of the system***. Testing shall ensure that high-risk AI systems perform consistently for their intended purpose and they are in compliance with the requirements set out in this Chapter.	5. High-risk AI systems shall be tested ~~for the purposes of identifying the most appropriate risk management measures. Testing shall ensure that high-risk AI systems perform consistently for~~***in order to ensure that high-risk AI systems perform in a manner that is consistent with*** their intended purpose and they are in compliance with the requirements set out in this Chapter.	5. High-risk AI systems shall be tested for the purposes of identifying the most appropriate ***and targeted*** risk management measures. Testing shall ensure that high-risk AI systems perform consistently for their intended purpose and they are in compliance with the requirements set out in this Chapter. Text Origin: EP Mandate
Article 9(6)				
G 238	6. Testing procedures shall be suitable to achieve the intended purpose of the AI system and do not need to go beyond what is necessary to achieve that purpose.	6. Testing procedures shall be suitable to achieve the intended purpose of the AI system ~~and do not need to go beyond what is necessary to achieve that purpose~~.	6. Testing procedures ~~shall be suitable to achieve the intended purpose of the AI system and do not need to go beyond what is necessary to achieve that purpose~~***may include testing in real world conditions in accordance with Article 54a***.	6. Testing procedures ~~shall be suitable to achieve the intended purpose of the AI system and do not need to go beyond what is necessary to achieve that purpose~~***may include testing in real world conditions in accordance with Article 54a***.

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				Text Origin: Council Mandate
Article 9(7)				
G 239	7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.	7. The testing of the high-risk AI systems shall be performed, ~~as appropriate, at any point in time throughout the development process, and, in any event,~~ prior to the placing on the market or the putting into service. Testing shall be made against ~~preliminarily~~***prior*** defined metrics, and probabilistic thresholds that are appropriate to the intended purpose ***or reasonably foreseeable misuse*** of the high-risk AI system.	7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.	7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against ~~preliminarily~~***prior*** defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system. Text Origin: Council Mandate
Article 9(8)				
G 240	8. When implementing the risk management system described in paragraphs 1 to 7, specific consideration shall be given to whether the high-risk AI system is likely to be accessed by or have an impact on children.	8. When implementing the risk management system described in paragraphs 1 to 7, ~~specific consideration shall be given~~***providers shall give specific consideration*** to whether the high-risk AI system is likely to ~~be accessed by or have an impact on~~***adversely impact vulnerable groups of people or*** children.	8. ~~When implementing~~ The risk management system described in paragraphs 1 to 7~~, specific consideration shall be given~~ ***shall give specific consideration*** to whether the high-risk AI system is likely to be accessed by or have an impact on ~~children~~***persons under the age of 18***.	8. When implementing the risk management system described in paragraphs 1 to ~~7, specific~~ ***6, providers shall give*** consideration ~~shall be given to whether~~***to whether in view of its intended purpose*** the high-risk AI system is likely to ~~be accessed by or have an impact on children~~***adversely impact persons under the age of 18 and, as appropriate, other vulnerable groups of people***. Text Origin: Council Mandate
Article 9(9)				

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G 241	9. For credit institutions regulated by Directive 2013/36/EU, the aspects described in paragraphs 1 to 8 shall be part of the risk management procedures established by those institutions pursuant to Article 74 of that Directive.	9. For ***providers and AI systems already covered by Union law that require them to establish a specific risk management, including*** credit institutions regulated by Directive 2013/36/EU, the aspects described in paragraphs 1 to 8 shall be part of ***or combined with*** the risk management procedures established by ~~those institutions pursuant to Article 74 of that Directive~~***that Union law***.	9. For ~~credit institutions regulated by Directive 2013/36/EU~~***providers of high-risk AI systems that are subject to requirements regarding internal risk management processes under relevant sectorial Union law***, the aspects described in paragraphs 1 to 8 ~~shall~~***may*** be part of the risk management procedures established ~~by those institutions~~ pursuant to ~~Article 74 of that Directive~~***that law***.	9. For ~~credit institutions regulated by Directive 2013/36/EU~~***providers of high-risk AI systems that are subject to requirements regarding internal risk management processes under relevant sectorial Union law***, the aspects described in paragraphs 1 to 8 ~~shall~~***may*** be part of ***or combined with*** the risk management procedures established ~~by those institutions~~ pursuant to ~~Article 74 of that Directive~~***that law***. Text Origin: Council Mandate
Article 10				
G 242	Article 10 Data and data governance	Article 10 Data and data governance	Article 10 Data and data governance	Article 10 Data and data governance Text Origin: Commission Proposal
Article 10(-1)(1)				
G 243	1. High-risk AI systems which make use of techniques involving the training of 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 to 5.	1. High-risk AI systems which make use of techniques involving the training of 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 to 5 ***as far as this is technically feasible according to the specific market segment or scope of application***.	1. High-risk AI systems which make use of techniques involving the training of 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 to 5.	1. High-risk AI systems which make use of techniques involving the training of 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 to 5 ***whenever such datasets are used***. Text Origin: Commission

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				Proposal
Article 10(1), second subparagraph new				
243a		***Techniques that do not require labelled input data such as unsupervised learning and reinforcement learning shall be developed on the basis of data sets such as for testing and verification that meet the quality criteria referred to in paragraphs 2 to 5.***		
Article 10(2)				
244	2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. Those practices shall concern in particular,	2. Training, validation and testing data sets shall be subject to ~~appropriate~~ data governance ~~and management practices~~***appropriate for the context of use as well as the intended purpose of the AI system***. Those ~~practices~~***measures*** shall concern in particular,	2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. Those practices shall concern in particular~~,~~***:***	2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices ***appropriate for the intended purpose of the AI system***. Those practices shall concern in particular, Text Origin: Commission Proposal
Article 10(2), point (a)				
245	(a) the relevant design choices;	(a) the relevant design choices;	(a) the relevant design choices;	(a) the relevant design choices; Text Origin: Commission Proposal
Article 10(2), point (aa)				

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245a		***(aa) transparency as regards the original purpose of data collection;***		***(aa) data collection processes and origin of data, and in the case of personal data, the original purpose of data collection;***
Article 10(2), point (b)				
246	(b) data collection;	(b) data collection ***processes***;	(b) data collection ***processes***;	(b) ~~data collection;~~***[deleted]***
Article 10(2), point (c)				
247	(c) relevant data preparation processing operations, such as annotation, labelling, cleaning, enrichment and aggregation;	(c) ~~relevant~~ data preparation processing operations, such as annotation, labelling, cleaning, ***updating***, enrichment and aggregation;	(c) relevant data preparation processing operations, such as annotation, labelling, cleaning, enrichment and aggregation;	(c) relevant data preparation processing operations, such as annotation, labelling, cleaning, ***updating,*** enrichment and aggregation; Text Origin: EP Mandate
Article 10(2), point (d)				
248	(d) the formulation of relevant assumptions, notably with respect to the information that the data are supposed to measure and represent;	(d) the formulation of ~~relevant~~ assumptions, notably with respect to the information that the data are supposed to measure and represent;	(d) the formulation of relevant assumptions, notably with respect to the information that the data are supposed to measure and represent;	(d) the formulation of ~~relevant~~ assumptions, notably with respect to the information that the data are supposed to measure and represent; Text Origin: EP Mandate
Article 10(2), point (e)				
249	(e) a prior assessment of the availability, quantity and suitability of the data sets that are needed;	(e) ~~a prior~~***an*** assessment of the availability, quantity and suitability of the data sets that are needed;	(e) a prior assessment of the availability, quantity and suitability of the data sets that are needed;	(e) ~~a prior~~***an*** assessment of the availability, quantity and suitability of the data sets that are needed;

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: EP Mandate
Article 10(2), point (f)				
250	(f) examination in view of possible biases;	(f) examination in view of possible biases ***that are likely to affect the health and safety of persons, negatively impact fundamental rights or lead to discrimination prohibited under Union law, especially where data outputs influence inputs for future operations ('feedback loops') and appropriate measures to detect, prevent and mitigate possible biases***;	(f) examination in view of possible biases ***that are likely to affect health and safety of natural persons or lead to discrimination prohibited by Union law***;	(f) examination in view of possible biases ***that are likely to affect the health and safety of persons, negatively impact fundamental rights or lead to discrimination prohibited under Union law, especially where data outputs influence inputs for future operations***; Text Origin: EP Mandate
Article 10(2), point (fa)				
250a		***(fa) appropriate measures to detect, prevent and mitigate possible biases;***		***(fa) appropriate measures to detect, prevent and mitigate possible biases identified according to point f;*** Text Origin: EP Mandate
Article 10(2), point (g)				
251	(g) the identification of any possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed.	(g) the identification of ~~any possible~~***relevant*** data gaps or shortcomings ***that prevent compliance with this Regulation***, and how those gaps and shortcomings can be addressed.	(g) the identification of any possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed.	(g) the identification of ~~any possible~~***relevant*** data gaps or shortcomings ***that prevent compliance with this Regulation***, and how those gaps and shortcomings can be addressed.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: EP Mandate
Article 10(3)				
G 252	3. Training, validation and testing data sets shall be relevant, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.	3. Training ***datasets, and where they are used***, validation and testing ~~data sets~~***datasets, including the labels,*** shall be relevant, ***sufficiently*** representative, ~~free of~~***appropriately vetted for*** errors and ***be as*** complete ***as possible in view of the intended purpose***. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons ~~on which~~***in relation to whom*** the high-risk AI system is intended to be used. These characteristics of the ~~data sets may~~***datasets shall*** be met at the level of individual ~~data sets~~***datasets*** or a combination thereof.	3. Training, validation and testing data sets shall be relevant, representative, ***and to the best extent possible,*** free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.	3. Training, validation and testing ~~data sets~~***datasets*** shall be relevant, ***sufficiently*** representative, ***and to the best extent possible,*** free of errors and complete ***in view of the intended purpose***. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons ~~on which~~***in relation to whom*** the high-risk AI system is intended to be used.~~-~~ These characteristics of the data sets may be met at the level of individual data sets or a combination thereof. Text Origin: EP Mandate G
Article 10(4)				
G 253	4. Training, validation and testing data sets shall take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.	4. ~~Training, validation and testing data sets~~***Datasets*** shall take into account, to the extent required by the intended purpose ***or reasonably foreseeable misuses of the AI system***, the characteristics or elements that are particular to the specific geographical***, contextual***, behavioural or functional setting within which the high-risk AI	4. Training, validation and testing data sets shall take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.	4. ~~Training, validation and testing data sets~~***Datasets*** shall take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical***, contextual***, behavioural or functional setting within which the high-risk AI system is intended to be used. G

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		system is intended to be used.		Text Origin: EP Mandate
Article 10(4a)(5)				
G 254	5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.	5. To the extent that it is strictly necessary for the purposes of ensuring ~~bias monitoring,~~***negative bias*** detection and correction in relation to the high-risk AI systems, the providers of such systems may ***exceptionally*** process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving***. In particular, all the following conditions shall apply in order for this processing to occur:*** ~~measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.~~	5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.	5. To the extent that it is strictly necessary for the purposes of ensuring bias ~~monitoring,~~ detection and correction in relation to the high-risk AI systems ***in accordance with the second paragraph, point f and fa***, the providers of such systems may ***exceptionally*** process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons~~, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.~~***. In addition to provisions set out in the Regulation (EU) 2016/679, Directive (EU) 2016/680 and Regulation (EU) 2018/1725, all the following conditions shall apply in order for such processing to occur:*** G
Article 10(5), first subparagraph, point (a new)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 254a		*(a) the bias detection and correction cannot be effectively fulfilled by processing synthetic or anonymised data;*		*(a) the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;* G
Article 10(5), first subparagraph, point (a new)				
G 254b		*(b) the data are pseudonymised;*		*(b) the special categories of personal data processed for the purpose of this paragraph 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;* G
Article 10(5), first subparagraph, point (a new)				
G 254c		*(c) the provider takes appropriate technical and organisational measures to ensure that the data processed for the purpose of this paragraph are secured, protected, subject to suitable safeguards and only authorised persons have access to those data with appropriate confidentiality obligations;*		*(c) the special categories of personal data processed for the purpose of this paragraph 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 only authorised persons have access to those personal data with appropriate confidentiality obligations;* G
Article 10(5), first subparagraph, point (a new)				

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G 254d		*(d) the data processed for the purpose of this paragraph are not to be transmitted, transferred or otherwise accessed by other parties;*		*(d) the special categories of personal data processed for the purpose of this paragraph are not to be transmitted, transferred or otherwise accessed by other parties;* G
Article 10(5), first subparagraph, point (a new)				
G 254e		*(e) the data processed for the purpose of this paragraph are protected by means of appropriate technical and organisational measures and deleted once the bias has been corrected or the personal data has reached the end of its retention period;*		*(e) the special categories of personal data processed for the purpose of this paragraph are deleted once the bias has been corrected or the personal data has reached the end of its retention period, whatever comes first;* G
Article 10(5), first subparagraph, point (f new)				
G 254f		*(f) effective and appropriate measures are in place to ensure availability, security and resilience of processing systems and services against technical or physical incidents;*		G
Article 10(5), first subparagraph, point (g new)				
G 254g		*(g) effective and appropriate measures are in place to ensure physical security of locations where the data are stored and processed, internal IT and IT security*		G

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		governance and management, certification of processes and products;		
Article 10(5), second subparagraph new				
G 254h		***Providers having recourse to this provision shall draw up documentation explaining why the processing of special categories of personal data was necessary to detect and correct biases.***		***f) the records of processing activities pursuant to Regulation (EU) 2016/679, Directive (EU) 2016/680 and Regulation (EU) 2018/1725 includes justification why the processing of special categories of personal data was strictly necessary to detect and correct biases and this objective could not be achieved by processing other data.*** G
Article 10(6)				
G 255	6. Appropriate data governance and management practices shall apply for the development of high-risk AI systems other than those which make use of techniques involving the training of models in order to ensure that those high-risk AI systems comply with paragraph 2.	6. Appropriate data governance and management practices shall apply for the development of high-risk AI systems other than those which make use of techniques involving the training of models in order to ensure that those high-risk AI systems comply with paragraph 2.	6. ~~*Appropriate data governance and management practices shall apply*~~ For the development of high-risk AI systems ~~*other than those which make use of*~~***not using*** techniques involving the training of models***, paragraphs 2 to 5 shall apply only to the testing data sets*** ~~*in order to ensure that those high-risk AI systems comply with paragraph 2*~~.	6. ~~*Appropriate data governance and management practices shall apply*~~ For the development of high-risk AI systems ~~*other than those which make use of*~~***not using*** techniques involving the training of models***, paragraphs 2 to 5 shall apply only to the testing data sets*** ~~*in order to ensure that those high-risk AI systems comply with paragraph 2*~~. G Text Origin: Council Mandate
Article 10(6a new)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 255a		***6a. Where the provider cannot comply with the obligations laid down in this Article because that provider does not have access to the data and the data is held exclusively by the deployer, the deployer may, on the basis of a contract, be made responsible for any infringement of this Article.***		G
Article 11				
G 256	Article 11 Technical documentation	Article 11 Technical documentation	Article 11 Technical documentation	Article 11 Technical documentation Text Origin: Commission Proposal G
Article 11(1), first subparagraph				
G 257	1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date.	1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date.	1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date.	1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date. Text Origin: Commission Proposal G
Article 11(1), second subparagraph				
G 258	The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI	The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI	The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI	The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.	system complies with the requirements set out in this Chapter and provide national ~~competent~~***supervisory*** authorities and notified bodies with ~~all~~ the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV ***or, in the case of SMEs and start-ups, any equivalent documentation meeting the same objectives, subject to approval of the competent national authority***.	system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all 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 ***or, in the case of SMEs, including start-ups, any equivalent documentation meeting the same objectives, unless deemed inappropriate by the competent authority***.	system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with ~~all~~ 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. ***SMEs, including start-ups, may provide the elements of the technical documentation specified in Annex IV in a simplified manner. For this purpose, the Commission shall establish a simplified technical documentation form targeted at the needs of small and micro enterprises. Where an SME, including start-ups, 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 purpose of conformity assessment.*** Text Origin: Auxiliary 1
Article 11(2)				
G 259	2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service one single technical	2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service one single technical	2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service one single technical	2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service one single technical G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	documentation shall be drawn up containing all the information set out in Annex IV as well as the information required under those legal acts.	documentation shall be drawn up containing all the information set out in ~~Annex IV~~***paragraph 1*** as well as the information required under those legal acts.	documentation shall be drawn up containing all the information set out in Annex IV as well as the information required under those legal acts.	documentation shall be drawn up containing all the information set out in ~~Annex IV~~***paragraph 1*** as well as the information required under those legal acts. Text Origin: EP Mandate
Article 11(3)				
G 260	3. The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend Annex IV where necessary to ensure that, in the light of technical progress, the technical documentation provides all the necessary information to assess the compliance of the system with the requirements set out in this Chapter.	3. The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend Annex IV where necessary to ensure that, in the light of technical progress, the technical documentation provides all the necessary information to assess the compliance of the system with the requirements set out in this Chapter.	3. The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend Annex IV where necessary to ensure that, in the light of technical progress, the technical documentation provides all the necessary information to assess the compliance of the system with the requirements set out in this Chapter.	3. The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend Annex IV where necessary to ensure that, in the light of technical progress, the technical documentation provides all the necessary information to assess the compliance of the system with the requirements set out in this Chapter. Text Origin: Commission Proposal
Article 11(3a new)				
G 260a		***3a. Providers that are credit institutions regulated by Directive 2013/36/EU shall maintain the technical documentation as part of the documentation concerning internal governance, arrangements, processes and mechanisms pursuant to Article 74 of that Directive.***		

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Article 12				
261	Article 12 Record-keeping	Article 12 Record-keeping	Article 12 Record-keeping	Article 12 Record-keeping Text Origin: Commission Proposal
Article 12(1)				
262	1. High-risk AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the high-risk AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications.	1. High-risk AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the high-risk AI systems is operating. Those logging capabilities shall conform to ***the state of the art and*** recognised standards or common specifications.	1. High-risk AI systems shall ~~be designed and developed with capabilities enabling~~***technically allow for*** the automatic recording of events ('logs') ~~while the high-risk AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications~~***over the duration of the life cycle of the system***.	1. High-risk AI systems shall ~~be designed and developed with capabilities enabling~~***technically allow for*** the automatic recording of events ('logs') ~~while the high-risk AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications~~***over the duration of the lifetime of the system***. Text Origin: Council Mandate
Article 12(2)				
263	2. The logging capabilities shall ensure a level of traceability of the AI system's functioning throughout its lifecycle that is appropriate to the intended purpose of the system.	2. ~~The logging capabilities shall~~***In order to*** ensure a level of traceability of the AI system's functioning throughout its ~~lifecycle~~***entire lifetime*** that is appropriate to the intended purpose of the system***, the logging capabilities shall facilitate the monitoring of operations as referred to in Article 29(4) as well as the post market monitoring referred to in Article 61. In***	2. ~~The logging capabilities shall~~***In order to*** ensure a level of traceability of the AI system's functioning ~~throughout its lifecycle~~ that is appropriate to the intended purpose of the system~~.~~***, logging capabilities shall enable the recording of events relevant for:***	2. ~~The logging capabilities shall~~***In order to*** ensure a level of traceability of the AI system's functioning ~~throughout its lifecycle~~ that is appropriate to the intended purpose of the system~~.~~***, logging capabilities shall enable the recording of events relevant for:*** Text Origin: Council Mandate

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		particular, they shall enable the recording of events relevant for the identification of situations that may:		
Article 12(2), point (a new)				
G 263a		***(a) result in the AI system presenting a risk within the meaning of Article65(1); or***		G
Article 12(2), point (b new)				
G 263b		***(b) lead to a substantial modification of the AI system.***		G
Article 12(2a new)				
G 263c		***2a. High-risk AI systems shall be designed and developed with, the logging capabilities enabling the recording of energy consumption, the measurement or calculation of resource use and environmental impact of the high-risk AI system during all phases of the system's lifecycle.***		G
Article 12(2a)				
G 263d			***2a. (i) identification of situations that may result in the AI system presenting a risk within the***	***2a. (i) identification of situations that may result in the AI system presenting a risk within the*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			meaning of Article 65(1) or in a substantial modification; ***(ii) facilitation of the post-market monitoring referred to in Article 61; and*** ***(iii) monitoring of the operation of high-risk AI systems referred to in Article 29(4).***	***meaning of Article 65(1) or in a substantial modification;*** ***(ii) facilitation of the post-market monitoring referred to in Article 61; and*** ***(iii) monitoring of the operation of high-risk AI systems referred to in Article 29(4).*** Text Origin: Council Mandate
Article 12(3)				
G 264	3. In particular, logging capabilities shall enable the monitoring of the operation of the high-risk AI system with respect to the occurrence of situations that may result in the AI system presenting a risk within the meaning of Article 65(1) or lead to a substantial modification, and facilitate the post-market monitoring referred to in Article 61.	*deleted*	*deleted*	3. ~~*In particular, logging capabilities shall enable the monitoring of the operation of the high-risk AI system with respect to the occurrence of situations that may result in the AI system presenting a risk within the meaning of Article 65(1) or lead to a substantial modification, and facilitate the post-market monitoring referred to in Article 61.*~~***deleted*** G
Article 12(4)				
G 265	4. For high-risk AI systems referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a minimum:	4. For high-risk AI systems referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a minimum:	4. For high-risk AI systems referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a minimum:	4. For high-risk AI systems referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a minimum: Text Origin: Commission Proposal G
Article 12(4), point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 266	(a) recording of the period of each use of the system (start date and time and end date and time of each use);	(a) recording of the period of each use of the system (start date and time and end date and time of each use);	(a) recording of the period of each use of the system (start date and time and end date and time of each use);	(a) recording of the period of each use of the system (start date and time and end date and time of each use); Text Origin: Commission Proposal
Article 12(4), point (b)				
G 267	(b) the reference database against which input data has been checked by the system;	(b) the reference database against which input data has been checked by the system;	(b) the reference database against which input data has been checked by the system;	(b) the reference database against which input data has been checked by the system; Text Origin: Commission Proposal
Article 12(4), point (c)				
G 268	(c) the input data for which the search has led to a match;	(c) the input data for which the search has led to a match;	(c) the input data for which the search has led to a match;	(c) the input data for which the search has led to a match; Text Origin: Commission Proposal
Article 12(4), point (d)				
G 269	(d) the identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5).	(d) the identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5).	(d) the identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5).	(d) the identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5). Text Origin: Commission Proposal
Article 13				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 270	Article 13 Transparency and provision of information to users	Article 13 Transparency and provision of information~~ to users~~	Article 13 Transparency and provision of information to users	Article 13 Transparency and provision of information to ~~users~~***deployers*** Text Origin: EP Mandate
Article 13(-1)(1)				
G 271	1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users to interpret the system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured, with a view to achieving compliance with the relevant obligations of the user and of the provider set out in Chapter 3 of this Title.	-1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable ***providers and*** users to ~~interpret~~***reasonably understand*** the system's ~~output and use it appropriately. An appropriate type and degree of transparency shall be ensured~~***functioning. Appropriate transparency shall be ensured in accordance with the intended purpose of the AI system***, with a view to achieving compliance with the relevant obligations of the ~~user and of the provider~~***provider and user*** set out in Chapter 3 of this Title.	1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent ~~to enable users to interpret the system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured,~~ with a view to achieving compliance with the relevant obligations of the user and of the provider set out in Chapter 3 of this Title ***and enabling users to understand and use the system appropriately***.	1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable ~~users~~***deployers*** to interpret the system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured~~,~~ with a view to achieving compliance with the relevant obligations of the ~~user and of the provider~~***provider and deployer*** set out in Chapter 3 of this Title.
Article 13(1), second subparagraph new				
G 271a		***Transparency shall thereby mean that, at the time the high-risk AI system is placed on the market, all technical means available in accordance with the generally***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		acknowledged state of art are used to ensure that the AI system's output is interpretable by the provider and the user. The user shall be enabled to understand and use the AI system appropriately by generally knowing how the AI system works and what data it processes, allowing the user to explain the decisions taken by the AI system to the affected person pursuant to Article 68(c).		
Article 13(2)				
G 272	2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to users.	2. High-risk AI systems shall be accompanied by ***intelligible*** instructions for use in an appropriate digital format or ***made*** otherwise ***available in a durable medium*** that include concise, ~~complete, correct and clear~~***correct, clear and to the extent possible complete*** information that ***helps operating and maintaining the AI system as well as supporting informed decision-making by users and is reasonably***~~is~~ relevant, accessible and comprehensible to users.	2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to users.	2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to users. Text Origin: Commission Proposal
Article 13(3)				
G 273	3. The information referred to in paragraph 2 shall specify:	3. ***To achieve the outcomes referred to in paragraph 1,***~~The~~ information referred to in paragraph	3. The information referred to in paragraph 2 shall specify:	3. The ~~information referred to in paragraph 2 shall specify~~***instructions for use shall***

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		2 shall specify:		***contain at least the following information***:
Article 13(3), point (a)				
274	(a) the identity and the contact details of the provider and, where applicable, of its authorised representative;	(a) the identity and the contact details of the provider and, where applicable, of its authorised ~~representative~~***representatives***;	(a) the identity and the contact details of the provider and, where applicable, of its authorised representative;	(a) the identity and the contact details of the provider and, where applicable, of its authorised representative; Text Origin: Commission Proposal
Article 13(3), point (aa)				
274a		***(aa) where it is not the same as the provider, the identity and the contact details of the entity that carried out the conformity assessment and, where applicable, of its authorised representative;***		***(aa)***
Article 13(3), point (b)				
275	(b) the characteristics, capabilities and limitations of performance of the high-risk AI system, including:	(b) the characteristics, capabilities and limitations of performance of the high-risk AI system, including***, where appropriate***:	(b) the characteristics, capabilities and limitations of performance of the high-risk AI system, including:	(b) the characteristics, capabilities and limitations of performance of the high-risk AI system, including: Text Origin: Council Mandate
Article 13(3), point (b)(i)				
276	(i) its intended purpose;	(i) its intended purpose;	(i) its intended purpose***, inclusive of the specific geographical,***	(i) its intended purpose;

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			behavioural or functional setting within which the high-risk AI system is intended to be used;	Text Origin: EP Mandate
Article 13(3), point (b)(ii)				
G 277	(ii) the level of accuracy, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;	(ii) the level of accuracy, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any ***clearly*** known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;	(ii) the level of accuracy, ***including its metrics,*** robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;	(ii) the level of accuracy, ***including its metrics,*** robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity; Text Origin: Council Mandate G
Article 13(3), point (b)(iii)				
G 278	(iii) any known or foreseeable circumstance, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health and safety or fundamental rights;	(iii) any ***clearly*** known or foreseeable circumstance, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health and safety***, fundamental rights or the environment, including, where appropriate, illustrative examples of such limitations and of scenarios for which the system should not be used*** ~~or fundamental rights~~;	(iii) any known or foreseeable circumstance, related to the use of the high-risk AI system in accordance with its intended purpose ~~or under conditions of reasonably foreseeable misuse~~, which may lead to risks to the health and safety or fundamental rights ***referred to in Article 9(2)***;	(iii) any known or foreseeable circumstance, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health and safety or fundamental rights ***referred to in Article 9(2)***; Text Origin: EP Mandate G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 13(3), point (b)(iiia)				
G 278a		***(iiia) the degree to which the AI system can provide an explanation for decisions it takes;***		***(iiia) where applicable, the technical capabilities and characteristics of the AI system to provide information that is relevant to explain its output.*** G
Article 13(3), point (b)(iv)				
G 279	(iv) its performance as regards the persons or groups of persons on which the system is intended to be used;	(iv) its performance as regards the persons or groups of persons on which the system is intended to be used;	(iv) ***when appropriate, its behaviour regarding specific***~~its performance as regards the~~ persons or groups of persons on which the system is intended to be used;	(iv) ***when appropriate,*** its performance ~~as regards the~~***regarding specific*** persons or groups of persons on which the system is intended to be used; G Text Origin: Commission Proposal
Article 13(3), point (b)(v)				
G 280	(v) when appropriate, specifications for the input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the AI system.	(v) ~~when appropriate, specifications for the~~***relevant information about user actions that may influence system performance, including type or quality of*** input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the AI system.	(v) when appropriate, specifications for the input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the AI system~~.~~***;***	(v) when appropriate, specifications for the input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the AI system. G Text Origin: Commission Proposal
Article 13(3), point (b)(va)				

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280a			***(va) when appropriate, description of the expected output of the system.***	***(va) where applicable, information to enable deployers to interpret the system's output and use it appropriately.***
Article 13(3), point (c)				
281	(c) the changes to the high-risk AI system and its performance which have been pre-determined by the provider at the moment of the initial conformity assessment, if any;	(c) the changes to the high-risk AI system and its performance which have been pre-determined by the provider at the moment of the initial conformity assessment, if any;	(c) the changes to the high-risk AI system and its performance which have been pre-determined by the provider at the moment of the initial conformity assessment, if any;	(c) the changes to the high-risk AI system and its performance which have been pre-determined by the provider at the moment of the initial conformity assessment, if any; Text Origin: Commission Proposal
Article 13(3), point (d)				
282	(d) the human oversight measures referred to in Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users;	(d) the human oversight measures referred to in Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users;	(d) the human oversight measures referred to in Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users;	(d) the human oversight measures referred to in Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the ~~users~~***deployers***; Text Origin: Commission Proposal
Article 13(3), point (e)				
283	(e) the expected lifetime of the high-risk AI system and any necessary maintenance and care measures to ensure the proper	(e) ~~*the expected lifetime of the high-risk AI system and*~~ any necessary maintenance and care measures to ensure the proper functioning of that	(e) ***the computational and hardware resources needed,*** the expected lifetime of the high-risk AI system and any necessary	(e) ***the computational and hardware resources needed,*** the expected lifetime of the high-risk AI system and any necessary

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	functioning of that AI system, including as regards software updates.	AI system, including as regards software updates, ***through its expected lifetime***.	maintenance and care measures, ***including their frequency,*** to ensure the proper functioning of that AI system, including as regards software updates~~.~~**;**	maintenance and care measures, ***including their frequency,*** to ensure the proper functioning of that AI system, including as regards software updates~~.~~**;** Text Origin: Council Mandate
Article 13(3), point (ea)				
G 283a			***(ea) a description of the mechanism included within the AI system that allows users to properly collect, store and interpret the logs, where relevant.***	***(ea)***
Article 13(3), point (eb)				
G 283b		***(ea) a description of the mechanisms included within the AI system that allows users to properly collect, store and interpret the logs in accordance with Article 12(1).***		***(ea) where relevant, a description of the mechanisms included within the AI system that allows users to properly collect, store and interpret the logs in accordance with Article 12.*** Text Origin: EP Mandate
Article 13(3), point (ec)				
G 283c		***(eb) The information shall be provided at least in the language of the country where the AI system is used.***		***(ec)***
Article 13(3a)				

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G 283d		***3a. In order to comply with the obligations laid down in this Article, providers and users shall ensure a sufficient level of AI literacy in line with Article 4b.***		***3a.*** agreement to delete
Article 14				
G 284	Article 14 Human oversight	Article 14 Human oversight	Article 14 Human oversight	Article 14 Human oversight Text Origin: Commission Proposal
Article 14(1)				
G 285	1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use.	1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they ~~can~~ be effectively overseen by natural persons ***as proportionate to the risks associated with those systems. Natural persons in charge of ensuring human oversight shall have sufficient level of AI literacy in accordance with Article 4b and the necessary support and authority to exercise that function,*** during the period in which the AI system is in use ***and to allow for thorough investigation after an incident***.	1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use.	1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use.
Article 14(2)				

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G 286	2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.	2. Human oversight shall aim at preventing or minimising the risks to health, safety ~~or~~, fundamental rights ***or environment*** that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter ***and where decisions based solely on automated processing by AI systems produce legal or otherwise significant effects on the persons or groups of persons on which the system is to be used***.	2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.	2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter. Text Origin: EP Mandate
Article 14(3)				
G 287	3. Human oversight shall be ensured through either one or all of the following measures:	3. Human oversight shall ***take into account the specific risks, the level of automation, and context of the AI system and shall*** be ensured through either one or all of the following ***types of*** measures:	3. Human oversight shall be ensured through either one or all of the following ***types of*** measures:	3. ~~Human~~***The*** oversight ***measures shall be commensurate to the risks, level of autonomy and context of use of the AI system and*** shall be ensured through either one or all of the following ***types of*** measures:
Article 14(3), point (a)				
G 288	(a) identified and built, when technically feasible, into the high-risk AI system by the provider before it is placed on the market or put into service;	(a) identified and built, when technically feasible, into the high-risk AI system by the provider before it is placed on the market or put into service;	(a) ***measures*** identified and built, when technically feasible, into the high-risk AI system by the provider before it is placed on the market or put into service;	(a) ***measures*** identified and built, when technically feasible, into the high-risk AI system by the provider before it is placed on the market or put into service;

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				Text Origin: Council Mandate
Article 14(3), point (b)				
289	(b) identified by the provider before placing the high-risk AI system on the market or putting it into service and that are appropriate to be implemented by the user.	(b) identified by the provider before placing the high-risk AI system on the market or putting it into service and that are appropriate to be implemented by the user.	(b) ***measures*** identified by the provider before placing the high-risk AI system on the market or putting it into service and that are appropriate to be implemented by the user.	(b) ***measures*** identified by the provider before placing the high-risk AI system on the market or putting it into service and that are appropriate to be implemented by the user. Text Origin: Council Mandate
Article 14(4)				
290	4. The measures referred to in paragraph 3 shall enable the individuals to whom human oversight is assigned to do the following, as appropriate to the circumstances:	4. ***For the purpose of implementing paragraphs 1 to 3, the high-risk AI system***~~The measures referred to in paragraph 3~~ shall ~~enable the individuals~~***be provided to the user in such a way that natural persons*** to whom human oversight is assigned ~~to do the following~~***are enabled***, as appropriate ***and proportionate*** to the circumstances:	4. ***For the purpose of implementing paragraphs 1 to 3, the high-risk AI system***~~The measures referred to in paragraph 3~~ shall ~~enable the individuals~~***be provided to the user in such a way that natural persons*** to whom human oversight is assigned ~~to do the following~~***are enabled***, as appropriate ***and proportionate*** to the circumstances:	4. ***For the purpose of implementing paragraphs 1 to 3, the high-risk AI system***~~The measures referred to in paragraph 3~~ shall ~~enable the individuals~~***be provided to the user in such a way that natural persons*** to whom human oversight is assigned ~~to do the following~~***are enabled***, as appropriate ***and proportionate*** to the circumstances: Text Origin: Council Mandate
Article 14(4), point (a)				
291	(a) fully understand the capacities and limitations of the high-risk AI system and be able to duly monitor its operation, so that signs of anomalies, dysfunctions and	(a) ~~fully~~***be aware of and sufficiently*** understand the ***relevant*** capacities and limitations of the high-risk AI system and be able to duly monitor its operation, so that signs of	(a) ~~fully~~***to*** understand the capacities and limitations of the high-risk AI system and be able to duly monitor its operation~~, so that signs of anomalies, dysfunctions and~~	(a) ~~fully~~***to properly*** understand the ***relevant*** capacities and limitations of the high-risk AI system and be able to duly monitor its operation, ~~so that signs of~~***also in view of detecting and***

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	unexpected performance can be detected and addressed as soon as possible;	anomalies, dysfunctions and unexpected performance can be detected and addressed as soon as possible;	~~unexpected performance can be detected and addressed as soon as possible~~;	***addressing*** anomalies, dysfunctions and unexpected performance ~~can be detected and addressed as soon as possible~~; Text Origin: Council Mandate
Article 14(4), point (b)				
G 292	(b) remain aware of the possible tendency of automatically relying or over-relying on the output produced by a high-risk AI system ('automation bias'), in particular for high-risk AI systems used to provide information or recommendations for decisions to be taken by natural persons;	(b) remain aware of the possible tendency of automatically relying or over-relying on the output produced by a high-risk AI system ('automation bias'), in particular for high-risk AI systems used to provide information or recommendations for decisions to be taken by natural persons;	(b) ***to*** remain aware of the possible tendency of automatically relying or over-relying on the output produced by a high-risk AI system ('automation bias'), ~~in particular for high-risk AI systems used to provide information or recommendations for decisions to be taken by natural persons~~;	(b) ***to*** remain aware of the possible tendency of automatically relying or over-relying on the output produced by a high-risk AI system ('automation bias'), in particular for high-risk AI systems used to provide information or recommendations for decisions to be taken by natural persons; Text Origin: Commission Proposal
Article 14(4), point (c)				
G 293	(c) be able to correctly interpret the high-risk AI system's output, taking into account in particular the characteristics of the system and the interpretation tools and methods available;	(c) be able to correctly interpret the high-risk AI system's output, taking into account in particular the characteristics of the system and the interpretation tools and methods available;	(c) ~~be able~~ to correctly interpret the high-risk AI system's output, taking into account ~~in particular the characteristics of the system and~~***for example*** the interpretation tools and methods available;	(c) ~~be able~~ to correctly interpret the high-risk AI system's output, taking into account ~~in particular the characteristics of the system and~~***for example*** the interpretation tools and methods available; Text Origin: Council Mandate
Article 14(4), point (d)				
G 294				

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	(d) be able to decide, in any particular situation, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system;	(d) be able to decide, in any particular situation, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system;	(d) ~~be able~~ to decide, in any particular situation, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system;	(d) ~~be able~~ to decide, in any particular situation, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system; Text Origin: Council Mandate
Article 14(4), point (e)				
295	(e) be able to intervene on the operation of the high-risk AI system or interrupt the system through a "stop" button or a similar procedure.	(e) be able to intervene on the operation of the high-risk AI system or interrupt, the system through a "stop" button or a similar procedure ***that allows the system to come to a halt in a safe state, except if the human interference increases the risks or would negatively impact the performance in consideration of generally acknowledged state-of-the-art***.	(e) ~~be able~~ to intervene on the operation of the high-risk AI system or interrupt the system through a "stop" button or a similar procedure.	(e) ~~be able~~ to intervene on the operation of the high-risk AI system or interrupt, the system through a ~~"stop"~~ ***"stop"*** button or a similar procedure ***that allows the system to come to a halt in a safe state***.
Article 14(5)				
296	5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the identification resulting from the system unless this has been verified and confirmed by at least two natural persons.	5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the identification resulting from the system unless this has been verified and confirmed by at least two natural persons ***with the necessary competence, training and authority***.	5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the identification resulting from the system unless this has been ***separately*** verified and confirmed by at least two natural persons. ***The requirement for a separate***	5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the ~~user~~***deployer*** on the basis of the identification resulting from the system unless this has been ***separately*** verified and confirmed by at least two natural persons ***with the necessary competence, training and***

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			verification by at least two natural persons shall not apply to high risk AI systems used for the purpose of law enforcement, migration, border control or asylum, in cases where Union or national law considers the application of this requirement to be disproportionate.	***authority.*** ***The requirement for a separate verification by at least two natural persons shall not apply to high risk AI systems used for the purpose of law enforcement, migration, border control or asylum, in cases where Union or national law considers the application of this requirement to be disproportionate***.
Article 15				
G 297	Article 15 Accuracy, robustness and cybersecurity	Article 15 Accuracy, robustness and cybersecurity	Article 15 Accuracy, robustness and cybersecurity	Article 15 Accuracy, robustness and cybersecurity Text Origin: Auxiliary 1
Article 15(1)				
G 298	1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle.	1. High-risk AI systems shall be designed and developed ~~*in such a way that they achieve,*~~***following the principle of security by design and by default.*** In the light of their intended purpose, ***they should achieve*** an appropriate level of accuracy, robustness***, safety,*** and cybersecurity, and perform consistently in those respects throughout their lifecycle. ***Compliance with these requirements shall include***	1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle.	1. High-risk AI systems shall be designed and developed in such a way that they achieve~~*, in the light of their intended purpose,*~~ an appropriate level of accuracy, robustness**,** and cybersecurity, and perform consistently in those respects throughout their lifecycle. Text Origin: EP Mandate

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		implementation of state-of-the-art measures, according to the specific market segment or scope of application.		
Article 15(1a)				
G 298a		***1a. To address the technical aspects of how to measure the appropriate levels of accuracy and robustness set out in paragraph 1 of this Article, the AI Office shall bring together national and international metrology and benchmarking authorities and provide non-binding guidance on the matter as set out in Article 56, paragraph 2, point (a).***		***1a. To address the technical aspects of how to measure the appropriate levels of accuracy and robustness set out in paragraph 1 of this Article and any other relevant performance metrics, the Commission shall, in cooperation with relevant stakeholder and organisations such as metrology and benchmarking authorities, encourage as appropriate, the development of benchmarks and measurement methodologies.*** Text Origin: EP Mandate
Article 15(1b new)				
G 298b		***1b. To address any emerging issues across the internal market with regard to cybersecurity, the European Union Agency for Cybersecurity (ENISA) shall be involved alongside the European Artificial Intelligence Board as set out Article 56, paragraph 2, point (b).***		

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Article 15(2)				
G 299	2. The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use.	2. The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use. ***The language used shall be clear, free of misunderstandings or misleading statements.***	2. The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use.	2. The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use. Text Origin: Commission Proposal G
Article 15(3), first subparagraph				
G 300	3. High-risk AI systems shall be resilient as regards errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems.	3. ***Technical and organisational measures shall be taken to ensure that*** high-risk AI systems shall be ***as*** resilient as ~~regards~~***possible regarding*** errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems.	3. High-risk AI systems shall be resilient as regards errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems.	3. High-risk AI systems shall be ***as*** resilient as ~~regards~~***possible regarding*** errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems. ***Technical and organisational measures shall be taken towards this regard.*** Text Origin: Commission Proposal G
Article 15(3), second subparagraph				
G 301	The robustness of high-risk AI systems may be achieved through technical redundancy solutions, which may include backup or fail-safe plans.	The robustness of high-risk AI systems may be achieved ***by the appropriate provider with input from the user, where necessary,*** through technical redundancy solutions, which may include backup	The robustness of high-risk AI systems may be achieved through technical redundancy solutions, which may include backup or fail-safe plans.	The robustness of high-risk AI systems may be achieved through technical redundancy solutions, which may include backup or fail-safe plans. G

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		or fail-safe plans.		Text Origin: EP Mandate
Article 15(3), third subparagraph				
G 302	High-risk AI systems that continue to learn after being placed on the market or put into service shall be developed in such a way to ensure that possibly biased outputs due to outputs used as an input for future operations ('feedback loops') are duly addressed with appropriate mitigation measures.	High-risk AI systems that continue to learn after being placed on the market or put into service shall be developed in such a way to ensure that possibly biased outputs ~~due to outputs used as an~~***influencing*** input for future operations ('feedback loops')***and malicious manipulation of inputs used in learning during operation*** are duly addressed with appropriate mitigation measures.	High-risk AI systems that continue to learn after being placed on the market or put into service shall be developed in such a way to ~~ensure that possibly biased outputs due to outputs used as an~~***eliminate or reduce as far as possible the risk of possibly biased outputs influencing*** input for future operations ('feedback loops') are duly addressed with appropriate mitigation measures.	High-risk AI systems that continue to learn after being placed on the market or put into service shall be developed in such a way to ~~ensure that possibly biased outputs due to outputs used as an~~***eliminate or reduce as far as possible the risk of possibly biased outputs influencing*** input for future operations ('feedback loops') are duly addressed with appropriate mitigation measures. Text Origin: Council Mandate
Article 15(4), first subparagraph				
G 303	4. High-risk AI systems shall be resilient as regards attempts by unauthorised third parties to alter their use or performance by exploiting the system vulnerabilities.	4. High-risk AI systems shall be resilient as regards ***to*** attempts by unauthorised third parties to alter their use***, behaviour, outputs*** or performance by exploiting the system vulnerabilities.	4. High-risk AI systems shall be resilient as regards attempts by unauthorised third parties to alter their use or performance by exploiting the system vulnerabilities.	4. High-risk AI systems shall be resilient as regards ***to*** attempts by unauthorised third parties to alter their use***, outputs*** or performance by exploiting the system vulnerabilities. Text Origin: EP Mandate
Article 15(4), second subparagraph				
G 304	The technical solutions aimed at ensuring the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the	The technical solutions aimed at ensuring the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the	The technical solutions aimed at ensuring the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the	The technical solutions aimed at ensuring the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	risks.	risks.	risks.	risks. Text Origin: Commission Proposal
Article 15(4), third subparagraph				
G 305	The technical solutions to address AI specific vulnerabilities shall include, where appropriate, measures to prevent and control for attacks trying to manipulate the training dataset ('data poisoning'), inputs designed to cause the model to make a mistake ('adversarial examples'), or model flaws.	The technical solutions to address AI specific vulnerabilities shall include, where appropriate, measures to prevent***, detect, respond to, resolve*** and control for attacks trying to manipulate the training dataset ('data poisoning'), ***or pre-trained components used in training ('model poisoning') ,*** inputs designed to cause the model to make a mistake ('adversarial examples'***) or 'model evasion'***), ***confidentiality attacks*** or model flaws***, which could lead to harmful decision-making***.	The technical solutions to address AI specific vulnerabilities shall include, where appropriate, measures to prevent and control for attacks trying to manipulate the training dataset ('data poisoning'), inputs designed to cause the model to make a mistake ('adversarial examples'), or model flaws.	The technical solutions to address AI specific vulnerabilities shall include, where appropriate, measures to prevent***, detect, respond to, resolve*** and control for attacks trying to manipulate the training dataset ('data poisoning'), ***or pre-trained components used in training ('model poisoning') ,*** inputs designed to cause the model to make a mistake ('adversarial examples'***) or 'model evasion'***), ***confidentiality attacks*** or model flaws. Text Origin: EP Mandate
Chapter 3				
G 306	Chapter 3 OBLIGATIONS OF PROVIDERS AND USERS OF HIGH-RISK AI SYSTEMS and other parties	Chapter 3 OBLIGATIONS OF PROVIDERS AND ~~USERS~~***DEPLOYERS*** OF HIGH-RISK AI SYSTEMS ~~and other parties~~***AND OTHER PARTIES***	Chapter 3 OBLIGATIONS OF PROVIDERS AND USERS OF HIGH-RISK AI SYSTEMS ~~and other parties~~***AND OTHER PARTIES***	Chapter 3 OBLIGATIONS OF PROVIDERS AND ~~USERS~~***DEPLOYERS*** OF HIGH-RISK AI SYSTEMS ~~and other parties~~***AND OTHER PARTIES*** Text Origin: EP Mandate
Article 16				

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G 307	Article 16 Obligations of providers of high-risk AI systems	Article 16 Obligations of providers ***and deployers*** of high-risk AI systems ***and other parties***	Article 16 Obligations of providers of high-risk AI systems	Article 16 Obligations of providers of high-risk AI systems Text Origin: Commission Proposal
Article 16, first paragraph				
G 308	Providers of high-risk AI systems shall:	Providers of high-risk AI systems shall:	Providers of high-risk AI systems shall:	Providers of high-risk AI systems shall: Text Origin: Commission Proposal
Article 16, first paragraph, point (a)				
G 309	(a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title;	(a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title ***before placing them on the market or putting them into service***;	(a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title;	(a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title; Text Origin: Commission Proposal
Article 16, first paragraph, point (aa)				
G 309a			***(aa) indicate their name, registered trade name or registered trade mark, the address at which they can be contacted on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as applicable;***	***(aa) indicate their name, registered trade name or registered trade mark, the address at which they can be contacted on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as applicable;***

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				Text Origin: Council Mandate
Article 16, first paragraph, point (ab)				
G 309b		***(aa) indicate their name, registered trade name or registered trade mark, and their address and contact information on the high-risk AI system or, where that is not possible, on its accompanying documentation, as appropriate;***		***(ab)*** G
Article 16, first paragraph, point (ab new)				
G 309c		***(ab) ensure that natural persons to whom human oversight of high-risk AI systems is assigned are specifically made aware of the risk of automation or confirmation bias;***		G
Article 16, first paragraph, point (ac new)				
G 309d		***(ac) provide specifications for the input data, or any other relevant information in terms of the datasets used, including their limitation and assumptions, taking into account the intended purpose and the foreseeable and reasonably foreseeable misuses of the AI system;***		G
Article 16, first paragraph, point (b)				

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G 310	(b) have a quality management system in place which complies with Article 17;	(b) have a quality management system in place which complies with Article 17;	(b) have a quality management system in place which complies with Article 17;	(b) have a quality management system in place which complies with Article 17; Text Origin: Commission Proposal
Article 16, first paragraph, point (c)				
G 311	(c) draw-up the technical documentation of the high-risk AI system;	(c) draw-up ***and keep*** the technical documentation of the high-risk AI system ***referred to in Article 11***;	(c) ~~*draw-up the technical*~~***keep the*** documentation ~~*of the high-risk AI system*~~***referred to in Article 18***;	(c) ~~*draw-up the technical*~~***keep the*** documentation ~~*of the high-risk AI system*~~ ***referred to in Article 18***;
Article 16, first paragraph, point (d)				
G 312	(d) when under their control, keep the logs automatically generated by their high-risk AI systems;	(d) when under their control, keep the logs automatically generated by their high-risk AI systems ***that are required for ensuring and demonstrating compliance with this Regulation, in accordance with Article 20***;	(d) when under their control, keep the logs automatically generated by their high-risk AI systems ***as referred to in Article 20***;	(d) when under their control, keep the logs automatically generated by their high-risk AI systems ***as referred to in Article 20***; Text Origin: Council Mandate
Article 16, first paragraph, point (e)				
G 313	(e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure, prior to its placing on the market or putting into service;	(e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure, prior to its placing on the market or putting into service***, in accordance with Article 43***;	(e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure ***as referred to in Article 43***, prior to its placing on the market or putting into service;	(e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure ***as referred to in Article 43***, prior to its placing on the market or putting into service; Text Origin: Council Mandate

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Article 16, first paragraph, point (ea)				
313a		***(ea) draw up an EU declaration of conformity in accordance with Article 48;***		***(ea) draw up an EU declaration of conformity in accordance with Article 48;*** Text Origin: EP Mandate
Article 16, first paragraph, point (eb)				
313b		***(eb) affix the CE marking to the high-risk AI system to indicate conformity with this Regulation, in accordance with Article 49;***		***(eb) affix the CE marking to the high-risk AI system to indicate conformity with this Regulation, in accordance with Article 49;*** Text Origin: EP Mandate
Article 16, first paragraph, point (f)				
314	(f) comply with the registration obligations referred to in Article 51;	(f) comply with the registration obligations referred to in Article 51;	(f) comply with the registration obligations referred to in Article ~~51~~***51(1)***;	(f) comply with the registration obligations referred to in Article ~~51~~***51(1)***; Text Origin: Council Mandate
Article 16, first paragraph, point (g)				
315	(g) take the necessary corrective actions, if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title;	(g) take the necessary corrective actions~~, if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title~~ ***as referred to in Article 21 and provide information in that regard***;	(g) take the necessary corrective actions ***as referred to in Article 21***, if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title;	(g) take the necessary corrective actions~~, if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title~~ ***and provide information as required in Article 21***; Text Origin: EP Mandate

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Article 16, first paragraph, point (h)				
316	(h) inform the national competent authorities of the Member States in which they made the AI system available or put it into service and, where applicable, the notified body of the non-compliance and of any corrective actions taken;	*deleted*	(h) inform the ***relevant*** national competent ~~*authorities*~~***authority*** of the Member States in which they made the AI system available or put it into service and, where applicable, the notified body of the non-compliance and of any corrective actions taken;	
Article 16, first paragraph, point (i)				
317	(i) to affix the CE marking to their high-risk AI systems to indicate the conformity with this Regulation in accordance with Article 49;	*deleted*	*(i)* to affix the CE marking to their high-risk AI systems to indicate the conformity with this Regulation in accordance with Article 49;	(i) ~~*to affix the CE marking to their high-risk AI systems to indicate the conformity with this Regulation in accordance with Article 49;*~~***Moved above in line 313b***
Article 16, first paragraph, point (j)				
318	(j) upon request of a national competent authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title.	(j) upon ***a reasoned*** request of a national ~~*competent*~~***supervisory*** authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title.	(j) upon request of a national competent authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title.	(j) upon ***a reasoned*** request of a national competent authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title.
Article 16, first paragraph, point (ja)				
318a		***(ja) ensure that the high-risk AI system complies with accessibility***		***(ja) ensure that the high-risk AI system complies with accessibility***

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		requirements.		***requirements, in accordance with Directive 2019/882 on accessibility requirements for products and services and Directive 2016/2102 on the accessibility of the websites and mobile applications of public sector bodies.***
Article 17				
G 319	Article 17 Quality management system	Article 17 Quality management system	Article 17 Quality management system	Article 17 Quality management system Text Origin: Commission Proposal
Article 17(1)				
G 320	1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:	1. Providers of high-risk AI systems shall ~~put~~***have*** a quality management system in place that ensures compliance with this Regulation. ~~That system~~***It*** shall be documented in a systematic and orderly manner in the form of written policies, procedures ~~and~~***or*** instructions, and ***can be incorporated into an existing quality management system under Union sectoral legislative acts. It*** shall include at least the following aspects:	1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:	1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects: Text Origin: Council Mandate
Article 17(1), point (a)				
G 321				

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	(a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the high-risk AI system;	*deleted*	*(a)* a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the high-risk AI system;	(a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the high-risk AI system;
Article 17(1), point (b)				
G 322	(b) techniques, procedures and systematic actions to be used for the design, design control and design verification of the high-risk AI system;	(b) techniques, procedures and systematic actions to be used for the design, design control and design verification of the high-risk AI system;	(b) techniques, procedures and systematic actions to be used for the design, design control and design verification of the high-risk AI system;	(b) techniques, procedures and systematic actions to be used for the design, design control and design verification of the high-risk AI system; Text Origin: Commission Proposal G
Article 17(1), point (c)				
G 323	(c) techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the high-risk AI system;	(c) techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the high-risk AI system;	(c) techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the high-risk AI system;	(c) techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the high-risk AI system; Text Origin: Commission Proposal G
Article 17(1), point (d)				
G 324	(d) examination, test and validation procedures to be carried out before, during and after the development of the high-risk AI system, and the	(d) examination, test and validation procedures to be carried out before, during and after the development of the high-risk AI system, and the	(d) examination, test and validation procedures to be carried out before, during and after the development of the high-risk AI system, and the	(d) examination, test and validation procedures to be carried out before, during and after the development of the high-risk AI system, and the G

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	frequency with which they have to be carried out;	frequency with which they have to be carried out;	frequency with which they have to be carried out;	frequency with which they have to be carried out; Text Origin: Commission Proposal
Article 17(1), point (e)				
G 325	(e) technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, the means to be used to ensure that the high-risk AI system complies with the requirements set out in Chapter 2 of this Title;	(e) technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, ***or do not cover all of the relevant requirements,*** the means to be used to ensure that the high-risk AI system complies with the requirements set out in Chapter 2 of this Title;	(e) technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, the means to be used to ensure that the high-risk AI system complies with the requirements set out in Chapter 2 of this Title;	(e) technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, ***or do not cover all of the relevant requirements set out in Chapter II of this Title,*** the means to be used to ensure that the high-risk AI system complies with ~~the~~***those*** requirements ~~set out in Chapter 2 of this Title~~; Text Origin: EP Mandate
Article 17(1), point (f)				
G 326	(f) systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market or putting into service of high-risk AI systems;	(f) systems and procedures for data management, including data ***acquisition, data*** collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market or putting into service of high-risk AI systems;	(f) systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market or putting into service of high-risk AI systems;	(f) systems and procedures for data management, including data ***acquisition, data*** collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market or putting into service of high-risk AI systems; Text Origin: EP Mandate

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Article 17(1), point (g)				
327	(g) the risk management system referred to in Article 9;	(g) the risk management system referred to in Article 9;	(g) the risk management system referred to in Article 9;	(g) the risk management system referred to in Article 9; Text Origin: Commission Proposal
Article 17(1), point (h)				
328	(h) the setting-up, implementation and maintenance of a post-market monitoring system, in accordance with Article 61;	(h) the setting-up, implementation and maintenance of a post-market monitoring system, in accordance with Article 61;	(h) the setting-up, implementation and maintenance of a post-market monitoring system, in accordance with Article 61;	(h) the setting-up, implementation and maintenance of a post-market monitoring system, in accordance with Article 61; Text Origin: Commission Proposal
Article 17(1), point (i)				
329	(i) procedures related to the reporting of serious incidents and of malfunctioning in accordance with Article 62;	(i) procedures related to the reporting of serious incidents and of malfunctioning in accordance with Article 62;	(i) procedures related to the reporting of ~~serious incidents and of malfunctioning~~***a serious incident*** in accordance with Article 62;	(i) procedures related to the reporting of ~~serious incidents and of malfunctioning~~***a serious incident*** in accordance with Article 62; Text Origin: Council Mandate
Article 17(1), point (j)				
330	(j) the handling of communication with national competent authorities, competent authorities, including sectoral ones, providing or	(j) the handling of communication with ~~national~~***relevant*** competent authorities, ~~competent authorities,~~ including sectoral ones~~, providing or~~	(j) the handling of communication with national competent authorities, competent authorities, including sectoral ones, providing or	(j) the handling of communication with national competent authorities, ~~competent~~***other relevant*** authorities, including ~~sectoral ones,~~***those***

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	supporting the access to data, notified bodies, other operators, customers or other interested parties;	~~supporting the access to data, notified bodies, other operators, customers or other interested parties~~;	supporting the access to data, notified bodies, other operators, customers or other interested parties;	providing or supporting the access to data, notified bodies, other operators, customers or other interested parties;
Article 17(1), point (k)				
G 331	(k) systems and procedures for record keeping of all relevant documentation and information;	(k) systems and procedures for record keeping of all relevant documentation and information;	(k) systems and procedures for record keeping of all relevant documentation and information;	(k) systems and procedures for record keeping of all relevant documentation and information; Text Origin: Commission Proposal
Article 17(1), point (l)				
G 332	(l) resource management, including security of supply related measures;	(l) resource management, including security of supply related measures;	(l) resource management, including security of supply related measures;	(l) resource management, including security of supply related measures; Text Origin: Commission Proposal
Article 17(1), point (m)				
G 333	(m) an accountability framework setting out the responsibilities of the management and other staff with regard to all aspects listed in this paragraph.	(m) an accountability framework setting out the responsibilities of the management and other staff with regard to all aspects listed in this paragraph.	(m) an accountability framework setting out the responsibilities of the management and other staff with regard to all aspects listed in this paragraph.	(m) an accountability framework setting out the responsibilities of the management and other staff with regard to all aspects listed in this paragraph. Text Origin: Commission Proposal
Article 17(2)				
G 334				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation.	2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation. ***Providers shall in any event respect the degree of rigour and the level of protection required to ensure compliance of their AI systems with this Regulation.***	2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation.	2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation. ***Providers shall in any event respect the degree of rigour and the level of protection required to ensure compliance of their AI systems with this Regulation.*** Text Origin: EP Mandate
Article 17(2a)				
G 334a			***2a. For providers of high-risk AI systems that are subject to obligations regarding quality management systems under relevant sectorial Union law, the aspects described in paragraph 1 may be part of the quality management systems pursuant to that law.***	***2a. For providers of high-risk AI systems that are subject to obligations regarding quality management systems or their equivalent function under relevant sectorial Union law, the aspects described in paragraph 1 may be part of the quality management systems pursuant to that law.*** Text Origin: Council Mandate
Article 17(3)				
G 335	3. For providers that are credit institutions regulated by Directive 2013/36/ EU, the obligation to put a quality management system in place shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to Article	3. For providers that are credit institutions regulated by Directive 2013/36/ EU, the obligation to put a quality management system in place shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to Article	3. For providers that are ~~credit~~***financial*** institutions ~~regulated by Directive 2013/36/ EU~~***subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation***, the obligation to put ***in place*** a quality management	3. For providers that are ~~credit~~***financial*** institutions ~~regulated by Directive 2013/36/ EU~~***subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation***, the obligation to put ***in place*** a quality management

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	74 of that Directive. In that context, any harmonised standards referred to in Article 40 of this Regulation shall be taken into account.	74 of that Directive. In that context, any harmonised standards referred to in Article 40 of this Regulation shall be taken into account.	system ~~in place~~***with the exception of paragraph 1, points (g), (h) and (i)*** shall be deemed to be fulfilled by complying with the rules on internal governance arrangements~~, processes and mechanisms~~ ***or processes*** pursuant to ~~Article 74 of that Directive~~***the relevant Union financial services legislation***. In that context, any harmonised standards referred to in Article 40 of this Regulation shall be taken into account.	system ~~in place~~***with the exception of paragraph 1, points (g), (h) and (i)*** shall be deemed to be fulfilled by complying with the rules on internal governance arrangements~~, processes and mechanisms~~ ***or processes*** pursuant to ~~Article 74 of that Directive~~***the relevant Union financial services legislation***. In that context, any harmonised standards referred to in Article 40 of this Regulation shall be taken into account.
Article 18				
G 336	Article 18 Obligation to draw up technical documentation	*deleted*	Article 18 ~~Obligation to draw up technical documentation~~***Documentation keeping***	Article 18 ~~Obligation to draw up technical documentation~~***Documentation keeping*** Text Origin: Council Mandate
Article 18(1)				
G 337	1. Providers of high-risk AI systems shall draw up the technical documen-tation referred to in Article 11 in accordance with Annex IV.	*deleted*	1. ~~Providers of high-risk AI systems shall draw up the technical documen-tation referred to in Article 11 in accordance with Annex IV.~~***The provider shall, for a period ending 10 years after the AI system has been placed on the market or put into service, keep at the disposal of the national competent authorities:***	1. ~~Providers of high-risk AI systems shall draw up the technical documen-tation referred to in Article 11 in accordance with Annex IV.~~***The provider shall, for a period ending 10 years after the AI system has been placed on the market or put into service, keep at the disposal of the national competent authorities:*** Text Origin: Council Mandate

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 18(1), point (a)				
337a			*(a) the technical documentation referred to in Article 11;*	*(a) the technical documentation referred to in Article 11;* Text Origin: Council Mandate
Article 18(1), point (b)				
337b			*(b) the documentation concerning the quality management system referred to in Article 17;*	*(b) the documentation concerning the quality management system referred to in Article 17;* Text Origin: Council Mandate
Article 18(1), point (c)				
337c			*(c) the documentation concerning the changes approved by notified bodies where applicable;*	*(c) the documentation concerning the changes approved by notified bodies where applicable;* Text Origin: Council Mandate
Article 18(1), point (d)				
337d			*(d) the decisions and other documents issued by the notified bodies where applicable;*	*(d) the decisions and other documents issued by the notified bodies where applicable;* Text Origin: Council Mandate
Article 18(1), point (e)				
337e				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			(e) the EU declaration of conformity referred to in Article 48.	***(e) the EU declaration of conformity referred to in Article 48.*** Text Origin: Council Mandate
Article 18(1), point (f)				
G 337f			***1a. Each Member State shall determine conditions under which the documentation referred to in paragraph 1 remains at the disposal of the national competent authorities for the period indicated in that paragraph for the cases when a provider or its authorised representative established on its territory goes bankrupt or ceases its activity prior to the end of that period.***	***1a. Each Member State shall determine conditions under which the documentation referred to in paragraph 1 remains at the disposal of the national competent authorities for the period indicated in that paragraph for the cases when a provider or its authorised representative established on its territory goes bankrupt or ceases its activity prior to the end of that period.*** Text Origin: Council Mandate
Article 18(2)				
G 338	2. Providers that are credit institutions regulated by Directive 2013/36/EU shall maintain the technical documentation as part of the documentation concerning internal governance, arrangements, processes and mechanisms pursuant to Article 74 of that Directive.	*deleted*	2. Providers that are ~~credit~~***financial*** institutions ~~regulated by Directive 2013/36/EU~~***subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation*** shall maintain the technical documentation as part of the documentation ~~concerning internal governance, arrangements, processes and mechanisms pursuant to Article 74 of that Directive~~***kept***	2. Providers that are ~~credit~~***financial*** institutions ~~regulated by Directive 2013/36/EU~~***subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation*** shall maintain the technical documentation as part of the documentation ~~concerning internal governance, arrangements, processes and mechanisms pursuant to Article 74 of that Directive~~***kept***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			under the relevant Union financial services legislation.	***under the relevant Union financial services legislation***. Text Origin: Council Mandate
Article 19				
G 339	Article 19 Conformity assessment	*deleted*	Article 19 Conformity assessment	Article 19 ~~*Conformity assessment*~~***deleted*** G
Article 19(1)				
G 340	1. Providers of high-risk AI systems shall ensure that their systems undergo the relevant conformity assessment procedure in accordance with Article 43, prior to their placing on the market or putting into service. Where the compliance of the AI systems with the requirements set out in Chapter 2 of this Title has been demonstrated following that conformity assessment, the providers shall draw up an EU declaration of conformity in accordance with Article 48 and affix the CE marking of conformity in accordance with Article 49.	*deleted*	*1.* Providers of high-risk AI systems shall ensure that their systems undergo the relevant conformity assessment procedure in accordance with Article 43, prior to their placing on the market or putting into service. Where the compliance of the AI systems with the requirements set out in Chapter 2 of this Title has been demonstrated following that conformity assessment, the providers shall draw up an EU declaration of conformity in accordance with Article 48 and affix the CE marking of conformity in accordance with Article 49.	1. ~~*Providers of high-risk AI systems shall ensure that their systems undergo the relevant conformity assessment procedure in accordance with Article 43, prior to their placing on the market or putting into service. Where the compliance of the AI systems with the requirements set out in Chapter 2 of this Title has been demonstrated following that conformity assessment, the providers shall draw up an EU declaration of conformity in accordance with Article 48 and affix the CE marking of conformity in accordance with Article 49.*~~***deleted*** G
Article 19(2)				
G 341	2. For high-risk AI systems referred to in point 5(b) of Annex III that are placed on the market or put into	*deleted*	*deleted*	2. ~~*For high-risk AI systems referred to in point 5(b) of Annex III that are placed on the market or put into*~~ G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	service by providers that are credit institutions regulated by Directive 2013/36/EU, the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to101 of that Directive.			~~service by providers that are credit institutions regulated by Directive 2013/36/EU, the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to101 of that Directive.~~***deleted***
Article 20				
G 342	Article 20 Automatically generated logs	Article 20 Automatically generated logs	Article 20 Automatically generated logs	Article 20 Automatically generated logs Text Origin: Commission Proposal
Article 20(1)				
G 343	1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. The logs shall be kept for a period that is appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under Union or national law.	1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control~~ by virtue of a contractual arrangement with the user or otherwise by law.~~***. Without prejudice to applicable Union or national law,*** the logs shall be kept for a period ~~that is appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under Union or national law~~***of at least 6 months. The retention period shall be in accordance with industry standards and appropriate to the intended***	1. Providers of high-risk AI systems shall keep the logs***, referred to in Article 12(1),*** automatically generated by their high-risk AI systems, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. ~~The logs~~***They*** shall ~~be kept~~***keep them*** for a period ~~that is appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under Union or national law~~***of at least six months, unless provided otherwise in applicable Union or national law, in particular in Union law on the protection of***	1. Providers of high-risk AI systems shall keep the logs***, referred to in Article 12(1),*** automatically generated by their high-risk AI systems, to the extent such logs are under their control~~ by virtue of a contractual arrangement with the user or otherwise by law.~~***. Without prejudice to applicable Union or national law,*** the logs shall be kept for a period ~~that is~~ appropriate ~~in the light of~~***to*** the intended purpose of ***the*** high-risk AI system***, of at least 6 months, unless provided otherwise in applicable*** ~~and applicable legal obligations under~~ Union or national law***, in particular in Union law on*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		purpose of high-risk AI system.	***personal data***.	***the protection of personal data***.
Article 20(2)				
G 344	2. Providers that are credit institutions regulated by Directive 2013/36/EU shall maintain the logs automatically generated by their high-risk AI systems as part of the documentation under Articles 74 of that Directive.	2. Providers that are credit institutions regulated by Directive 2013/36/EU shall maintain the logs automatically generated by their high-risk AI systems as part of the documentation under Articles 74 of that Directive.	2. Providers that are ~~credit~~***financial*** institutions ~~regulated by Directive 2013/36/EU~~***subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation*** shall maintain the logs automatically generated by their high-risk AI systems as part of the documentation ***kept*** under ~~Articles 74 of that Directive~~***the relevant financial service legislation***.	2. Providers that are ~~credit~~***financial*** institutions ~~regulated by Directive 2013/36/EU~~***subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation*** shall maintain the logs automatically generated by their high-risk AI systems as part of the documentation ***kept*** under ~~Articles 74 of that Directive~~***the relevant financial service legislation***. Text Origin: Council Mandate
Article 21				
G 345	Article 21 Corrective actions	Article 21 Corrective actions	Article 21 Corrective actions	Article 21 Corrective actions ***and duty of information*** Text Origin: Commission Proposal
Article 21				
G 345a		*deleted*		
Article 21, first paragraph				

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G 346	Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective actions to bring that system into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the high-risk AI system in question and, where applicable, the authorised representative and importers accordingly.	Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective actions to bring that system into conformity, to withdraw it***, to disable it*** or to recall it, as appropriate. ***In the cases referred to in the first paragraph, providers*** ~~They~~ shall ***immediately*** inform***:*** ***a.*** the distributors***;*** ***b. the importers;*** ***c. the national competent authorities*** of the ~~high-risk~~***Member States in which they made the*** AI system ~~in question and,~~***available or put it into service; and*** ***d.*** where ~~applicable, the authorised representative and importers accordingly~~***possible, the deployer***.	Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system which they have placed on the market or put into service is not in conformity with this Regulation shall immediately ***investigate, where applicable, the causes in collaboration with the reporting user and*** take the necessary corrective actions to bring that system into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the high-risk AI system in question and, where applicable, the authorised representative and importers accordingly.	Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective actions to bring that system into conformity, to withdraw it***, to disable it,*** or to recall it, as appropriate. They shall inform the distributors of the high-risk AI system in question and, where applicable, the ***deployers, the*** authorised representative and importers accordingly. G
Article 21, first paragraph a				
G 346a		***The providers shall also inform the authorised representative, if one was appointed in accordance with Article 25, and the notified body if the high-risk AI system had to undergo a third-party conformity assessment in accordance with***		***Where the high-risk AI system presents a risk within the meaning of Article 65(1) and the provider becomes aware of that risk, they shall immediately investigate the causes, in collaboration with the reporting deployer, where*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Article 43. Where applicable, they shall also investigate the causes in collaboration with the deployer.		***applicable, and inform the market surveillance authorities of the Member States in which they made the high-risk AI system available and, where applicable, the notified body that issued a certificate for the high-risk AI system in accordance with Article 44, in particular, of the nature of the non-compliance and of any relevant corrective action taken.*** Text Origin: EP Mandate
Article 22				
G 347	Article 22 Duty of information	Article 22 Duty of information	Article 22 Duty of information	Article 22 ~~Duty of information~~***deleted*** Text Origin: Commission Proposal
Article 22, first paragraph				
G 348	Where the high-risk AI system presents a risk within the meaning of Article 65(1) and that risk is known to the provider of the system, that provider shall immediately inform the national competent authorities of the Member States in which it made the system available and, where applicable, the notified body that issued a certificate for the high-risk AI system, in particular of the non-compliance and of any corrective	Where the high-risk AI system presents a risk within the meaning of Article 65(1) and ~~that risk is known to the provider of the system~~***the provider of the system becomes aware of that risk***, that provider shall immediately inform the national ~~competent~~***supervisory*** authorities of the Member States in which it made the system available and, where applicable, the notified body that issued a certificate for the	Where the high-risk AI system presents a risk within the meaning of Article 65(1) and that risk is known to the provider of the system, that provider shall immediately inform the national competent authorities of the Member States in which it made the system available and, where applicable, the notified body that issued a certificate for the high-risk AI system, in particular of the non-compliance and of any corrective	~~Where the high-risk AI system presents a risk within the meaning of Article 65(1) and that risk is known to the provider of the system, that provider shall immediately inform the national competent authorities of the Member States in which it made the system available and, where applicable, the notified body that issued a certificate for the high-risk AI system, in particular of the non-compliance and of any corrective~~

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	actions taken.	high-risk AI system, in particular ***the nature*** of the non-compliance and of any ***relevant*** corrective actions taken.	actions taken.	~~*actions taken.*~~ Text Origin: EP Mandate
Article 22, first paragraph a				
G 348a		***1a In the cases referred to inthe first paragraph, providers of the high-risk AI system shall immediately inform:*** ***a) the distributors;*** ***b) the importers;*** ***c) the national competent authorities of the Member States in which they made the AI system available or put it into service; and*** ***d) where possible, the deployers.***		G
Article 22, third paragraph				
G 348b		***1b The providers shall also inform the authorised representative, if one was appointed in accordance with Article 25.***		G
Article 22, fourth paragraph				
G 348c		*deleted*		G
Article 22, fifth paragraph				
G *348d*				G

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		deleted		
Article 22, sixth paragraph				
G *348e*		*deleted*		G
Article 23				
G *349*	Article 23 Cooperation with competent authorities	Article 23 Cooperation with competent authorities***, the Office and the Commission***	Article 23 Cooperation with competent authorities	Article 23 Cooperation with competent authorities G
Article 23, first paragraph				
G 350	Providers of high-risk AI systems shall, upon request by a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member State concerned. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue	Providers ***and where applicable, deployers*** of high-risk AI systems shall, upon ***a reasoned*** request by a national competent authority ***or where applicable, by the AI Office or the Commission, provide them***~~, provide that authority~~ with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member State concerned. ~~Upon a reasoned request from a national competent authority, providers shall also give that~~	Providers of high-risk AI systems shall, upon request by a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in ~~an official Union language determined~~***a language which can be easily understood*** by the ***authority of the*** Member State concerned. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs***, referred to in Article 12(1),*** automatically	Providers of high-risk AI systems shall, upon ***a reasoned*** request by a ~~national~~ competent authority, provide that authority ~~with~~ all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in ~~an official Union~~***a*** language ~~determined by the Member State concerned. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated~~***which can be easily understood*** by the ~~high-~~ G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	of a contractual arrangement with the user or otherwise by law.	~~*authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.*~~	generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.	~~*risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law*~~***authority in an official Union language determined by the Member State concerned***.
Article 23, first paragraph a				
G 350a		*deleted*		G
Article 23, first paragraph a				
G *350b*		***1a Upon a reasoned request by a national competent authority or, where applicable, by the Commission, providers and, where applicable, deployers shall also give the requesting national competent authority or the Commission, as applicable, access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control.***		***1a Upon a reasoned request by a national competent authority providers shall also give the requesting national competent authority, as applicable, access to the logs referred to in Article 12(1) automatically generated by the high-risk AI system to the extent such logs are under their control.*** Text Origin: EP Mandate G
Article 23, paragraph 1b				
G 350c		***(1b) Any information obtained by a national competent authority or by the Commission pursuant to the provisions of this Article shall be considered a trade secret and be***		***(1b) Any information obtained by a national competent authority pursuant to the provisions of this Article shall be treated in compliance with the confidentiality*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		treated in compliance with the confidentiality obligations set out in Article 70.		***obligations set out in Article 70.*** Text Origin: EP Mandate
Article 23a				
G 350d			***Article 23a*** ***Conditions for other persons to be subject to the obligations of a provider***	Deleted from here, included in article 28 G
Article 23a(1)				
G 350e			***1. Any natural or legal person shall be considered a provider of a new high-risk AI system for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16, in any of the following circumstances:***	G
Article 23a(1), point (a)				
G 350f			***(a) they put their name or trademark on a high-risk AI system already placed on the market or put into service, without prejudice to contractual arrangements stipulating that the obligations are allocated otherwise;***	G
Article 23a(1), point (b)				
G 350g				G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			(b) they make a substantial modification to a high-risk AI system already placed on the market or put into service;	
Article 23a(1), point (c)				
G 350h			***(c) they modify the intended purpose of an AI system which is not high-risk and is already placed on the market or put ito service, in a way which makes the modified system a high-risk AI system;***	G
Article 23a(1), point (d)				
G 350i			***(d) they place on the market or put into service a general purpose AI system as a high-risk AI system or as a component of a high-risk AI system.***	G
Article 23a(2)				
G 350j			***2. Where the circumstances referred to in paragraph 1, point (a) or (c), occur, the provider that initially placed the high-risk AI system on the market or put it into service shall no longer be considered a provider for the purposes of this Regulation.***	G
Article 23a(3), first subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 350k			***3. For high-risk AI systems that are safety components of products to which the legal acts listed in Annex II, section A apply, the manufacturer of those products shall be considered the provider of the high-risk AI system and shall be subject to the obligations under Article 16 under either of the following scenarios:***	G
Article 23a(3), second subparagraph				
G 350l			***(i) the high-risk AI system is placed on the market together with the product under the name or trademark of the product manufacturer;*** ***(ii) the high-risk AI system is put into service under the the name or trademark of the product manufacturer after the product has been placed on the market.***	G
Article 23a				
G 350m		*deleted*		G
Article 24				
G *351*	Article 24 Obligations of product	Article 24 Obligations of product	*deleted*	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	manufacturers	manufacturers		
Article 24, first paragraph				
G *352*	Where a high-risk AI system related to products to which the legal acts listed in Annex II, section A, apply, is placed on the market or put into service together with the product manufactured in accordance with those legal acts and under the name of the product manufacturer, the manufacturer of the product shall take the responsibility of the compliance of the AI system with this Regulation and, as far as the AI system is concerned, have the same obligations imposed by the present Regulation on the provider.	Where a high-risk AI system related to products to which the legal acts listed in Annex II, section A, apply, is placed on the market or put into service together with the product manufactured in accordance with those legal acts and under the name of the product manufacturer, the manufacturer of the product shall take the responsibility of the compliance of the AI system with this Regulation and, as far as the AI system is concerned, have the same obligations imposed by the present Regulation on the provider.	*deleted*	G
Article 25				
G *353*	Article 25 Authorised representatives	Article 25 Authorised representatives	Article 25 Authorised representatives	Article 25 Authorised representatives Text Origin: Commission Proposal G
Article 25(1)				
G 354	1. Prior to making their systems available on the Union market, where an importer cannot be identified, providers established	1. Prior to making their systems available on the Union market, ~~*where an importer cannot be identified,*~~ providers established	1. Prior to making their systems available on the Union market~~,~~ ~~*where an importer cannot be identified,*~~ providers established	1. Prior to making their systems available on the Union market~~,~~ ~~*where an importer cannot be identified,*~~ providers established G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.	outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.	outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.	outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union. Text Origin: Council Mandate
Article 25(1a)				
G 354a		***1a. The authorised representative shall reside or be established in one of the Member States where the activities pursuant to Article 2, paragraphs 1(cb) are taking place.***		Text Origin: EP Mandate G
Article 25(1b)				
G 354b		***1b. The provider shall provide its authorised representative with the necessary powers and resources to comply with its tasks under this Regulation.***		***1b. The provider shall enable its authorised representative to perform its tasks under this Regulation.*** Text Origin: EP Mandate G
Article 25(1c)(2)				
G 355	2. The authorised representative shall perform the tasks specified in the mandate received from the provider. The mandate shall empower the authorised representative to carry out the following tasks:	2. The authorised representative shall perform the tasks specified in the mandate received from the provider. ***It shall provide a copy of the mandate to the market surveillance authorities upon request, in one of the official languages of the institution of the Union determined by the national***	2. The authorised representative shall perform the tasks specified in the mandate received from the provider. ***For the purpose of this Regulation,*** the mandate shall empower the authorised representative to carry out ***only*** the following tasks:	2. The authorised representative shall perform the tasks specified in the mandate received from the provider. ***It shall provide a copy of the mandate to the market surveillance authorities upon request, in one of the official languages of the institution of the Union determined by the national*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		competent authority. For the purpose of this Regulation, the mandate shall empower the authorised representative to carry out the following tasks:		***competent authority. For the purpose of this Regulation,*** the mandate shall empower the authorised representative to carry out the following tasks: Text Origin: EP Mandate
Article 25(1c)(2), point (-a)				
G 355a			***(-a) verify that the EU declaration of conformity and the technical documentation have been drawn up and that an appropriate conformity assessment procedure has been carried out by the provider;***	***(-a) verify that the EU declaration of conformity and the technical documentation have been drawn up and that an appropriate conformity assessment procedure has been carried out by the provider;*** Text Origin: Council Mandate
Article 25(1c)(2), point (a)				
G 356	(a) keep a copy of the EU declaration of conformity and the technical documentation at the disposal of the national competent authorities and national authorities referred to in Article 63(7);	(a) ~~*keep a copy of*~~***ensure that*** the EU declaration of conformity and the technical documentation ~~*at the disposal of the national competent authorities and national authorities referred to in Article 63(7)*~~***have been drawn up and that an appropriate conformity assessment procedure has been carried out by the provider***;	(a) keep ~~*a copy*~~***at the disposal*** of the ~~*EU declaration of conformity and the technical documentation at the disposal*~~***national competent authorities and national authorities referred to in Article 63(7), for a period ending 10 years after the high-risk AI system has been placed on the market or put into service, the contact details*** of the ~~*national competent authorities and national authorities referred to in Article 63(7)*~~***provider by which the authorised representative has been appointed, a copy of the EU***	(a) keep ~~*a copy*~~***at the disposal*** of the ~~*EU declaration of conformity and the technical documentation at the disposal*~~***national competent authorities and national authorities referred to in Article 63(7), for a period ending 10 years after the high-risk AI system has been placed on the market or put into service, the contact details*** of the ~~*national competent authorities and national authorities referred to in Article 63(7)*~~***provider by which the authorised representative has been appointed, a copy of the EU***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			declaration of conformity, the technical documentation and, if applicable, the certificate issued by the notified body;	***declaration of conformity, the technical documentation and, if applicable, the certificate issued by the notified body***; Text Origin: Council Mandate
Article 25, second paragraph, point (aa)				
G 356a		***(aa) keep at the disposal of the national competent authorities and national authorities referred to in Article 63(7), a copy of the EU declaration of conformity, the technical documentation and, if applicable, the certificate issued by the notified body;***		G
Article 25(1c)(2), point (b)				
G 357	(b) provide a national competent authority, upon a reasoned request, with all the information and documentation necessary to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law;	(b) provide a national competent authority, upon a reasoned request, with all the information and documentation necessary to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider ~~by virtue of a contractual arrangement with the user or otherwise by law~~;	(b) provide a national competent authority, upon a reasoned request, with all the information and documentation***, including that kept according to point (b),*** necessary to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title, including access to the logs***, referred to in Article 12(1),*** automatically generated by the high-risk AI system to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or	(b) provide a national competent authority, upon a reasoned request, with all the information and documentation***, including that kept according to point (a),*** necessary to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title, including access to the logs***, as referred to in Article 12(1),*** automatically generated by the high-risk AI system to the extent such logs are under the control of the provider ~~by virtue of a contractual arrangement with the user or~~ G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			otherwise by law;	~~otherwise by law~~; Text Origin: Council Mandate
Article 25(1c)(2), point (c)				
G 358	(c) cooperate with competent national authorities, upon a reasoned request, on any action the latter takes in relation to the high-risk AI system.	(c) cooperate with ~~competent~~ national ***supervisory*** authorities, upon a reasoned request, on any action the ~~latter~~***authority*** takes ~~in relation to~~***to reduce and mitigate the risks posed by*** the high-risk AI system~~.~~***;***	(c) cooperate with ~~competent~~ national ***competent*** authorities, upon a reasoned request, on any action the latter takes in relation to the high-risk AI system~~.~~***;***	(c) cooperate with competent ~~national~~ authorities, upon a reasoned request, on any action the latter takes in relation to the high-risk AI system~~.~~***, in particular to reduce and mitigate the risks posed by the high-risk AI system;*** Text Origin: Council Mandate
Article 25(2), point (ca)				
G 358a			***(ca) comply with the registration obligations referred to in Article 51(1) and, if the registration of the system is carried out by the provider itself, verify that the information referred to in Annex VIII, Part II, 1 to 11, is correct.***	
Article 25(1c)(2), point (ca)				
G 358b		***(ca) where applicable, comply with the registration obligations referred in Article 51, or, if the registration is carried out by the provider itself, ensure that the information referred to in point 3 of Annex VIII is correct.***		***(ca) where applicable, comply with the registration obligations referred in Article 51(1), or, if the registration is carried out by the provider itself, ensure that the information referred to in [point 3] of Annex VIII is correct.***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: EP Mandate
Article 25, paragraph 2a				
G 358c		***2a The authorised representative shall be mandated to be addressed, in addition to or instead of the provider, by, in particular, the national supervisory authority or the national competent authorities, on all issues related to ensuring compliance with this Regulation.***		***2a The mandate shall empower the authorised representative to be addressed, in addition to or instead of the provider, by the competent authorities, on all issues related to ensuring compliance with this Regulation.*** Text Origin: EP Mandate
Article 25, paragraph 2b				
G 358d		***(2b) The authorised representative shall terminate the mandate if it considers or has reason to consider that the provider acts contrary to its obligations under this Regulation. In such a case, it shall also immediately inform the national supervisory authority of the Member State in which it is established, as well as, where applicable, the relevant notified body, about the termination of the mandate and the reasons thereof.***		***(2b) The authorised representative shall terminate the mandate if it considers or has reason to consider that the provider acts contrary to its obligations under this Regulation. In such a case, it shall also immediately inform the market surveillance authority of the Member State in which it is established, as well as, where applicable, the relevant notified body, about the termination of the mandate and the reasons thereof.*** Text Origin: EP Mandate
Article 25(2a), first subparagraph				
G 358e				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			2a. The authorised representative shall terminate the mandate if it has sufficient reasons to consider that the provider acts contrary to its obligations under this Regulation. In such a case, it shall also immediately inform the market surveillance authority of the Member State in which it is established, as well as, where applicable, the relevant notified body, about the termination of the mandate and the reasons thereof.	
Article 25(1d)				
G 358f			***The authorised representative shall be legally liable for defective AI systems on the same basis as, and jointly and severally with, the provider in respect of its potential liability under Council Directive 85/374/EEC.***	Text Origin: Council Mandate
Article 26				
G 359	Article 26 Obligations of importers	Article 26 Obligations of importers	Article 26 Obligations of importers	Article 26 Obligations of importers Text Origin: Commission Proposal
Article 26(1)				
G 360				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	1. Before placing a high-risk AI system on the market, importers of such system shall ensure that:	1. Before placing a high-risk AI system on the market, importers of such system shall ensure that ***such a system is in conformity with this Regulation by ensuring that***:	1. Before placing a high-risk AI system on the market, importers of such system shall ensure that ***such a system is in conformity with this Regulation by verifying that***:	1. Before placing a high-risk AI system on the market, importers of such system shall ensure that ***such a system is in conformity with this Regulation by verifying that***: Text Origin: Council Mandate
Article 26(1), point (a)				
G 361	(a) the appropriate conformity assessment procedure has been carried out by the provider of that AI system	(a) the ~~appropriate~~***relevant*** conformity assessment procedure ***referred to in Article 43*** has been carried out by the provider of that AI system***;***	(a) the ~~appropriate~~***relevant*** conformity assessment procedure ***referred to in Article 43*** has been carried out by the provider of that AI system***;***	(a) the ~~appropriate~~***relevant*** conformity assessment procedure ***referred to in Article 43*** has been carried out by the provider of that AI system***;*** Text Origin: Council Mandate
Article 26(1), point (b)				
G 362	(b) the provider has drawn up the technical documentation in accordance with Annex IV;	(b) the provider has drawn up the technical documentation in accordance with ***Article 11 and*** Annex IV;	(b) the provider has drawn up the technical documentation in accordance with Annex IV;	(b) the provider has drawn up the technical documentation in accordance with ***Article 11 and*** Annex IV; Text Origin: EP Mandate
Article 26(1), point (c)				
G 363	(c) the system bears the required conformity marking and is accompanied by the required documentation and instructions of use.	(c) the system bears the required conformity marking and is accompanied by the required documentation and instructions of use.	(c) the system bears the required ***CE*** conformity marking and is accompanied by the ~~required documentation~~***EU declaration of conformity*** and instructions of use~~.~~***;***	(c) the system bears the required ***CE*** conformity marking and is accompanied by the ~~required documentation~~***EU declaration of conformity*** and instructions of use~~.~~***;***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Council Mandate
Article 26(1), point (ca)				
363a			***(ca) the authorised representative referred to in Article 25 has been established by the provider.***	
Article 26(1), point (ca)				
363b		***(ca) where applicable, the provider has appointed an authorised representative in accordance with Article 25(1).***		***(ca) the provider has appointed an authorised representative in accordance with Article 25(1).*** Text Origin: EP Mandate
Article 26(2)				
364	2. Where an importer considers or has reason to consider that a high-risk AI system is not in conformity with this Regulation, it shall not place that system on the market until that AI system has been brought into conformity. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the importer shall inform the provider of the AI system and the market surveillance authorities to that effect.	2. Where an importer considers or has reason to consider that a high-risk AI system is not in conformity with this Regulation, ***or is counterfeit, or accompanied by falsified documentation*** it shall not place that system on the market until that AI system has been brought into conformity. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the importer shall inform the provider of the AI system and the market surveillance authorities to that effect.	2. Where an importer ~~considers or has reason~~***has sufficient reasons*** to consider that a high-risk AI system is not in conformity with this Regulation, ***or is falsified, or accompanied by falsified documentation,*** it shall not place that system on the market until that AI system has been brought into conformity. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the importer shall inform the provider of the AI system***, the authorised representatives*** and the market surveillance authorities to that effect.	2. Where an importer ~~considers or has~~***has sufficient*** reason to consider that a high-risk AI system is not in conformity with this Regulation, ***or is falsified, or accompanied by falsified documentation,*** it shall not place that system on the market until that AI system has been brought into conformity. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the importer shall inform the provider of the AI system***, the authorised representatives*** ~~-~~and the market surveillance authorities to that effect.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 26(3)				
365	3. Importers shall indicate their name, registered trade name or registered trade mark, and the address at which they can be contacted on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as applicable.	3. Importers shall indicate their name, registered trade name or registered trade mark, and the address at which they can be contacted on the high-risk AI system ~~or, where that is not possible,~~***and*** on its packaging or its accompanying documentation, ~~as~~***where*** applicable.	3. Importers shall indicate their name, registered trade name or registered trade mark, and the address at which they can be contacted on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as applicable.	3. Importers shall indicate their name, registered trade name or registered trade mark, and the address at which they can be contacted on the high-risk AI system ~~or, where that is not possible,~~***and*** on its packaging or its accompanying documentation, ~~as~~***where*** applicable. Text Origin: EP Mandate
Article 26(4)				
366	4. Importers shall ensure that, while a high-risk AI system is under their responsibility, where applicable, storage or transport conditions do not jeopardise its compliance with the requirements set out in Chapter 2 of this Title.	4. Importers shall ensure that, while a high-risk AI system is under their responsibility, where applicable, storage or transport conditions do not jeopardise its compliance with the requirements set out in Chapter 2 of this Title.	4. Importers shall ensure that, while a high-risk AI system is under their responsibility, where applicable, storage or transport conditions do not jeopardise its compliance with the requirements set out in Chapter 2 of this Title.	4. Importers shall ensure that, while a high-risk AI system is under their responsibility, where applicable, storage or transport conditions do not jeopardise its compliance with the requirements set out in Chapter 2 of this Title. Text Origin: Council Mandate
Article 26(4a)				
366a			***4a. Importers shall keep, for a period ending 10 years after the AI system has been placed on the market or put into service, a copy of the certificate issued by the notified body, where applicable, of the instructions for use and of the EU***	***4a. Importers shall keep, for a period ending 10 years after the AI system has been placed on the market or put into service, a copy of the certificate issued by the notified body, where applicable, of the instructions for use and of the EU***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			declaration of conformity.	***declaration of conformity.*** Text Origin: Council Mandate
Article 26(5)				
367	5. Importers shall provide national competent authorities, upon a reasoned request, with all necessary information and documentation to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title in a language which can be easily understood by that national competent authority, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law. They shall also cooperate with those authorities on any action national competent authority takes in relation to that system.	5. Importers shall provide national competent authorities, upon a reasoned request, with all ***the*** necessary information and documentation to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title in a language which can be easily understood by ~~that national competent authority~~***them***, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider ~~by virtue of a contractual arrangement with the user or otherwise by law. They shall also cooperate with those authorities on any action national competent authority takes in relation to that system.~~***in accordance with Article 20.***	5. Importers shall provide national competent authorities, upon a reasoned request, with all necessary information and documentation***, including that kept in accordance with paragraph 5,*** to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title in a language which can be easily understood by that national competent authority~~, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law.~~***. To this purpose*** they shall also ~~cooperate with those authorities on any action national competent authority takes in relation to that system~~***ensure that the technical documentation can be made available to those authorities***.	5. Importers shall provide national competent authorities, upon a reasoned request, with all ***the*** necessary information and documentation ***including that kept in accordance with paragraph 4a*** to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title in a language which can be easily understood by ~~that national competent authority, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law.~~***them. To this purpose*** they shall also ~~cooperate with those authorities on any action national competent authority takes in relation to that system~~***ensure that the technical documentation can be made available to those authorities***.
Article 26(5a)				
367a			***5a. Importers shall cooperate with***	Text Origin: Council Mandate

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			national competent authorities on any action those authorities take in relation to an AI system, of which they are the importer.	
Article 26(5b)				
367b		***5a. Importers shall cooperate with national competent authorities on any action those authorities take to reduce and mitigate the risks posed by the high-risk AI system.***		***5a. Importers shall cooperate with national competent authorities on any action those authorities take, in particular to reduce and mitigate the risks posed by the high-risk AI system.*** Text Origin: EP Mandate
Article 27				
368	Article 27 Obligations of distributors	Article 27 Obligations of distributors	Article 27 Obligations of distributors	Article 27 Obligations of distributors Text Origin: Commission Proposal
Article 27(1)				
369	1. Before making a high-risk AI system available on the market, distributors shall verify that the high-risk AI system bears the required CE conformity marking, that it is accompanied by the required documentation and instruction of use, and that the provider and the importer of the	1. Before making a high-risk AI system available on the market, distributors shall verify that the high-risk AI system bears the required CE conformity marking, that it is accompanied by the required documentation and instruction of use, and that the provider and the importer of the	1. Before making a high-risk AI system available on the market, distributors shall verify that the high-risk AI system bears the required CE conformity marking, that it is accompanied by ~~the required documentation~~***a copy of EU declaration of conformity*** and instruction of use, and that the	1. Before making a high-risk AI system available on the market, distributors shall verify that the high-risk AI system bears the required CE conformity marking, that it is accompanied by ~~the required documentation~~***a copy of EU declaration of conformity*** and instruction of use, and that the

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	system, as applicable, have complied with the obligations set out in this Regulation.	system, as applicable, have complied with ~~the~~***their*** obligations set out in this Regulation ***in Articles 16 and 26 respectively***.	provider and the importer of the system, as applicable, have complied with ~~the~~***their*** obligations set out ~~in this Regulation~~***Article 16, point (b) and 26(3) respectively***.	provider and the importer of the system, as applicable, have complied with ~~the~~***their*** obligations set out in ~~this Regulation~~***Article 16, point (aa) and (b) and 26(3) respectively***.
Article 27(2)				
G 370	2. Where a distributor considers or has reason to consider that a high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title, it shall not make the high-risk AI system available on the market until that system has been brought into conformity with those requirements. Furthermore, where the system presents a risk within the meaning of Article 65(1), the distributor shall inform the provider or the importer of the system, as applicable, to that effect.	2. Where a distributor considers or has reason to consider***, on the basis of the information in its possession*** that a high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title, it shall not make the high-risk AI system available on the market until that system has been brought into conformity with those requirements. Furthermore, where the system presents a risk within the meaning of Article 65(1), the distributor shall inform the provider or the importer of the system***, the relevant national competent authority***, as applicable, to that effect.	2. Where a distributor considers or has reason to consider that a high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title, it shall not make the high-risk AI system available on the market until that system has been brought into conformity with those requirements. Furthermore, where the system presents a risk within the meaning of Article 65(1), the distributor shall inform the provider or the importer of the system, as applicable, to that effect.	2. Where a distributor considers or has reason to consider***, on the basis of the information in its possession,*** that a high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title, it shall not make the high-risk AI system available on the market until that system has been brought into conformity with those requirements. Furthermore, where the system presents a risk within the meaning of Article 65(1), the distributor shall inform the provider or the importer of the system, as applicable, to that effect. G
Article 27(3)				
G 371	3. Distributors shall ensure that, while a high-risk AI system is under their responsibility, where applicable, storage or transport conditions do not jeopardise the compliance of the system with the requirements set out in Chapter 2 of	3. Distributors shall ensure that, while a high-risk AI system is under their responsibility, where applicable, storage or transport conditions do not jeopardise the compliance of the system with the requirements set out in Chapter 2 of	3. Distributors shall ensure that, while a high-risk AI system is under their responsibility, where applicable, storage or transport conditions do not jeopardise the compliance of the system with the requirements set out in Chapter 2 of	3. Distributors shall ensure that, while a high-risk AI system is under their responsibility, where applicable, storage or transport conditions do not jeopardise the compliance of the system with the requirements set out in Chapter 2 of G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	this Title.	this Title.	this Title.	this Title. Text Origin: Council Mandate
Article 27(4)				
G 372	4. A distributor that considers or has reason to consider that a high-risk AI system which it has made available on the market is not in conformity with the requirements set out in Chapter 2 of this Title shall take the corrective actions necessary to bring that system into conformity with those requirements, to withdraw it or recall it or shall ensure that the provider, the importer or any relevant operator, as appropriate, takes those corrective actions. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the distributor shall immediately inform the national competent authorities of the Member States in which it has made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective actions taken.	4. A distributor that considers or has reason to consider***, on the basis of the information in its possession,*** that a high-risk AI system which it has made available on the market is not in conformity with the requirements set out in Chapter 2 of this Title shall take the corrective actions necessary to bring that system into conformity with those requirements, to withdraw it or recall it or shall ensure that the provider, the importer or any relevant operator, as appropriate, takes those corrective actions. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the distributor shall immediately inform the ***provider or importer of the system and the*** national competent authorities of the Member States in which it has made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective actions taken.	4. A distributor that considers or has reason to consider that a high-risk AI system which it has made available on the market is not in conformity with the requirements set out in Chapter 2 of this Title shall take the corrective actions necessary to bring that system into conformity with those requirements, to withdraw it or recall it or shall ensure that the provider, the importer or any relevant operator, as appropriate, takes those corrective actions. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the distributor shall immediately inform the national competent authorities of the Member States in which it has made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective actions taken.	4. A distributor that considers or has reason to consider***, on the basis of the information in its possession,*** that a high-risk AI system which it has made available on the market is not in conformity with the requirements set out in Chapter 2 of this Title shall take the corrective actions necessary to bring that system into conformity with those requirements, to withdraw it or recall it or shall ensure that the provider, the importer or any relevant operator, as appropriate, takes those corrective actions. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the distributor shall immediately inform the ***provider or importer of the system and the*** national competent authorities of the Member States in which it has made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective actions taken. Text Origin: EP Mandate G
Article 27(5)				

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G 373	5. Upon a reasoned request from a national competent authority, distributors of high-risk AI systems shall provide that authority with all the information and documentation necessary to demonstrate the conformity of a high-risk system with the requirements set out in Chapter 2 of this Title. Distributors shall also cooperate with that national competent authority on any action taken by that authority.	5. Upon a reasoned request from a national competent authority, distributors of ***the*** high-risk AI ~~systems~~***system*** shall provide that authority with all the information and documentation ***in their possession or available to them, in accordance with the obligations of distributors as outlined in paragraph 1, that are*** necessary to demonstrate the conformity of a high-risk system with the requirements set out in Chapter 2 of this Title. ~~Distributors shall also cooperate with that national competent authority on any action taken by that authority.~~	5. Upon a reasoned request from a national competent authority, distributors of high-risk AI systems shall provide that authority with all the information and documentation ~~necessary to demonstrate the conformity of a high-risk system with the requirements set out in Chapter 2 of this Title. Distributors shall also cooperate with that national competent authority on any action taken by that authority~~***regarding its activities as described in paragraph 1 to 4***.	5. Upon a reasoned request from a national competent authority, distributors of ~~high-risk AI systems~~***the high- risk AI system*** shall provide that authority with all the information and documentation ***regarding its activities as described in paragraph 1 to 4*** necessary to demonstrate the conformity of a high-risk system with the requirements set out in Chapter 2 of this Title. ~~Distributors shall also cooperate with that national competent authority on any action taken by that authority.~~
Article 27(5a)				
G 373a			***5a. Distributors shall cooperate with national competent authorities on any action those authorities take in relation to an AI system, of which they are the distributor.***	***5a. Distributors shall cooperate with national competent authorities on any action those authorities take in relation to an AI system, of which they are the distributor, in particular to reduce or mitigate the risk posed by the high-risk AI system.*** Text Origin: Council Mandate
Article 27(5a)				
G 373b		***5a. Distributors shall cooperate***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		with national competent authorities on any action those authorities take to reduce and mitigate the risks posed by the high-risk AI system.		
Article 28				
374	Article 28 Obligations of distributors, importers, users or any other third-party	Article 28 ~~*Obligations of*~~ ***Responsibilities along the AI value chain of providers,*** distributors, importers, ~~*users or any*~~ ***deployers or*** other ~~*third party*~~ ***third parties***	*deleted*	Article 28 ~~*Obligations of distributors, importers, users or any other third-party*~~***Responsibilities along the AI value chain*** Text Origin: EP Mandate
Article 28(1)				
375	1. Any distributor, importer, user or other third-party shall be considered a provider for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16, in any of the following circumstances:	1. Any distributor, importer, ~~*user*~~***deployer*** or other third-party shall be considered a provider ***of a high-risk AI system*** for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16, in any of the following circumstances:	*deleted*	1. Any distributor, importer, ~~*user*~~***deployer*** or other third-party shall be considered a provider ***of a high-risk AI system*** for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16, in any of the following circumstances: Text Origin: EP Mandate
Article 28(1), point (a)				
376	(a) they place on the market or put into service a high-risk AI system under their name or trademark;	(a) they ~~*place on the market or put into service*~~***put their name or trademarkt on*** a high-risk AI system ~~*under their name or trademark*~~***already placed on the***	*deleted*	(a) they ~~*place*~~***put their name or trademark on a high-risk AI system already placed*** on the market or put into service***, without prejudice to contractual arrangements***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		market or put into service;		***stipulating that the obligations are allocated otherwise.*** ~~*a high-risk AI system under their name or trademark;*~~
Article 28(1), point (b)				
G 377	(b) they modify the intended purpose of a high-risk AI system already placed on the market or put into service;	(b) they ~~*modify the intended purpose of*~~***make a substantial modification to*** a high-risk AI system ***that has*** already ***been*** placed on the market or ***has already been*** put into service ***and in a way that it remains a high-risk AI system in accordance with Article 6***;	*deleted*	(b) they ~~*modify the intended purpose of*~~***make a substantial modification to*** a high-risk AI system ***that has*** already ***been*** placed on the market or ***has already been*** put into service ***and in a way that it remains a high-risk AI system in accordance with Article 6***; Text Origin: EP Mandate
Article 28(1), point (ba)				
G 377a		***(ba) they make a substantial modification to an AI system, including a general purpose AI system, which has not been classified as high-risk and has already been placed on the market or put into service in such manner that the AI system becomes a high risk AI system in accordance with Article 6***	***(ba) they modify the intended purpose of an AI system which is not high-risk and is already placed on the market or put ito service, in a way which makes the modified system a high-risk AI system;***	***(ba) they modify the intended purpose of an AI system, including a general purpose AI system, which has not been classified as high-risk and has already been placed on the market or put into service in such manner that the AI system becomes a high risk AI system in accordance with Article 6*** Text Origin: EP Mandate
Article 28(1), point (c)				
G 378	(c) they make a substantial	(c) they make a substantial		(c) ~~*they make a substantial*~~

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	modification to the high-risk AI system.	modification to the high-risk AI system.	*deleted*	~~*modification to the high-risk AI system.*~~***deleted***
Article 28(2)				
379	2. Where the circumstances referred to in paragraph 1, point (b) or (c), occur, the provider that initially placed the high-risk AI system on the market or put it into service shall no longer be considered a provider for the purposes of this Regulation.	2. Where the circumstances referred to in paragraph 1, point ~~*(b) or (c),*~~***(a) to (ba)*** occur, the provider that initially placed the ~~*high-risk*~~ AI system on the market or put it into service shall no longer be considered a provider ***of that specific AI system*** for the purposes of this Regulation. ***This former provider shall provide the new provider with the technical documentation and all other relevant and reasonably expected information capabilities of the AI system, technical access or other assistance based on the generally acknowledged state of the art that are required for the fulfilment of the obligations set out in this Regulation.*** ***This paragraph shall also apply to providers of foundation models as defined in Article 3 when the foundation model is directly integrated in an high-risk AI system.***	*deleted*	2. Where the circumstances referred to in paragraph 1, point ~~*(b) or (c),*~~***(a) to (ba)*** occur, the provider that initially placed the ~~*high-risk*~~ AI system on the market or put it into service shall no longer be considered a provider ***of that specific AI system*** for the purposes of this Regulation. ***This former provider shall closely cooperate 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 paragraph shall not apply in the cases where the former provider has expressly excluded the change of its system into a high-risk system and therefore the obligation to hand over the documentation.*** Text Origin: EP Mandate
Article 28(2a)				

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G 379a		*2a. The provider of a high risk AI system and the third party that supplies tools, services, components or processes that are used or integrated in the high risk AI system shall, by written agreement specify the information, capabilities, technical access, and or other assistance, based on the generally acknowledged state of the art, that the third party is required to provide in order to enable the provider of the high risk AI system to fully comply with the obligations under this Regulation.* *The Commission shall develop and recommend non-binding model contractual terms between providers of high-risk AI systems and third parties that supply tools, services, components or processes that are used or integrated in high-risk AI systems in order to assist both parties in drafting and negotiating contracts with balanced contractual rights and obligations, consistent with each party's level of control. When developing non-binding model contractual terms, the Commission shall take into account possible contractual requirements applicable in specific sectors or business cases. The non-binding contractual terms shall be published and be available free of charge in an easily usable*	*2a. For high-risk AI systems that are safety components of products to which the legal acts listed in Annex II, section A apply, the manufacturer of those products shall be considered the provider of the high-risk AI system and shall be subject to the obligations under Article 16 under either of the following scenarios:* *(i) the high-risk AI system is placed on the market together with the product under the name or trademark of the product manufacturer;* *(ii) the high-risk AI system is put into service under the the name or trademark of the product manufacturer after the product has been placed on the market.*	*2a. For high-risk AI systems that are safety components of products to which the legal acts listed in Annex II, section A apply, the manufacturer of those products shall be considered the provider of the high-risk AI system and shall be subject to the obligations under Article 16 under either of the following scenarios:* *(i) the high-risk AI system is placed on the market together with the product under the name or trademark of the product manufacturer;* *(ii) the high-risk AI system is put into service under the the name or trademark of the product manufacturer after the product has been placed on the market.* *2b. The provider of a high risk AI system and the third party that supplies an AI system, tools, services, components, or processes that are used or integrated in a high-risk AI system shall, by written agreement, specify the necessary information, capabilities, technical access and other assistance based on the generally acknowledged state of the art, in order to enable the provider of the high risk AI system to fully comply with the obligations set out in this Regulation. This* G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		electronic format on the AI Office's website.		***obligation shall not apply to third parties making accessible to the public tools, services, processes, or AI components other than general-purpose AI models under a free and open licence.*** ***The AI Office may develop and recommend voluntary model contractual terms between providers of high-risk AI systems and third parties that supply tools, services, components or processes that are used or integrated in high-risk AI systems.*** ***When developing voluntary model contractual terms, the AI Office shall take into account possible contractual requirements applicable in specific sectors or business cases. The model contractual terms shall be published and be available free of charge in an easily usable electronic format.*** Text Origin: EP Mandate
Article 28(2b)				
G 379b		***2b. For the purposes of this Article, trade secrets shall be preserved and shall only be disclosed provided that all specific necessary measures pursuant to Directive (EU) 2016/943 are taken in advance to***		***2b. Paragraphs 2 and 2a are without prejudice to the need to respect and protect intellectual property rights and confidential business information or trade secrets in accordance with Union*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		preserve their confidentiality, in particular with respect to third parties. Where necessary, appropriate technical and organizational arrangements can be agreed to protect intellectual property rights or trade secrets.		***and national law.*** Text Origin: EP Mandate
Article 28a				
G 379c		***Article 28a*** ***Unfair contractual terms unilaterally imposed on an SME or startup*** ***1. A contractual term concerning the supply of tools, services, components or processes that are used or integrated in a high risk AI system or the remedies for the breach or the termination of related obligations which has been unilaterally imposed by an enterprise on a SME or startup shall not be binding on the latter enterprise if it is unfair.*** ***2. A contractual term is not to be considered unfair where it arises from applicable Union law.*** ***3. A contractual term is unfair if it is of such a nature that it objectively impairs the ability of the party upon whom the term has been unilaterally imposed to protect its legitimate commercial interest in the information in question or its use grossly deviates from good***		G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		commercial practice in the supply of tools, services, components or processes that are used or integrated in a high-risk AI system, contrary to good faith and fair dealing or creates a significant imbalance between the rights and the obligations of the parties in the contract. A contractual term is also unfair if it has the effect of shifting penalties referred to in Article 71 or associated litigation costs across parties to the contract, as referred to in Article 71(8). ***4. A contractual term is unfair for the purposes of this Article if its object or effect is to:*** ***(a) exclude or limit the liability of the party that unilaterally imposed the term for intentional acts or gross negligence;*** ***(b) exclude the remedies available to the party upon whom the term has been unilaterally imposed in the case of non-performance of contractual obligations or the liability of the party that unilaterally imposed the term in the case of a breach of those obligations;*** ***(c) give the party that unilaterally imposed the term the exclusive right to determine whether the technical documentation, information supplied are in conformity with the contract or to interpret any term of the contract.***		

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		5. A contractual term shall be considered to be unilaterally imposed within the meaning of this Article if it has been supplied by one contracting party and the other contracting party has not been able to influence its content despite an attempt to negotiate it. The contracting party that supplied a contractual term shall bears the burden of proving that that term has not been unilaterally imposed. *6. Where the unfair contractual term is severable from the remaining terms of the contract, those remaining terms shall remain binding. The party that supplied the contested term shall not argue that the term is an unfair term.* *7. This Article shall apply to all new contracts entered into force after ... [date of entry into force of this Regulation]. Businesses shall review existing contractual obligations that are subject to this Regulation by …[three years after the date of entry into force of this Regulation].* *8. Given the rapidity in which innovations occur in the markets, the list of unfair contractual terms within Article 28a shall be reviewed regularly by the Commission and be updated to new business practices if necessary.*		

Article 28a

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 379d		***Article 28b*** ***Obligations of the provider of a foundation model*** ***1. A provider of a foundation model shall, prior to making it available on the market or putting it into service, ensure that it is compliant with the requirements set out in this Article, regardless of whether it is provided as a standalone model or embedded in an AI system or a product, or provided under free and open source licences, as a service, as well as other distribution channels.*** ***2. For the purpose of paragraph 1, the provider of a foundation model shall:*** ***(a) demonstrate through appropriate design, testing and analysis the identification, the reduction and mitigation of reasonably foreseeable risks to health, safety, fundamental rights, the environment and democracy and the rule of law prior and throughout development with appropriate methods such as with the involvement of independent experts, as well as the documentation of remaining non-mitigable risks after development*** ***(b) process and incorporate only datasets that are subject to appropriate data governance measures for foundation models, in***		G

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		particular measures to examine the suitability of the data sources and possible biases and appropriate mitigation ***(c) design and develop the foundation model in order to achieve throughout its lifecycle appropriate levels of performance, predictability, interpretability, corrigibility, safety and cybersecurity assessed through appropriate methods such as model evaluation with the involvement of independent experts, documented analysis, and extensive testing during conceptualisation, design, and development;*** ***(d) design and develop the foundation model, making use of applicable standards to reduce energy use, resource use and waste, as well as to increase energy efficiency, and the overall efficiency of the system, whithout prejudice to relevant existing Union and national law. This obligation shall not apply before the standards referred to in Article 40 are published. Foundation models shall be designed with capabilities enabling the measurement and logging of the consumption of energy and resources, and, where technically feasible, other environmental impact the deployment and use of the systems may have over their entire lifecycle;***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		(e) draw up extensive technical documentation and intelligible instructions for use, in order to enable the downstream providers to comply with their obligations pursuant to Articles 16 and 28(1);. *(f) establish a quality management system to ensure and document compliance with this Article, with the possibility to experiment in fulfilling this requirement,* *(g) register that foundation model in the EU database referred to in Article 60, in accordance with the instructions outlined in Annex VIII point C.* *When fulfilling those requirements, the generally acknowledged state of the art shall be taken into account, including as reflected in relevant harmonised standards or common specifications, as well as the latest assessment and measurement methods, reflected in particular in benchmarking guidance and capabilities referred to in Article 58a;* *3. Providers of foundation models shall, for a period ending 10 years after their foundation models have been placed on the market or put into service, keep the technical documentation referred to in paragraph 2(e) at the disposal of the national competent authorities*		

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		4. Providers of foundation models used in AI systems specifically intended to generate, with varying levels of autonomy, content such as complex text, images, audio, or video ("generative AI") and providers who specialise a foundation model into a generative AI system, shall in addition a) comply with the transparency obligations outlined in Article 52 (1), b) train, and where applicable, design and develop the foundation model in such a way as to ensure adequate safeguards against the generation of content in breach of Union law in line with the generally-acknowledged state of the art, and without prejudice to fundamental rights, including the freedom of expression, c) without prejudice to Union or national or Union legislation on copyright, document and make publicly available a sufficiently detailed summary of the use of training data protected under copyright law.		
Article 29				
380	Article 29 Obligations of users of high-risk AI systems	Article 29 Obligations of users of high-risk AI systems	Article 29 Obligations of users of high-risk AI systems	Article 29 Obligations of ~~users~~***deployers*** of high-risk AI systems

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				Text Origin: Commission Proposal
Article 29(1)				
G 381	1. Users of high-risk AI systems shall use such systems in accordance with the instructions of use accompanying the systems, pursuant to paragraphs 2 and 5.	1. ~~Users~~***Deployers*** of high-risk AI systems shall ***take appropriate technical and organisational measures to ensure they*** use such systems in accordance with the instructions of use accompanying the systems, pursuant to paragraphs 2 and 5 ***of this Article***.	1. Users of high-risk AI systems shall use such systems in accordance with the instructions of use accompanying the systems, pursuant to paragraphs 2 and 5 ***of this Article***.	1. ~~Users~~***Deployers*** of high-risk AI systems shall ***take appropriate technical and organisational measures to ensure they*** use such systems in accordance with the instructions of use accompanying the systems, pursuant to paragraphs 2 and 5 ***of this Article***. Text Origin: EP Mandate
Article 29(1a)				
G 381a			***1a. Users shall assign human oversight to natural persons who have the necessary competence, training and authority.***	***1a. Deployers shall assign human oversight to natural persons who have the necessary competence, training and authority, as well as the necessary support.***
Article 29(1b)				
G 381b		***1a.*** ***To the extent deployers exercise control over the high-risk AI system, they shall*** ***i) implement human oversight according to the requirements laid down in this Regulation***		***1a.*** ***To the extent deployers exercise control over the high-risk AI system, they shall ensure that the natural persons assigned to ensure human oversight of the high-risk AI systems have the necessary competence, training and authority as well as the necessary support***

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		(ii) ensure that the natural persons assigned to ensure human oversight of the high-risk AI systems are competent, properly qualified and trained, and have the necessary resources in order to ensure the effective supervision of the AI system in accordance with Article 14 ***(iii) ensure that relevant and appropriate robustness and cybersecurity measures are regularly monitored for effectiveness and are regularly adjusted or updated.***		Text Origin: EP Mandate
Article 29(2)				
G 382	2. The obligations in paragraph 1 are without prejudice to other user obligations under Union or national law and to the user's discretion in organising its own resources and activities for the purpose of implementing the human oversight measures indicated by the provider.	2. The obligations in paragraph 1 ***and 1a,*** are without prejudice to other ~~user~~***deployer*** obligations under Union or national law and to the ~~user~~***deployer***'s discretion in organising its own resources and activities for the purpose of implementing the human oversight measures indicated by the provider.	2. The obligations in paragraph 1 ***and 1a*** are without prejudice to other user obligations under Union or national law and to the user's discretion in organising its own resources and activities for the purpose of implementing the human oversight measures indicated by the provider.	2. The obligations in paragraph 1 ***and 1a,*** are without prejudice to other ~~user~~***deployer*** obligations under Union or national law and to the ~~user~~***deployer***'s discretion in organising its own resources and activities for the purpose of implementing the human oversight measures indicated by the provider. Text Origin: EP Mandate
Article 29(3)				
G 383	3. Without prejudice to paragraph 1, to the extent the user exercises	3. Without prejudice to paragraph 1 ***and 1a***, to the extent the	3. Without prejudice to paragraph 1, to the extent the user exercises	3. Without prejudice to paragraph 1 ***and 1a***, to the extent the

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	control over the input data, that user shall ensure that input data is relevant in view of the intended purpose of the high-risk AI system.	~~user~~***deployer*** exercises control over the input data, that ~~user~~***deployer*** shall ensure that input data is relevant ***and sufficiently representative*** in view of the intended purpose of the high-risk AI system.	control over the input data, that user shall ensure that input data is relevant in view of the intended purpose of the high-risk AI system.	~~user~~***deployer*** exercises control over the input data, that ~~user~~***deployer*** shall ensure that input data is relevant ***and sufficiently representative*** in view of the intended purpose of the high-risk AI system. Text Origin: EP Mandate
Article 29(4), first subparagraph				
G 384	4. Users shall monitor the operation of the high-risk AI system on the basis of the instructions of use. When they have reasons to consider that the use in accordance with the instructions of use may result in the AI system presenting a risk within the meaning of Article 65(1) they shall inform the provider or distributor and suspend the use of the system. They shall also inform the provider or distributor when they have identified any serious incident or any malfunctioning within the meaning of Article 62 and interrupt the use of the AI system. In case the user is not able to reach the provider, Article 62 shall apply mutatis mutandis.	4. ~~Users~~***Deployers*** shall monitor the operation of the high-risk AI system on the basis of the instructions of use ***and when relevant, inform providers in accordance with Article 61***. When they have reasons to consider that the use in accordance with the instructions of use may result in the AI system presenting a risk within the meaning of Article 65(1) they shall***, without undue delay,*** inform the provider or distributor and ***relevant national supervisory authorities and*** suspend the use of the system. They shall also ***immediately*** inform ***first*** the provider***, and then the importer*** or distributor ***and relevant national supervisory authorities*** when they have identified any serious incident or any malfunctioning within the meaning of Article 62 and interrupt the use of the AI system. ~~In case the user~~***If the deployer*** is not able to	4. Users shall ***implement human oversight and*** monitor the operation of the high-risk AI system on the basis of the instructions of use. When they have reasons to consider that the use in accordance with the instructions of use may result in the AI system presenting a risk within the meaning of Article 65(1) they shall inform the provider or distributor and suspend the use of the system. They shall also inform the provider or distributor when they have identified any serious incident ~~or any malfunctioning within the meaning of Article 62~~ and interrupt the use of the AI system. In case the user is not able to reach the provider, Article 62 shall apply mutatis mutandis. ***This obligation shall not cover sensitive operational data of users of AI systems which are law enforcement authorities.***	4. ~~Users~~***4. Deployers*** shall monitor the operation of the high-risk AI system on the basis of the instructions of use ***and when relevant, inform providers in accordance with Article 61***. When they have reasons to consider that the use in accordance with the instructions of use may result in the AI system presenting a risk within the meaning of Article 65(1) they shall***, without undue delay,*** inform the provider or distributor and ***relevant market surveillance authority and*** suspend the use of the system. They shall also ***immediately*** inform ***first*** the provider***, and then the importer*** or distributor ***and relevant market surveillance authorities*** when they have identified any serious incident ~~or any malfunctioning within the meaning of Article 62 and interrupt the use of the AI system. In case the~~ G

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		reach the provider, Article 62 shall apply mutatis mutandis.		~~user is not able to reach the provider, Article 62 shall apply mutatis mutandis~~***If the deployer is not able to reach the provider, Article 62 shall apply mutatis mutandis. This obligation shall not cover sensitive operational data of users of AI systems which are law enforcement authorities***. Text Origin: EP Mandate
Article 29(4), second subparagraph				
385	For users that are credit institutions regulated by Directive 2013/36/EU, the monitoring obligation set out in the first subparagraph shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to Article 74 of that Directive.	For ~~users~~***deployers*** that are credit institutions regulated by Directive 2013/36/EU, the monitoring obligation set out in the first subparagraph shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to Article 74 of that Directive.	For users that are ~~credit~~***financial*** institutions ~~regulated by Directive 2013/36/EU~~***subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation***, the monitoring obligation set out in the first subparagraph shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to ~~Article 74 of that Directive~~***the relevant financial service legislation***.	For ~~users~~***deployers*** that are ~~credit~~***financial*** institutions ~~regulated by Directive 2013/36/EU~~***subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation***, the monitoring obligation set out in the first subparagraph shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to ~~Article 74 of that Directive~~***the relevant financial service legislation***. Text Origin: Council Mandate
Article 29(5), first subparagraph				
386	5. Users of high-risk AI systems shall keep the logs automatically	5. ~~Users~~***Deployers*** of high-risk AI systems shall keep the logs	5. Users of high-risk AI systems shall keep the logs***, referred to in***	5. ~~Users~~***Deployers*** of high-risk AI systems shall keep the logs

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	generated by that high-risk AI system, to the extent such logs are under their control. The logs shall be kept for a period that is appropriate in the light of the intended purpose of the high-risk AI system and applicable legal obligations under Union or national law.	automatically generated by that high-risk AI system, to the extent ***that*** such logs are under their control ***and are required for ensuring and demonstrating compliance with this Regulation, for ex-post audits of any reasonably foreseeable malfunction, incidents or misuses of the system, or for ensuring and monitoring for the proper functioning of the system throughout its lifecycle. Without prejudice to applicable Union or national law,*** ~~.~~ the logs shall be kept for a period ~~that is appropriate in the light of the intended purpose of the high-risk AI system and applicable legal obligations under Union or national law~~***of at least six months. The retention period shall be in accordance with industry standards and appropriate to the intended purpose of the high-risk AI system***.	***Article 12(1),*** automatically generated by that high-risk AI system, to the extent such logs are under their control. ~~The logs~~***They*** shall ~~be kept~~***keep them*** for a period ~~that is appropriate in the light of the intended purpose of the high-risk AI system and applicable legal obligations under Union or national law~~***of at least six months, unless provided otherwise in applicable Union or national law, in particular in Union law on the protection of personal data***.	automatically generated by that high-risk AI system~~,~~ to the extent such logs are under their control~~.~~ ~~The logs shall be kept~~ for a period ~~that is~~ appropriate ~~in the light of~~***to*** the intended purpose of the high-risk AI system***, of at least six months, unless provided otherwise in applicable*** ~~and applicable legal obligations under~~ Union or national law***, in particular in Union law on the protection of personal data***.
Article 29(5), second subparagraph				
G 387	Users that are credit institutions regulated by Directive 2013/36/EU shall maintain the logs as part of the documentation concerning internal governance arrangements, processes and mechanisms pursuant to Article 74 of that Directive.	~~Users~~***Deployers*** that are credit institutions regulated by Directive 2013/36/EU shall maintain the logs as part of the documentation concerning internal governance arrangements, processes and mechanisms pursuant to Article 74 of that Directive.	Users that are ~~credit~~***financial*** institutions ~~regulated by Directive 2013/36/EU~~***subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation*** shall maintain the logs as part of the documentation ~~concerning internal governance~~	~~Users~~***Deployers*** that are ~~credit~~***financial*** institutions ~~regulated by Directive 2013/36/EU~~***subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation*** shall maintain the logs as part of the documentation ~~concerning internal governance~~ G

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			~~arrangements, processes and mechanisms~~kept pursuant to ~~Article 74 of that Directive~~the relevant Union financial service legislation.	~~arrangements, processes and mechanisms~~kept pursuant to ~~Article 74 of that Directive~~the relevant Union financial service legislation. Text Origin: Council Mandate
Article 29(5), second subparagraph, point (a)				
G 387a		(a) Prior to putting into service or use a high-risk AI system at the workplace, deployers shall consult workers representatives with a view to reaching an agreement in accordance with Directive 2002/14/EC and inform the affected employees that they will be subject to the system.		(a) Prior to putting into service or use a high-risk AI system at the workplace, deployers who are employers shall inform workers representatives and the affected workers that they will be subject to the system. This information shall be provided, where applicable, in accordance with the rules and procedures laid down in Union and national law and practice on information of workers and their representatives. Text Origin: EP Mandate
Article 29(5), second subparagraph, point (b)				
G 387b		(b) Deployers of high-risk AI systems that are public authorities or Union institutions, bodies, offices and agencies or undertakings referred to in Article 51(1a)(b) shall comply with the registration obligations referred to in Article 51.		(b) Deployers of high-risk AI systems that are public authorities or Union institutions, bodies, offices and agencies shall comply with the registration obligations referred to in Article 51. When they find that the system that they envisage to use has not been registered in the EU database

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				referred to in Article 60 they shall not use that system and shall inform the provider or the distributor. Text Origin: EP Mandate
Article 29(5), second subparagraph, point (c)				
G 387c			***5a. Users of high-risk AI systems that are public authorities, agencies or bodies, with the exception of law enforcement, border control, immigration or asylum authorities, shall comply with the registration obligations referred to in Article 51. When they find that the system that they envisage to use has not been registered in the EU database referred to in Article 60 they shall not use that system and shall inform the provider or the distributor.***	***(c) Deployers of high-risk AI systems that are public authorities, including Union institutions, bodies, offices and agencies referred to in Article 51(1a)(b) shall comply with the registration obligations referred to in Article 51.*** G
Article 29(6)				
G 388	6. Users of high-risk AI systems shall use the information provided under Article 13 to comply with their obligation to carry out a data protection impact assessment under Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, where applicable.	6. ~~Users~~***Where applicable, deployers*** of high-risk AI systems shall use the information provided under Article 13 to comply with their obligation to carry out a data protection impact assessment under Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, ~~where applicable~~***a***	6. Users of high-risk AI systems shall use the information provided under Article 13 to comply with their obligation to carry out a data protection impact assessment under Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, where applicable.	6. ~~Users~~***Where applicable, deployers*** of high-risk AI systems shall use the information provided under Article 13 to comply with their obligation to carry out a data protection impact assessment under Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, ~~where applicable.~~ G

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		summary of which shall be published, having regard to the specific use and the specific context in which the AI system is intended to operate. Deployers may revert in part to those data protection impact assessments for fulfilling some of the obligations set out in this article, insofar as the data protection impact assesment fulfill those obligations.		Text Origin: EP Mandate
Article 29(6a)				
G 388a			***6a. Users shall cooperate with national competent authorities on any action those authorities take in relation to an AI system, of which they are the user.***	
Article 29(6a)				
G 388b				***6a. Without prejudice to Directive (EU) 2016/680, in the framework of an investigation for the targeted search of a person convicted or suspected of having committed a criminal offence, the deployer of an AI system for post-remote biometric identification shall request an authorisation, prior, or without undue delay and no later than 48hours, by a judicial authority or an administrative authority whose decision is binding and subject to***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				judicial review, for the use of the system, except when the system is used for the initial identification of a potential suspect based on objective and verifiable facts directly linked to the offence. Each use shall be limited to what is strictly necessary for the investigation of a specific criminal offence. ***If the requested authorisation provided for in the first subparagraph of this paragraph is rejected, the use of the post remote biometric identification system linked to that authorisation shall be stopped with immediate effect and the personal data linked to the use of the system for which the authorisation was requested shall be deleted.*** ***In any case, such AI system for post remote biometric identification shall not be used for law enforcement purposes in an untargeted way, without any link to a criminal offence, a criminal proceeding, a genuine and present or genuine and foreseeable threat of a criminal offence or the search for a specific missing person.*** ***It shall be ensured that no decision that produces an adverse legal effect on a person may be taken by***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				the law enforcement authorities solely based on the output of these post remote biometric identification systems. ***This paragraph is without prejudice to the provisions of Article 10 of the Directive (EU) 2016/680 and Article 9 of the GDPR for the processing of biometric data.*** ***Regardless of the purpose or deployer, each use of these systems shall be documented in the relevant police file and shall be made available to the relevant market surveillance authority and the national data protection authority upon request, excluding the disclosure of sensitive operational data related to law enforcement. This subparagraph shall be without prejudice to the powers conferred by the Directive 2016/680 to supervisory authorities.*** ***Deployers shall, in addition, submit annual reports to the relevant market surveillance and national data protection authorities on the uses of post-remote biometric identification systems, excluding the disclosure of sensitive operational data related to law enforcement. The reports can be aggregated to cover several deployments in one operation.***

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				Member States may introduce, in accordance with Union law, more restrictive laws on the use of post remote biometric identification systems.
Article 29(6b)				
G 388c		***6b. Without prejudice to Article 52, deployers of high-risk AI systems referred to in Annex III, which make decisions or assist in making decisions related to natural persons, shall inform the natural persons that they are subject to the use of the high-risk AI system. This information shall include the intended purpose and the type of decisions it makes. The deployer shall also inform the natural person about its right to an explanation referred to in Article 68c.***		***6b. Without prejudice to Article 52, deployers of high-risk AI systems referred to in Annex III that make decisions or assist in making decisions related to natural persons shall inform the natural persons that they are subject to the use of the high-risk AI system. For high risk AI systems used for law enforcement purposes Article 13 of Directive 2016/680 shall apply.*** Text Origin: EP Mandate
Article 29(6c)				
G 388d		***6c. Deployers shall cooperate with the relevant national competent authorities on any action those authorities take in relation with the high-risk system in order to implement this Regulation.***		***6c. Deployers shall cooperate with the relevant national competent authorities on any action those authorities take in relation with the high-risk system in order to implement this Regulation.*** Text Origin: EP Mandate

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 29(6d)				
388e				
Article 29a				
388f		***Article 29a*** ***Fundamental rights impact assessment for high-risk AI systems*** ***Prior to putting a high-risk AI system as defined in Article 6(2) into use, with the exception of AI systems intended to be used in area 2 of Annex III, deployers shall conduct an assessment of the systems' impact in the specific context of use. This assessment shall include, at a minimum, the following elements:*** ***(a) a clear outline of the intended purpose for which the system will be used;*** ***(b) a clear outline of the intended geographic and temporal scope of the system's use;*** ***(c) categories of natural persons and groups likely to be affected by the use of the system;*** ***(d) verification that the use of the system is compliant with relevant Union and national law on fundamental rights;*** ***(e) the reasonably foreseeable impact on fundamental rights of putting the high-risk AI system into use;*** ***(f) specific risks of harm likely to***		***Article 29a*** ***Fundamental rights impact assessment for high-risk AI systems*** ***1. Prior to deploying a high-risk AI system as defined in Article 6(2) into use, with the exception of AI systems intended to be used in the area listed in point 2 of Annex III, deployers that are bodies governed by public law or private operators providing public services and operators deploying high-risk systems referred to in Annex III, point 5, b) and d) shall perform an assessment of the impact on fundamental rights that the use of the system may produce. For that purpose, deployers shall perform an assessment consisting of:*** ***a) a description of the deployer's processes in which the high-risk AI system will be used in line with its intended purpose;*** ***b) a description of the period of time and frequency in which each high-risk AI system is intended to be used***

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		impact marginalised persons or vulnerable groups; *(g) the reasonably foreseeable adverse impact of the use of the system on the environment;* *(h) a detailed plan as to how the harms and the negative impact on fundamental rights identified will be mitigated.* *(i) the governance system the deployer will put in place, including human oversight, complaint-handling and redress.* *2. If a detailed plan to mitigate the risks outlined in the course of the assessment outlined in paragraph 1 cannot be identified, the deployer shall refrain from putting the high-risk AI system into use and inform the provider and the National supervisory authority without undue delay. National supervisory authorities, pursuant to Articles 65 and 67, shall take this information into account when investigating systems which present a risk at national level.* *3. The obligation outlined under paragraph 1 applies for the first use of the high-risk AI system. The deployer may, in similar cases, draw back on previously conducted fundamental rights impact assessment or existing assessment carried out by providers. If, during the use of the high-risk AI system, the deployer considers that the*		*c) the categories of natural persons and groups likely to be affected by its use in the specific context;* *d) the specific risks of harm likely to impact the categories of persons or group of persons identified pursuant point (c), taking into account the information given by the provider pursuant to article 13;* *e) a description of the implementation of human oversight measures, according to the instructions of use;* *f) the measures to be taken in case of the materialization of these risks, including their arrangements for internal governance and complaint mechanisms.* *2. The obligation laid down in paragraph 1 applies to the first use of the high-risk AI system. The deployer may, in similar cases, rely on previously conducted fundamental rights impact assessments or existing impact assessments carried out by provider. If, during the use of the high-risk AI system, the deployer considers that any of the factors listed in paragraph 1change are or no*

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		criteria listed in paragraph 1 are not longer met, it shall conduct a new fundamental rights impact assessment. *4. In the course of the impact assessment, the deployer, with the exception of SMEs, shall shall notify national supervisory authority and relevant stakeholders and shall, to best extent possible, involve representatives of the persons or groups of persons that are likely to be affected by the high-risk AI system, as identified in paragraph 1, including but not limited to: equality bodies, consumer protection agencies, social partners and data protection agencies, with a view to receiving input into the impact assessment. The deployer shall allow a period of six weeks for bodies to respond. SMEs may voluntarily apply the provisions laid down in this paragraph.* *In the case referred to in Article 47(1), public authorities may be exempted from this obligations.* *5. The deployer that is a public authority or an undertaking referred to in Article 51(1a) (b) shall publish a summary of the results of the impact assessment as part of the registration of use pursuant to their obligation under Article 51(2).* *6. Where the deployer is already*		*longer up to date, the deployer will take the necessary steps to update the information.* *3. Once the impact assessment has been performed, the deployer shall notify the market surveillance authority of the results of the assessment, submitting the filled template referred to in paragraph 5 as a part of the notification. In the case referred to in Article 47(1), deployers may be exempted from these obligations.* *4. If any of the obligations laid down in this article are 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 fundamental rights impact assessment referred to in paragraph 1 shall be conducted in conjunction with that data protection impact assessment.* *5. The AI Office shall develop a template for a questionnaire, including through an automated tool, to facilitate users to implement the obligations of this Article in a simplified manner.* Text Origin: EP Mandate

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		required to carry out a data protection impact assessment under Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the fundamental rights impact assessment referred to in paragraph 1 shall be conducted in conjunction with the data protection impact assessment. The data protection impact assessment shall be published as an addendum.		
Chapter 4				
G 389	Chapter 4 NOTIFIYING AUTHORITIES AND NOTIFIED BODIES	Chapter 4 NOTIFIYING AUTHORITIES AND NOTIFIED BODIES	Chapter 4 NOTIFIYING AUTHORITIES AND NOTIFIED BODIES	Chapter 4 NOTIFIYING AUTHORITIES AND NOTIFIED BODIES Text Origin: Commission Proposal G
Article 30				
G 390	Article 30 Notifying authorities	Article 30 Notifying authorities	Article 30 Notifying authorities	Article 30 Notifying authorities Text Origin: Commission Proposal G
Article 30(1)				
G 391	1. Each Member State shall designate or establish a notifying authority responsible for setting up and carrying out the necessary	1. Each Member State shall designate or establish a notifying authority responsible for setting up and carrying out the necessary	1. Each Member State shall designate or establish ~~a~~***at least one*** notifying authority responsible for setting up and carrying out the	1. Each Member State shall designate or establish ~~a~~***at least one*** notifying authority responsible for setting up and carrying out the G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring.	procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring. ***Those procedures shall be developed in cooperation between the notifying authorities of all Member States.***	necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring.	necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring. ***These procedures shall be developed in cooperation between the notifying authorities of all Member States.***
Article 30(2)				
G 392	2. Member States may designate a national accreditation body referred to in Regulation (EC) No 765/2008 as a notifying authority.	2. Member States may designate a national accreditation body referred to in Regulation (EC) No 765/2008 as a notifying authority.	2. Member States may ~~designate~~***decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by*** a national accreditation body ~~referred to in~~ ***within the meaning of and in accordance with*** Regulation (EC) No 765/2008 ~~as a notifying authority~~.	2. Member States may ~~designate~~***decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by*** a national accreditation body ~~referred to in~~ ***within the meaning of and in accordance with*** Regulation (EC) No 765/2008 ~~as a notifying authority~~. G
Article 30(3)				
G 393	3. Notifying authorities shall be established, organised and operated in such a way that no conflict of interest arises with conformity assessment bodies and the objectivity and impartiality of their activities are safeguarded.	3. Notifying authorities shall be established, organised and operated in such a way that no conflict of interest arises with conformity assessment bodies and the objectivity and impartiality of their activities are safeguarded.	3. Notifying authorities shall be established, organised and operated in such a way that no conflict of interest arises with conformity assessment bodies and the objectivity and impartiality of their activities are safeguarded.	3. Notifying authorities shall be established, organised and operated in such a way that no conflict of interest arises with conformity assessment bodies and the objectivity and impartiality of their activities are safeguarded. Text Origin: Commission Proposal G
Article 30(4)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 394	4. Notifying authorities shall be organised in such a way that decisions relating to the notification of conformity assessment bodies are taken by competent persons different from those who carried out the assessment of those bodies.	4. Notifying authorities shall be organised in such a way that decisions relating to the notification of conformity assessment bodies are taken by competent persons different from those who carried out the assessment of those bodies.	4. Notifying authorities shall be organised in such a way that decisions relating to the notification of conformity assessment bodies are taken by competent persons different from those who carried out the assessment of those bodies.	4. Notifying authorities shall be organised in such a way that decisions relating to the notification of conformity assessment bodies are taken by competent persons different from those who carried out the assessment of those bodies. Text Origin: Commission Proposal
Article 30(5)				
G 395	5. Notifying authorities shall not offer or provide any activities that conformity assessment bodies perform or any consultancy services on a commercial or competitive basis.	5. Notifying authorities shall not offer or provide any activities that conformity assessment bodies perform or any consultancy services on a commercial or competitive basis.	5. Notifying authorities shall not offer or provide any activities that conformity assessment bodies perform or any consultancy services on a commercial or competitive basis.	5. Notifying authorities shall not offer or provide any activities that conformity assessment bodies perform or any consultancy services on a commercial or competitive basis. Text Origin: Commission Proposal
Article 30(6)				
G 396	6. Notifying authorities shall safeguard the confidentiality of the information they obtain.	6. Notifying authorities shall safeguard the confidentiality of the information they obtain.	6. Notifying authorities shall safeguard the confidentiality of the information they obtain ***in accordance with Article 70***.	6. Notifying authorities shall safeguard the confidentiality of the information they obtain ***in accordance with Article 70***.
Article 30(7)				
G 397	7. Notifying authorities shall have a sufficient number of competent	7. Notifying authorities shall have a sufficient number of competent	7. Notifying authorities shall have ~~*a sufficient*~~***an adequate*** number of	7. Notifying authorities shall have ***an adequate*** ~~*a sufficient*~~ number of

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	personnel at their disposal for the proper performance of their tasks.	personnel at their disposal for the proper performance of their tasks. ***Where applicable, competent personnel shall have the necessary expertise, such as a degree in an appropriate legal field, in the supervision of fundamental rights enshrined in the Charter of Fundamental Rights of the European Union.***	competent personnel at their disposal for the proper performance of their tasks.	competent personnel at their disposal for the proper performance of their tasks. ***Competent personnel shall have the necessary expertise, where applicable, for their function, in fields such as information technologies, artificial intelligence and law, including the supervision of fundamental rights.***
Article 30(8)				
G 398	8. Notifying authorities shall make sure that conformity assessments are carried out in a proportionate manner, avoiding unnecessary burdens for providers and that notified bodies perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of the AI system in question.	8. Notifying authorities shall make sure that conformity assessments are carried out in a proportionate ***and timely*** manner, avoiding unnecessary burdens for providers, and that notified bodies perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of the AI system in question. ***Particular attention shall be paid to minimising administrative burdens and compliance costs for micro and small enterprises as defined in the Annex to Commission Recommendation 2003/361/EC.***	*deleted*	G
Article 31				
G *399*	Article 31 Application of a conformity	Article 31 Application of a conformity	Article 31 Application of a conformity	Article 31 Application of a conformity G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	assessment body for notification	assessment body for notification	assessment body for notification	assessment body for notification Text Origin: Commission Proposal
Article 31(1)				
G 400	1. Conformity assessment bodies shall submit an application for notification to the notifying authority of the Member State in which they are established.	1. Conformity assessment bodies shall submit an application for notification to the notifying authority of the Member State in which they are established.	1. Conformity assessment bodies shall submit an application for notification to the notifying authority of the Member State in which they are established.	1. Conformity assessment bodies shall submit an application for notification to the notifying authority of the Member State in which they are established. Text Origin: Commission Proposal
Article 31(2)				
G 401	2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 33. Any valid document related to existing designations of the applicant notified body under any other Union harmonisation	2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 33. Any valid document related to existing designations of the applicant notified body under any other Union harmonisation	2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the ~~artificial intelligence technologies~~***AI systems*** for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 33. Any valid document related to existing designations of the applicant notified body under any other Union harmonisation	2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the ~~artificial intelligence technologies~~***types of AI systems*** for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 33. Any valid document related to existing designations of the applicant notified body under any other Union harmonisation

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	legislation shall be added.	legislation shall be added.	legislation shall be added.	legislation shall be added.
Article 31(3)				
G 402	3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 33. 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 their designation procedure under this Regulation, as appropriate.	3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 33. 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 their designation procedure under this Regulation, as appropriate.	3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with ***all*** the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 33. 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 their designation procedure under this Regulation, as appropriate. ***The notified body shall update the documentation referred to in paragraph 2 and paragraph 3 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 33.***	3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with ***all*** the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 33. 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 their designation procedure under this Regulation, as appropriate. ***The notified body shall update the documentation referred to in paragraph 2 and paragraph 3 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 33.*** G
Article 32				
G 403	Article 32 Notification procedure	Article 32 Notification procedure	Article 32 Notification procedure	Article 32 Notification procedure G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Article 32(1)				
404	1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 33.	1. Notifying authorities ~~may~~***shall*** notify only conformity assessment bodies which have satisfied the requirements laid down in Article 33.	1. Notifying authorities may ***only*** notify ~~only~~ conformity assessment bodies which have satisfied the requirements laid down in Article 33.	1. Notifying authorities may ~~notify~~ only ***notify*** conformity assessment bodies which have satisfied the requirements laid down in Article 33.
Article 32(2)				
405	2. Notifying authorities shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.	2. Notifying authorities shall notify the Commission and the other Member States 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 ***those bodies to*** the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.	2. Notifying authorities shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission ***of each conformity assessment body referred to in paragraph 1***. Text Origin: EP Mandate
Article 32(3)				
406	3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies concerned.	3. The notification ***referred to in paragraph 2*** shall include full details of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies concerned***, as well as the relevant attestation of competence***.	3. The notification ***referred to in paragraph 2*** shall include full details of the conformity assessment activities, the conformity assessment module or modules and the ~~artificial intelligence technologies concerned~~***AI systems concerned and the relevant attestation of competence. Where a notification is***	3. The notification ***referred to in paragraph 2*** shall include full details of the conformity assessment activities, the conformity assessment module or modules and the ~~artificial intelligence technologies~~***types of AI systems*** concerned ***and the relevant attestation of competence. Where a notification is not based on an***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			not based on an accreditation certificate as referred to in Article 31 (2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 33.	***accreditation certificate as referred to in Article 31 (2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 33***.
Article 32(4)				
G 407	4. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within one month of a notification.	4. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within ~~one month of a~~***two weeks of the validation of the*** notification ***where it includes an accreditation certificate referred to in Article 31(2), or within two months of the notification where it incudes documentary evidence referred to in Article 31(3***.	4. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within ~~one month~~***two weeks*** of a notification ***by a notifying authority where it includes an accreditation certificate referred to in Article 31(2), or within two months of a notification by the notifying authority where it includes documentary evidence referred to in Article 31(3)***.	4. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within ~~one month~~***two weeks of a notification by a notifying authority where it includes an accreditation certificate referred to in Article 31(2), or within two months*** of a notification ***by the notifying authority where it includes documentary evidence referred to in Article 31(3)***. G
Article 32(4a)				
G 407a		***4a. Where objections are raised, the Commission shall without delay enter into consultation with the***		***4a. Where objections are raised, the Commission shall without delay enter into consultation with the*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		relevant Member States and the conformity assessment body. In view thereof, the Commission shall decide whether the authorisation is justified or not. The Commission shall address its decision to the Member State concerned and the relevant conformity assessment body.		***relevant Member States and the conformity assessment body. In view thereof, the Commission shall decide whether the authorisation is justified or not. The Commission shall address its decision to the Member State concerned and the relevant conformity assessment body.***
Article 32(4b)				
G 407b		***4b. Member States shall notify the Commission and the other Member States of conformity assessment bodies.***		***4b. Deleted [covered by par.2]*** G
Article 32(5)				
G 408	5. Notifying authorities shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.	5. Notifying authorities shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.	*deleted*	G
Article 33				
G *409*	Article 33 Notified bodies	Article 33 Notified bodies	Article 33 ***Requirements relating to notified bodies*** ~~*notified bodies*~~	Article 33 ***Requirements relating to notified bodies*** ~~*notified bodies*~~ Text Origin: Council Mandate G
Article 33(1)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 410	1. Notified bodies shall verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43.	1. Notified bodies shall verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43.	1. ***A*** notified ~~*bodies*~~***body*** shall ~~*verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43*~~***be established under national law and have legal personality***.	1. ***A*** notified ~~*bodies*~~***body*** shall ~~*verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43*~~***be established under national law of a Member State and have legal personality***.
Article 33(2)				
G 411	2. Notified bodies shall satisfy the organisational, quality management, resources and process requirements that are necessary to fulfil their tasks.	2. Notified bodies shall satisfy the organisational, quality management, resources and process requirements that are necessary to fulfil their tasks ***as well as the minimum cybersecurity requirements set out for public administration entities identified as operators of essential services pursuant to Directive (EU 2022/2555***.	2. Notified bodies shall satisfy the organisational, quality management, resources and process requirements that are necessary to fulfil their tasks.	2. Notified bodies shall satisfy the organisational, quality management, resources and process requirements that are necessary to fulfil their tasks***, as well as suitable cybersecurity requirements***.
Article 33(3)				
G 412	3. The organisational structure, allocation of responsibilities, reporting lines and operation of notified bodies shall be such as to ensure that there is confidence in the performance by and in the results of the conformity assessment activities that the notified bodies conduct.	3. The organisational structure, allocation of responsibilities, reporting lines and operation of notified bodies shall be such as to ensure that there is confidence in the performance by and in the results of the conformity assessment activities that the notified bodies conduct.	3. The organisational structure, allocation of responsibilities, reporting lines and operation of notified bodies shall be such as to ensure that there is confidence in the performance by and in the results of the conformity assessment activities that the notified bodies conduct.	3. The organisational structure, allocation of responsibilities, reporting lines and operation of notified bodies shall be such as to ensure that there is confidence in the performance by and in the results of the conformity assessment activities that the notified bodies conduct. Text Origin: Commission Proposal

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 33(4)				
413	4. Notified bodies shall be independent of the provider of a high-risk AI system in relation to which it performs conformity assessment activities. Notified bodies shall also be independent of any other operator having an economic interest in the high-risk AI system that is assessed, as well as of any competitors of the provider.	4. Notified bodies shall be independent of the provider of a high-risk AI system in relation to which it performs conformity assessment activities. Notified bodies shall also be independent of any other operator having an economic interest in the high-risk AI system that is assessed, as well as of any competitors of the provider. ***This shall not preclude the use of assessed AI systems that are necessary for the operations of the conformity assessment body or the use of such systems for personal purposes.***	4. Notified bodies shall be independent of the provider of a high-risk AI system in relation to which it performs conformity assessment activities. Notified bodies shall also be independent of any other operator having an economic interest in the high-risk AI system that is assessed, as well as of any competitors of the provider.	4. Notified bodies shall be independent of the provider of a high-risk AI system in relation to which it performs conformity assessment activities. Notified bodies shall also be independent of any other operator having an economic interest in the high-risk AI system that is assessed, as well as of any competitors of the provider. ***This shall not preclude the use of assessed AI systems that are necessary for the operations of the conformity assessment body or the use of such systems for personal purposes.*** Text Origin: EP Mandate
Article 33(4a)				
413a		***4a. A conformity assessment pursuant to paragraph 1 shall be performed by employees of notified bodies who have not provided any other other service related to the matter assessed than the conformity assessment to the provider of a high-risk AI system nor to any legal person connected to that provider in the 12 months' period before the assessment and have committed to***		***4a. A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, development, marketing or use of high-risk AI systems, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		not providing them with such services in the 12 month period following the completion of the assessment.		***judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.***
Article 33(5)				
G 414	5. Notified bodies shall be organised and operated so as to safeguard the independence, objectivity and impartiality of their activities. Notified bodies shall document and implement a structure and procedures to safeguard impartiality and to promote and apply the principles of impartiality throughout their organisation, personnel and assessment activities.	5. Notified bodies shall be organised and operated so as to safeguard the independence, objectivity and impartiality of their activities. Notified bodies shall document and implement a structure and procedures to safeguard impartiality and to promote and apply the principles of impartiality throughout their organisation, personnel and assessment activities.	5. Notified bodies shall be organised and operated so as to safeguard the independence, objectivity and impartiality of their activities. Notified bodies shall document and implement a structure and procedures to safeguard impartiality and to promote and apply the principles of impartiality throughout their organisation, personnel and assessment activities.	5. Notified bodies shall be organised and operated so as to safeguard the independence, objectivity and impartiality of their activities. Notified bodies shall document and implement a structure and procedures to safeguard impartiality and to promote and apply the principles of impartiality throughout their organisation, personnel and assessment activities. Text Origin: Commission Proposal
Article 33(6)				
G 415	6. Notified bodies shall have documented procedures in place ensuring that their personnel, committees, subsidiaries, subcontractors and any associated body or personnel of external bodies respect the confidentiality of the information which comes into their possession during the performance of conformity assessment activities,	6. Notified bodies shall have documented procedures in place ensuring that their personnel, committees, subsidiaries, subcontractors and any associated body or personnel of external bodies respect the confidentiality of the information which comes into their possession during the performance of conformity assessment activities,	6. Notified bodies shall have documented procedures in place ensuring that their personnel, committees, subsidiaries, subcontractors and any associated body or personnel of external bodies respect the confidentiality of the information ***in accordance with Article 70*** which comes into their possession during the performance	6. Notified bodies shall have documented procedures in place ensuring that their personnel, committees, subsidiaries, subcontractors and any associated body or personnel of external bodies respect the confidentiality of the information ***in accordance with Article 70*** which comes into their possession during the performance

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	except when disclosure is required by law. The staff of notified bodies shall be bound to observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the notifying authorities of the Member State in which their activities are carried out.	except when disclosure is required by law. The staff of notified bodies shall be bound to observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the notifying authorities of the Member State in which their activities are carried out. ***Any information and documentation obtained by notified bodies pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.***	of conformity assessment activities, except when disclosure is required by law. The staff of notified bodies shall be bound to observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the notifying authorities of the Member State in which their activities are carried out.	of conformity assessment activities, except when disclosure is required by law. The staff of notified bodies shall be bound to observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the notifying authorities of the Member State in which their activities are carried out. Text Origin: Council Mandate
Article 33(7)				
G 416	7. Notified bodies shall have procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the AI system in question.	7. Notified bodies shall have procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the AI system in question.	7. Notified bodies shall have procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the AI system in question.	7. Notified bodies shall have procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the AI system in question. Text Origin: Commission Proposal
Article 33(8)				
G 417	8. Notified bodies shall take out appropriate liability insurance for their conformity assessment activities, unless liability is assumed	8. Notified bodies shall take out appropriate liability insurance for their conformity assessment activities, unless liability is assumed	8. Notified bodies shall take out appropriate liability insurance for their conformity assessment activities, unless liability is assumed	8. Notified bodies shall take out appropriate liability insurance for their conformity assessment activities, unless liability is assumed

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	by the Member State concerned in accordance with national law or that Member State is directly responsible for the conformity assessment.	by the Member State concerned in accordance with national law or that Member State is directly responsible for the conformity assessment.	by the Member State ~~concerned~~***in which they are located*** in accordance with national law or that Member State is ***itself*** directly responsible for the conformity assessment.	by the Member State ~~concerned~~***in which they are established*** in accordance with national law or that Member State is ***itself*** directly responsible for the conformity assessment. Text Origin: Council Mandate
Article 33(9)				
G 418	9. Notified bodies shall be capable of carrying out all the tasks falling to them under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by notified bodies themselves or on their behalf and under their responsibility.	9. Notified bodies shall be capable of carrying out all the tasks falling to them under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by notified bodies themselves or on their behalf and under their responsibility.	9. Notified bodies shall be capable of carrying out all the tasks falling to them under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by notified bodies themselves or on their behalf and under their responsibility.	9. Notified bodies shall be capable of carrying out all the tasks falling to them under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by notified bodies themselves or on their behalf and under their responsibility. Text Origin: Commission Proposal
Article 33(10)				
G 419	10. Notified bodies shall have sufficient internal competences to be able to effectively evaluate the tasks conducted by external parties on their behalf. To that end, at all times and for each conformity assessment procedure and each type of high-risk AI system in relation to which they have been designated, the notified	10. Notified bodies shall have sufficient internal competences to be able to effectively evaluate the tasks conducted by external parties on their behalf. To that end, at all times and for each conformity assessment procedure and each type of high-risk AI system in relation to which they have been designated, the notified	10. Notified bodies shall have sufficient internal competences to be able to effectively evaluate the tasks conducted by external parties on their behalf. ~~*To that end, at all times and for each conformity assessment procedure and each type of high-risk AI system in relation to which they have been designated,*~~ The notified	10. Notified bodies shall have sufficient internal competences to be able to effectively evaluate the tasks conducted by external parties on their behalf. ~~*To that end, at all times and for each conformity assessment procedure and each type of high-risk AI system in relation to which they have been designated,*~~ The notified

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	body shall have permanent availability of sufficient administrative, technical and scientific personnel who possess experience and knowledge relating to the relevant artificial intelligence technologies, data and data computing and to the requirements set out in Chapter 2 of this Title.	body shall have permanent availability of sufficient administrative, technical and scientific personnel who possess experience and knowledge relating to the relevant artificial intelligence technologies, data and data computing and to the requirements set out in Chapter 2 of this Title.	body shall have permanent availability of sufficient administrative, technical***, legal*** and scientific personnel who possess experience and knowledge relating to the relevant artificial intelligence technologies, data and data computing and to the requirements set out in Chapter 2 of this Title.	body shall have permanent availability of sufficient administrative, technical***, legal*** and scientific personnel who possess experience and knowledge relating to the relevant ***types of*** artificial intelligence ~~*technologies*~~***systems***, data and data computing and to the requirements set out in Chapter 2 of this Title. Text Origin: Council Mandate
Article 33(11)				
G 420	11. Notified bodies shall participate in coordination activities as referred to in Article 38. They shall also take part directly or be represented in European standardisation organisations, or ensure that they are aware and up to date in respect of relevant standards.	11. Notified bodies shall participate in coordination activities as referred to in Article 38. They shall also take part directly or be represented in European standardisation organisations, or ensure that they are aware and up to date in respect of relevant standards.	11. Notified bodies shall participate in coordination activities as referred to in Article 38. They shall also take part directly or be represented in European standardisation organisations, or ensure that they are aware and up to date in respect of relevant standards.	11. Notified bodies shall participate in coordination activities as referred to in Article 38. They shall also take part directly or be represented in European standardisation organisations, or ensure that they are aware and up to date in respect of relevant standards. Text Origin: Commission Proposal
Article 33(12)				
G 421	12. Notified bodies shall make available and submit upon request all relevant documentation, including the providers' documentation, to the notifying authority referred to in Article 30 to allow it to conduct its assessment,	12. Notified bodies shall make available and submit upon request all relevant documentation, including the providers' documentation, to the notifying authority referred to in Article 30 to allow it to conduct its assessment,	*deleted*	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	designation, notification, monitoring and surveillance activities and to facilitate the assessment outlined in this Chapter.	designation, notification, monitoring and surveillance activities and to facilitate the assessment outlined in this Chapter.		
Article 33a				
G *421a*			***Article 33a*** ***Presumption of conformity with requirements relating to notified bodies***	***Article 33a*** ***Presumption of conformity with requirements relating to notified bodies*** Text Origin: Council Mandate
Article 33a, first paragraph				
G 421b			***Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union it shall be presumed to comply with the requirements set out in Article 33 in so far as the applicable harmonised standards cover those requirements.***	***Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union it shall be presumed to comply with the requirements set out in Article 33 in so far as the applicable harmonised standards cover those requirements.*** Text Origin: Council Mandate
Article 34				
G 422	Article 34 Subsidiaries of and subcontracting	Article 34 Subsidiaries of and subcontracting	Article 34 Subsidiaries of and subcontracting	Article 34 Subsidiaries of and subcontracting

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	by notified bodies	by notified bodies	by notified bodies	by notified bodies Text Origin: Commission Proposal
Article 34(1)				
423	1. Where a notified body subcontracts specific tasks connected with the conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements laid down in Article 33 and shall inform the notifying authority accordingly.	1. Where a notified body subcontracts specific tasks connected with the conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements laid down in Article 33 and shall inform the notifying authority accordingly.	1. Where a notified body subcontracts specific tasks connected with the conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements laid down in Article 33 and shall inform the notifying authority accordingly.	1. Where a notified body subcontracts specific tasks connected with the conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements laid down in Article 33 and shall inform the notifying authority accordingly. Text Origin: Commission Proposal
Article 34(2)				
424	2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.	2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.	2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.	2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established. Text Origin: Commission Proposal
Article 34(3)				
425	3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the provider.	3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the provider.	3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the provider.	3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the provider.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Notified bodies shall make a list of their subsidiaries publicly available.		***Notified bodies shall make a list of their subsidiaries publicly available.*** Text Origin: EP Mandate
Article 34(4)				
G 426	4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.	4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the ~~assessment~~***verification*** of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.	4. ~~*Notified bodies shall keep at the disposal of the notifying authority*~~ The relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation ***shall be kept at the disposal of the notifying authority for a period of 5 years from the termination date of the subcontracting activity***.	4. ~~*Notified bodies shall keep at the disposal of the notifying authority*~~ The relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation ***shall be kept at the disposal of the notifying authority for a period of 5 years from the termination date of the subcontracting activity***. G
Article 34a				
G 426a			***Article 34a*** ***Operational obligations of notified bodies***	***Article 34a*** ***Operational obligations of notified bodies*** Text Origin: Council Mandate G
Article 34a(1)				
G 426b			***1. Notified bodies shall verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43.***	***1. Notified bodies shall verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43.*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Council Mandate
Article 34a(2)				
G 426c			***2. Notified bodies shall perform their activities while avoiding unnecessary burdens for providers, and taking due account of the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of the high risk AI system in question. In so doing, the notified body shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the high risk AI system with the requirements of this Regulation.***	***2. Notified bodies shall perform their activities while avoiding unnecessary burdens for providers, and taking due account of the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of the high risk AI system in question. In so doing, the notified body shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the high risk AI system with the requirements of this Regulation. Particular attention shall be paid to minimising administrative burdens and compliance costs for micro and small enterprises as defined in Commission Recommendation 2003/361/EC.*** G
Article 34a(3)				
G 426d			***3. Notified bodies shall make available and submit upon request all relevant documentation, including the providers' documentation, to the notifying authority referred to in Article 30 to allow that authority to conduct its assessment, designation,***	***3. Notified bodies shall make available and submit upon request all relevant documentation, including the providers' documentation, to the notifying authority referred to in Article 30 to allow that authority to conduct its assessment, designation,*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			notification, monitoring activities and to facilitate the assessment outlined in this Chapter.	***notification, monitoring activities and to facilitate the assessment outlined in this Chapter.***
Article 35				
G 427	Article 35 Identification numbers and lists of notified bodies designated under this Regulation	Article 35 Identification numbers and lists of notified bodies ~~*designated under this Regulation*~~	Article 35 Identification numbers and lists of notified bodies designated under this Regulation	Article 35 Identification numbers and lists of notified bodies designated under this Regulation Text Origin: Commission Proposal
Article 35(1)				
G 428	1. The Commission shall assign an identification number to notified bodies. It shall assign a single number, even where a body is notified under several Union acts.	1. The Commission shall assign an identification number to notified bodies. It shall assign a single number, even where a body is notified under several Union acts.	1. The Commission shall assign an identification number to notified bodies. It shall assign a single number, even where a body is notified under several Union acts.	1. The Commission shall assign an identification number to notified bodies. It shall assign a single number, even where a body is notified under several Union acts. Text Origin: Commission Proposal
Article 35(2)				
G 429	2. The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified. The Commission shall	2. The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified. The Commission shall	2. The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified. The Commission shall	2. The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified. The Commission shall

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	ensure that the list is kept up to date.	ensure that the list is kept up to date.	ensure that the list is kept up to date.	ensure that the list is kept up to date. Text Origin: Commission Proposal
Article 36				
G 430	Article 36 Changes to notifications	Article 36 Changes to notifications	Article 36 Changes to notifications	Article 36 Changes to notifications Text Origin: Commission Proposal
Article 36(-1)				
G 430a			***-1. The notifying authority shall notify the Commission and the other Member States of any relevant changes to the notification of a notified body via the electronic notification tool referred to in Article 32(2).***	***-1. The notifying authority shall notify the Commission and the other Member States of any relevant changes to the notification of a notified body via the electronic notification tool referred to in Article 32(2).*** Text Origin: Council Mandate
Article 36(-1a), first subparagraph				
G 430b			***-1a. The procedures described in Article 31 and 32 shall apply to extensions of the scope of the notification. For changes to the notification other than extensions of its scope, the procedures laid down in the following paragraphs shall apply.***	***-1a. The procedures described in Article 31 and 32 shall apply to extensions of the scope of the notification. For changes to the notification other than extensions of its scope, the procedures laid down in the following paragraphs shall apply.***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Council Mandate
Article 36(-1a), second subparagraph				
G 430c			***Where a notified body decides to cease its conformity assessment activities it shall inform the notifying authority and the providers concerned as soon as possible and in the case of a planned cessation one year before ceasing its activities. The certificates may remain valid for a temporary period of nine months after cessation of the notified body's activities on condition that another notified body has confirmed in writing that it will assume responsibilities for the AI systems covered by those certificates. The new notified body shall complete a full assessment of the AI systems affected by the end of that period before issuing new certificates for those systems. Where the notified body has ceased its activity, the notifying authority shall withdraw the designation.***	***Where a notified body decides to cease its conformity assessment activities it shall inform the notifying authority and the providers concerned as soon as possible and in the case of a planned cessation one year before ceasing its activities. The certificates may remain valid for a temporary period of nine months after cessation of the notified body's activities on condition that another notified body has confirmed in writing that it will assume responsibilities for the AI systems covered by those certificates. The new notified body shall complete a full assessment of the AI systems affected by the end of that period before issuing new certificates for those systems. Where the notified body has ceased its activity, the notifying authority shall withdraw the designation.*** Text Origin: Council Mandate
Article 36(1)				
G 431	1. Where a notifying authority has suspicions or has been informed that	1. Where a notifying authority has suspicions or has been informed that	1. Where a notifying authority has ~~suspicions or has been~~	1. Where a notifying authority has ~~suspicions or has been~~

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	a notified body no longer meets the requirements laid down in Article 33, or that it is failing to fulfil its obligations, that authority shall without delay investigate the matter with the utmost diligence. In that context, it shall inform the notified body concerned about the objections raised and give it the possibility to make its views known. If the notifying authority comes to the conclusion that the notified body investigation no longer meets the requirements laid down in Article 33 or that it is failing to fulfil its obligations, it shall restrict, suspend or withdraw the notification as appropriate, depending on the seriousness of the failure. It shall also immediately inform the Commission and the other Member States accordingly.	a notified body no longer meets the requirements laid down in Article 33, or that it is failing to fulfil its obligations, that authority shall without delay investigate the matter with the utmost diligence. In that context, it shall inform the notified body concerned about the objections raised and give it the possibility to make its views known. If the notifying authority comes to the conclusion that the notified body ~~investigation~~ no longer meets the requirements laid down in Article 33 or that it is failing to fulfil its obligations, it shall restrict, suspend or withdraw the notification as appropriate, depending on the seriousness of the failure. It shall also immediately inform the Commission and the other Member States accordingly.	~~informed~~***sufficient reasons to consider*** that a notified body no longer meets the requirements laid down in Article 33, or that it is failing to fulfil its obligations, ~~that authority shall without delay investigate the matter with the utmost diligence. In that context, it shall inform~~***the notifying authority shall, provided that the*** the notified body ~~concerned about the objections raised and give it the possibility~~***had the opportunity*** to make its views known~~. If the notifying authority comes to the conclusion that the notified body investigation no longer meets the requirements laid down in Article 33 or that it is failing to fulfil its obligations, it shall~~ ***,*** restrict, suspend or withdraw ~~the~~ notification as appropriate, depending on the seriousness of the failure ***to meet those requirements or fulfil those obligations***. It shall ~~also~~ immediately inform the Commission and the other Member States accordingly.	~~informed~~***sufficient reasons to consider*** that a notified body no longer meets the requirements laid down in Article 33, or that it is failing to fulfil its obligations, ~~that~~***the notifying*** authority shall without delay investigate the matter with the utmost diligence. In that context, it shall inform the notified body concerned about the objections raised and give it the possibility to make its views known. If the notifying authority comes to the conclusion that the notified body ~~investigation~~ no longer meets the requirements laid down in Article 33 or that it is failing to fulfil its obligations, it shall restrict, suspend or withdraw ~~the~~ notification as appropriate, depending on the seriousness of the failure ***to meet those requirements or fulfil those obligations***. It shall ~~also~~ immediately inform the Commission and the other Member States accordingly. Text Origin: Council Mandate
Article 36(2)				
432	2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying authority shall take	2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying authority shall take	*deleted*	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	appropriate steps to ensure that the files of that notified body are either taken over by another notified body or kept available for the responsible notifying authorities at their request.	appropriate steps to ensure that the files of that notified body are either taken over by another notified body or kept available for the responsible notifying authorities***, and market surveillance authority*** at their request.		
Article 36(2a)				
G *432a*			***2a. Where its designation has been suspended, restricted, or fully or partially withdrawn, the notified body shall inform the manufacturers concerned at the latest within 10 days.***	***2a. Where its designation has been suspended, restricted, or fully or partially withdrawn, the notified body shall inform the manufacturers concerned at the latest within 10 days.*** G
Article 36(2b)				
G 432b			***2b. In the event of restriction, suspension or withdrawal of a notification, the notifying authority shall take appropriate steps to ensure that the files of the notified body concerned are kept and make them available to notifying authorities in other Member States and to market surveillance authorities at their request.***	***2b. In the event of restriction, suspension or withdrawal of a notification, the notifying authority shall take appropriate steps to ensure that the files of the notified body concerned are kept and make them available to notifying authorities in other Member States and to market surveillance authorities at their request.*** G
Article 36(2c)				
G 432c			***2c. In the event of restriction, suspension or withdrawal of a***	***2c. In the event of restriction, suspension or withdrawal of a*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			designation, the notifying authority shall:	***designation, the notifying authority shall:***
Article 36(2c), point (a)				
G 432d			***(a) assess the impact on the certificates issued by the notified body;***	***(a) assess the impact on the certificates issued by the notified body;*** Text Origin: Council Mandate
Article 36(2c), point (b)				
G 432e			***(b) submit a report on its findings to the Commission and the other Member States within three months of having notified the changes to the notification;***	***(b) submit a report on its findings to the Commission and the other Member States within three months of having notified the changes to the notification;*** Text Origin: Council Mandate
Article 36(2c), point (c)				
G 432f			***(c) require the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued in order to ensure the conformity of AI systems on the market;***	***(c) require the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued in order to ensure the conformity of AI systems on the market;*** Text Origin: Council Mandate
Article 36(2c), point (d)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 432g			*(d) inform the Commission and the Member States about certificates of which it has required their suspension or withdrawal;*	*(d) inform the Commission and the Member States about certificates of which it has required their suspension or withdrawal;* Text Origin: Council Mandate
Article 36(2c), point (e)				
G 432h			*(e) provide the national competent authorities of the Member State in which the provider has its registered place of business with all relevant information about the certificates for which it has required suspension or withdrawal. That competent authority shall take the appropriate measures, where necessary, to avoid a potential risk to health, safety or fundamental rights.*	*(e) provide the national competent authorities of the Member State in which the provider has its registered place of business with all relevant information about the certificates for which it has required suspension or withdrawal. That competent authority shall take the appropriate measures, where necessary, to avoid a potential risk to health, safety or fundamental rights.* Text Origin: Council Mandate
Article 36(2d)				
G 432i			*2d. With the exception of certificates unduly issued, and where a notification has been suspended or restricted, the certificates shall remain valid in the following circumstances:*	*2d. With the exception of certificates unduly issued, and where a notification has been suspended or restricted, the certificates shall remain valid in the following circumstances:* Text Origin: Council Mandate

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 36(2d), point (a)				
G 432j			*(a) the notifying authority has confirmed, within one month of the suspension or restriction, that there is no risk to health, safety or fundamental rights in relation to certificates affected by the suspension or restriction, and the notifying authority has outlined a timeline and actions anticipated to remedy the suspension or restriction; or*	*(a) the notifying authority has confirmed, within one month of the suspension or restriction, that there is no risk to health, safety or fundamental rights in relation to certificates affected by the suspension or restriction, and the notifying authority has outlined a timeline and actions anticipated to remedy the suspension or restriction; or* Text Origin: Council Mandate
Article 36(2d), point (b)				
G 432k			*(b) the notifying authority has confirmed that no certificates relevant to the suspension will be issued, amended or re-issued during the course of the suspension or restriction, and states whether the notified body has the capability of continuing to monitor and remain responsible for existing certificates issued for the period of the suspension or restriction. In the event that the authority responsible for notified bodies determines that the notified body does not have the capability to support existing certificates issued, the provider shall provide to the national competent authorities of the*	*(b) the notifying authority has confirmed that no certificates relevant to the suspension will be issued, amended or re-issued during the course of the suspension or restriction, and states whether the notified body has the capability of continuing to monitor and remain responsible for existing certificates issued for the period of the suspension or restriction. In the event that the authority responsible for notified bodies determines that the notified body does not have the capability to support existing certificates issued, the provider shall provide to the national competent authorities of the*

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Member State in which the provider of the system covered by the certificate has its registered place of business, within three months of the suspension or restriction, a written confirmation that another qualified notified body is temporarily assuming the functions of the notified body to monitor and remain responsible for the certificates during the period of suspension or restriction.	***Member State in which the provider of the system covered by the certificate has its registered place of business, within three months of the suspension or restriction, a written confirmation that another qualified notified body is temporarily assuming the functions of the notified body to monitor and remain responsible for the certificates during the period of suspension or restriction.*** Text Origin: Council Mandate
Article 36(2e), first subparagraph				
G 432l			***2e. With the exception of certificates unduly issued, and where a designation has been withdrawn, the certificates shall remain valid for a period of nine months in the following circumstances:***	***2e. With the exception of certificates unduly issued, and where a designation has been withdrawn, the certificates shall remain valid for a period of nine months in the following circumstances:*** Text Origin: Council Mandate
Article 36(2e), first subparagraph, point (a)				
G 432m			***(a) where the national competent authority of the Member State in which the provider of the AI system covered by the certificate has its registered place of business has confirmed that there is no risk to health, safety and fundamental***	***(a) where the national competent authority of the Member State in which the provider of the AI system covered by the certificate has its registered place of business has confirmed that there is no risk to health, safety and fundamental***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			rights associated with the systems in question; and	***rights associated with the systems in question; and***
Article 36(2e), first subparagraph, point (b)				
G 432n			***(b) another notified body has confirmed in writing that it will assume immediate responsibilities for those systems and will have completed assessment of them within twelve months of the withdrawal of the designation.***	***(b) another notified body has confirmed in writing that it will assume immediate responsibilities for those systems and will have completed assessment of them within twelve months of the withdrawal of the designation.*** Text Origin: Council Mandate
Article 36(2e), second subparagraph				
G 432o			***In the circumstances referred to in the first subparagraph, the national competent authority of the Member State in which the provider of the system covered by the certificate has its place of business may extend the provisional validity of the certificates for further periods of three months, which altogether shall not exceed twelve months.***	***In the circumstances referred to in the first subparagraph, the national competent authority of the Member State in which the provider of the system covered by the certificate has its place of business may extend the provisional validity of the certificates for further periods of three months, which altogether shall not exceed twelve months.*** Text Origin: Council Mandate
Article 36(2f)				
G 432p			***The national competent authority or the notified body assuming the functions of the notified body***	***2f. The national competent authority or the notified body assuming the functions of the***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			affected by the change of notification shall immediately inform the Commission, the other Member States and the other notified bodies thereof.	***notified body affected by the change of notification shall immediately inform the Commission, the other Member States and the other notified bodies thereof.*** Text Origin: Council Mandate
Article 37				
G 433	Article 37 Challenge to the competence of notified bodies	Article 37 Challenge to the competence of notified bodies	Article 37 Challenge to the competence of notified bodies	Article 37 Challenge to the competence of notified bodies Text Origin: Commission Proposal
Article 37(1)				
G 434	1. The Commission shall, where necessary, investigate all cases where there are reasons to doubt whether a notified body complies with the requirements laid down in Article 33.	1. The Commission shall, where necessary, investigate all cases where there are reasons to doubt ~~whether~~***the competence of*** a notified body ~~complies with the requirements laid down in Article 33~~***or the continued fulfilment by a notified body of the applicable requirements and responsibilities***.	1. The Commission shall, where necessary, investigate all cases where there are reasons to doubt whether a notified body complies with the requirements laid down in Article 33.	1. The Commission shall, where necessary, investigate all cases where there are reasons~~-~~ to doubt ~~whether~~***the competence of*** a notified body ~~complies with~~***or the continued fulfilment by a notified body of*** the requirements laid down in Article 33 ***and their applicable responsibilities***.
Article 37(2)				
G 435	2. The Notifying authority shall provide the Commission, on request, with all relevant information relating to the notification of the notified	2. The Notifying authority shall provide the Commission, on request, with all relevant information relating to the notification ***or the***	2. The notifying authority shall provide the Commission, on request, with all relevant information relating to the notification of the notified	2. The Notifying authority shall provide the Commission, on request, with all relevant information relating to the notification ***or the***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	body concerned.	***maintenance of the competence*** of the notified body concerned.	body concerned.	***maintenance of the competence*** of the notified body concerned. Text Origin: EP Mandate
Article 37(3)				
G 436	3. The Commission shall ensure that all confidential information obtained in the course of its investigations pursuant to this Article is treated confidentially.	3. The Commission shall ensure that all ~~*confidential*~~***sensitive*** information obtained in the course of its investigations pursuant to this Article is treated confidentially.	3. The Commission shall ensure that all confidential information obtained in the course of its investigations pursuant to this Article is treated confidentially ***in accordance with Article 70***.	3. The Commission shall ensure that all ~~*confidential*~~***sensitive*** information obtained in the course of its investigations pursuant to this Article is treated confidentially ***in accordance with Article 70***. Text Origin: EP Mandate
Article 37(4)				
G 437	4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements laid down in Article 33, it shall adopt a reasoned decision requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(2).	4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements ~~*laid down in Article 33*~~***for its notification***, it shall ~~*adopt a reasoned decision requesting*~~***inform*** the notifying Member State ***accordingly and request it*** to take the necessary corrective measures, including ***suspension or*** withdrawal of ***the*** notification if necessary***. Where the Member State fails to take the necessary corrective measures, the Commission may, by means of an implementing act, suspend, restrict or withdraw the designation***. That implementing act shall be adopted in accordance with	4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements laid down in Article 33, it shall ~~*adopt a reasoned decision requesting the notifying Member State*~~***inform the notifying authority of the reasons of such an ascertainment and request it*** to take the necessary corrective measures, including ***the suspension, restriction or*** withdrawal of ~~*notification*~~***the designation*** if necessary***. Where the notifying authority fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the notification***. That	4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements ~~*laid down in Article 33*~~***for its notification***, it shall ~~*adopt a reasoned decision requesting*~~ ***inform*** -the notifying Member State ***accordingly and request it*** to take the necessary corrective measures, including ***suspension or*** withdrawal of ***the*** notification if necessary***. Where the Member State fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the designation***. That implementing act shall be adopted in accordance with

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		the examination procedure referred to in Article 74(2).	implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(2).	the examination procedure referred to in Article 74(2).
Article 38				
G 438	Article 38 Coordination of notified bodies	Article 38 Coordination of notified bodies	Article 38 Coordination of notified bodies	Article 38 Coordination of notified bodies Text Origin: Commission Proposal
Article 38(1)				
G 439	1. The Commission shall ensure that, with regard to the areas covered by this Regulation, appropriate coordination and cooperation between notified bodies active in the conformity assessment procedures of AI systems pursuant to this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.	1. The Commission shall ensure that, with regard to the areas covered by this Regulation, appropriate coordination and cooperation between notified bodies active in the conformity assessment procedures of AI systems pursuant to this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.	1. The Commission shall ensure that, with regard to ~~the areas covered by this Regulation~~***high-risk AI systems***, appropriate coordination and cooperation between notified bodies active in the conformity assessment procedures~~ of AI systems~~ pursuant to this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.	1. The Commission shall ensure that, with regard to ~~the areas covered by this Regulation~~***high-risk AI systems***, appropriate coordination and cooperation between notified bodies active in the conformity assessment procedures~~ of AI systems~~ pursuant to this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.
Article 38(2)				
G 440	2. Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.	2. Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.	2. ~~Member States~~***The notifying authority*** shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.	2. ~~Member States~~***The notifying authority*** shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Council Mandate
Article 38(2a)				
G 440a		***2a. The Commission shall provide for the exchange of knowledge and best practices between the Member States' national authorities responsible for notification policy.***		***2a. The Commission shall provide for the exchange of knowledge and best practices between the Member States' notifying authorities.*** Text Origin: EP Mandate
Article 39				
G 441	Article 39 Conformity assessment bodies of third countries	Article 39 Conformity assessment bodies of third countries	Article 39 Conformity assessment bodies of third countries	Article 39 Conformity assessment bodies of third countries Text Origin: Commission Proposal
Article 39, first paragraph				
G 442	Conformity assessment bodies established under the law of a third country with which the Union has concluded an agreement may be authorised to carry out the activities of notified Bodies under this Regulation.	Conformity assessment bodies established under the law of a third country with which the Union has concluded an agreement may be authorised to carry out the activities of notified Bodies under this Regulation.	Conformity assessment bodies established under the law of a third country with which the Union has concluded an agreement may be authorised to carry out the activities of notified Bodies under this Regulation***, provided that they meet the requirements in Article 33***.	Conformity assessment bodies established under the law of a third country with which the Union has concluded an agreement may be authorised to carry out the activities of notified Bodies under this Regulation***, provided that they meet the requirements in Article 33 or they ensure an equivalent level of compliance***.
Chapter 5				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 443	Chapter 5 STANDARDS, CONFORMITY ASSESSMENT, CERTIFICATES, REGISTRATION	Chapter 5 STANDARDS, CONFORMITY ASSESSMENT, CERTIFICATES, REGISTRATION	Chapter 5 STANDARDS, CONFORMITY ASSESSMENT, CERTIFICATES, REGISTRATION	Chapter 5 STANDARDS, CONFORMITY ASSESSMENT, CERTIFICATES, REGISTRATION Text Origin: Commission Proposal
Article 40				
G 444	Article 40 Harmonised standards	Article 40 Harmonised standards	Article 40 Harmonised standards	Article 40 Harmonised standards ***and standardisation deliverables*** Text Origin: Commission Proposal
Article 40, first paragraph				
G 445	High-risk AI systems which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title, to the extent those standards cover those requirements.	High-risk AI systems ***and foundation models*** which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union ***in accordance with Regulation (EU) 1025/2012*** shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title ***or Article 28b***, to the extent those standards cover those requirements.	High-risk AI systems ***or general purpose AI systems*** which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title ***or, as applicable, with requirements set out in Article 4a and Article 4b***, to the extent those standards cover those requirements.	High-risk AI systems which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union ***in accordance with Regulation (EU) 1025/2012*** shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title ***or, as applicable, with the requirements set out in [Chapter on GPAI]***, to the extent those standards cover those requirements.
Article 40, first paragraph a				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 445a			*-1. When issuing a standardisation request to European standardisation organisations in accordance with Article 10 of Regulation 1025/2012, the Commission shall specify that standards are coherent, clear and drafted in such a way that they aim to fulfil in particular the following objectives:*	*2. The Commission shall issue standardisation requests covering all requirements of Title II Chapter III and as applicable [GPAI Chapter] of this Regulation, in accordance with Article 10 of Regulation EU (No)1025/2012 without undue delay. The standardisation request shall also ask for deliverables on reporting and documentation processes to improve AI systems resource performance, such as reduction of energy and other resources consumption of the high-risk AI system during its lifecycle, and on energy efficient development of general-purpose AI models. When preparing standardisation request, the Commission shall consult the Board and relevant stakeholders, including the Advisory Forum.* Text Origin: Council Mandate
Article 40, third paragraph				
G 445b			*(a) ensure that AI systems placed on the market or put into service in the Union are safe and respect Union values and strengthen the Union's open strategic autonomy;*	*When issuing a standardisation request to European standardisation organisations, the Commission shall specify that standards have to be consistent, including with the existing and future standards developed in the various sectors for products covered*

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				by the existing Union safety legislation listed in Annex II, clear and aimed at ensuring that AI systems or models placed on the market or put into service in the Union meet the relevant requirements laid down in this Regulation.
Article 40, third paragraph, point (a)				
G 445c			***(b) promote investment and innovation in AI, including through increasing legal certainty, as well as competitiveness and growth of the Union market;***	Text Origin: Council Mandate G
Article 40, third paragraph, point (b)				
G 445d			***(c) enhance multistakeholder governance, representative of all relevant European stakeholders (e.g. industry, SMEs, civil society, researchers);***	Text Origin: Council Mandate G
Article 40, third paragraph, point (c)				
G 445e			***(d) contribute to strengthening global cooperation on standardisation in the field of AI that is consistent with Union values and interests.***	Text Origin: Council Mandate G
Article 40, fourth paragraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 445f			***The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the above objectives.***	***The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the above objectives in accordance with Article 24 of Regulation EU 1025/2012.*** Text Origin: Council Mandate
Article 40, (1a)				
G 445g		***1a. The Commission shall issue standardisation requests covering all requirements of this Regulation, in accordance with Article 10 of Regulation EU (No)1025/2012 by... [two months after the date of entry into force of this Regulation]. When preparing standardisation request, the Commission shall consult the AI Office and the Advisory Forum;***		
Article 40, fifth paragraph				
G 445h		***1c The actors involved in the standardisation process shall take into account the general principles for trustworthy AI set out in Article 4(a), seek to promote investment and innovation in AI as well as competitiveness and growth of the Union market, and contribute to strengthening global cooperation***		***1c The actors involved in the standardisation process shall seek to promote investment and innovation in AI, including through increasing legal certainty, as well as competitiveness and growth of the Union market, and contribute to strengthening global cooperation on standardisation and taking into***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		on standardisation and taking into account existing international standards in the field of AI that are consistent with Union values, fundamental rights and interests, and ensure a balanced representation of interests and effective participation of all relevant stakeholders in accordance with Articles 5, 6, and 7 of Regulation (EU) No 1025/2012		***account existing international standards in the field of AI that are consistent with Union values, fundamental rights and interests, and enhance multi-stakeholder governance ensuring a balanced representation of interests and effective participation of all relevant stakeholders in accordance with Articles 5, 6, and 7 of Regulation (EU) No 1025/2012*** Text Origin: EP Mandate
Article 40, (1b)				
G 445i		***1b When issuing a standardisation request to European standardisation organisations, the Commission shall specify that standards have to be consistent, including with the sectorial law listed in Annex II, and aimed at ensuring that AI systems or foundation models placed on the market or put into service in the Union meet the relevant requirements laid down in this Regulation;***		
Article 41				
G 446	Article 41 Common specifications	Article 41 Common specifications	Article 41 Common specifications	Article 41 Common specifications Text Origin: Commission

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Proposal
Article 41(1)				
G 447	1. Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns, the Commission may, by means of implementing acts, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).	*deleted*	1. ~~*Where harmonised standards referred to in Article 40 do not exist or where*~~ The Commission ~~*considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns, the Commission may, by means of implementing acts, adopt*~~***is empowered to adopt, after consulting the AI Board referred to in Article 56, implementing acts in accordance with the examination procedure referred to in Article 74(2) establishing*** common ***technical*** specifications ~~*in respect of*~~***for*** the requirements set out in Chapter 2 of this Title~~*. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).*~~***, or, as applicable, with requirements set out in Article 4a and Article 4b, where the following conditions have been fulfilled:***	1. ~~*Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns, the Commission may, by means of implementing acts, adopt common specifications in respect of the*~~***The Commission is empowered to adopt, after consulting the Advisory Forum referred to in Article 58, implementing acts in accordance with the examination procedure referred to in Article 74(2) establishing common specifications for the requirements set out in Chapter 2 of this Title or, as applicable, with*** requirements set out in ~~*Chapter 2 of this Title. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).*~~***Article [GPAI Chapter], for AI systems within the scope of this Regulation, where the following conditions have been fulfilled:***
Article 41(1), point (a)				
G 447a				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			(a) no reference to harmonised standards covering the relevant essential safety or fundamental right concerns is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;	*(a) the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more European standardisation organisations to draft a harmonised standard for the requirements set out in Chapter 2 of this Title; and* *(i) the request has not been accepted by any of the European standardisation organisations; or* *(ii) the harmonised standards addressing that request are not delivered within the deadline set in accordance with article 10(1) of Regulation 1025/2012; or* *(iii) the relevant harmonised standards insufficiently address fundamental rights concerns; or* *(iv) the harmonised standards do not comply with the request; and*
Article 41(1), point (b)				
G 447b			*(b) the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more European standardisation organisations to draft a harmonised standard for the requirements set out in Chapter 2 of this Title;*	*(b) no reference to harmonised standards covering the requirements referred to in Chapter II of this Title has been published in the Official Journal of the European Union, in accordance with Regulation (EU) No 1025/2012, and no such reference is expected to be published within a reasonable period.* Text Origin: Council Mandate G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 41(1), point (c)				
G 447c			***(c) the request referred to in point (b) has not been accepted by any of the European standardisation organisations or the harmonised standards addressing that request are not delivered within the deadline set in accordance with article 10(1) of Regulation 1025/2012 or those standards do not comply with the request.***	***(c)*** Text Origin: Council Mandate
Article 41(1), point (d)				
G 447d			***1a. Before preparing a draft implementing act, the Commission shall inform the committee referred to in Article 22 of Regulation EU (No) 1025/2012 that it considers that the conditions in paragraph 1 are fulfilled.***	***1a. Before preparing a draft implementing act, the Commission shall inform the committee referred to in Article 22 of Regulation EU (No) 1025/2012 that it considers that the conditions in paragraph 1 are fulfilled.*** Text Origin: Council Mandate
Article 41(1), point (e)				
G 447e		***1a. The Commission may, by means of implementing act adopted in accordance with the examination procedure referred to in Article 74(2) and after consulting the AI Office and the AI Advisory Forum,***		Included in row 477

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		adopt common specifications in respect of the requirements set out in Chapter 2 of this Title or Article 28b wherein all of the following conditions are fulfilled: ***(a) there is no reference to harmonised standards already published in the Official Journal of the European Union related to the essential requirement(s), unless the harmonised standard in question is an existing standard that must be revised;*** ***(b) the Commission has requested one or more European standardisation organisations to draft a harmonised standard for the essential requirement(s) set out in Chapter 2;*** ***(c) the request referred to in point (b) has not been accepted by any of the European standardisation organisations; or there are undue delays in the establishment of an appropriate harmonised standard; or the standard provided does not satisfy the requirements of the relevant Union law, or does not comply with the request of the Commission.***		
Article 41(1), point (f)				
G 447f		***1b. The Commission shall develop common specifications for the methodology to fulfil the reporting***		G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		and documentation requirement on the consumption of energy and resources during development, training and deployment of the high risk AI system.		
Article 41(1c)				
G 447g		***1c. Where the Commission considers there to be a need to address specific fundamental rights concerns, common specifications adopted by the Commission in accordance with paragraph 1a shall also address those specific fundamental rights concerns.***		G
Article 41(2)				
G 448	2. The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant bodies or expert groups established under relevant sectorial Union law.	2. The Commission ***shall, throughout the whole process of drafting***~~, when preparing~~ the common specifications referred to in ~~paragraph 1, shall gather the views of relevant~~***paragraphs 1a and 1b, regularly consult the AI Office and the Advisory Forum, the European standardisation organisations and*** bodies or expert groups established under relevant sectorial Union law ***as well as other relevant stakeholders. The Commission shall fulfil the objectives referred to in Article 40 (1c) and duly justify why it decided to resort to common***	2. ***In the early preparation of the draft implementing act establishing***~~The Commission, when preparing~~ the common ~~specifications~~***specification, the Commission shall fulfil the objectives*** referred to in ~~paragraph 1, shall~~***Article 40(2) and*** gather the views of relevant bodies or expert groups established under relevant sectorial Union law. ***Based on that consultation, the Commission shall prepare the draft implementing act.***	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		specifications. ***Where the Commission intends to adopt common specifications pursuant to paragraph 1a of this Article, it shall also clearly identify the specific fundamental rights concern to be addressed.*** ***When adopting common specifications pursuant to paragraphs 1a and 1b of this Article, the Commission shall take into account the opinion issued by the AI Office referred to in Article 56e(b) of this Regulation. Where the Commission decides not to follow the opinion of the AI Office, it shall provide a reasoned explanation to the AI Office.***		
Article 41(3)				
G 449	3. High-risk AI systems which are in conformity with the common specifications referred to in paragraph 1 shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title, to the extent those common specifications cover those requirements.	3. High-risk AI systems which are in conformity with the common specifications referred to in ~~paragraph 1~~***paragraphs 1a and 1b*** shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title, to the extent those common specifications cover those requirements~~.~~	3. High-risk AI systems ***or general purpose AI systems*** which are in conformity with the common specifications referred to in paragraph 1 shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title ***or, as applicable, with requirements set out in Article 4a and Article 4b***, to the extent those common specifications cover those requirements.	3. High-risk AI systems which are in conformity with the common specifications referred to in paragraph 1***, or parts thereof,*** shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title, to the extent those common specifications cover those requirements. G
Article 41(3a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 449a		***3a. Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the publication of its reference in the Official Journal of the European Union, the Commission shall assess the harmonised standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal acts referred to in paragraph 1 and 1b, or parts thereof which cover the same requirements set out in Chapter 2 of this Title.***		***3a. Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the publication of its reference in the Official Journal of the European Union, the Commission shall assess the harmonised standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal acts referred to in paragraph 1 and 1b, or parts thereof which cover the same requirements set out in Chapter 2 of this Title.*** Text Origin: EP Mandate G
Article 41(4)				
G 450	4. Where providers do not comply with the common specifications referred to in paragraph 1, they shall duly justify that they have adopted technical solutions that are at least equivalent thereto.	4. Where providers ***of high-risk AI systems*** do not comply with the common specifications referred to in paragraph 1, they shall duly justify that they have adopted technical solutions that ~~are~~***meet the requirements referred to in Chapter II to a level*** at least equivalent thereto~~.~~***:***	*deleted*	4. Where providers ***of high-risk AI systems*** do not comply with the common specifications referred to in paragraph 1, they shall duly justify that they have adopted technical solutions that ~~are~~***meet the requirements referred to in Chapter II to a level*** at least equivalent thereto. Text Origin: EP Mandate G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 41(4a)				
G 450a			***4a. When references of a harmonised standard are published in the Official Journal of the European Union, implementing acts referred to in paragraph 1, which cover the requirements set out in Chapter 2 of this Title or requirements set out in Article 4a and Article 4b, shall be repealed, as applicable.***	G
Article 41(4a)				
G 450b			***4b. When a Member State considers that a common specification does not entirely satisfy the requirements set out in Chapter 2 of this Title or requirements set out in Article 4a and Article 4b, as applicable, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if appropriate, amend the implementing act establishing the common specification in question.***	***4b. When a Member State considers that a common specification does not entirely satisfy the requirements set out in Chapter 2 of this Title, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if appropriate, amend the implementing act establishing the common specification in question.*** Text Origin: Council Mandate	G
Article 42				
G 451	Article 42 Presumption of conformity with certain requirements	Article 42 Presumption of conformity with certain requirements	Article 42 Presumption of conformity with certain requirements	Article 42 Presumption of conformity with certain requirements G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Article 42(1)				
G 452	1. Taking into account their intended purpose, high-risk AI systems that have been trained and tested on data concerning the specific geographical, behavioural and functional setting within which they are intended to be used shall be presumed to be in compliance with the requirement set out in Article 10(4).	1. Taking into account their intended purpose, high-risk AI systems that have been trained and tested on data concerning the specific geographical, behavioural ***contextual*** and functional setting within which they are intended to be used shall be presumed to be in compliance with the ~~requirement~~***respective requirements*** set out in Article 10(4).	1. ~~*Taking into account their intended purpose,*~~ High-risk AI systems that have been trained and tested on data ~~*concerning*~~***reflecting*** the specific geographical, behavioural ~~*and*~~***or*** functional setting within which they are intended to be used shall be presumed to be in compliance with the ~~*requirement*~~***respective requirements*** set out in Article 10(4).	1. ~~*Taking into account their intended purpose,*~~ High-risk AI systems that have been trained and tested on data ~~*concerning*~~***reflecting*** the specific geographical, behavioural***, contextual or*** ~~*and*~~ functional setting within which they are intended to be used shall be presumed to be in compliance with the ~~*requirement*~~***respective requirements*** set out in Article 10(4). G
Article 42(2)				
G 453	2. High-risk AI systems that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 of the European Parliament and of the Council[1] and the references of which have been published in the Official Journal of the European Union shall be presumed to be in compliance with the cybersecurity requirements set out in Article 15 of this Regulation in so far as the cybersecurity	2. High-risk AI systems that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 of the European Parliament and of the Council[1] and the references of which have been published in the Official Journal of the European Union shall be presumed to be in compliance with the cybersecurity requirements set out in Article 15 of this Regulation in so far as the cybersecurity	2. High-risk AI systems ***or general purpose AI systems*** that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 of the European Parliament and of the Council[1] and the references of which have been published in the Official Journal of the European Union shall be presumed to be in compliance with the cybersecurity requirements set out in Article 15 of this Regulation in so far as the	2. High-risk AI systems that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 of the European Parliament and of the Council~~[1]~~[1] and the references of which have been published in the Official Journal of the European Union shall be presumed to be in compliance with the cybersecurity requirements set out in Article 15 of this Regulation in so far as the cybersecurity G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	certificate or statement of conformity or parts thereof cover those requirements. _____ 1. Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 1).	certificate or statement of conformity or parts thereof cover those requirements. _____ 1. Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 1).	cybersecurity certificate or statement of conformity or parts thereof cover those requirements. _____ 1. ***[1]*** Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 1).	certificate or statement of conformity or parts thereof cover those requirements. _____ ~~1. Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 1).~~
Article 43				
G 454	Article 43 Conformity assessment	Article 43 Conformity assessment	Article 43 Conformity assessment	Article 43 Conformity assessment Text Origin: Commission Proposal
Article 43(1), first subparagraph				
G 455	1. For high-risk AI systems listed in point 1 of Annex III, where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider has applied harmonised standards referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall follow one of the following procedures:	1. For high-risk AI systems listed in point 1 of Annex III, where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider has applied harmonised standards referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall ~~follow~~***opt for*** one of the following procedures~~:~~**;**	1. For high-risk AI systems listed in point 1 of Annex III, where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider has applied harmonised standards referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall ~~follow~~***opt for*** one of the following procedures:	1. For high-risk AI systems listed in point 1 of Annex III, where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider has applied harmonised standards referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall ~~follow~~***opt for*** one of the following procedures:

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 43(1), first subparagraph, point (a)				
456	(a) the conformity assessment procedure based on internal control referred to in Annex VI;	(a) the conformity assessment procedure based on internal control referred to in Annex VI; ***or***	(a) the conformity assessment procedure based on internal control referred to in Annex VI; ***or***	(a) the conformity assessment procedure based on internal control referred to in Annex VI; ***or*** Text Origin: Council Mandate
Article 43(1), first subparagraph, point (b)				
457	(b) the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation, with the involvement of a notified body, referred to in Annex VII.	(b) the conformity assessment procedure based on assessment of the quality management system and ~~assessment~~ of the technical documentation, with the involvement of a notified body, referred to in Annex VII~~.~~***;***	(b) the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation, with the involvement of a notified body, referred to in Annex VII.	(b) the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation, with the involvement of a notified body, referred to in Annex VII. Text Origin: Council Mandate
Article 43(1), second subparagraph				
458	Where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider has not applied or has applied only in part harmonised standards referred to in Article 40, or where such harmonised standards do not exist and common specifications referred to in Article 41 are not available, the provider shall follow the conformity assessment procedure set out in Annex VII.	~~Where,~~ In demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider ~~has not applied or has applied only in part~~***shall follow the conformity assessment procedure set out in Annex VII in the following cases:*** ***(a) where*** harmonised standards referred to in Article 40, ~~or where such harmonised standards~~***the reference number of which has been published in the Official***	Where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider has not applied or has applied only in part harmonised standards referred to in Article 40, or where such harmonised standards do not exist and common specifications referred to in Article 41 are not available, the provider shall follow the conformity assessment procedure set out in Annex VII.	~~Where,~~ In demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider ~~has not applied or has applied only in part~~***shall follow the conformity assessment procedure set out in Annex VII in the following cases:*** ***(a) where*** harmonised standards referred to in Article 40, ~~or where such harmonised standards~~ do not exist and common specifications referred to in Article 41 are not

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Journal of the European Union, covering all relevant safety requirements for the AI system, do not exist and common specifications referred to in Article 41 are not available~~,~~***;*** ***(b) where the technical specifications referred to in point (a) exist but the provider has not applied them or has applied them only in part;*** ***(c) where one or more of the technical specifications referred to in point (a) has been published with a restriction and only on the part of the standard that was restricted;*** ***(d) when*** the provider ~~*shall follow the conformity assessment procedure set out in Annex VII*~~***considers that the nature, design, construction or purpose of the AI system necessitate third party verification, regardless of its risk level***.		available~~,~~***;*** ***(aa)*** the provider ~~*shall follow the conformity assessment procedure set out in Annex VII.*~~***has not applied or has applied only in part the harmonised standard;*** ***(b) where the common specifications referred to in point (a) exist but the provider has not applied them;*** ***(c) where one or more of the harmonised standards referred to in point (a) has been published with a restriction and only on the part of the standard that was restricted;***
Article 43(1), third subparagraph				
G 459	For the purpose of the conformity assessment procedure referred to in Annex VII, the provider may choose any of the notified bodies. However, when the system is intended to be put into service by law enforcement, immigration or asylum authorities as well as EU institutions, bodies or agencies, the market surveillance authority referred to in Article 63(5)	For the purpose of ***carrying out*** the conformity assessment procedure referred to in Annex VII, the provider may choose any of the notified bodies. However, when the system is intended to be put into service by law enforcement, immigration or asylum authorities as well as EU institutions, bodies or agencies, the market surveillance	For the purpose of the conformity assessment procedure referred to in Annex VII, the provider may choose any of the notified bodies. However, when the system is intended to be put into service by law enforcement, immigration or asylum authorities as well as EU institutions, bodies or agencies, the market surveillance authority referred to in Article 63(5)	For the purpose of the conformity assessment procedure referred to in Annex VII, the provider may choose any of the notified bodies. However, when the system is intended to be put into service by law enforcement, immigration or asylum authorities as well as EU institutions, bodies or agencies, the market surveillance authority referred to in Article 63(5) G

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	or (6), as applicable, shall act as a notified body.	authority referred to in Article 63(5) or (6), as applicable, shall act as a notified body.	or (6), as applicable, shall act as a notified body.	or (6), as applicable, shall act as a notified body. Text Origin: Council Mandate
Article 43(2)				
G 460	2. For high-risk AI systems referred to in points 2 to 8 of Annex III, providers shall follow the conformity assessment procedure based on internal control as referred to in Annex VI, which does not provide for the involvement of a notified body. For high-risk AI systems referred to in point 5(b) of Annex III, placed on the market or put into service by credit institutions regulated by Directive 2013/36/EU, the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to101 of that Directive.	2. For high-risk AI systems referred to in points 2 to 8 of Annex III, providers shall follow the conformity assessment procedure based on internal control as referred to in Annex VI, which does not provide for the involvement of a notified body. For high-risk AI systems referred to in point 5(b) of Annex III, placed on the market or put into service by credit institutions regulated by Directive 2013/36/EU, the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to101 of that Directive.	2. For high-risk AI systems referred to in points 2 to 8 of Annex III ***and for general purpose AI systems referred in Title 1a***, providers shall follow the conformity assessment procedure based on internal control as referred to in Annex VI, which does not provide for the involvement of a notified body. ~~*For high-risk AI systems referred to in point 5(b) of Annex III, placed on the market or put into service by credit institutions regulated by Directive 2013/36/EU, the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to101 of that Directive.*~~	2. For high-risk AI systems referred to in points 2 to 8 of Annex III~~,~~ providers shall follow the conformity assessment procedure based on internal control as referred to in Annex VI, which does not provide for the involvement of a notified body. ~~*For high-risk AI systems referred to in point 5(b) of Annex III, placed on the market or put into service by credit institutions regulated by Directive 2013/36/EU, the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to101 of that Directive.*~~ Text Origin: Council Mandate
Article 43(3), first subparagraph				
G 461	3. For high-risk AI systems, to which legal acts listed in Annex II, section A, apply, the provider shall follow the relevant conformity assessment as required under those legal acts. The requirements set out in Chapter 2 of this Title shall apply to those high-risk AI systems and	3. For high-risk AI systems, to which legal acts listed in Annex II, section A, apply, the provider shall follow the relevant conformity assessment as required under those legal acts. The requirements set out in Chapter 2 of this Title shall apply to those high-risk AI systems and	3. For high-risk AI systems, to which legal acts listed in Annex II, section A, apply, the provider shall follow the relevant conformity assessment as required under those legal acts. The requirements set out in Chapter 2 of this Title shall apply to those high-risk AI systems and	3. For high-risk AI systems, to which legal acts listed in Annex II, section A, apply, the provider shall follow the relevant conformity assessment as required under those legal acts. The requirements set out in Chapter 2 of this Title shall apply to those high-risk AI systems and

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	shall be part of that assessment. Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII shall also apply.	shall be part of that assessment. Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII shall also apply.	shall be part of that assessment. Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII shall also apply.	shall be part of that assessment. Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII shall also apply. Text Origin: Council Mandate
Article 43(3), second subparagraph				
G 462	For the purpose of that assessment, notified bodies which have been notified under those legal acts shall be entitled to control the conformity of the high-risk AI systems with the requirements set out in Chapter 2 of this Title, provided that the compliance of those notified bodies with requirements laid down in Article 33(4), (9) and (10) has been assessed in the context of the notification procedure under those legal acts.	For the purpose of that assessment, notified bodies which have been notified under those legal acts shall be entitled to control the conformity of the high-risk AI systems with the requirements set out in Chapter 2 of this Title, provided that the compliance of those notified bodies with requirements laid down in Article 33(4), (9) and (10) has been assessed in the context of the notification procedure under those legal acts.	For the purpose of that assessment, notified bodies which have been notified under those legal acts shall be entitled to control the conformity of the high-risk AI systems with the requirements set out in Chapter 2 of this Title, provided that the compliance of those notified bodies with requirements laid down in Article 33(4), (9) and (10) has been assessed in the context of the notification procedure under those legal acts.	For the purpose of that assessment, notified bodies which have been notified under those legal acts shall be entitled to control the conformity of the high-risk AI systems with the requirements set out in Chapter 2 of this Title, provided that the compliance of those notified bodies with requirements laid down in Article 33(4), (9) and (10) has been assessed in the context of the notification procedure under those legal acts. Text Origin: Council Mandate
Article 43(3), third subparagraph				
G 463	Where the legal acts listed in Annex II, section A, enable the manufacturer of the product to opt out from a third-party conformity assessment, provided that that manufacturer has applied all harmonised standards covering all the relevant requirements, that manufacturer may make use of that	Where the legal acts listed in Annex II, section A, enable the manufacturer of the product to opt out from a third-party conformity assessment, provided that that manufacturer has applied all harmonised standards covering all the relevant requirements, that manufacturer may make use of that	Where the legal acts listed in Annex II, section A, enable the manufacturer of the product to opt out from a third-party conformity assessment, provided that that manufacturer has applied all harmonised standards covering all the relevant requirements, that manufacturer may make use of that	Where the legal acts listed in Annex II, section A, enable the manufacturer of the product to opt out from a third-party conformity assessment, provided that that manufacturer has applied all harmonised standards covering all the relevant requirements, that manufacturer may make use of that

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	option only if he has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering the requirements set out in Chapter 2 of this Title.	option only if he has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering the requirements set out in Chapter 2 of this Title.	option only if he has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering the requirements set out in Chapter 2 of this Title.	option only if he has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering the requirements set out in Chapter 2 of this Title. Text Origin: Council Mandate
Article 43(4), first subparagraph				
G 464	4. High-risk AI systems shall undergo a new conformity assessment procedure whenever they are substantially modified, regardless of whether the modified system is intended to be further distributed or continues to be used by the current user.	4. High-risk AI systems ***that have already been subject to a conformity assessment procedure*** shall undergo a new conformity assessment procedure whenever they are substantially modified, regardless of whether the modified system is intended to be further distributed or continues to be used by the current ~~user.~~***deployer;***	*deleted*	4. High-risk AI systems ***that have already been subject to a conformity assessment procedure*** shall undergo a new conformity assessment procedure whenever they are substantially modified, regardless of whether the modified system is intended to be further distributed or continues to be used by the current ~~user~~***deployer***. G
Article 43(4), second subparagraph				
G 465	For high-risk AI systems that continue to learn after being placed on the market or put into service, changes to the high-risk AI system and its performance that have been pre-determined by the provider at the moment of the initial conformity assessment and are part of the information contained in the technical documentation referred to in point 2(f) of Annex IV, shall not	For high-risk AI systems that continue to learn after being placed on the market or put into service, changes to the high-risk AI system and its performance that have been pre-determined by the provider at the moment of the initial conformity assessment and are part of the information contained in the technical documentation referred to in point 2(f) of Annex IV, shall not	*deleted*	For high-risk AI systems that continue to learn after being placed on the market or put into service, changes to the high-risk AI system and its performance that have been pre-determined by the provider at the moment of the initial conformity assessment and are part of the information contained in the technical documentation referred to in point 2(f) of Annex IV, shall not G

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	constitute a substantial modification.	constitute a substantial modification.		constitute a substantial modification. Text Origin: EP Mandate
Article 43(4a)				
G 465a		***4a The specific interests and needs of SMEs shall be taken into account when setting the fees for third-party conformity assessment under this Article, reducing those fees proportionately to their size and market share;***		G
Article 43(5)				
G 466	5. The Commission is empowered to adopt delegated acts in accordance with Article 73 for the purpose of updating Annexes VI and Annex VII in order to introduce elements of the conformity assessment procedures that become necessary in light of technical progress.	5. The Commission is empowered to adopt delegated acts in accordance with Article 73 for the purpose of updating Annexes VI and Annex VII in order to introduce elements of the conformity assessment procedures that become necessary in light of technical progress. ***When preparing such delegated acts, the Commission shall consult the AI Office and the stakeholders affected.***	5. The Commission is empowered to adopt delegated acts in accordance with Article 73 for the purpose of updating Annexes VI and Annex VII in ~~*order to introduce elements of the conformity assessment procedures that become necessary in*~~ light of technical progress.	5. The Commission is empowered to adopt delegated acts in accordance with Article 73 for the purpose of updating Annexes VI and Annex VII in ~~*order to introduce elements of the conformity assessment procedures that become necessary in*~~ light of technical progress. G
Article 43(6)				
G 467	6. The Commission is empowered to adopt delegated acts to amend paragraphs 1 and 2 in order to	6. The Commission is empowered to adopt delegated acts to amend paragraphs 1 and 2 in order to	6. The Commission is empowered to adopt delegated acts to amend paragraphs 1 and 2 in order to	6. The Commission is empowered to adopt delegated acts to amend paragraphs 1 and 2 in order to G

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	subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex VII or parts thereof. The Commission shall adopt such delegated acts taking into account the effectiveness of the conformity assessment procedure based on internal control referred to in Annex VI in preventing or minimizing the risks to health and safety and protection of fundamental rights posed by such systems as well as the availability of adequate capacities and resources among notified bodies.	subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex VII or parts thereof. The Commission shall adopt such delegated acts taking into account the effectiveness of the conformity assessment procedure based on internal control referred to in Annex VI in preventing or minimizing the risks to health and safety and protection of fundamental rights posed by such systems as well as the availability of adequate capacities and resources among notified bodies. ***When preparing such delegated acts, the Commission shall consult the AI Office and the stakeholders affected.***	subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex VII or parts thereof. The Commission shall adopt such delegated acts taking into account the effectiveness of the conformity assessment procedure based on internal control referred to in Annex VI in preventing or minimizing the risks to health and safety and protection of fundamental rights posed by such systems as well as the availability of adequate capacities and resources among notified bodies.	subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex VII or parts thereof. The Commission shall adopt such delegated acts taking into account the effectiveness of the conformity assessment procedure based on internal control referred to in Annex VI in preventing or minimizing the risks to health and safety and protection of fundamental rights posed by such systems as well as the availability of adequate capacities and resources among notified bodies.
Article 44				
G 468	Article 44 Certificates	Article 44 Certificates	Article 44 Certificates	Article 44 Certificates Text Origin: Commission Proposal G
Article 44(1)				
G 469	1. Certificates issued by notified bodies in accordance with Annex VII shall be drawn-up in an official Union language determined by the	1. Certificates issued by notified bodies in accordance with Annex VII shall be drawn-up in ~~an~~***one or several*** official Union	1. Certificates issued by notified bodies in accordance with Annex VII shall be drawn-up in ~~an official Union~~***a a*** language ~~determined by~~	1. Certificates issued by notified bodies in accordance with Annex VII shall be drawn-up in ~~an official Union language determined~~***a*** G

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	Member State in which the notified body is established or in an official Union language otherwise acceptable to the notified body.	~~language~~languages determined by the Member State in which the notified body is established or in ~~an~~one or several official Union ~~language~~languages otherwise acceptable to the notified body.	~~the Member State in which the notified body is established or in an official Union language otherwise acceptable to~~which can be easily understood by the relevant authorities in the Member State in which the notified body is established.	language which can be easily understood by the relevant authorities in the Member State in which the notified body is established. ~~or in an official Union language otherwise acceptable to the notified body.~~
Article 44(2)				
470	2. Certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the provider, the validity of a certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures.	2. Certificates shall be valid for the period they indicate, which shall not exceed ~~five~~four years. On application by the provider, the validity of a certificate may be extended for further periods, each not exceeding ~~five~~four years, based on a re-assessment in accordance with the applicable conformity assessment procedures.	2. Certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the provider, the validity of a certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.	2. Certificates shall be valid for the period they indicate, which shall not exceed five years for AI systems covered by Annex II and four years for AI systems covered by Annex III. On application by the provider, the validity of a certificate may be extended for further periods, each not exceeding five years for AI systems covered by Annex II and four years for AI systems covered by Annex III, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.
Article 44(3)				
471	3. Where a notified body finds that an AI system no longer meets the requirements set out in Chapter 2 of	3. Where a notified body finds that an AI system no longer meets the requirements set out in Chapter 2 of	3. Where a notified body finds that an AI system no longer meets the requirements set out in Chapter 2 of	3. Where a notified body finds that an AI system no longer meets the requirements set out in Chapter 2 of

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	this Title, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it, unless compliance with those requirements is ensured by appropriate corrective action taken by the provider of the system within an appropriate deadline set by the notified body. The notified body shall give reasons for its decision.	this Title, it shall~~, taking account of the principle of proportionality,~~ suspend or withdraw the certificate issued or impose any restrictions on it, unless compliance with those requirements is ensured by appropriate corrective action taken by the provider of the system within an appropriate deadline set by the notified body. The notified body shall give reasons for its decision.	this Title, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it, unless compliance with those requirements is ensured by appropriate corrective action taken by the provider of the system within an appropriate deadline set by the notified body. The notified body shall give reasons for its decision.	this Title, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it, unless compliance with those requirements is ensured by appropriate corrective action taken by the provider of the system within an appropriate deadline set by the notified body. The notified body shall give reasons for its decision. Text Origin: Council Mandate
Article 45				
G 472	Article 45 Appeal against decisions of notified bodies	Article 45 Appeal against decisions of notified bodies	Article 45 Appeal against decisions of notified bodies	G
Article 45, first paragraph				
G 473	Member States shall ensure that an appeal procedure against decisions of the notified bodies is available to parties having a legitimate interest in that decision.	Member States shall ensure that an appeal procedure against decisions of the notified bodies***, including on issued conformity certificates*** is available to parties having a legitimate interest in that decision.	~~*Member States shall ensure that*~~ An appeal procedure against decisions of the notified bodies ~~*is available to parties having a legitimate interest in that decision*~~***shall be available***.	~~*Member States shall ensure that*~~ An appeal procedure against decisions of the notified bodies ~~*is available to parties having a legitimate interest in that decision*~~***, including on issued conformity certificates, shall be available***. G
Article 46				
G 474	Article 46 Information obligations of notified	Article 46 Information obligations of notified	Article 46 Information obligations of notified	Article 46 Information obligations of notified G

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	bodies	bodies	bodies	bodies Text Origin: Council Mandate
Article 46(1)				
G 475	1. Notified bodies shall inform the notifying authority of the following:	1. Notified bodies shall inform the notifying authority of the following:	1. Notified bodies shall inform the notifying authority of the following:	1. Notified bodies shall inform the notifying authority of the following: Text Origin: Council Mandate
Article 46(1), point (a)				
G 476	(a) any Union technical documentation assessment certificates, any supplements to those certificates, quality management system approvals issued in accordance with the requirements of Annex VII;	(a) any Union technical documentation assessment certificates, any supplements to those certificates, quality management system approvals issued in accordance with the requirements of Annex VII;	(a) any Union technical documentation assessment certificates, any supplements to those certificates, quality management system approvals issued in accordance with the requirements of Annex VII;	(a) any Union technical documentation assessment certificates, any supplements to those certificates, quality management system approvals issued in accordance with the requirements of Annex VII; Text Origin: Council Mandate
Article 46(1), point (b)				
G 477	(b) any refusal, restriction, suspension or withdrawal of a Union technical documentation assessment certificate or a quality management system approval issued in accordance with the requirements of Annex VII;	(b) any refusal, restriction, suspension or withdrawal of a Union technical documentation assessment certificate or a quality management system approval issued in accordance with the requirements of Annex VII;	(b) any refusal, restriction, suspension or withdrawal of a Union technical documentation assessment certificate or a quality management system approval issued in accordance with the requirements of Annex VII;	(b) any refusal, restriction, suspension or withdrawal of a Union technical documentation assessment certificate or a quality management system approval issued in accordance with the requirements of Annex VII; Text Origin: Council Mandate

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Article 46(1), point (c)				
478	(c) any circumstances affecting the scope of or conditions for notification;	(c) any circumstances affecting the scope of or conditions for notification;	(c) any circumstances affecting the scope of or conditions for notification;	(c) any circumstances affecting the scope of or conditions for notification; Text Origin: Council Mandate
Article 46(1), point (d)				
479	(d) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;	(d) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;	(d) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;	(d) any request for information which they have received from market surveillance authorities regarding conformity assessment activities; Text Origin: Council Mandate
Article 46(1), point (e)				
480	(e) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.	(e) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.	(e) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.	(e) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting. Text Origin: Council Mandate
Article 46(2)				
481	2. Each notified body shall inform the other notified bodies of:	2. Each notified body shall inform the other notified bodies of:	2. Each notified body shall inform the other notified bodies of:	2. Each notified body shall inform the other notified bodies of: Text Origin: Council Mandate

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Article 46(2), point (a)				
482	(a) quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued;	(a) quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued;	(a) quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued;	(a) quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued; Text Origin: Council Mandate
Article 46(2), point (b)				
483	(b) EU technical documentation assessment certificates or any supplements thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or supplements thereto which it has issued.	(b) EU technical documentation assessment certificates or any supplements thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or supplements thereto which it has issued.	(b) EU technical documentation assessment certificates or any supplements thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or supplements thereto which it has issued.	(b) EU technical documentation assessment certificates or any supplements thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or supplements thereto which it has issued. Text Origin: Council Mandate
Article 46(3)				
484	3. Each notified body shall provide the other notified bodies carrying out similar conformity assessment activities covering the same artificial intelligence technologies with relevant information on issues relating to negative and, on request, positive conformity assessment results.	3. Each notified body shall provide the other notified bodies carrying out similar conformity assessment activities ~~covering the same artificial intelligence technologies~~ with relevant information on issues relating to negative and, on request, positive conformity assessment results.	3. Each notified body shall provide the other notified bodies carrying out similar conformity assessment activities covering the same ~~artificial intelligence technologies~~***AI systems*** with relevant information on issues relating to negative and, on request, positive conformity assessment results.	3. Each notified body shall provide the other notified bodies carrying out similar conformity assessment activities covering the same ~~artificial intelligence technologies~~***types ofAI systems*** with relevant information on issues relating to negative and, on request, positive conformity assessment results.

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Article 46(3a)				
484a			***3a. The obligations referred to in paragraphs 1 to 3 shall be complied with in accordance with Article 70.***	***3a. The obligations referred to in paragraphs 1 to 3 shall be complied with in accordance with Article 70.*** Text Origin: Council Mandate
Article 47				
485	Article 47 Derogation from conformity assessment procedure	Article 47 Derogation from conformity assessment procedure	Article 47 Derogation from conformity assessment procedure	Article 47 Derogation from conformity assessment procedure Text Origin: Commission Proposal
Article 47(1)				
486	1. By way of derogation from Article 43, any market surveillance authority may authorise the placing on the market or putting into service of specific high-risk AI systems within the territory of the Member State concerned, for exceptional reasons of public security or the protection of life and health of persons, environmental protection and the protection of key industrial and infrastructural assets. That authorisation shall be for a limited period of time, while the necessary conformity assessment procedures	1. By way of derogation from Article 43, any ~~market surveillance~~***national supervisory*** authority may ***request a judicial authority to*** authorise the placing on the market or putting into service of specific high-risk AI systems within the territory of the Member State concerned, for exceptional reasons of ~~public security or~~ the protection of life and health of persons, environmental protection and the protection of ~~key industrial and infrastructural assets~~***critical infrastructure***. That authorisation	1. By way of derogation from Article 43 ***and upon a duly justified request***, any market surveillance authority may authorise the placing on the market or putting into service of specific high-risk AI systems within the territory of the Member State concerned, for exceptional reasons of public security or the protection of life and health of persons, environmental protection and the protection of key industrial and infrastructural assets. That authorisation shall be for a limited period of time~~,~~ while the necessary	1. ***1.*** By way of derogation from Article 43 ***and upon a duly justified request***, any market surveillance authority may authorise the placing on the market or putting into service of specific high-risk AI systems within the territory of the Member State concerned, for exceptional reasons of public security or the protection of life and health of persons, environmental protection and the protection of key industrial and infrastructural assets. That authorisation shall be for a limited period of time~~,~~ while the necessary

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	are being carried out, and shall terminate once those procedures have been completed. The completion of those procedures shall be undertaken without undue delay.	shall be for a limited period of time, while the necessary conformity assessment procedures are being carried out, and shall terminate once those procedures have been completed. The completion of those procedures shall be undertaken without undue delay.	conformity assessment procedures are being carried out, ~~*and shall terminate once those procedures have been completed*~~***taking into account the exceptional reasons justifying the derogation***. The completion of those procedures shall be undertaken without undue delay.	conformity assessment procedures are being carried out, ~~*and shall terminate once those procedures have been completed*~~***taking into account the exceptional reasons justifying the derogation***. The completion of those procedures shall be undertaken without undue delay.
Article 47(1a)				
G 486a			***1a. In a duly justified situation of urgency for exceptional reasons of public security or in case of specific, substantial and imminent threat to the life or physical safety of natural persons, law enforcement authorities or civil protection authorities may put a specific high-risk AI system into service without the authorisation referred to in paragraph 1 provided that such authorisation is requested during or after the use without undue delay, and if such authorisation is rejected, its use shall be stopped with immediate effect and all the results and outputs of this use shall be immediately discarded.***	***1a. In a duly justified situation of urgency for exceptional reasons of public security or in case of specific, substantial and imminent threat to the life or physical safety of natural persons, law enforcement authorities or civil protection authorities may put a specific high-risk AI system into service without the authorisation referred to in paragraph 1 provided that such authorisation is requested during or after the use without undue delay, and if such authorisation is rejected, its use shall be stopped with immediate effect and all the results and outputs of this use shall be immediately discarded.*** G
Article 47(2)				
G 487	2. The authorisation referred to in paragraph 1 shall be issued only if	2. The authorisation referred to in paragraph 1 shall be issued only if	2. The authorisation referred to in paragraph 1 shall be issued only if	2. The authorisation referred to in paragraph 1 shall be issued only if G

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	the market surveillance authority concludes that the high-risk AI system complies with the requirements of Chapter 2 of this Title. The market surveillance authority shall inform the Commission and the other Member States of any authorisation issued pursuant to paragraph 1.	the ~~market surveillance~~***national supervisory authority and judicial*** authority ~~concludes~~***conclude*** that the high-risk AI system complies with the requirements of Chapter 2 of this Title. The ~~market surveillance~~***national supervisory*** authority shall inform the Commission***, the AI office,*** and the other Member States of any ***request made and any subsequent*** authorisation issued pursuant to paragraph 1.	the market surveillance authority concludes that the high-risk AI system complies with the requirements of Chapter 2 of this Title. The market surveillance authority shall inform the Commission and the other Member States of any authorisation issued pursuant to paragraph 1. ***This obligation shall not cover sensitive operational data in relation to the activities of law enforcement authorities.***	the market surveillance authority concludes that the high-risk AI system complies with the requirements of Chapter 2 of this Title. The market surveillance authority shall inform the Commission and the other Member States of any authorisation issued pursuant to paragraph 1. ***This obligation shall not cover sensitive operational data in relation to the activities of law enforcement authorities.***
Article 47(3)				
G 488	3. Where, within 15 calendar days of receipt of the information referred to in paragraph 2, no objection has been raised by either a Member State or the Commission in respect of an authorisation issued by a market surveillance authority of a Member State in accordance with paragraph 1, that authorisation shall be deemed justified.	3. Where, within 15 calendar days of receipt of the information referred to in paragraph 2, no objection has been raised by either a Member State or the Commission in respect ***to the request of the national supervisory authority for*** ~~of~~ an authorisation issued by a ~~market surveillance~~***national supervisory*** authority of a Member State in accordance with paragraph 1, that authorisation shall be deemed justified.	*deleted*	*3.* Where, within 15 calendar days of receipt of the information referred to in paragraph 2, no objection has been raised by either a Member State or the Commission in respect of an authorisation issued by a market surveillance authority of a Member State in accordance with paragraph 1, that authorisation shall be deemed justified. Text Origin: Commission Proposal
Article 47(4)				
G 489	4. Where, within 15 calendar days of receipt of the notification referred to in paragraph 2, objections are	4. Where, within 15 calendar days of receipt of the notification referred to in paragraph 2, objections are	*deleted*	*4.* Where, within 15 calendar days of receipt of the notification referred to in paragraph 2, objections are

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	raised by a Member State against an authorisation issued by a market surveillance authority of another Member State, or where the Commission considers the authorisation to be contrary to Union law or the conclusion of the Member States regarding the compliance of the system as referred to in paragraph 2 to be unfounded, the Commission shall without delay enter into consultation with the relevant Member State; the operator(s) concerned shall be consulted and have the possibility to present their views. In view thereof, the Commission shall decide whether the authorisation is justified or not. The Commission shall address its decision to the Member State concerned and the relevant operator or operators.	raised by a Member State against ~~an authorisation~~***a request*** issued by a ~~market surveillance~~***national supervisory*** authority of another Member State, or where the Commission considers the authorisation to be contrary to Union law or the conclusion of the Member States regarding the compliance of the system as referred to in paragraph 2 to be unfounded, the Commission shall without delay enter into consultation with the relevant Member State ***and the AI Office***; the operator(s) concerned shall be consulted and have the possibility to present their views. In view thereof, the Commission shall decide whether the authorisation is justified or not. The Commission shall address its decision to the Member State concerned and the relevant operator ~~or operators~~***(s)***.		raised by a Member State against an authorisation issued by a market surveillance authority of another Member State, or where the Commission considers the authorisation to be contrary to Union law or the conclusion of the Member States regarding the compliance of the system as referred to in paragraph 2 to be unfounded, the Commission shall without delay enter into consultation with the relevant Member State; the operator(s) concerned shall be consulted and have the possibility to present their views. In view thereof, the Commission shall decide whether the authorisation is justified or not. The Commission shall address its decision to the Member State concerned and the relevant operator or operators.
Article 47(5)				
G 490	5. If the authorisation is considered unjustified, this shall be withdrawn by the market surveillance authority of the Member State concerned.	5. If the authorisation is considered unjustified, this shall be withdrawn by the ~~market surveillance~~***national supervisory*** authority of the Member State concerned.	*deleted*	5. If the authorisation is considered unjustified, this shall be withdrawn by the market surveillance authority of the Member State concerned. G
Article 47(6)				
G 491	6. By way of derogation from	6. By way of derogation from	6. ~~By way of derogation from~~	6. ~~By way of derogation from~~ G

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	paragraphs 1 to 5, for high-risk AI systems intended to be used as safety components of devices, or which are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746, Article 59 of Regulation (EU) 2017/745 and Article 54 of Regulation (EU) 2017/746 shall apply also with regard to the derogation from the conformity assessment of the compliance with the requirements set out in Chapter 2 of this Title.	paragraphs 1 to 5, for high-risk AI systems intended to be used as safety components of devices, or which are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746, Article 59 of Regulation (EU) 2017/745 and Article 54 of Regulation (EU) 2017/746 shall apply also with regard to the derogation from the conformity assessment of the compliance with the requirements set out in Chapter 2 of this Title.	~~paragraphs 1 to 5,~~ For high-risk AI systems ~~intended to be used as safety components of devices, or which are themselves devices,~~***related to products*** covered by ~~Regulation (EU) 2017/745 and Regulation (EU) 2017/746, Article 59 of Regulation (EU) 2017/745 and Article 54 of Regulation (EU) 2017/746 shall apply also with regard to the derogation from~~***Union harmonisation legislation referred to in Annex II Section A, only*** the conformity assessment ~~of the compliance with the requirements set out in Chapter 2 of this Title~~***derogation procedures established in that legislation shall apply***.	~~paragraphs 1 to 5,~~ For high-risk AI systems ~~intended to be used as safety components of devices, or which are themselves devices,~~***related to products*** covered by ~~Regulation (EU) 2017/745 and Regulation (EU) 2017/746, Article 59 of Regulation (EU) 2017/745 and Article 54 of Regulation (EU) 2017/746 shall apply also with regard to the derogation from~~***Union harmonisation legislation referred to in Annex II Section A, only*** the conformity assessment ~~of the compliance with the requirements set out in Chapter 2 of this Title~~***derogation procedures established in that legislation shall apply***.
Article 48				
G 492	Article 48 EU declaration of conformity	Article 48 EU declaration of conformity	Article 48 EU declaration of conformity	Article 48 EU declaration of conformity Text Origin: Commission Proposal
Article 48(1)				
G 493	1. The provider shall draw up a written EU declaration of conformity for each AI system and keep it at the disposal of the national competent authorities for 10 years after the AI	1. The provider shall draw up a written ***machine readable, physical or electronic*** EU declaration of conformity for each ***high-risk*** AI system and keep it at the disposal of	1. The provider shall draw up a written ***or electronically signed*** EU declaration of conformity for each AI system and keep it at the disposal of the national competent authorities	1. The provider shall draw up a written ***machine readable, physical or electronically signed*** EU declaration of conformity for each ***high-risk*** AI system and keep it at

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	system has been placed on the market or put into service. The EU declaration of conformity shall identify the AI system for which it has been drawn up. A copy of the EU declaration of conformity shall be given to the relevant national competent authorities upon request.	the national ***supervisory authority and the national*** competent authorities for 10 years after the AI ***high-risk*** system has been placed on the market or put into service. ~~*The EU declaration of conformity shall identify the AI system for which it has been drawn up.*~~ A copy of the EU declaration of conformity shall be ~~*given to*~~***submitted to the national supervisory authority and*** the relevant national competent authorities upon request.	for 10 years after the AI system has been placed on the market or put into service. The EU declaration of conformity shall identify the AI system for which it has been drawn up. A copy of the EU declaration of conformity shall be ~~*given*~~***submitted*** to the relevant national competent authorities upon request.	the disposal of the national competent authorities for 10 years after the AI ***high-risk*** system has been placed on the market or put into service. The EU declaration of conformity shall identify the ***high-risk*** AI system for which it has been drawn ~~*up. A*~~***up.A*** copy of the EU declaration of conformity shall be ~~*given*~~***submitted*** to the relevant national competent authorities upon request.
Article 48(2)				
G 494	2. The EU declaration of conformity shall state that the high-risk AI system in question meets the requirements set out in Chapter 2 of this Title. The EU declaration of conformity shall contain the information set out in Annex V and shall be translated into an official Union language or languages required by the Member State(s) in which the high-risk AI system is made available.	2. The EU declaration of conformity shall state that the high-risk AI system in question meets the requirements set out in Chapter 2 of this Title. The EU declaration of conformity shall contain the information set out in Annex V and shall be translated into an official Union language or languages required by the Member State(s) in which the high-risk AI system is ***placed on the market or*** made available.	2. The EU declaration of conformity shall state that the high-risk AI system in question meets the requirements set out in Chapter 2 of this Title. The EU declaration of conformity shall contain the information set out in Annex V and shall be translated into ~~*an official Union language or languages required by*~~***a language that can be easily understood by the national competent authorities of*** the Member State(s) in which the high-risk AI system is made available.	2. The EU declaration of conformity shall state that the high-risk AI system in question meets the requirements set out in Chapter 2 of this Title. The EU declaration of conformity shall contain the information set out in Annex V and shall be translated into ~~*an official Union language or languages required*~~***a language that can be easily understood*** by the ***national competent authorities of the*** Member State(s) in which the high-risk AI system is ***placed on the market or*** made available. G
Article 48(3)				
G 495	3. Where high-risk AI systems are	3. Where high-risk AI systems are	3. Where high-risk AI systems are	3. Where high-risk AI systems are G

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	subject to other Union harmonisation legislation which also requires an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all Union legislations applicable to the high-risk AI system. The declaration shall contain all the information required for identification of the Union harmonisation legislation to which the declaration relates.	subject to other Union harmonisation legislation which also requires an EU declaration of conformity, a single EU declaration of conformity ~~shall~~***may*** be drawn up in respect of all Union legislations applicable to the high-risk AI system. The declaration shall contain all the information required for identification of the Union harmonisation legislation to which the declaration relates.	subject to other Union harmonisation legislation which also requires an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all Union legislations applicable to the high-risk AI system. The declaration shall contain all the information required for identification of the Union harmonisation legislation to which the declaration relates.	subject to other Union harmonisation legislation which also requires an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all Union legislations applicable to the high-risk AI system. The declaration shall contain all the information required for identification of the Union harmonisation legislation to which the declaration relates. Text Origin: Council Mandate
Article 48(4)				
G 496	4. By drawing up the EU declaration of conformity, the provider shall assume responsibility for compliance with the requirements set out in Chapter 2 of this Title. The provider shall keep the EU declaration of conformity up-to-date as appropriate.	4. By drawing up the EU declaration of conformity, the provider shall assume responsibility for compliance with the requirements set out in Chapter 2 of this Title. The provider shall keep the EU declaration of conformity up-to-date as appropriate.	4. By drawing up the EU declaration of conformity, the provider shall assume responsibility for compliance with the requirements set out in Chapter 2 of this Title. The provider shall keep the EU declaration of conformity up-to-date as appropriate.	4. By drawing up the EU declaration of conformity, the provider shall assume responsibility for compliance with the requirements set out in Chapter 2 of this Title. The provider shall keep the EU declaration of conformity up-to-date as appropriate. Text Origin: Commission Proposal
Article 48(5)				
G 497	5. The Commission shall be empowered to adopt delegated acts in accordance with Article 73 for the purpose of updating the content of the EU declaration of conformity set out in Annex V in order to introduce	5. ***After consulting the AI Office,*** the Commission shall be empowered to adopt delegated acts in accordance with Article 73 for the purpose of updating the content of the EU declaration of conformity set	5. The Commission shall be empowered to adopt delegated acts in accordance with Article 73 for the purpose of updating the content of the EU declaration of conformity set out in Annex V in order to introduce	5. The Commission shall be empowered to adopt delegated acts in accordance with Article 73 for the purpose of updating the content of the EU declaration of conformity set out in Annex V in order to introduce

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	elements that become necessary in light of technical progress.	out in Annex V in order to introduce elements that become necessary in light of technical progress.	elements that become necessary in light of technical progress.	elements that become necessary in light of technical progress. Text Origin: EP Mandate
Article 49				
G 498	Article 49 CE marking of conformity	Article 49 CE marking of conformity	Article 49 CE marking of conformity	Article 49 CE marking of conformity Text Origin: Commission Proposal
Article 49(1)				
G 499	1. The CE marking shall be affixed visibly, legibly and indelibly for high-risk AI systems. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it shall be affixed to the packaging or to the accompanying documentation, as appropriate.	1. The ***physical*** CE marking shall be affixed visibly, legibly and indelibly for high-risk AI systems~~.~~ ***before the high-risk AI system is placed on the market*** Where that is not possible or not warranted on account of the nature of the high-risk AI system, it shall be affixed to the packaging or to the accompanying documentation, as appropriate. ***It may be followed by a pictogram or any other marking indicating a special risk of use.***	1. The CE marking ~~*shall be affixed visibly, legibly and indelibly for high-risk AI systems. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it*~~***of conformity*** shall be ~~*affixed*~~***subject*** to the ~~*packaging or to the accompanying documentation, as appropriate*~~***general principles set out in Article 30 of Regulation (EC) No 765/2008***.	1. The CE marking ~~*shall be affixed visibly, legibly and indelibly for high-risk AI systems. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it*~~***of conformity*** shall be ~~*affixed*~~***subject*** to the ~~*packaging or to the accompanying documentation, as appropriate*~~***general principles set out in Article 30 of Regulation (EC) No 765/2008***. Text Origin: Council Mandate
Article 49(1a)				
G 499a		***1a. For digital only high-risk AI systems, a digital CE marking shall be used, only if it can be easily accessed via the interface from***		***1a. For high-risk AI systems provided digitally, a digital CE marking shall be used, only if it can be easily accessed via the interface***

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		which the AI system is accessed or via an easily accessible machine-readable code or other electronic means.		***from which the AI system is accessed or via an easily accessible machine-readable code or other electronic means.*** Text Origin: EP Mandate
Article 49(2)				
G 500	2. The CE marking referred to in paragraph 1 of this Article shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.	2. The CE marking referred to in paragraph 1 of this Article shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.	2. The CE marking ~~*referred to in paragraph 1 of this Article*~~***shall be affixed visibly, legibly and indelibly for high-risk AI systems. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it*** shall be ~~*subject*~~***affixed*** to the ~~*general principles set out in Article 30 of Regulation (EC) No 765/2008*~~***packaging or to the accompanying documentation, as appropriate***.	2. The CE marking ~~*referred to in paragraph 1 of this Article*~~***shall be affixed visibly, legibly and indelibly for high-risk AI systems. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it*** shall be ~~*subject*~~***affixed*** to the ~~*general principles set out in Article 30 of Regulation (EC) No 765/2008*~~***packaging or to the accompanying documentation, as appropriate***. Text Origin: Council Mandate
Article 49(3)				
G 501	3. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 43. The identification number shall also be indicated in any promotional material which mentions that the high-risk AI	3. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 43. The identification number ***of the notified body shall be affixed by the body itself or, under its instructions, by the provider's***	3. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 43. The identification number shall also be indicated in any promotional material which mentions that the high-risk AI	3. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 43. The identification number ***of the notified body shall be affixed by the body itself or, under its instructions, by the provider or***

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	system fulfils the requirements for CE marking.	***authorised representative. The identification number*** shall also be indicated in any promotional material which mentions that the high-risk AI system fulfils the requirements for CE marking.	system fulfils the requirements for CE marking.	***by its authorised representative. The identification number*** shall also be indicated in any promotional material which mentions that the high-risk AI system fulfils the requirements for CE marking.
Article 49(3a)				
G 501a		***3a. Where high-risk AI systems are subject to other Union law which also provides for the affixing of the CE marking, the CE marking shall indicate that the high-risk AI system also fulfil the requirements of that other law.***		***3a. Where high-risk AI systems are subject to other Union law which also provides for the affixing of the CE marking, the CE marking shall indicate that the high-risk AI system also fulfil the requirements of that other law.*** G
Article 50				
G 502	Article 50 Document retention	Article 50 Document retention	*deleted*	Article 50 ~~*Document retention*~~***Moved to Article 18*** G
Article 50, first paragraph				
G 503	The provider shall, for a period ending 10 years after the AI system has been placed on the market or put into service, keep at the disposal of the national competent authorities:	The provider shall, for a period ending 10 years, after the AI system has been placed on the market or put into service~~,~~ keep at the disposal of the national ***supervisory authority and the national*** competent authorities:	*deleted*	G
Article 50, first paragraph, point (a)				

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G 504	*(a)* the technical documentation referred to in Article 11;	(a) the technical documentation referred to in Article 11;	*deleted*	G
Article 50, first paragraph, point (b)				
G 505	*(b)* the documentation concerning the quality management system referred to Article 17;	(b) the documentation concerning the quality management system referred to Article 17;	*deleted*	G
Article 50, first paragraph, point (c)				
G 506	*(c)* the documentation concerning the changes approved by notified bodies where applicable;	(c) the documentation concerning the changes approved by notified bodies where applicable;	*deleted*	G
Article 50, first paragraph, point (d)				
G 507	*(d)* the decisions and other documents issued by the notified bodies where applicable;	(d) the decisions and other documents issued by the notified bodies where applicable;	*deleted*	G
Article 50, first paragraph, point (e)				
G 508	*(e)* the EU declaration of conformity referred to in Article 48.	(e) the EU declaration of conformity referred to in Article 48.	*deleted*	G
Article 51				
G 509	Article 51 Registration	Article 51 Registration	Article 51 ***Registration of relevant operators and of high-risk AI systems listed in***	Article 51 Registration G

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			Annex III~~*Registration*~~	Text Origin: Commission Proposal
Article 51, first paragraph				
G 510	Before placing on the market or putting into service a high-risk AI system referred to in Article 6(2), the provider or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60.	Before placing on the market or putting into service a high-risk AI system referred to in Article 6(2)~~,~~ the provider or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60~~.~~***, in accordance with Article 60(2);***	Before placing on the market or putting into service a high-risk AI system ***listed in Annex III with the exception of high-risk AI systems*** referred to in ~~*Article 6(2)*~~***Annex III, points 1, 6 and 7 in the areas of law enforcement, migration, asylum and border control management, and high risk AI systems referred to in Annex III point 2***, the provider ~~*or,*~~***and*** where applicable, the authorised representative shall register ~~*that system*~~***themselves*** in the EU database referred to in Article 60. ***The provider or, where applicable the authorised representative, shall also register their systems in that database.***	Before placing on the market or putting into service a high-risk AI system ***listed in Annex III, with the exception of high risk AI systems*** referred to in ~~*Article 6(2)*~~***Annex III point 2***, the provider or, where applicable, the authorised representative shall register ~~*that*~~***themselves and their*** system in the EU database referred to in Article 60. G
Article 51, first paragraph a				
G 510a			***-1. Before using a high-risk AI system listed in Annex III, users of high-risk AI systems that are public authorities, agencies or bodies, or entities acting on their behalf, shall register themselves in the EU database referred to in Article 60 and select the system that they envisage to use.***	G

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Article 51, third paragraph				
510b			***The obligations laid down in the previous subparagraph shall not apply to law enforcement, border control, immigration or asylum authorities, agencies or bodies and authorities, agencies or bodies using high-risk AI systems referred to Annex III point 2, as well as to entities acting on their behalf.***	Text Origin: Council Mandate
Article 51, fourth paragraph				
510c		***1a Before putting into service or using a high-risk AI system in accordance with Article 6(2), the following categories of deployers shall register the use of that AI system in the EU database referred to in Article 60:*** ***a) deployers who are public authorities or Union institutions, bodies, offices or agencies or deployers acting on their behalf;*** ***b) deployers who are undertakings designated as a gatekeeper under Regulation (EU) 2022/1925.***		***1a. Before placing on the market or putting into service an AI system for which the provider has concluded that it is not high-risk in application of the procedure under Article 6(2a), the provider or, where applicable, the authorised representative shall register themselves and that system in the EU database referred to in Article 60.***
Article 51, fifth paragraph				
510d				

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Article 51, sixth paragraph				
G 510e				G
Article 51, seventh paragraph				
G 510f				G
Article 51, eighth paragraph				
G 510g		***1b Deployers who do not fall under subparagraph 1a. shall be entitled to voluntarily register the use of a high-risk AI system referred to in Article 6(2) in the EU database referred to in Article 60.***		***1b. Before putting into service or using a high-risk AI system listed in Annex III, with the exception of high-risk AI systems listed in Annex III, point 2, deployers who are public authorities, agencies or bodies or persons acting on their behalf shall register themselves, select the system and register its use in the EU database referred to in Article 60.*** G
Article 51, ninth paragraph				
G 510h		***1c An updated registration entry must be completed immediately following each substantial modification.***		***1c. For high-risk AI systems referred to Annex III, points 1, 6 and 7 in the areas of law enforcement, migration, asylum and border control management, the registration referred to in paragraphs 1 to 1b shall be done in a secure non-public section of the EU database referred to in Article 60 and include only the following information, as applicable:*** ***- points 1 to 9 of Annex VIII,*** G

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				section A with the exception of points 5a, 7 and 8 ***- points 1 to 3 of Annex VIII, section B*** ***- points 1 to 9 of Annex VIII, section X with the exception of points 6 and 7*** ***points 1 to 5 of Annex VIIIa with the exception of point 4.*** ***Only the Commission and national authorities referred to in Art. 63 (5) shall have access to these restricted sections of the EU database.*** ***1d. High risk AI systems referred to in Annex III, point 2 shall be registered at national level.***
TITLE IV				
G 511	TITLE IV TRANSPARENCY OBLIGATIONS FOR CERTAIN AI SYSTEMS	TITLE IV TRANSPARENCY OBLIGATIONS ~~*FOR CERTAIN AI SYSTEMS*~~	TITLE IV TRANSPARENCY OBLIGATIONS FOR ***PROVIDERS AND USERS OF*** CERTAIN AI SYSTEMS	TITLE IV TRANSPARENCY OBLIGATIONS FOR ***PROVIDERS AND DEPLOYERS OF*** CERTAIN AI SYSTEMS ***AND GPAI MODELS*** Text Origin: Presidency2
Article 52				
G 512	Article 52 Transparency obligations for certain AI systems	Article 52 Transparency obligations ~~*for certain AI systems*~~	Article 52 ***Transparency obligations for providers and users of certain AI***	Article 52 ***Transparency obligations for providers and users of certain AI***

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			systems~~*Transparency obligations for certain AI systems*~~	***systems and GPAI models***~~*Transparency obligations for certain AI systems*~~ Text Origin: Presidency2
Article 52(1)				
G 513	1. Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that natural persons are informed that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences, unless those systems are available for the public to report a criminal offence.	1. Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that ***the AI system, the provider itself or the user informs the*** natural ~~*persons are informed*~~***person exposed to an AI system*** that they are interacting with an AI system ***in a timely, clear and intelligible manner***, unless this is obvious from the circumstances and the context of use. ***Where appropriate and relevant, this information shall also include which functions are AI enabled, if there is human oversight, and who is responsible for the decision-making process, as well as the existing rights and processes that, according to Union and national law, allow natural persons or their representatives to object against the application of such systems to them and to seek judicial redress against decisions taken by or harm caused by AI systems, including their right to seek an explanation.*** This obligation shall not apply to AI	1. Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that natural persons are informed that they are interacting with an AI system, unless this is obvious from the ***point of view of a natural person who is reasonably well-informed, observant and circumspect, taking into account the*** circumstances and the context of use. This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences***, subject to appropriate safeguards for the rights and freedoms of third parties***, unless those systems are available for the public to report a criminal offence.	1. Providers shall ensure that AI systems intended to ***directly*** interact with natural persons are designed and developed in such a way that ***the concerned*** natural persons are informed that they are interacting with an AI system, unless this is obvious from ***the point of view of a natural person who is reasonably well-informed, observant and circumspect, taking into account*** the circumstances and the context of use. This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences, ***subject to appropriate safeguards for the rights and freedoms of third parties*** unless those systems are available for the public to report a criminal offence. ***1a. Providers of AI systems, including GPAI systems, generating synthetic audio, image, video or text content, shall ensure the outputs of the AI system are marked in a*** G

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		systems authorised by law to detect, prevent, investigate and prosecute criminal offences, unless those systems are available for the public to report a criminal offence.		***machine-readable format and detectable as artificially generated or manipulated. Providers shall ensure their technical solutions are effective, interoperable, robust and reliable as far as this is technically feasible, taking into account specificities and limitations of different types of content, costs of implementation and the generally acknowledged state-of-the-art, as may be reflected in relevant technical standards.*** ***This obligation shall not apply to the extent the AI systems perform an assistive function for standard editing or do not substantially alter the input data provided by the deployer or the semantics thereof, or where authorised by law to detect, prevent, investigate and prosecute criminal offences.***
Article 52(2)				
G 514	2. Users of an emotion recognition system or a biometric categorisation system shall inform of the operation of the system the natural persons exposed thereto. This obligation shall not apply to AI systems used for biometric categorisation, which are permitted by law to detect, prevent and investigate criminal offences.	2. Users of an emotion recognition system or a biometric categorisation system ***which is not prohibited pursuant to Article 5*** shall inform ***in a timely, clear and intelligible manner*** of the operation of the system the natural persons exposed thereto ***and obtain their consent prior to the processing of their biometric and other personal data***	2. Users of ~~an emotion recognition system or~~ a biometric categorisation system shall inform of the operation of the system the natural persons exposed thereto. This obligation shall not apply to AI systems used for biometric categorisation, which are permitted by law to detect, prevent and investigate criminal offences***, subject to appropriate***	2. ~~Users~~***Deployers*** of an emotion recognition system or a biometric categorisation system shall inform of the operation of the system the natural persons exposed thereto ***and process the personal data in accordance with Regulation (EU) 2016/679, Regulation (EU) 2016/1725 and Directive (EU) 2016/280, as applicable***. This G

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		in accordance with Regulation (EU) 2016/679, Regulation (EU) 2016/1725 and Directive (EU) 2016/280, as applicable. This obligation shall not apply to AI systems used for biometric categorisation, which are permitted by law to detect, prevent and investigate criminal offences.	***safeguards for the rights and freedoms of third parties***.	obligation shall not apply to AI systems used for biometric ~~categorisation~~***categorization and emotion recognition***, which are permitted by law to detect, prevent and investigate criminal offences***, subject to appropriate safeguards for the rights and freedoms of third parties, and in compliance with Union law***.
Article 52(2a)				
G 514a			***2a. Users of an emotion recognition system shall inform of the operation of the system the natural persons exposed thereto. This obligation shall not apply to AI systems used for emotion recognition which are permitted by law to detect, prevent and investigate criminal offences, subject to appropriate safeguards for the rights and freedoms of third parties.***	G
Article 52(3), first subparagraph				
G 515	3. Users of an AI system that generates or manipulates image, audio or video content that appreciably resembles existing persons, objects, places or other entities or events and would falsely appear to a person to be authentic or	3. Users of an AI system that generates or manipulates ~~image~~***text***, audio or ~~video~~***visual*** content that ~~appreciably resembles existing persons, objects, places or other entities or events and would falsely appear to a person to be authentic~~	3. Users of an AI system that generates or manipulates image, audio or video content that appreciably resembles existing persons, objects, places or other entities or events and would falsely appear to a person to be authentic or	3. ~~Users~~***Deployers*** of an AI system that generates or manipulates image, audio or video content ***constituting a deep fake, shall disclose that the content has been artificially generated or manipulated. This obligation shall not apply*** G

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	truthful ('deep fake'), shall disclose that the content has been artificially generated or manipulated.	~~or truthful~~***would falsely appear to be authentic or truthful and which features depictions of people appearing to say or do things they did not say or do, without their consent*** ('deep fake'), shall disclose ***in an appropriate, timely, clear and visible manner*** that the content has been artificially generated or manipulated***, as well as, whenever possible, the name of the natural or legal person that generated or manipulated it. Disclosure shall mean labelling the content in a way that informs that the content is inauthentic and that is clearly visible for the recipient of that content. To label the content, users shall take into account the generally acknowledged state of the art and relevant harmonised standards and specifications***.	truthful ('deep fake'), shall disclose that the content has been artificially generated or manipulated.	***where the use is authorised by law to detect, prevent, investigate and prosecute criminal offence. Where the content forms part of an evidently artistic, creative, satirical, fictional analogous work or programme, the transparency obligations set out in this paragraph are limited to disclosure of the existence of such***~~that appreciably resembles existing persons, objects, places or other entities or events and would falsely appear to a person to be authentic or truthful ('deep fake'), shall disclose that the content has been artificially~~ generated or manipulated ***content in an appropriate manner that does not hamper the display or enjoyment of the work***.
Article 52(3), second subparagraph				
G 516	However, the first subparagraph shall not apply where the use is authorised by law to detect, prevent, investigate and prosecute criminal offences or it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, and subject to appropriate safeguards for the rights	***3a*** ~~However, the first subparagraph~~ ***Paragraph 3*** shall not apply where the use ~~is authorised by law to detect, prevent, investigate and prosecute criminal offences or~~ ***of an AI system that generates or manipulates text, audio or visual content is authorized by law or if*** it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and	However, the first subparagraph shall not apply where the use is authorised by law to detect, prevent, investigate and prosecute criminal offences or ~~it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, and~~***where the content is part of an evidently***	~~However, the first subparagraph~~***Deployers of an AI system that generates or manipulates text which is published with the purpose of informing the public on matters of public interest shall disclose that the text has been artificially generated or manipulated. This obligation*** shall not apply where the use is authorised by law to detect, prevent, investigate G

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	and freedoms of third parties.	sciences guaranteed in the Charter of Fundamental Rights of the EU, and subject to appropriate safeguards for the rights and freedoms of third parties. ***Where the content forms part of an evidently creative, satirical, artistic or fictional cinematographic, video games visuals and analogous work or programme, transparency obligations set out in paragraph 3 are limited to disclosing of the existence of such generated or manipulated content in an appropriate clear and visible manner that does not hamper the display of the work and disclosing the applicable copyrights, where relevant. It shall also not prevent law enforcement authorities from using AI systems intended to detect deep fakes and prevent, investigate and prosecute criminal offences linked with their use.***	***creative, satirical, artistic or fictional work or programme*** subject to appropriate safeguards for the rights and freedoms of third parties.	and prosecute criminal offences or ~~*it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, and subject to appropriate safeguards*~~***where the AI-generated content has undergone a process of human review or editorial control and where a natural or legal person holds editorial responsibility*** for the ~~*rights and freedoms of third parties*~~***publication of the content***.
Article 52(3a)				
G 516a		***3b The information referred to in paragraphs 1 to 3 shall be provided to the natural persons at the latest at the time of the first interaction or exposure. It shall be accessible to vulnerable persons, such as persons with disabilities or children, complete, where relevant and appropriate, with intervention or***		***3a. The information referred to in paragraphs 1 to 3 shall be provided to the concerned natural persons in a clear and distinguishable manner at the latest at the time of the first interaction or exposure. The information shall respect the applicable accessibility requirements.*** G

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		flagging procedures for the exposed natural person taking into account the generally acknowledged state of the art and relevant harmonised standards and common specifications.		
Article 52(3b)				
G 516b			***3a. The information referred to in paragraphs 1 to 3 shall be provided to natural persons in a clear and distinguishable manner at the latest at the time of the first interaction or exposure.***	
Article 52(4)				
G 517	4. Paragraphs 1, 2 and 3 shall not affect the requirements and obligations set out in Title III of this Regulation.	4. Paragraphs 1, 2 and 3 shall not affect the requirements and obligations set out in Title III of this Regulation.	4. Paragraphs 1, 2***, 2a*** and 3 ***and 3a*** shall not affect the requirements and obligations set out in Title III of this Regulation ***and shall be without prejudice to other transparency obligations for users of AI systems laid down in Union or national law***.	4. Paragraphs 1, 2 and 3 shall not affect the requirements and obligations set out in Title III of this Regulation ***and shall be without prejudice to other transparency obligations for users of AI systems laid down in Union or national law.*** ***4a. 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 and labelling of artificially generated or manipulated content. The Commission is empowered to adopt***

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				implementing acts to approve these codes of practice in accordance with the procedure laid down in Article 52e paragraphs 6-8. If it deems the code is not adequate, the Commission is empowered to adopt an implementing act specifying the common rules for the implementation of those obligations in accordance with the examination procedure laid down in Article 73 paragraph 2.
Article 52a				
G 517a				***TITLE VIIIA GENERAL PURPOSE AI MODELS*** ***CHAPTER 1 CLASSIFICATION RULES*** ***Article 52a Classification of general-purpose AI models as general purpose AI models with systemic risk*** G
Article 52a(1)				
G 517b				***1. A general-purpose AI model shall be classified as general-purpose AI model with systemic risk if it meets any of the following criteria:*** G

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Article 52a(1), point (a)				
G 517c				***(a) it has high impact capabilities evaluated on the basis of appropriate technical tools and methodologies, including indicators and benchmarks;*** G
Article 52a(1), point (b)				
G 517d				***(b) based on a decision of the Commission, ex officio or following a qualified alert by the scientific panel that a general purpose AI model has capabilities or impact equivalent to those of point a).*** G
Article 52a(2)				
G 517e				***2. A general-purpose AI model shall be presumed to have high impact capabilities pursuant to point a) of paragraph 1 when the cumulative amount of compute used for its training measured in floating point operations (FLOPs) is greater than 10^25.*** G
Article 52a(3)				
G 517f				***3. The Commission shall adopt delegated acts in accordance with Article 73(2) to amend the thresholds listed in the paragraphs*** G

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				above, as well as to supplement benchmarks and indicators in light of evolving technological developments, such as algorithmic improvements or increased hardware efficiency, when necessary, for these thresholds to reflect the state of the art.
Title IVa				
G 517g				G
Chapter I				
G 517h				G
Article 52b				
G 517i				***Article 52b Procedure*** G
Article 52b(1)				
G 517j				***1. Where a general-purpose AI model meets the requirements referred to in points (a) of Article A(1), the relevant provider shall notify the Commission without delay and in any event within 2 weeks after those requirements are met or it becomes known that these requirements will be met. That*** G

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				notification shall include the information necessary to demonstrate that the relevant requirements have been met. If the Commission becomes aware of a general purpose AI model presenting systemic risks of which it has not been notified, it may decide to designate it as a model with systemic risk.
Article 52b(2)				
G 517k				***2. The provider of a general-purpose AI model that meets the requirements referred to in points (a) of Article A(1) may present, with its notification, sufficiently substantiated arguments to demonstrate that, exceptionally, although it meets the said requirements, the general-purpose AI model does not present, due to its specific characteristics, systemic risks and therefore should not be classified as general-purpose AI model with systemic risk.***
Article 52b(3)				
G 517l				***3. Where the Commission concludes that the arguments submitted pursuant to paragraph 2 are not sufficiently substantiated and the relevant provider was not***

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				able to demonstrate that the general purpose AI model does not present, due to its specific characteristics, systemic risks, it shall reject those arguments and the general-purpose AI model shall be considered as general purpose AI model with systemic risk.
Article 52b(4)				
G 517m				***4. The Commission may designate a general purpose AI model as presenting systemic risks, ex officio or following a qualified alert of the scientific panel pursuant to point (a) of Article [Alerts of systemic risks by the scientific panel] (1) on the basis of criteria set out in Annex YY. The Commission shall be empowered to specify and update the criteria in Annex YY by means of delegated acts in accordance with Article 74 (2).*** ***4a. Upon a reasoned request of a provider whose model has been designated as a general-purpose AI model with systemic risk pursuant to paragraph 4, the Commission shall take the request into account and may decide to reassess whether the general-purpose AI model can still be considered to present systemic risks on the basis of the criteria set out in Annex YY. Such*** G

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				request shall contain objective, concrete and new reasons that have arisen since the designation decision. Providers may request reassessment at the earliest six months after the designation decision. Where the Commission, following its reassessment, decides to maintain the designation as general-purpose AI model with systemic risk, providers may request reassessment at the earliest six months after this decision.
Article 52b(5)				
G 517n				***5. The Commission shall ensure that a list of general-purpose AI models with systemic risk is published and shall keep that list up to date, without prejudice to the need to respect and protect intellectual property rights and confidential business information or trade secrets in accordance with Union and national law.*** G
Chapter II				
G 517o				***Chapter II*** ***Obligations for providers of general purpose AI models*** G
Article 52c				

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G 517p				***Article 52c*** ***Obligations for providers of general purpose AI models***
Article 52c(1)				
G 517q				***1. Providers of general purpose AI models shall:***
Article 52c(1), point (a)				
G 517r				***(a) draw up and keep up-to-date the technical documentation of the model, including its training and testing process and the results of its evaluation, which shall contain, at a minimum, the elements set out in Annex XX for the purpose of providing it, upon request, to the AI Office and the national competent authorities;***
Article 52c(1), point (b)				
G 517s				***(b) draw up, keep up-to-date and make available information and documentation to providers of AI systems who intend to integrate the general-purpose AI model in their AI system. Without prejudice to the need to respect and protect intellectual property rights and confidential business information***

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				or trade secrets in accordance with Union and national law, the information and documentation shall:
Article 52c(1), point (b)(i)				
G 517t				***(i) enable providers of AI systems to have a good understanding of the capabilities and limitations of the general purpose AI model and to comply with their obligations pursuant to this Regulation; and*** G
Article 52c(1), point (b)(ii)				
G 517u				***(ii) contain, at a minimum, the elements set out in Annex XY;*** G
Article 52c(1), point (c)				
G 517v				***(c) put in place a policy to respect Union copyright law in particular to identify and respect, including through state of the art technologies, the reservations of rights expressed pursuant to Article 4(3) of Directive (EU) 2019/790;*** G
Article 52c(2)				
G 517w				***-2. The obligations set out in paragraph 1, with the exception of*** G

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				letters (c) and (d), shall not apply to providers of AI models that are made accessible to the public under a free and open licence that allows for the access, usage, modification, and distribution of the model, and whose parameters, including the weights, the information on the model architecture, and the information on model usage, are made publicly available. This exception shall not apply to general purpose AI models with systemic risks. ***2. Providers of general purpose AI models shall cooperate as necessary with the Commission and the national competent authorities in the exercise of their competences and powers pursuant to this Regulation.***
Article 52c(1), point (d)				
G 517x				***(d) draw up and make publicly available a sufficiently detailed summary about the content used for training of the general-purpose AI model, according to a template provided by the AI Office;*** G
Article 52c(3)				
G 517y				G

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				3. Providers of general purpose AI models may rely on codes of practice within the meaning of Article E demonstrate compliance with the obligations in paragraph 1, until a harmonised standard is published. Compliance with a European harmonised standard grants providers the presumption of conformity. Providers of general-purpose AI models with systemic risks who do not adhere to an approved code of practice shall demonstrate alternative adequate means of compliance for approval of the Commission.
Article 52c(4)				
G 517z				***4. For the purpose of facilitating compliance with Annex XX, notably point 2, (d) and (e), the Commission shall be empowered to adopt delegated acts in accordance with Article 73 to detail measurement and calculation methodologies with a view to allow comparable and verifiable documentation.*** ***4a. The Commission is empowered to adopt delegated acts in accordance with Article 73(2) to amend Annexes XX and XY in the light of the evolving technological developments.*** G

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				4b. Any information and documentation obtained pursuant to the provisions of this Article, including trade secrets, shall be treated in compliance with the confidentiality obligations set out in Article 70. ***New article 52ca*** ***Authorised representative*** ***1. Prior to placing a general purpose AI model on the Union market providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union and shall enable it to perform its tasks under this Regulation.*** ***2. The authorised representative shall perform the tasks specified in the mandate received from the provider. It shall provide a copy of the mandate to the AI Office upon request, in one of the official languages of the institutions of the Union. For the purpose of this Regulation, the mandate shall empower the authorised representative to carry out the following tasks:*** ***a) verify that the technical documentation specified in Annex***

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				IXa has been drawn up and all obligations referred to in Articles 52c and, where applicable, Article 52d have been fulfilled by the provider; ***b) keep a copy of the technical documentation at the disposal of the AI Office and national competent authorities, for a period ending 10 years after the model has been placed on the market and the contact details of the provider by which the authorised representative has been appointed;*** ***c) provide the AI Office, upon a reasoned request, with all the information and documentation, including that kept according to point (a), necessary to demonstrate the compliance with the obligations in this Title;*** ***d) cooperate with the AI Office and national competent authorities, upon a reasoned request, on any action the latter takes in relation to the general-purpose AI model with systemic risks, including when the model is integrated into AI systems placed on the market or put into service in the Union;*** ***3. The mandate shall empower the authorised representative to be addressed, in addition to or instead***

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				of the provider, by the AI Office or the national competent authorities, on all issues related to ensuring compliance with this Regulation. ***4. The authorised representative shall terminate the mandate if it considers or has reason to consider that the provider acts contrary to its obligations under this Regulation. In such a case, it shall also immediately inform the AI Office about the termination of the mandate and the reasons thereof.*** ***5. The obligation set out in this article shall not apply to providers of general purpose AI models that are made accessible to the public under a free and open source licence that allows for the access, usage, modification, and distribution of the model, and whose parameters, including the weights, the information on the model architecture, and the information on model usage, are made publicly available, unless the general purpose AI models present systemic risks.***
Chapter III				
G 517aa				***Chapter III*** ***Obligations for providers of general purpose AI models with systemic*** G

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				risk
Article 52d				
G 517ab				***Article 52d*** ***Obligations for providers of general-purpose AI models with systemic risk*** G
Article 52d(1)				
G 517ac				***1. In addition to the obligations listed in Article C, providers of general-purpose AI models with systemic risk shall:*** G
Article 52d(1), point (a)				
G 517ad				***(a) perform model evaluation in accordance with standardised protocols and tools reflecting the state of the art, including conducting and documenting adversarial testing of the model with a view to identify and mitigate systemic risk;*** G
Article 52d(1), point (b)				
G 517ae				***(b) assess and mitigate possible systemic risks at Union level, including their sources, that may stem from the development, placing*** G

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				on the market, or use of general purpose AI models with systemic risk;
Article 52d(1), point (c)				
G 517af				***(c) keep track of, document and report without undue delay to the AI Office and, as appropriate, to national competent authorities, relevant information about serious incidents and possible corrective measures to address them;*** G
Article 52d(1), point (d)				
G 517ag				***(d) ensure an adequate level of cybersecurity protection for the general purpose AI model with systemic risk and the physical infrastructure of the model.*** G
Article 52d(2)				
G 517ah				***2. Providers of general purpose AI models with systemic risk may rely on codes of practice within the meaning of Article E to demonstrate compliance with the obligations in paragraph 1, until a harmonised standard is published. Compliance with a European harmonised standard grants providers the presumption of*** G

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				conformity. Providers of general-purpose AI models with systemic risks who do not adhere to an approved code of practice shall demonstrate alternative adequate means of compliance for approval of the Commission.
Article 52d(3)				
G 517ai				***3. Any information and documentation obtained pursuant to the provisions of this Article, including trade secrets, shall be treated in compliance with the confidentiality obligations set out in Article 70.*** G
Article 52e				
G 517aj				***Article 52e*** ***Codes of practice*** G
Article 52e(1)				
G 517ak				***1. The AI Office shall encourage and facilitate the drawing up of codes of practice at Union level as an element to contribute to the proper application of this Regulation, taking into account international approaches.*** G
Article 52e(2)				

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G 517al				***2. The AI Office and the AI Board shall aim to ensure that the codes of practice cover, but not necessarily be limited to, the obligations provided for in Articles C and D, including the following issues:***
Article 52e(2), point (a)				
G 517am				***(a) means to ensure that the information referred to in Article C (a) and (b) is kept up to date in the light of market and technological developments, and the adequate level of detail for the summary about the content used for training;***
Article 52e(2), point (b)				
G 517an				***(b) the identification of the type and nature of the systemic risks at Union level, including their sources when appropriate;***
Article 52e(2), point (c)				
G 517ao				***(c) the measures, procedures and modalities for the assessment and management of the systemic risks at Union level, including the documentation thereof. The assessment and management of the systemic risks at Union level shall***

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				be proportionate to the risks, take into consideration their severity and probability and take into account the specific challenges of tackling those risks in the light of the possible ways in which such risks may emerge and materialize along the AI value chain.
Article 52e(3)				
G 517ap				***3. The AI Office may invite the providers of general-purpose AI models, as well as relevant national competent authorities, to participate in the drawing up of codes of practice. Civil society organisations, industry, academia and other relevant stakeholders, such as downstream providers and independent experts, may support the process.*** G
Article 52e(4)				
G 517aq				***4. The AI Office and the Board shall aim to ensure that the codes of practice clearly set out their specific objectives and contain commitments or measures, including key performance indicators as appropriate, to ensure the achievement of those objectives and take due account of the needs and interests of all interested*** G

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				parties, including affected persons, at Union level.
Article 52e(5)				
G 517ar				***5. The AI Office may invite all providers of general-purpose AI models to participate in the codes of practice. For providers of general-purpose AI models not presenting systemic risks this participation should be limited to obligations foreseen in paragraph 2 point a) of this Article, unless they declare explicitly their interest to join the full code.*** G
Article 52e(6)				
G 517as				***6. The AI Office shall aim to ensure that participants to the codes of practice report regularly to the AI Office on the implementation of the commitments and the measures taken and their outcomes, including as measured against the key performance indicators as appropriate. Key performance indicators and reporting commitments shall take into account differences in size and capacity between different participants.*** G
Article 52e(7)				

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G 517at				***7. The AI Office and the AI 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 AI Office and the Board shall assess whether the codes of practice cover the obligations provided for in Articles C and D, including the issues listed in paragraph 2 of this Article, and shall regularly monitor and evaluate the achievement of their objectives. They shall publish their assessment of the adequacy of the codes of practice. The Commission may, by way of implementing acts, decide to approve the code of practice and give it a general validity within the Union. Those implementing acts shall be adopted in accordance with the examination procedure set out in Article 74(2).***
Article 52e(8)				
G 517au				***8. As appropriate, the AI Office shall also encourage and facilitate review and adaptation of the codes of practice, in particular in light of emerging standards. The AI Office shall assist in the assessment of available standards.***

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Article 52e(9)				
G 517av				***9. If, by the time the Regulation becomes applicable, a Code of Practice cannot be finalised, or if the AI Office deems it is not adequate following under paragraph 6, the Commission may provide, by means of implementing acts, common rules for the implementation of the obligations provided for in Articles C [Article 52c] and D [Article 52d], including the issues set out in paragraph 2.***
TITLE V				
G 518	TITLE V MEASURES IN SUPPORT OF INNOVATION	TITLE V MEASURES IN SUPPORT OF INNOVATION	TITLE V MEASURES IN SUPPORT OF INNOVATION	TITLE V MEASURES IN SUPPORT OF INNOVATION Text Origin: Commission Proposal
Article 53				
G 519	Article 53 AI regulatory sandboxes	Article 53 AI regulatory sandboxes	Article 53 AI regulatory sandboxes	Article 53 AI regulatory sandboxes Text Origin: Commission Proposal
Article 53(-1)				

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G 519a			***-1. National competent authorities may establish AI regulatory sandboxes for the development, training, testing and validation of innovative AI systems under the direct supervision, guidance and support by the national competent authority, before those systems are placed on the market or put into service. Such regulatory sandboxes may include testing in real world conditions supervised by the national competent authorities.***	G
Article 53(-1a)				
G 519b			***-1a. Where appropriate, national competent authorities shall cooperate with other relevant authorities and may allow for the involvement of other actors within the AI ecosystem.***	G
Article 53(-1b)				
G 519c			***-1b. This Article shall not affect other regulatory sandboxes established under national or Union law, including in cases where the products or services that are tested in them are linked to the use of innovative AI systems. Member States shall ensure an appropriate level of cooperation***	G

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			between the authorities supervising those other sandboxes and the national competent authorities.	
Article 53(1)				
G 520	1. AI regulatory sandboxes established by one or more Member States competent authorities or the European Data Protection Supervisor shall provide a controlled environment that facilitates the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan. This shall take place under the direct supervision and guidance by the competent authorities with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.	1. ~~*AI regulatory sandboxes established by one or more Member States competent authorities or the European Data Protection Supervisor*~~***Member States shall establish at least one AI regulatory sandbox at national level, which*** shall ~~*provide a controlled environment that facilitates the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan. This shall take place under the direct supervision and guidance by the competent authorities with a view to ensuring compliance with the requirements of this Regulation and, where relevant,*~~***be operational at the latest on the day of the entry into application of this Regulation This sandbox can also be established jointly with one or several*** other ~~*Union and*~~ Member States ~~*legislation supervised within the sandbox*~~.	*deleted*	1. ~~*AI regulatory sandboxes established by one or more Member States competent authorities or the European Data Protection Supervisor*~~***Member States shall ensure that their competent authorities establish at least one AI regulatory sandbox at national level, which*** shall ~~*provide a controlled environment that facilitates the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan. This shall take place under the direct supervision and guidance by the competent authorities with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox*~~***be operational 24 months after entry into force. This sandbox may also be established jointly with one or several other Member States' competent authorities. The Commission may provide technical support, advice and tools for the*** G

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				establishment and operation of AI regulatory sandboxes. ***The obligation established in previous paragraph can also be fulfilled by participation in an existing sandbox insofar as this participation provides equivalent level of national coverage for the participating Member States***.
Article 53(1a)				
G 520a			***1a. The establishment of AI regulatory sandboxes under this Regulation shall aim to contribute to one or more of the following objectives:***	G
Article 53(1a), point (a)				
G 520b			***(a) foster innovation and competitiveness and facilitate the development of an AI ecosystem;***	G
Article 53(1a), point (b)				
G 520c			***(b) facilitate and accelerate access to the Union market for AI systems, in particular when provided by small and medium enterprises (SMEs), including start-ups;***	G
Article 53(1a), point (c)				

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G 520d			*(c) improve legal certainty and contribute to the sharing of best practices through cooperation with the authorities involved in the AI regulatory sandbox with a view to ensuring future compliance with this Regulation and, where appropriate, with other Union and Member States legislation;*	G
Article 53(1a), point (d)				
G 520e			*(d) contribute to evidence-based regulatory learning.*	G
Article 53(1a)				
G 520f		*1a. Additional AI regulatory sandboxes at regional or local levels or jointly with other Member States may also be established;*		*1a. Additional AI regulatory sandboxes at regional or local levels or jointly with other Member States' competent authorities may also be established;* Text Origin: EP Mandate	G
Article 53(1b)				
G 520g		*1b. The Commission and the European Data Protection Supervisor, on their own, jointly or in collaboration with one or more Member States may also establish AI regulatory sandboxes at Union*		*1b. The European Data Protection Supervisor may also establish an AI regulatory sandbox for the EU institutions, bodies and agencies and exercise the roles and the tasks of national competent authorities in*	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		level;		***accordance with this chapter.*** Text Origin: EP Mandate
Article 53(1c)				
G 520h		***1c. Establishing authorities shall allocate sufficient resources to comply with this Article effectively and in a timely manner.***		***1c. Member States shall ensure that competent authorities referred to in paragraphs 1 and 1a allocate sufficient resources to comply with this Article effectively and in a timely manner.*** ***Where appropriate, national competent authorities shall cooperate with other relevant authorities and may allow for the involvement of other actors within the AI ecosystem.*** ***This Article shall not affect other regulatory sandboxes established under national or Union law. Member States shall ensure an appropriate level of cooperation between the authorities supervising those other sandboxes and the national competent authorities.*** Text Origin: EP Mandate
Article 53(1d)				
G 520i		***1d. AI regulatory sandboxes shall, in accordance with criteria set out in Article 53a, provide for a***		***1d. AI regulatory sandboxes established under Article 53(1) of this Regulation shall, in accordance***

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		controlled environment that fosters innovation and facilitates the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan agreed between the prospective providers and the establishing authority.		***with Articles 53 and 53a, 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 placement on the market or putting into service pursuant to a specific sandbox plan agreed between the prospective providers and the competent authority. Such regulatory sandboxes may include testing in real world conditions supervised in the sandbox.***
Article 53(1e)				
G 520j		***1e. Establishing authorities shall provide guidance and supervision within the sandbox with a view to identify risks, in particular to fundamental rights, democracy and rule of law, health and safety and the environment, test and demonstrate mitigation measures for identified risks, and their effectiveness and ensure compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation.***		***1e. Competent authorities shall provide, as appropriate, guidance, supervision and support within the sandbox with a view to identifying risks, in particular to fundamental rights, health and safety, testing, mitigation measures, and their effectiveness in relation to the obligations and requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.***
Article 53(1f)				
G 520k		***1f. Establishing authorities shall***		***1f. Competent authorities shall***

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		provide sandbox prospective providers who develop high-risk AI systems with guidance and supervision on how to fulfil the requirements set out in this Regulation, so that the AI systems may exit the sandbox being in presumption of conformity with the specific requirements of this Regulation that were assessed within the sandbox. Insofar as the AI system complies with the requirements when exiting the sandbox, it shall be presumed to be in conformity with this regulation. In this regard, the exit reports created by the establishing authority shall be taken into account by market surveillance authorities or notified bodies, as applicable, in the context of conformity assessment procedures or market surveillance checks.		***provide providers and prospective providers with guidance on regulatory expectations and how to fulfil the requirements and obligations set out in this Regulation.*** ***Upon request of the provider or prospective provider of the AI system, the competent authority shall provide a written proof of the activities successfully carried out in the sandbox. The competent authority shall also provide an exit report detailing the activities carried out in the sandbox and the related results and learning outcomes. Providers may use such documentation to demonstrate the compliance with this Regulation through the conformity assessment process or relevant market surveillance activities. In this regard, the exit reports and the written proof provided by the national competent authority shall be taken positively into account by market surveillance authorities and notified bodies, with a view to accelerate conformity assessment procedures to a reasonable extent.*** ***1fa Subject to the confidentiality provisions in Article 70 and with the agreement of the sandbox provider/prospective provider, the European Commission and the***

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				Board shall be authorised to access the exit reports and shall take them into account, as appropriate, when exercising their tasks under this Regulation. If both provider and prospective provider and the national competent authority explicitly agree to this, the exit report can be made publicly available through the single information platform referred to in this article.
Article 53(1g)				
G 520l		***1g. The establishment of AI regulatory sandboxes shall aim to contribute to the following objectives:*** ***a) for the competent authorities to provide guidance to AI systems prospective providers providers to achieve regulatory compliance with this Regulation or where relevant other applicable Union and Member States legislation;*** ***b) for the prospective providers to allow and facilitate the testing and development of innovative solutions related to AI systems;*** ***c) regulatory learning in a controlled environment.***		***1g. The establishment of AI regulatory sandboxes shall aim to contribute to the following objectives:*** ***a) improve legal certainty to achieve regulatory compliance with this Regulation or, where relevant, other applicable Union and Member States legislation;*** ***b) support the sharing of best practices through cooperation with the authorities involved in the AI regulatory sandbox;*** ***c) foster innovation and competitiveness and facilitate the development of an AI ecosystem;*** ***d) contribute to evidence-based*** G

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				regulatory learning; ***e) facilitate and accelerate access to the Union market for AI systems, in particular when provided by small and medium-sized enterprises (SMEs), including start-ups.***
Article 53(2)				
G 521	2. Member States shall ensure that to the extent the innovative AI systems 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 and those other national authorities are associated to the operation of the AI regulatory sandbox.	2. ~~*Member States*~~***Establishing authorities*** shall ensure that**,** to the extent the innovative AI systems 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 ***personal*** data, the national data protection authorities***, or in cases referred to in paragraph 1b the EDPS,*** and those other national authorities are associated to the operation of the AI regulatory sandbox ***and involved in the supervision of those aspects to the full extent of their respective tasks and powers***.	*deleted*	2. ~~*Member States*~~***National competent authorities*** shall ensure that**,** to the extent the innovative AI systems 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**,** and those other national authorities are associated to the operation of the AI regulatory sandbox ***and involved in the supervision of those aspects to the extent of their respective tasks and powers, as applicable***. Text Origin: EP Mandate
Article 53(2a), first subparagraph				
G 521a			***2a. Access to the AI regulatory sandboxes shall be open to any provider or prospective provider of an AI system who fulfils the***	

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			eligibility and selection criteria referred to in paragraph 6(a) and who has been selected by the national competent authorities following the selection procedure referred to in paragraph 6(b). Providers or prospective providers may also submit applications in partnership with users or any other relevant third parties.	
Article 53(2a), second subparagraph				
G 521b			***Participation in the AI regulatory sandbox shall be limited to a period that is appropriate to the complexity and scale of the project. This period may be extended by the national competent authority.***	G
Article 53(2a), third subparagraph				
G 521c			***Participation in the AI regulatory sandbox shall be based on a specific plan referred to in paragraph 6 of this Article that shall be agreed between the participant(s) and the national competent authoritie(s), as applicable.***	G
Article 53(3)				
G 522	3. The AI regulatory sandboxes shall not affect the supervisory and	3. The AI regulatory sandboxes shall not affect the supervisory and	3. ***The participation in*** the AI regulatory sandboxes shall not affect	3. The AI regulatory sandboxes shall not affect the supervisory and G

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	corrective powers of the competent authorities. Any significant risks to health and safety and fundamental rights identified during the development and testing of such systems shall result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place.	corrective powers of the competent authorities***, including at regional or local level***. Any significant risks to ***fundamental rights, democracy and rule of law,*** health and safety ~~*and fundamental rights*~~***or the environment*** identified during the development and testing of such ***AI*** systems shall result in immediate ***and adequate*** mitigation***. Competent authorities shall have the power to temporarily or permanently suspend the testing process, or participation*** ~~*and, failing that,*~~ in the ~~*suspension of the development and testing process until such mitigation takes place*~~***sandbox if no effective mitigation is possible and inform the AI office of such decision***.	the supervisory and corrective powers of the ~~*competent authorities. Any significant risks to health and safety and fundamental rights identified during the development and testing of such systems shall result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place*~~***authorities supervising the sandbox. Those authorities shall exercise their supervisory powers in a flexible manner within the limits of the relevant legislation, using their discretionary powers when implementing legal provisions to a specific AI sandbox project, with the objective of supporting innovation in AI in the Union***.	corrective powers of the competent authorities ***supervising the sandboxes, including at regional or local level***. Any significant risks to health and safety and fundamental rights identified during the development and testing of such ***AI*** systems shall result in ~~*immediate*~~***an adequate*** mitigation***. National competent authorities shall have the power to temporarily or permanently suspend the testing process, or participation*** ~~*and, failing that,*~~ in the ~~*suspension*~~***sandbox if no effective mitigation is possible and inform the AI Office of such decision. National competent authorities shall exercise their supervisory powers within the limits*** of the ~~*development and testing process until such mitigation takes place*~~***relevant legislation, using their discretionary powers when implementing legal provisions to a specific AI sandbox project, with the objective of supporting innovation in AI in the Union***.
Article 53(3a), first subparagraph				
G 522a			***3a. Provided that the participant(s) respect the sandbox plan and the terms and conditions for their participation as referred to in paragraph 6(c) and follow in good***	G

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			faith the guidance given by the authorities, no administrative fines shall be imposed by the authorities for infringement of applicable Union or Member State legislation relating to the AI system supervised in the sandbox, including the provisions of this Regulation.	
Article 53(4)				
G 523	4. Participants in the AI regulatory sandbox shall remain liable under applicable Union and Member States liability legislation for any harm inflicted on third parties as a result from the experimentation taking place in the sandbox.	4. ~~*Participants*~~***Prospective providers*** in the AI regulatory sandbox shall remain liable under applicable Union and Member States liability legislation for any harm inflicted on third parties as a result ~~*from*~~***of*** the experimentation taking place in the sandbox. ***However, provided that the prospective provider(s) respect the specific plan referred to in paragraph 1c and the terms and conditions for their participation and follow in good faith the guidance given by the establishing authorities, no administrative fines shall be imposed by the authorities for infringements of this Regulation.***	4. ~~*Participants in the AI regulatory sandbox shall*~~***The participants*** remain liable under applicable Union and Member States liability legislation for any ~~*harm inflicted on third parties as a result from the experimentation taking place in the*~~***damage caused in the course of their participation in an AI regulatory*** sandbox.	4. ~~*Participants*~~***Providers and prospective providers*** in the AI regulatory sandbox shall remain liable under applicable Union and Member States liability legislation for any ~~*harm*~~ ***damage*** inflicted on third parties as a result ~~*from*~~***of*** the experimentation taking place in the sandbox. ***However, provided that the prospective provider(s) respect the specific plan and the terms and conditions for their participation and follow in good faith the guidance given by the national competent authority, no administrative fines shall be imposed by the authorities for infringements of this Regulation. To the extent that other competent authorities responsible for other Union and Member States' legislation have been actively involved in the supervision of the AI system in the sandbox and have provided guidance for compliance,*** G

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				no administrative fines shall be imposed regarding that legislation. ***4b. The AI regulatory sandboxes shall be designed and implemented in such a way that, where relevant, they facilitate cross-border cooperation between national competent authorities.***
Article 53(4a), first subparagraph				
G 523a			***4a. Upon request of the provider or prospective provider of the AI system, the national competent authority shall provide, where applicable, a written proof of the activities successfully carried out in the sandbox. The national competent authority shall also provide an exit report detailing the activities carried out in the sandbox and the related results and learning outcomes. Such written proof and exit report could be taken into account by market surveillance authorities or notified bodies, as applicable, in the context of conformity assessment procedures or market surveillance checks.***	G
Article 53(4a), second subparagraph				
G 523b			***Subject to the confidentiality provisions in Article 70 and with***	G

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			the agreement of the sandbox participants, the European Commission and the AI Board shall be authorised to access the exit reports and shall take them into account, as appropriate, when exercising their tasks under this Regulation. If both the participant and the national competent authority explicitly agree to this, the exit report can be made publicly available through the single information platform referred to in article 55(3)(b).	
Article 53(4b)				
G 523c			***4b. The AI regulatory sandboxes shall be designed and implemented in such a way that, where relevant, they facilitate cross-border cooperation between the national competent authorities.***	G
Article 53(5)				
G 524	5. Member States' competent authorities that have established AI regulatory sandboxes shall coordinate their activities and cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results from the	5. ~~*Member States' competent*~~***Establishing*** authorities ~~*that have established AI regulatory sandboxes*~~ shall coordinate their activities and cooperate within the framework of the ~~*European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the*~~	5. ~~*Member States'*~~***National*** competent authorities ~~*that have established*~~***shall make publicly available annual reports on the implementation of the*** AI regulatory sandboxes***, including good practices, lessons learnt and recommendations on*** ~~*shall coordinate*~~ their ~~*activities and*~~	5. ~~*Member States'*~~***National*** competent authorities ~~*that have established AI regulatory sandboxes*~~ shall coordinate their activities and cooperate within the framework of the ~~*European Artificial Intelligence*~~ Board. ~~*They shall submit annual reports to the Board and the Commission on the results from the*~~ G

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	implementation of those scheme, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application of this Regulation and other Union legislation supervised within the sandbox.	~~results from the implementation of those scheme, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application of this Regulation and other Union legislation supervised within the sandbox~~***AI office***.	~~cooperate within the framework of the European Artificial Intelligence Board. They shall submit~~***setup and, where relevant, on the application of this Regulation and other Union legislation supervised within the sandbox. Those*** annual reports ~~to the Board and the Commission on the results from the implementation of those scheme, including~~***shall be submitted to the AI Board which shall make publicly available a summary of all*** good practices, lessons learnt and recommendations***. This obligation to make annual reports publicly available shall not cover sensitive operational data in relation to the activities of law enforcement, border control, immigration or asylum authorities. The Commission and the AI Board shall, where appropriate, take the annual reports into account when exercising their tasks under this Regulation*** ~~on their setup and, where relevant, on the application of this Regulation and other Union legislation supervised within the sandbox~~.	~~implementation of those scheme, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application of this Regulation and other Union legislation supervised within the sandbox.~~ Text Origin: EP Mandate
Article 53(5a)				
G 524a			***5a. The Commission shall ensure that information about AI regulatory sandboxes, including about those established under this***	G

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			Article, is available through the single information platform referred to in Article 55(3)(b).	
Article 53(5a)				
G 524b		***5a. Establishing authorities shall inform the AI Office of the establishment of a sandbox and may ask for support and guidance. A list of planned and existing sandboxes shall be made publicly available by the AI office and kept up to date in order to encourage more interaction in the regulatory sandboxes and transnational cooperation.***		***5a. National competent authorities shall inform the AI Office and the Board of the establishment of a sandbox and may ask for support and guidance. A list of planned and existing AI sandboxes shall be made publicly available by the AI Office and kept up to date in order to encourage more interaction in the regulatory sandboxes and cross-border cooperation.*** G
Article 53(5b)				
G 524c		***5b. Establishing authorities shall submit to the AI office and, unless the Commission is the sole establishing authority, to the Commission, annual reports, starting one year after the establishment of the sandbox and then every year until its termination and a final report. Those reports shall provide information on the progress and results of the implementation of those sandboxes, including best practices, incidents, lessons learnt and recommendations on their setup***		***5b. National competent authorities shall submit to the AI Office and to the Board, annual reports, starting one year after the establishment of the AI regulatory sandbox and then every year until its termination and a final report. Those reports shall provide information on the progress and results of the implementation of those sandboxes, including best practices, incidents, lessons learnt and recommendations on their setup and, where relevant, on the application and possible revision of this Regulation, including its*** G

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		and, where relevant, on the application and possible revision of this Regulation and other Union law supervised within the sandbox. Those annual reports or abstracts thereof shall be made available to the public, online.		***delegated and implementing acts, and other Union law supervised within the sandbox. Those annual reports or abstracts thereof shall be made available to the public, online.*** ***The Commission shall, where appropriate, take the annual reports into account when exercising their tasks under this Regulation.*** Text Origin: EP Mandate
Article 53(6)				
G 525	6. The modalities and the conditions of the operation of the AI regulatory sandboxes, including the eligibility criteria and the procedure for the application, selection, participation and exiting from the sandbox, and the rights and obligations of the participants shall be set out in implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).	6. The ~~modalities and the conditions of the operation of the AI regulatory~~***Commission shall develop a single and dedicated interface containing all relevant information related to*** sandboxes, ~~including the eligibility criteria and the procedure for the application, selection, participation and exiting from the sandbox, and the rights and obligations of the participants shall be set out in implementing acts. Those implementing acts~~***together with a single contact point at Union level to interact with the regulatory sandboxes and to allow stakeholders to raise enquiries with competent authorities, and to seek non-binding guidance on the conformity of innovative products, services, business models***	6. The modalities and the conditions ~~of the~~ ***for the establishment and*** operation of the AI regulatory sandboxes~~, including the eligibility criteria and the procedure for the application, selection, participation and exiting from the sandbox, and the rights and obligations of the participants~~ ***under this Regulation*** shall be ~~set out in~~***adopted through*** implementing acts~~. Those implementing acts shall be adopted~~ in accordance with the examination procedure referred to in Article 74(2).	6. The ~~modalities and the conditions of the operation of the AI regulatory sandboxes, including the eligibility criteria and the procedure for the application, selection, participation and exiting from the sandbox, and the rights and obligations of the participants shall be set out in implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2)~~***Commission shall develop a single and dedicated interface containing all relevant information related to sandboxes to allow stakeholders to interact with regulatory sandboxes and to raise enquiries with competent authorities, and to seek non-binding guidance on the conformity*** G

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		embedding AI technologies; ***The Commission*** shall ~~be adopted in accordance with the examination procedure referred to in Article 74(2)~~***proactively coordinate with national, regional and also local authorities, where relevant***.		***of innovative products, services, business models embedding AI technologies, in accordance with Article 55(1)(c).*** ***The Commission shall proactively coordinate with national competent authorities, where relevant***. Text Origin: EP Mandate
Article 53(6a), first subparagraph				
G 525a			***6a. The modalities and conditions shall to the best extent possible support flexibility for national competent authorities to establish and operate their AI regulatory sandboxes, foster innovation and regulatory learning and shall particularly take into account the special circumstances and capacities of participating SMEs, including start-ups.***	
Article 53(6a), second subparagraph				
G 525b			***Those implementing acts shall include common main principles on the following issues:***	
Article 53(6a), second subparagraph, point (a)				
G 525c			***(a) eligibility and selection for participation in the AI regulatory***	

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			sandbox;	
Article 53(6a), second subparagraph, point (b)				
G 525d			***(b) procedure for the application, participation, monitoring, exiting from and termination of the AI regulatory sandbox, including the sandbox plan and the exit report;***	G
Article 53(6a), second subparagraph, point (c)				
G 525e			***(c) the terms and conditions applicable to the participants.***	G
Article 53(6a)				
G 525f		***6a. For the purpose of paragraph 1 and 1a, the Commission shall play a complementary role, enabling Member States to build on their expertise and, on the other hand, assisting and providing technical understanding and resources to those Member States that seek guidance on the set-up and running of these regulatory sandboxes.***		***6a.*** Text Origin: EP Mandate G
Article 53(6b)				
G 525g		***53 a Modalities and functioning of AI regulatory sandboxes*** ***1. In order to avoid fragmentation***		***ARTICLE 53A*** ***Modalities and functioning of AI regulatory sandboxes*** G

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		across the Union, the Commission, in consultation with the AI office, shall adopt a delegated act detailing the modalities for the establishment, development, implementation, functioning and supervision of the AI regulatory sandboxes, including the eligibility criteria and the procedure for the application, selection, participation and exiting from the sandbox, and the rights and obligations of the participants based on the provisions set out in this Article; *2. The Commission is empowered to adopt delegated acts in accordance with the procedure referred to in Article 73, no later than 12 months following the entry into force of this Regulation and shall ensure that:* *a) regulatory sandboxes are open to any applying prospective provider of an AI system who fulfils eligibility and selection criteria. The criteria for accessing to the regulatory sandbox are transparent and fair and establishing authorities inform applicants of their decision within 3 months of the application;* *b) regulatory sandboxes allow broad and equal access and keep up with demand for participation;* *c) access to the AI regulatory sandboxes is free of charge for SMEs and start-ups without*		*In order to avoid fragmentation across the Union, the Commission shall adopt a an implementing act detailing the modalities for the establishment, development, implementation, operation and supervision of the AI regulatory sandboxes.* *The implementing act shall include common principles on the following issues:* *a) eligibility and selection for participation in the AI regulatory sandbox;* *b) procedure for the application, participation, monitoring, exiting from and termination of the AI regulatory sandbox, including the sandbox plan and the exit report;* *c) the terms and conditions applicable to the participants.* *The implementing acts shall ensure that:* *a) regulatory sandboxes are open to any applying prospective provider of an AI system who fulfils eligibility and selection criteria. The criteria for accessing to the regulatory sandbox are transparent and fair and establishing authorities inform applicants of*

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		prejudice to exceptional costs that establishing authorities may recover in a fair and proportionate manner; ***d) regulatory sandboxes facilitate the involvement of other relevant actors within the AI ecosystem, such as notified bodies and standardisation organisations (SMEs, start-ups, enterprises, innovators, testing and experimentation facilities, research and experimentation labs and digital innovation hubs, centers of excellence, individual researchers), in order to allow and facilitate cooperation with the public and private sector;*** ***e) they allow prospective providers to to fulfil, in a controlled environment, the conformity assessment obligations of this Regulation or the voluntary application of the codes of conduct referred to in Article 69;*** ***f) procedures, processes and administrative requirements for application, selection, participation and exiting the sandbox are simple, easily intelligible, clearly communicated in order to facilitate the participation of SMEs and start-ups with limited legal and administrative capacities and are streamlined across the Union, in order to avoid fragmentation and that participation in a regulatory***		***their decision within 3 months of the application;*** ***b) regulatory sandboxes allow broad and equal access and keep up with demand for participation; prospective providers may also submit applications in partnerships with users and other relevant third parties;*** ***c) the modalities and conditions concerning regulatory sandboxes shall to the best extent possible support flexibility for national competent authorities to establish and operate their AI regulatory sandboxes;*** ***d) access to the AI regulatory sandboxes is free of charge for SMEs and start-ups without prejudice to exceptional costs that national competent authorities may recover in a fair and proportionate manner;*** ***e) they facilitate prospective providers, by means of the learning outcomes of the sandboxes, to conduct the conformity assessment obligations of this Regulation or the voluntary application of the codes of conduct referred to in Article 69;*** ***f) regulatory sandboxes facilitate the involvement of other relevant***

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		sandbox established by a Member State, by the Commission, or by the EDPS is mutually and uniformly recognised and carries the same legal effects across the Union; ***g) participation in the AI regulatory sandbox is limited to a period that is appropriate to the complexity and scale of the project.*** ***h) the sandboxes shall facilitate the development of tools and infrastructure for testing, benchmarking, assessing and explaining dimensions of AI systems relevant to sandboxes, such as accuracy, robustness and cybersecurity as well as minimisation of risks to fundamental rights, environment and the society at large*** ***3. Prospective providers in the sandboxes, in particular SMEs and start-ups, shall be facilitated access to pre-deployment services such as guidance on the implementation of this Regulation, to other value-adding services such as help with standardisation documents and certification and consultation, and to other Digital Single Market initiatives such as Testing & Experimentation Facilities, Digital Hubs, Centres of Excellence, and EU benchmarking capabilities.***		***actors within the AI ecosystem, such as notified bodies and standardisation organisations (SMEs, start-ups, enterprises, innovators, testing and experimentation facilities, research and experimentation labs and digital innovation hubs, centers of excellence, individual researchers), in order to allow and facilitate cooperation with the public and private sector;*** ***g) procedures, processes and administrative requirements for application, selection, participation and exiting the sandbox are simple, easily intelligible, clearly communicated in order to facilitate the participation of SMEs and start-ups with limited legal and administrative capacities and are streamlined across the Union, in order to avoid fragmentation and that participation in a regulatory sandbox established by a Member State, or by the EDPS is mutually and uniformly recognised and carries the same legal effects across the Union;*** ***h) participation in the AI regulatory sandbox is limited to a period that is appropriate to the complexity and scale of the project. This period may be extended by the national competent authority;***

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				i) the sandboxes shall facilitate the development of tools and infrastructure for testing, benchmarking, assessing and explaining dimensions of AI systems relevant for regulatory learning , such as accuracy, robustness and cybersecurity as well as measures to mitigate risks to fundamental rights,[environment] and the society at large. ***3. Prospective providers in the sandboxes, in particular SMEs and start-ups, shall be directed, where relevant, to pre-deployment services such as guidance on the implementation of this Regulation, to other value-adding services such as help with standardisation documents and certification, Testing & Experimentation Facilities, Digital Hubs, Centres of Excellence, and [EU benchmarking capabilities].***
Article 53(6c)				
G 525h			***6b. When national competent authorities consider authorising testing in real world conditions supervised within the framework of an AI regulatory sandbox established under this Article, they shall specifically agree with the***	***4. When national competent authorities consider authorising testing in real world conditions supervised within the framework of an AI regulatory sandbox established under this Article, they shall specifically agree with the*** G

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			participants on the terms and conditions of such testing and in particular on the appropriate safeguards with the view to protect fundamental rights, health and safety. Where appropriate, they shall cooperate with other national competent authorities with a view to ensure consistent practices across the Union.	***participants on the terms and conditions of such testing and in particular on the appropriate safeguards with the view to protect fundamental rights, health and safety. Where appropriate, they shall cooperate with other national competent authorities with a view to ensure consistent practices across the Union.*** Text Origin: Council Mandate
Article 54				
G 526	Article 54 Further processing of personal data for developing certain AI systems in the public interest in the AI regulatory sandbox	Article 54 Further processing of ~~personal~~ data for developing certain AI systems in the public interest in the AI regulatory sandbox	Article 54 Further processing of personal data for developing certain AI systems in the public interest in the AI regulatory sandbox	Article 54 Further processing of personal data for developing certain AI systems in the public interest in the AI regulatory sandbox Text Origin: Council Mandate
Article 54(1)				
G 527	1. In the AI regulatory sandbox personal data lawfully collected for other purposes shall be processed for the purposes of developing and testing certain innovative AI systems in the sandbox under the following conditions:	1. In the AI regulatory sandbox personal data lawfully collected for other purposes ~~shall~~***may*** be processed ***solely*** for the purposes of developing and testing certain ~~innovative~~ AI systems in the sandbox ~~under~~***when all of*** the following conditions ***are met***:	1. In the AI regulatory sandbox personal data lawfully collected for other purposes ~~shall~~***may*** be processed for the purposes of developing***, testing and training of*** ~~and testing certain~~ innovative AI systems in the sandbox under the following ***cumulative*** conditions:	1. In the AI regulatory sandbox personal data lawfully collected for other purposes ~~shall~~***may*** be processed ***solely*** for the purposes of developing***, training*** and testing certain ~~innovative~~ AI systems in the sandbox ~~under~~***when all of*** the following conditions ***are met***:
Article 54(1), point (a)				

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528	(a) the innovative AI systems shall be developed for safeguarding substantial public interest in one or more of the following areas:	(a) ~~the innovative~~ AI systems shall be developed for safeguarding substantial public interest in one or more of the following areas:	(a) the innovative AI systems shall be developed for safeguarding substantial public interest ***by a public authority or another natural or legal person governed by public law or by private law and*** in one or more of the following areas:	(a) ~~the innovative~~ AI systems shall be developed for safeguarding substantial public interest ***by a public authority or another natural or legal person governed by public law or by private law and*** in one or more of the following areas:
Article 54(1), point (a)(i)				
529	(i) the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security, under the control and responsibility of the competent authorities. The processing shall be based on Member State or Union law;	*deleted*	*deleted*	
Article 54(1), point (a)(ii)				
530	*(ii)* public safety and public health, including disease prevention, control and treatment;	(ii) ***public safety and public health, including disease detection, diagnosis prevention, control and treatment;*** ~~public safety and public health, including disease prevention, control and treatment;~~	(ii) public safety and ~~public~~ health, including ~~disease~~ prevention, control and treatment ***of disease and improvement of health care systems***;	(ii) public safety and public health, including disease ***detection, diagnosis*** prevention, control and treatment ***and improvement of health care systems***;
Article 54(1), point (a)(iii)				
531	(iii) a high level of protection and	(iii) a high level of protection and	(iii) ~~a high level of~~ protection and	(iii) a high level of protection and

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	improvement of the quality of the environment;	improvement of the quality of the environment***, protection of biodiversity, pollution as well as climate change mitigation and adaptation***;	improvement of the quality of the environment***, including green transition, climate change mitigation and adaptation***;	improvement of the quality of the environment***, protection of biodiversity, pollution as well as green transition, climate change mitigation and adaptation***;
Article 54(1), point (a)(iiia)				
G 531a			***(iiia) energy sustainability, transport and mobility;***	***(iiia) energy sustainability*** G
Article 54(1), point (a)(iiib)				
G 531b		***(iiia) safety and resilience of transport systems, critical infrastructure and networks.***		***(iiib) safety and resilience of transport systems and mobility, critical infrastructure and networks;*** G
Article 54(1), point (a)(iiic)				
G 531c			***(iiib) efficiency and quality of public administration and public services;***	***(iiic) efficiency and quality of public administration and public services;*** G
Article 54(1), point (a)(iiic)				
G 531d			***(iiic) cybersecurity and resilience of critical infrastructure.***	G
Article 54(1), point (b)				
G 532	(b) the data processed are necessary	(b) the data processed are necessary	(b) the data processed are necessary	(b) the data processed are necessary G

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	for complying with one or more of the requirements referred to in Title III, Chapter 2 where those requirements cannot be effectively fulfilled by processing anonymised, synthetic or other non-personal data;	for complying with one or more of the requirements referred to in Title III, Chapter 2 where those requirements cannot be effectively fulfilled by processing anonymised, synthetic or other non-personal data;	for complying with one or more of the requirements referred to in Title III, Chapter 2 where those requirements cannot be effectively fulfilled by processing anonymised, synthetic or other non-personal data;	for complying with one or more of the requirements referred to in Title III, Chapter 2 where those requirements cannot be effectively fulfilled by processing anonymised, synthetic or other non-personal data; Text Origin: Council Mandate
Article 54(1), point (c)				
G 533	(c) there are effective monitoring mechanisms to identify if any high risks to the fundamental rights of the data subjects may arise during the sandbox experimentation as well as response mechanism to promptly mitigate those risks and, where necessary, stop the processing;	(c) there are effective monitoring mechanisms to identify if any high risks to the ~~fundamental rights~~***rights and freedoms*** of the data subjects***, as referred to in Article 35 of Regulation (EU) 2016/679 and in Article 35 of Regulation (EU) 2018/1725*** may arise during the sandbox experimentation as well as response mechanism to promptly mitigate those risks and, where necessary, stop the processing;	(c) there are effective monitoring mechanisms to identify if any high risks to the ~~fundamental rights~~***rights and freedoms*** of the data subjects***, as referred to in Article 35 of Regulation (EU) 2016/679 and in Article 39 of Regulation (EU) 2018/1725,*** may arise during the sandbox experimentation as well as response mechanism to promptly mitigate those risks and, where necessary, stop the processing;	(c) there are effective monitoring mechanisms to identify if any high risks to the ~~fundamental rights~~***rights and freedoms*** of the data subjects***, as referred to in Article 35 of Regulation (EU) 2016/679 and in Article 39 of Regulation (EU) 2018/1725,*** may arise during the sandbox experimentation as well as response mechanism to promptly mitigate those risks and, where necessary, stop the processing; Text Origin: Council Mandate
Article 54(1), point (d)				
G 534	(d) any personal data to be processed in the context of the sandbox are in a functionally separate, isolated and protected data processing environment under the control of the participants and only authorised persons have access to that data;	(d) any personal data to be processed in the context of the sandbox are in a functionally separate, isolated and protected data processing environment under the control of the ~~participants~~***prospective provider*** and only authorised persons have access	(d) any personal data to be processed in the context of the sandbox are in a functionally separate, isolated and protected data processing environment under the control of the participants and only authorised persons have access to that data;	(d) any personal data to be processed in the context of the sandbox are in a functionally separate, isolated and protected data processing environment under the control of the ~~participants~~***prospective provider*** and only authorised persons have access

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		to that ***those*** data;		to that ***those*** data; Text Origin: EP Mandate
Article 54(1), point (e)				
G 535	(e) any personal data processed are not be transmitted, transferred or otherwise accessed by other parties;	(e) any personal data processed are not be transmitted, transferred or otherwise accessed by other parties;	(e) any personal data processed are not ***to*** be transmitted, transferred or otherwise accessed by other parties ***that are not participants in the sandbox, unless such disclosure occurs in compliance with Regulation (EU) 2016/679 or, where applicable, Regulation 2018/725, and all participants have agreed to it***;	(e) ***Providers can only further share the originaly collected data in compliance with EU data protection law.*** Any personal data ~~processed are not be transmitted, transferred or otherwise accessed by other parties;~~***crated in the sandbox cannot be shared outside the sandbox*** Text Origin: Council Mandate
Article 54(1), point (f)				
G 536	(f) any processing of personal data in the context of the sandbox do not lead to measures or decisions affecting the data subjects;	(f) any processing of personal data in the context of the sandbox do not lead to measures or decisions affecting the data subjects ***nor affect the application of their rights laid down in Union law on the protection of personal data***;	(f) any processing of personal data in the context of the sandbox ~~do not lead to measures or decisions affecting~~***shall not affect the application of the rights of*** the data subjects ***as provided for under Union law on the protection of personal data, in particular in Article 22 of Regulation (EU) 2016/679 and Article 24 of Regulation (EU) 2018/1725***;	(f) any processing of personal data in the context of the sandbox do not lead to measures or decisions affecting the data subjects ***nor affect the application of their rights laid down in Union law on the protection of personal data***; Text Origin: EP Mandate
Article 54(1), point (g)				
G 537	(g) any personal data processed in	(g) any personal data processed in	(g) any personal data processed in	(g) ***(g)*** any personal data processed

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	the context of the sandbox are deleted once the participation in the sandbox has terminated or the personal data has reached the end of its retention period;	the context of the sandbox are ***protected by means of appropriate technical and organisational measures and*** deleted once the participation in the sandbox has terminated or the personal data has reached the end of its retention period;	the context of the sandbox are ***protected by means of appropriate technical and organisational measures and*** deleted once the participation in the sandbox has terminated or the personal data has reached the end of its retention period;	in the context of the sandbox are ***protected by means of appropriate technical and organisational measures and*** deleted once the participation in the sandbox has terminated or the personal data has reached the end of its retention period;
Article 54(1), point (h)				
G 538	(h) the logs of the processing of personal data in the context of the sandbox are kept for the duration of the participation in the sandbox and 1 year after its termination, solely for the purpose of and only as long as necessary for fulfilling accountability and documentation obligations under this Article or other application Union or Member States legislation;	(h) the logs of the processing of personal data in the context of the sandbox are kept for the duration of the participation in the sandbox ~~*and 1 year after its termination, solely for the purpose of and only as long as necessary for fulfilling accountability and documentation obligations under this Article or other application Union or Member States legislation*~~;	(h) the logs of the processing of personal data in the context of the sandbox are kept for the duration of the participation in the sandbox ~~*and 1 year after its termination, solely for the purpose of and only as long as necessary for fulfilling accountability and documentation obligations under this Article or other application*~~***, unless provided otherwise by*** Union or ~~*Member States legislation*~~***national law***;	(h) the logs of the processing of personal data in the context of the sandbox are kept for the duration of the participation in the sandbox ~~*and 1 year after its termination, solely for the purpose of and only as long as necessary for fulfilling accountability and documentation obligations under this Article or other application*~~***, unless provided otherwise by*** Union or ~~*Member States legislation*~~***national law***; Text Origin: Council Mandate
Article 54(1), point (i)				
G 539	(i) complete and detailed description of the process and rationale behind the training, testing and validation of the AI system is kept together with the testing results as part of the technical documentation in Annex IV;	(i) complete and detailed description of the process and rationale behind the training, testing and validation of the AI system is kept together with the testing results as part of the technical documentation in Annex IV;	(i) complete and detailed description of the process and rationale behind the training, testing and validation of the AI system is kept together with the testing results as part of the technical documentation in Annex IV;	(i) complete and detailed description of the process and rationale behind the training, testing and validation of the AI system is kept together with the testing results as part of the technical documentation in Annex IV;

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				Text Origin: Council Mandate
Article 54(1), point (j)				
G 540	(j) a short summary of the AI project developed in the sandbox, its objectives and expected results published on the website of the competent authorities.	(j) a short summary of the AI ~~project~~***system*** developed in the sandbox, its objectives***, hypotheses,*** and expected results***,*** published on the website of the competent authorities~~.~~***:***	(j) a short summary of the AI project developed in the sandbox, its objectives and expected results published on the website of the competent authorities. ***This obligation shall not cover sensitive operational data in relation to the activities of law enforcement, border control, immigration or asylum authorities.***	(j) a short summary of the AI project developed in the sandbox, its objectives and expected results published on the website of the competent authorities. ***This obligation shall not cover sensitive operational data in relation to the activities of law enforcement, border control, immigration or asylum authorities.*** Text Origin: Council Mandate
Article 54(1), point (ja)				
G 540a			***1a. For the purpose of prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security, under the control and responsibility of law enforcement authorities, the processing of personal data in AI regulatory sandboxes shall be based on a specific Member State or Union law and subject to the same cumulative conditions as referred to in paragraph 1.***	***1a. For the purpose of prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security, under the control and responsibility of law enforcement authorities, the processing of personal data in AI regulatory sandboxes shall be based on a specific Member State or Union law and subject to the same cumulative conditions as referred to in paragraph 1.***

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				Text Origin: Council Mandate
Article 54(2)				
G 541	2. Paragraph 1 is without prejudice to Union or Member States legislation excluding processing for other purposes than those explicitly mentioned in that legislation.	2. Paragraph 1 is without prejudice to Union or Member States legislation excluding processing for other purposes than those explicitly mentioned in that legislation.	2. Paragraph 1 is without prejudice to Union or Member States ~~legislation excluding~~***laws laying down the basis for the*** processing ***of personal data which is necessary for the purpose of developing, testing and training of innovative AI systems or any other legal basis, in compliance with Union law on the protection of personal data***~~for other purposes than those explicitly mentioned in that legislation~~.	2. Paragraph 1 is without prejudice to Union or Member States legislation excluding processing for other purposes than those explicitly mentioned in that legislation***, as well as to Union or Member States laws laying down the basis for the processing of personal data which is necessary for the purpose of developing, testing and training of innovative AI systems or any other legal basis, in compliance with Union law on the protection of personal data***. Text Origin: Council Mandate
Article 54a new				
G 541a		***54a Promotion of AI research and development in support of socially and environmentally beneficial outcomes*** ***1. Member States shall promote research and development of AI solutions which support socially and environmentally beneficial outcomes, including but not limited to development of AI-based solutions to increase accessibility for persons with disabilities, tackle***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		socio-economic inequalities, and meet sustainability and environmental targets, by: ***(a) providing relevant projects with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions;*** ***(b) earmarking public funding, including from relevant EU funds, for AI research and development in support of socially and environmentally beneficial outcomes;*** ***(c) organising specific awareness raising activities about the application of this Regulation, the availability of and application procedures for dedicated funding, tailored to the needs of those projects;*** ***(d) where appropriate, establishing accessible dedicated channels, including within the sandboxes, for communication with projects to provide guidance and respond to queries about the implementation of this Regulation.*** ***Member States shall support civil society and social stakeholders to lead or participate in such projects.***		
Article 54a				
G 541b			***Article 54a*** ***Testing of high-risk AI systems in***	***Article 54a*** ***Testing of high-risk AI systems in*** G

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			real world conditions outside AI regulatory sandboxes	***real world conditions outside AI regulatory sandboxes***
Article 54a(1), first subparagraph				
G 541c			***1. Testing of 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, in accordance with the provisions of this Article and the real-world testing plan referred to in this Article.***	***1. Testing of 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, in accordance with the provisions of this Article and the real-world testing plan referred to in this Article, without prejudice to the prohibitions under Article 5.***
Article 54a(1), second subparagraph				
G 541d			***The detailed elements of the real-world testing plan shall be specified in implementing acts adopted by the Commission in accordance with the examination procedure referred to in Article 74(2).***	***The detailed elements of the real-world testing plan shall be specified in implementing acts adopted by the Commission in accordance with the examination procedure referred to in Article 74(2).***
Article 54a(2)				
G 541e			***This provision shall be without prejudice to Union or Member State legislation for the testing in real world conditions of high-risk AI systems related to products covered by legislation listed in Annex II.***	***This provision shall be without prejudice to Union or national law for the testing in real world conditions of high-risk AI systems related to products covered by legislation listed in Annex II.***

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Article 54a(3)				
G 541f			***2. Providers or prospective providers may conduct testing of high-risk AI systems referred to in Annex III in real world conditions at any time before the placing on the market or putting into service of the AI system on their own or in partnership with one or more prospective users.***	***2. Providers or prospective providers may conduct testing of high-risk AI systems referred to in Annex III in real world conditions at any time before the placing on the market or putting into service of the AI system on their own or in partnership with one or more prospective deployers.*** G
Article 54a(4)				
G 541g			***3. The testing of high-risk AI systems in real world conditions under this Article shall be without prejudice to ethical review that may be required by national or Union law.***	***3. The testing of high-risk AI systems in real world conditions under this Article shall be without prejudice to ethical review that may be required by national or Union law.*** G
Article 54a(5)				
G 541h			***4. Providers or prospective providers may conduct the testing in real world conditions only where all of the following conditions are met:***	***4. Providers or prospective providers may conduct the testing in real world conditions only where all of the following conditions are met:*** G
Article 54a(5), point (a)				
G 541i			***(a) the provider or prospective***	***(a) the provider or prospective*** G

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			provider has drawn up a real-world testing plan and submitted it to the market surveillance authority in the Member State(s) where the testing in real world conditions is to be conducted;	***provider has drawn up a real-world testing plan and submitted it to the market surveillance authority in the Member State(s) where the testing in real world conditions is to be conducted;***
Article 54a(5), point (b)				
G 541j			***(b) the market surveillance authority in the Member State(s) where the testing in real world conditions is to be conducted have not objected to the testing within 30 days after its submission;***	***(b) the market surveillance authority in the Member State(s) where the testing in real world conditions is to be conducted has approved the testing in real world conditions and the real-world testing plan. Where the market surveillance authority in that Member State has not provided with an answer in 30 days, the testing in real world conditions and the real-world testing plan shall be understood as approved. In cases where national law does not foresee a tacit approval, the testing in real world conditions shall be subject to an authorisation;*** G
Article 54a(5), point (c)				
G 541k			***(c) the provider or prospective provider with the exception of high-risk AI systems referred to in Annex III, points 1, 6 and 7 in the areas of law enforcement, migration, asylum and border control management,***	***(c) the provider or prospective provider with the exception of high-risk AI systems referred to in Annex III, points 1, 6 and 7 in the areas of law enforcement, migration, asylum and border control management,*** G

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			and high risk AI systems referred to in Annex III point 2, has registered the testing in real world conditions in the EU database referred to in Article 60(5a) with a Union-wide unique single identification number and the information specified in Annex VIIIa;	***and high risk AI systems referred to in Annex III point 2, has registered the testing in real world conditions in the non public part of the EU database referred to in Article 60(3) with a Union-wide unique single identification number and the information specified in Annex VIIIa.***
Article 54a(5), point (d)				
G 541l			***(d) the provider or prospective provider conducting the testing in real world conditions is established in the Union or it has appointed a legal representative for the purpose of the testing in real world conditions who is established in the Union;***	***(d) the provider or prospective provider conducting the testing in real world conditions is established in the Union or it has appointed a legal representative who is established in the Union;***
Article 54a(5), point (e)				
G 541m			***(e) data collected and processed for the purpose of the testing in real world conditions shall not be transferred to countries outside the Union, unless the transfer and the processing provides equivalent safeguards to those provided under Union law;***	***(e) Data collected and processed for the purpose of the testing in real world conditions shall only be transferred to third countries outside the Union provided appropriate and applicable safeguards under Union law are implemented;***
Article 54a(5), point (f)				
G 541n				

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			(f) the testing in real world conditions does not last longer than necessary to achieve its objectives and in any case not longer than 12 months;	*(f) the testing in real world conditions does not last longer than necessary to achieve its objectives and in any case not longer than 6 months, which may be extended for an additional amount of 6 months, subject to prior notification by the provider to the market surveillance authority, accompanied by an explanation on the need for such time extension;*
Article 54a(5), point (g)				
G 541o			*(g) persons belonging to vulnerable groups due to their age, physical or mental disability are appropriately protected;*	*(g) persons belonging to vulnerable groups due to their age, physical or mental disability are appropriately protected;* G
Article 54a(5), point (h)				
G 541p			*(h) where a provider or prospective provider organises the testing in real world conditions in cooperation with one or more prospective users, the latter have been informed of all aspects of the testing that are relevant to their decision to participate, and given the relevant instructions on how to use the AI system referred to in Article 13; the provider or prospective provider and the user(s) shall conclude an agreement specifying their roles and*	*(h) where a provider or prospective provider organises the testing in real world conditions in cooperation with one or more prospective deployers, the latter have been informed of all aspects of the testing that are relevant to their decision to participate, and given the relevant instructions on how to use the AI system referred to in Article 13; the provider or prospective provider and the deployer(s) shall conclude an agreement specifying their roles* G

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			responsibilities with a view to ensuring compliance with the provisions for testing in real world conditions under this Regulation and other applicable Union and Member States legislation;	***and responsibilities with a view to ensuring compliance with the provisions for testing in real world conditions under this Regulation and other applicable Union and Member States legislation;***
Article 54a(5), point (i)				
G 541q			***(i) the subjects of the testing in real world conditions have given informed consent in accordance with Article 54b, or in the case of law enforcement, where the seeking of informed consent would prevent the AI system from being tested, the testing itself and the outcome of the testing in the real world conditions shall not have a negative effect on the subject;***	***(i) the subjects of the testing in real world conditions have given informed consent in accordance with Article 54b, or in the case of law enforcement, where the seeking of informed consent would prevent the AI system from being tested, the testing itself and the outcome of the testing in the real world conditions shall not have any negative effect on the subject and his or her personal data shall be deleted after the test is performed.*** G
Article 54a(5), point (j)				
G 541r			***(j) the testing in real world conditions is effectively overseen by the provider or prospective provider and user(s) with persons who are suitably qualified in the relevant field and have the necessary capacity, training and authority to perform their tasks;***	***(j) the testing in real world conditions is effectively overseen by the provider or prospective provider and deployer(s) with persons who are suitably qualified in the relevant field and have the necessary capacity, training and authority to perform their tasks;*** G
Article 54a(5), point (k)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 541s			*(k) the predictions, recommendations or decisions of the AI system can be effectively reversed or disregarded.*	*(k) the predictions, recommendations or decisions of the AI system can be effectively reversed and disregarded.*
Article 54a(6)				
G 541t			*5. Any subject of the testing in real world conditions, or his or her legally designated representative, as appropriate, may, without any resulting detriment and without having to provide any justification, withdraw from the testing at any time by revoking his or her informed consent. The withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on the informed consent before its withdrawal.*	*5 Any subject of the testing in real world conditions, or his or her legally designated representative, as appropriate, may, without any resulting detriment and without having to provide any justification, withdraw from the testing at any time by revoking his or her informed consent and request the immediate and permanent deletion of their personal data. The withdrawal of the informed consent shall not affect the activities already carried out.* *5a. In accordance with Article 63a, Member States shall confer their market surveillance authorities the powers of requiring providers and prospective providers information, of carrying out unannounced remote or on-site inspections and on performing checks on the development of the testing in real world conditions and the related products. Market surveillance authorities shall use these powers to ensure a safe development of these*

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				tests.
Article 54a(6)				
541u			***6. Any serious incident identified in the course of the testing in real world conditions shall be reported to the national market surveillance authority in accordance with Article 62 of this Regulation. The provider or prospective provider shall adopt immediate mitigation measures or, failing that, suspend the testing in real world conditions until such mitigation takes place or otherwise terminate it. The provider or prospective provider shall establish a procedure for the prompt recall of the AI system upon such termination of the testing in real world conditions.***	***6. Any serious incident identified in the course of the testing in real world conditions shall be reported to the national market surveillance authority in accordance with Article 62 of this Regulation. The provider or prospective provider shall adopt immediate mitigation measures or, failing that, suspend the testing in real world conditions until such mitigation takes place or otherwise terminate it. The provider or prospective provider shall establish a procedure for the prompt recall of the AI system upon such termination of the testing in real world conditions.***
Article 54a(7)				
541v			***7. Providers or prospective providers shall notify the national market surveillance authority in the Member State(s) where the testing in real world conditions is to be conducted of the suspension or termination of the testing in real world conditions and the final outcomes.***	***7. Providers or prospective providers shall notify the national market surveillance authority in the Member State(s) where the testing in real world conditions is to be conducted of the suspension or termination of the testing in real world conditions and the final outcomes.***
Article 54a(8)				

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G 541w			***8. The provider and prospective provider shall be liable under applicable Union and Member States liability legislation for any damage caused in the course of their participation in the testing in real world conditions.***	***8. The provider and prospective provider shall be liable under applicable Union and Member States liability legislation for any damage caused in the course of their participation in the testing in real world conditions.***
Article 54a(10)				
G 541x				
Article 54a(11)				
G 541y			***Article 54b*** ***Informed consent to participate in testing in real world conditions outside AI regulatory sandboxes***	***Article 54b*** ***Informed consent to participate in testing in real world conditions outside AI regulatory sandboxes***
Article 54a(12), first subparagraph				
G 541z			***1. For the purpose of testing in real world conditions under Article 54a, informed consent shall be freely given by the subject of testing prior to his or her participation in such testing and after having been duly informed with concise, clear, relevant, and understandable information regarding:***	***1. For the purpose of testing in real world conditions under Article 54a, informed consent shall be freely given by the subject of testing prior to his or her participation in such testing and after having been duly informed with concise, clear, relevant, and understandable information regarding:***
Article 54a(12), second subparagraph				
G 541aa				

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			(i) the nature and objectives of the testing in real world conditions and the possible inconvenience that may be linked to his or her participation; *(ii) the conditions under which the testing in real world conditions is to be conducted, including the expected duration of the subject's participation;* *(iii) the subject's rights and guarantees regarding participation, in particular his or her right to refuse to participate in and the right to withdraw from testing in real world conditions at any time without any resulting detriment and without having to provide any justification;* *(iv) the modalities for requesting the reversal or the disregard of the predictions, recommendations or decisions of the AI system;* *(v) the Union-wide unique single identification number of the testing in real world conditions in accordance with Article 54a(4c) and the contact details of the provider or its legal representative from whom further information can be obtained.*	*(i) the nature and objectives of the testing in real world conditions and the possible inconvenience that may be linked to his or her participation;* *(ii) the conditions under which the testing in real world conditions is to be conducted, including the expected duration of the subject's participation;* *(iii) the subject's rights and guarantees regarding participation, in particular his or her right to refuse to participate in and the right to withdraw from testing in real world conditions at any time without any resulting detriment and without having to provide any justification;* *(iv) the modalities for requesting the reversal or the disregard of the predictions, recommendations or decisions of the AI system;* *(v) the Union-wide unique single identification number of the testing in real world conditions in accordance with Article 54a(4c) and the contact details of the provider or its legal representative from whom further information can be obtained.*
Article 54a(13)				
G 541ab			*2. The informed consent shall be dated and documented and a copy shall be given to the subject or his*	*2 The informed consent shall be dated and documented and a copy shall be given to the subject or his* G

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			or her legal representative.	***or her legal representative.***
Article 55				
542	Article 55 Measures for small-scale providers and users	Article 55 Measures for ~~small-scale providers~~***SMEs, start-ups*** and users	Article 55 ***Support measures for operators, in particular SMEs, including start-ups*** ~~measures for small-scale providers and users~~	Article 55 Measures for ~~small-scale~~ providers and ~~users~~ ***deployers, in particular SMEs, including start-ups***
Article 55(1)				
543	1. Member States shall undertake the following actions:	1. Member States shall undertake the following actions:	1. Member States shall undertake the following actions:	1. Member States shall undertake the following actions: Text Origin: Council Mandate
Article 55(1), point (a)				
544	(a) provide small-scale providers and start-ups with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions;	(a) provide ~~small-scale providers~~***SMEs*** and start-ups***, established in the Union,*** with priority access to the AI regulatory sandboxes***,*** to the extent that they fulfil the eligibility conditions;	(a) provide ~~small-scale providers and~~***SMEs, including*** start-ups***,*** with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility ~~conditions~~***and selection criteria***;	(a) provide ~~small-scale providers and~~***SMEs, including*** start-ups***, having a registered office or a branch in the Union,*** with priority access to the AI regulatory sandboxes***,*** to the extent that they fulfil the eligibility conditions ***and selection criteria.*** ***The priority access shall not preclude other SMEs including start-ups other than those referred to in the first subparagraph to access to the AI regulatory sandbox, provided that they fulfil the eligibility conditions and***

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				selection criteria;
Article 55(1), point (b)				
545	(b) organise specific awareness raising activities about the application of this Regulation tailored to the needs of the small-scale providers and users;	(b) organise specific awareness raising and enhanced digital skills development activities ~~about~~on the application of this Regulation tailored to the needs of ~~the small-scale providers~~SMEs, start-ups and users;	(b) organise specific awareness raising and training activities about the application of this Regulation tailored to the needs of the ~~small-scale providers and users~~SMEs, including start-ups, and, as appropriate, local public authorities;	(b) organise specific awareness raising and training activities ~~about~~on the application of this Regulation tailored to the needs of ~~the small-scale providers and users~~SMEs including start-ups, users and, as appropriate, local public authorities;
Article 55(1), point (c)				
546	(c) where appropriate, establish a dedicated channel for communication with small-scale providers and user and other innovators to provide guidance and respond to queries about the implementation of this Regulation.	(c) utilise existing dedicated channels and where appropriate, establish ~~a~~new dedicated ~~channel~~channels for communication with ~~small-scale providers and user~~SMEs, start-ups, users and other innovators to provide guidance and respond to queries about the implementation of this Regulation~~.~~;	(c) where appropriate, establish a dedicated channel for communication with ~~small-scale providers and user and other innovators~~SMEs, including start-ups and, as appropriate, local public authorities to provide ~~guidance~~advice and respond to queries about the implementation of this Regulation, including as regards participation in AI regulatory sandboxes.	(c) utilise existing dedicated channels and where appropriate, establish ~~a dedicated channel~~new ones for communication with ~~small-scale providers and user and other innovators~~SMEs including start-ups, users, other innovators and, as appropriate, local public authorities to provide ~~guidance~~advice and respond to queries about the implementation of this Regulation, including as regards participation in AI regulatory sandboxes.;
Article 55(1), point (ca)				
546a		(ca) foster the participation of SMEs and other relevant stakeholders in the standardisation		(ca) facilitate the participation of SMEs and other relevant stakeholders in the standardisation

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		development process.		***development process.***
Article 55(2)				
547	2. The specific interests and needs of the small-scale providers shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size and market size.	2. The specific interests and needs of the ~~small-scale providers~~***SMEs, start-ups and users*** shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to ***development stage,*** their size***, market size*** and market ~~size~~***demand. The Commission shall regularly assess the certification and compliance costs for SMEs and start-ups, including through transparent consultations with SMEs, start-ups and users and shall work with Member States to lower such costs where possible. The Commission shall report on these findings to the European Parliament and to the Council as part of the report on the evaluation and review of this Regulation provided for in Article 84(2)***.	2. The specific interests and needs of the ~~small-scale~~***SME*** providers***,*** ***including start-ups,*** shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size***, market size and other relevant indicators*** ~~and market size~~.	2. The specific interests and needs of the ~~small-scale~~***SME*** providers***,*** ***including start-ups,*** shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size***, market size and other relevant indicators*** ~~and market size~~.
Article 55(2a)				
547a			***2a. The Commission shall undertake the following actions:***	***2a. The AI Office shall undertake the following actions:***
Article 55(2a), point (a)				

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G 547b			*(a) upon request of the AI Board, provide standardised templates for the areas covered by this Regulation;*	*(a) upon request of the AI Board, provide standardised templates for the areas covered by this Regulation;* G
Article 55(2a), point (b)				
G 547c			*(b) develop and maintain a single information platform providing easy to use information in relation to this Regulation for all operators across the Union;*	*(b) develop and maintain a single information platform providing easy to use information in relation to this Regulation for all operators across the Union;* G
Article 55(2a), point (c)				
G 547d			*(c) organise appropriate communication campaigns to raise awareness about the obligations arising from this Regulation;*	*(c) organise appropriate communication campaigns to raise awareness about the obligations arising from this Regulation;* G
Article 55(2a), point (d)				
G 547e			*(d) evaluate and promote the convergence of best practices in public procurement procedures in relation to AI systems.*	*(d) evaluate and promote the convergence of best practices in public procurement procedures in relation to AI systems.* G
Article 55(2a), point (e)				
G 547f			*Article 55a Derogations for specific operators*	*Article 55a Derogations for specific operators* G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Council Mandate
Article 55(2b)				
G 547g			***1. The obligations laid down in Article 17 of this Regulation shall not apply to microenterprises as defined in Article 2(3) of the Annex to the Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises, provided those enterprises do not have partner enterprises or linked enterprises as defined in Article 3 of the same Annex.***	***2b. Microenterprises as defined in Article 2(3) of the Annex to the Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises, provided those enterprises do not have partner enterprises or linked enterprises as defined in Article 3 of the same Annex may fulfil certain elements of the quality management system required by Article 17 of this Regulation in a simplified manner. For this purpose, the Commission shall develop guidelines on the elements of the quality management system which may be fulfilled in a simplified manner considering the needs of micro enterprises without affecting the level of protection and the need for compliance with the requirements for high-risk AI systems.*** G
Article 55(2c)				
G 547h			***2. Paragraph 1 shall not be interpreted as exempting those operators from fulfilling any other***	***2c. 2. Paragraph 1 shall not be interpreted as exempting those operators from fulfilling any other*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			requirements and obligations laid down in this Regulation, including those established in Articles 9, 61 and 62.	***requirements and obligations laid down in this Regulation, including those established in Articles 9, 10, 11, 12, 13, 14, 15, 61 and 62.***
Article 55a(3)				
547i			***3. Requirements and obligations for general purpose AI systems laid down in Article 4b shall not apply to micro, small and medium-sized enterprises, provided those enterprises do not have partner enterprises or linked enterprises as defined in Article 3 of the the Annex to the Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises.***	
TITLE VI				
548	TITLE VI GOVERNANCE	TITLE VI GOVERNANCE	TITLE VI GOVERNANCE	TITLE VI GOVERNANCE TO discuss with the governance paper Text Origin: Commission Proposal
Chapter -1				
548a				***Article 55b***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Governance at Union level ***1. The Commission shall develop Union expertise and capabilities in the field of artificial intelligence. For this purpose, the Commission has established the European AI Office by Decision [...]"*** ***2. Member States shall facilitate the tasks entrusted to the AI Office, as reflected in this Regulation***
Chapter 1				
G 549	Chapter 1 European Artificial Intelligence Board		Chapter 1 European Artificial Intelligence Board	Chapter 1 European Artificial Intelligence Board Text Origin: Commission Proposal
Article -56 - SECTION 1 - title				
G 549a		***SECTION 1*** ***General provisions on the European Artificial Intelligence Office***		
Article 56				
G 550	Article 56 Establishment of the European Artificial Intelligence Board	Article 56 Establishment of the European Artificial Intelligence ~~Board~~***Office***	Article 56 ***Establishment and structure of the European Artificial Intelligence***	Article 56 ***Establishment and structure of the European Artificial Intelligence***

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			Board~~*Establishment of the European Artificial Intelligence Board*~~	***Board*** ~~*Establishment of the European Artificial Intelligence Board*~~
Article 56(1)				
551	1. A 'European Artificial Intelligence Board' (the 'Board') is established.	1. ~~*A*~~***The*** 'European Artificial Intelligence ~~*Board*~~***Office***' (the '~~*Board') is*~~ ***AI Office') is hereby*** established. ***The AI Office shall be an independent body of the Union. It shall have legal personality.***	1. A 'European Artificial Intelligence Board' (the 'Board') is established.	1. A 'European Artificial Intelligence Board' (the 'Board') is established.
Article 56(2)				
552	2. The Board shall provide advice and assistance to the Commission in order to:	2. The ~~*Board*~~***AI Office*** shall ~~*provide advice and assistance to the Commission in order to:*~~***have a secretariat, and shall be adequately funded and staffed for the purpose of performing its tasks pursuant to this Regulation.***	*deleted*	
Article 56(2a)				
552a		***2a. The seat of the AI Office shall be in Brussels.***		
Article 56b new				
552b		***56 b Article 56 b Tasks of the AI Office The AI Office shall carry out the***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		following tasks: *a) support, advise, and cooperate with Member States, national supervisory authorities, the Commission and other Union institutions, bodies, offices and agencies with regard to the implementation of this Regulation;* *b) monitor and ensure the effective and consistent application of this Regulation, without prejudice to the tasks of national supervisory authorities;* *c) contribute to the coordination among national supervisory authorities responsible for the application of this Regulation,* *d) serve as a mediator in discussions about serious disagreements that may arise between competent authorities regarding the application of the Regulation* *e) coordinate joint investigations, pursuant to Article 66a;* *f) contribute to the effective cooperation with the competent authorities of third countries and with international organisations,* *g) collect and share Member States' expertise and best practices and to assist Member States national supervisory authorities and the Commission in developing the organizational and technical expertise required for the implementation of this Regulation,*		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		including by means of facilitating the creation and maintenance of a Union pool of experts *h) examine, on its own initiative or upon the request of its management board or the Commission, questions relating to the implementation of this Regulation and to issue opinions, recommendations or written contributions including with regard to:* *(i) technical specifications or existing standards; (ii) the Commission's guidelines* *(iii) codes of conduct and the application thereof, in close cooperation with industry and other relevant stakeholders;* *(iv) the possible revision of the Regulation, the preparation of the delegated acts, and possible alignments of this Regulation with the legal acts listed in Annex II;* *(v) trends, such as European global competitiveness in artificial intelligence, the uptake of artificial intelligence in the Union, the development of digital skills, and emerging systemic threats relating to artificial intelligence* *(vi) guidance on how this Regulation applies to the ever evolving typology of AI value chains, in particular on the resulting implications in terms of accountability of all the entities*		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		involved ***i) issue:*** ***(i) an annual report that includes an evaluation of the implementation of this Regulation, a review of serious incident reports as referred to in Article 62 and the functioning of the database referred to in Article 60 and*** ***(ii) recommendations to the Commission on the categorisation of prohibited practices, high-risk AI systems referred to in Annex III, the codes of conduct referred to in Article 69, and the application of the general principles outlines in Article 4a*** ***j) assist authorities in the establishment and development of regulatory sandboxes and to facilitate cooperation among regulatory sandboxes;*** ***k) organise meetings with Union agencies and governance bodies whose tasks are related to artificial intelligence and the implementation of this Regulation;*** ***l)organise quarterly consultations with the advisory forum, and, where appropriate, public consultations with other stakeholders, and to make the results of those consultations public on its website;*** ***m) promote public awareness and understanding of the benefits, risks, safeguards and rights and obligations in relation to the use of***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		AI systems; ***n) facilitate the development of common criteria and a shared understanding among market operators and competent authorities of the relevant concepts provided for in this Regulation;*** ***o) provide monitoring of foundation models and to organise a regular dialogue with the developers of foundation models with regard to their compliance as well as AI systems that make use of such AI models*** ***p) provide interpretive guidance on how the AI Act applies to the ever evolving typology of AI value chains, and what the resulting implications in terms of accountability of all the entities involved will be under the different scenarios based on the generally acknowledged state of the art, including as reflected in relevant harmonized standards;*** ***q) provide particular oversight and monitoring and institutionalize regular dialogue with the providers of foundation models about the compliance of foundation models as well as AI systems that make use of such AI models with Article 28b of this Regulation, and about industry best practices for self-governance. Any such meeting shall be open to national supervisory authorities, notified bodies and market***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		surveillance authorities to attend and contribute ***r) issue and periodically update guidelines on the thresholds that qualify training a foundation model as a large training run, record and monitor known instances of large training runs, and issue an annual report on the state of play in the development, proliferation, and use of foundation models alongside policy options to address risks and opportunities specific to foundation models.*** ***s) promote AI literacy pursuant to Article 4b.***		
Article 56(c) new				
G 552c		***56 c Article 56 c*** ***Accountability, independence, and transparency*** ***1. The AI Office shall:*** ***a. be accountable to the European Parliament and to the Council in accordance with this Regulation;*** ***b. act independently when carrying out its tasks or exercising its powers; and*** ***c. ensure a high level of transparency concerning its activities and develop good administrative practices in that regard.*** ***Regulation (EC) No 1049/2001 shall apply to documents held by***		G

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		the AI Office.		
Article 56(2), point (a)				
553	(a) contribute to the effective cooperation of the national supervisory authorities and the Commission with regard to matters covered by this Regulation;		*deleted*	
Article 56(2), point (b)				
554	*(b)* coordinate and contribute to guidance and analysis by the Commission and the national supervisory authorities and other competent authorities on emerging issues across the internal market with regard to matters covered by this Regulation;		*deleted*	
Article 56(2), point (c)				
555	*(c)* assist the national supervisory authorities and the Commission in ensuring the consistent application of this Regulation.		*deleted*	
Article 56(2a)				
555a			***2a. The Board shall be composed of one representative per Member State. The European Data***	***2. The Board shall be composed of one representative per Member State. The European Data***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Protection Supervisor shall participate as an observer. The Commission shall also attend the Board's meetings without taking part in the votes.	***Protection Supervisor, shall participate as observer. The AI Office shall also attend the Board's meetings without taking part in the votes. Other national and Union authorities, bodies or experts may be invited to the meetings by the Board on a case by case basis, where the issues discussed are of relevance for them.***
Article 56(2a), second subparagraph				
G 555b			***Other national and Union authorities, bodies or experts may be invited to the meetings by the Board on a case by case basis, where the issues discussed are of relevance for them.***	G
Article 56a new				
G 555c		***56 a Article 56 a Structure The administrative and management structure of the AI Office shall comprise: (a) a management board, including a chair (b) a secretariat managed by an executive director; (c) an advisory forum.***		G
Article 56(2b)				

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G 555d			***2b. Each representative shall be designated by their Member State for a period of 3 years, renewable once.***	***2a. Each representative shall be designated by their Member State for a period of 3 years, renewable once.***
Article 56(2c), first subparagraph				
G 555e			***2c. Member States shall ensure that their representatives in the Board:***	***2b. Member States shall ensure that their representatives in the Board:***
Article 56(2c), second subparagraph				
G 555f			***(i) have the relevant competences and powers in their Member State so as to contribute actively to the achievement of the board's tasks referred to in Article 58;*** ***(ii) are designated as a single contact point vis-à-vis the Board and, where appropriate, taking into account Member States' needs, as a single contact point for stakeholders;*** ***(iii) are empowered to facilitate consistency and coordination between national competent authorities in their Member State as regards the implementation of this Regulation, including through the collection of relevant data and information for the purpose of fulfilling their tasks on the Board.***	***(a) have the relevant competences and powers in their Member State so as to contribute actively to the achievement of the Board's tasks referred to in Article 58;*** ***(b) are designated as a single contact point vis-à-vis the Board and, where appropriate, taking into account Member States' needs, as a single contact point for stakeholders;*** ***(c) are empowered to facilitate consistency and coordination between national competent authorities in their Member State as regards the implementation of this Regulation, including through the collection of relevant data and information for the purpose of fulfilling their tasks on the Board.***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 56(2d), first subparagraph				
G 555g			***2d. The designated representatives of the Member States shall adopt the Board's rules of procedure by a two-thirds majority.***	***3. The designated representatives of the Member States shall adopt the Board's rules of procedure by a two-thirds majority. The rules of procedure shall, in particular, lay down procedures for the selection process, duration of mandate and specifications of the tasks of the Chair, the voting modalities, and the organisation of the Board's activities and its sub-groups.*** G
Article 56(2d), second subparagraph				
G 555h			***The rules of procedure shall, in particular, lay down procedures for the selection process, duration of mandate and specifications of the tasks of the Chair, the voting modalities, and the organisation of the Board's activities and its sub-groups.***	G
Article 56(2d), third subparagraph				
G 555i			***The Board shall establish a standing subgroup serving as a platform for stakeholders to advise the Board on all issues related to the implementation of this Regulation, including on the preparation of implementing and delegated acts. To this purpose,***	***3a. The Board shall establish two standing sub-groups to provide a platform for cooperation and exchange among market surveillance authorities and notifying authorities on issues related to market surveillance and notified bodies respectively.*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			organisations representing the interests of the providers and users of AI systems, including SMEs and start-ups, as well as civil society organisations, representatives of affected persons, researchers, standardisation organisations, notified bodies, laboratories and testing and experimentation facilities shall be invited to participate to this sub-group. The Board shall establish two standing sub-groups to provide a platform for cooperation and exchange among market surveillance authorities and notifying authorities on issues related to market surveillance and notified bodies respectively.	***The standing sub-group for market surveillance should act as the Administrative Cooperation Group (ADCO) for this Regulation in the meaning of Article 30 of Regulation (EU) 2019/1020.*** ***The Board may establish other standing or temporary sub-groups as appropriate for the purpose of examining specific issues. Where appropriate, representatives of the advisory forum as referred to in Article [XX] may be invited to such sub-groups or to specific meetings of those subgroups in the capacity of observers.***
Article 56(2d), fourth subparagraph				
G 555j			***The Board may establish other standing or temporary sub-groups as appropriate for the purpose of examining specific issues. Where appropriate, stakeholders referred to in the previous subparagraph may be invited to such sub-groups or to specific meetings of those subgroups in the capacity of observers.***	G
Article 56(2e)				
G 555k				G

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			2e. The Board shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.	***3b. The Board shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.***
Article 56(2f)				
555l			***2f. The Board shall be chaired by one of the representatives of the Member States. Upon request of the Chair, the Commission shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and its rules of procedure. The Commission shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.***	***4 The Board shall be chaired by one of the representatives of the Member States. The European AI Office shall provide the Secretariat for the Board. convene the meetings upon request of the Chair and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and its rules of procedure.***
Article 56a				
555m	Article 57 Structure of the Board Moved reference text	Article ~~57~~***56a*** ~~*Structure of the Board*~~***Secretariat*** Moved from row 556 [556 - 555m]		
Article 57				
556	Article 57 Structure of the Board	Moved to row 555m [556 - 555m]	*deleted*	
Article 57(1)				

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G 557	*1.* The Board shall be composed of the national supervisory authorities, who shall be represented by the head or equivalent high-level official of that authority, and the European Data Protection Supervisor. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.	1. The ~~*Board*~~***activities of the secretariat*** shall be ~~*composed of the national supervisory authorities, who*~~***managed by an executive director. The executive director*** shall be ~~*represented by the head or equivalent high-level official of that authority, and the European Data Protection Supervisor. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.*~~***accountable to the management board. Without prejudice to the respective powers of the management board and the Union institutions, the executive director shall neither seek nor take instructions from any government or from any other body***	*deleted*	G
Article 57(2)				
G 558	*2.* The Board shall adopt its rules of procedure by a simple majority of its members, following the consent of the Commission. The rules of procedure shall also contain the operational aspects related to the execution of the Board's tasks as listed in Article 58. The Board may establish sub-groups as appropriate for the purpose of examining specific questions.	2. The ~~*Board shall adopt its rules of procedure by a simple majority of its members, following the consent of the Commission. The rules of procedure*~~***executive director shall attend hearings on any matter linked to the AI Office's activities and*** shall ~~*also contain the operational aspects related to the execution*~~***report on the performance*** of the ~~*Board's tasks as listed in Article 58. The Board may establish*~~	*deleted*	G

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		~~sub-groups as appropriate for the purpose of examining specific questions~~***executive director's duties when invited to do so by the European Parliament or the Council***.		
Article 57(3)				
559	*3.* The Board shall be chaired by the Commission. The Commission shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. The Commission shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.	3. The ~~Board shall be chaired by the Commission. The Commission~~***executive director*** shall ~~convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. The Commission shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.~~***represent the AI Office, including in international for a for cooperation with regard to artificial intelligence;***	*deleted*	
Article 57(4)				
560	*4.* The Board may invite external experts and observers to attend its meetings and may hold exchanges with interested third parties to inform its activities to an appropriate extent. To that end the Commission may facilitate exchanges between the Board and other Union bodies,	4. The ***secretariat shall provide the management*** board ~~may invite external experts and observers to attend its meetings and may hold exchanges with interested third parties to inform its~~***and the advisory forum with the analytical, administrative and logistical***	*deleted*	

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	offices, agencies and advisory groups.	***support necessary to fulfil the tasks of the AI Office, including by:*** ***(a) Implementing the decisions, programmes and*** activities ~~*to an appropriate extent. To that end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups.*~~***adopted by the management board;*** ***(b) preparing each year the draft single programming document, the draft budget, the annual activity report on the AI Office, the draft opinions and the draft positions of the AI Office, and submit them to the management board*** ***(c) Coordinating with international fora for cooperation on artificial intelligence;***		
Article - 57(a) new - SECTION 2 - title				
G *560a*		***Article - 57a*** ***Title*** ***SECTION 2: Management Board***		G
Article - 57a				
G 560b		***Article - 57a*** ***Composition of the management board*** ***1. The management board shall be composed of the following members:***		G

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		(a) one representative of each Member State's national supervisory authority; *(b) one representative from the Commission;* *(c) one representative from the European Data Protection Supervisor (EDPS);* *(d) one representative from the European Union Agency for Cybersecurity (ENISA);* *(e) one representative from the Fundamental Rights Agency (FRA)* *Each representative of a national supervisory authority shall have one vote. The representatives of the Commission, the EDPS, the ENISA and the FRA shall not have voting rights. Each member shall have a substitute. The appointment of members and substitute members of the management board shall take into account the need to gender balance. The members of the management board and their substitute members shall be made public.* *2. The members and substitutes members of the management board shall not hold conflicting positions or commercial interests with regard to any topic related to the application of this Regulation.* *3. The rules for the meetings and voting of the management board and the appointment and removal of the Executive Director shall be*		

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		laid down in the rules of procedure referred to in Article – 57 b, point (a).		
Article - 57b new				
G 560c		***Article - 57b*** ***Functions of the management board*** ***1. The management board shall have the following tasks:*** ***(a) to make strategic decisions on the activities of the AI Office and to adopt its rules of procedure by a two-thirds majority of its members;*** ***(b) to implement its rules of procedure;*** ***(c) to adopt the AI Office's single programming document as well as it annual public report and transmit both to the European Parliament, to the Council, to the Commission, and to the Court of Auditors;*** ***(d) to adopt the AI Office's budget;*** ***(e) to appoint the executive director and, where relevant, to extend or curtail the executive director's term of office or remove him or her from office;*** ***(f) to decide on the establishment of the AI Office's internal structures and, where necessary, the modification of those internal structures necessary for the fulfilment of the AI Office tasks;***		G

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Article - 57c - new				
560d		***Article - 57c*** ***Chair of the management board*** ***1. The management board shall elect a Chair and two deputy Chairs from among its voting members, by simple majority.*** ***2. The term of office of the Chair and of the deputy Chairs shall be four years. The terms of the Chair and of the deputy Chairs renewable once.***		
Article 58				
561	Article 58 Tasks of the Board	Article 58 ~~*Tasks of the Board*~~***Advisory Forum***	Article 58 Tasks of the Board	Article 58 Tasks of the Board Text Origin: Commission Proposal
Article 58, first paragraph				
562	When providing advice and assistance to the Commission in the context of Article 56(2), the Board shall in particular:	~~*When providing advice and assistance to the Commission in the context of Article 56(2), the Board shall in particular:*~~***The advisory forum shall provide the AI Office with stakeholder input in matters relating to this Regulation, in particular with regard to the tasks set out in Article 56b point (l).***	~~*When providing*~~***The Board shall*** advice and ~~*assistance to the Commission in the context of Article 56(2),*~~***assist the Commission and the Member States in order to facilitate the consistent and effective application of this Regulation. For this purpose*** the Board ~~*shall*~~***may*** in particular:	~~*When providing advice and assistance to the Commission in the context of Article 56(2),*~~***The Board shall advise and assist the Commission and the Member States in order to facilitate the consistent and effective application of this Regulation. For this purpose*** the Board ~~*shall*~~***may*** in particular:

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Article 58, first paragraph, point (a)				
563	(a) collect and share expertise and best practices among Member States;		(a) collect and share ***technical and regulatory*** expertise and best practices among Member States;	(a) ~~*collect and share expertise and best practices among Member States*~~***contribute to the coordination among national competent authorities responsible for the application of this Regulation and, in cooperation and subject to agreement of the concerned market surveillance authorities, support joint activities of market surveillance authorities referred to in Article 63(7a)***;
Article 58, first paragraph, point (b)				
564	(b) contribute to uniform administrative practices in the Member States, including for the functioning of regulatory sandboxes referred to in Article 53;		(b) contribute to ~~*uniform*~~***the harmonisation of*** administrative practices in the Member States, including ~~*for*~~***in relation to the derogation from the conformity assessment procedures referred to in Article 47,*** the functioning of regulatory sandboxes ***and testing in real world conditions*** referred to in Article 53***, 54 and 54a***;	(b) ~~*contribute to uniform administrative practices in the Member States, including for the functioning of*~~***collect and share technical and*** regulatory ~~*sandboxes referred to in Article 53*~~***expertise and best practices among Member States***;
Article 58, first paragraph, point (ba)				
564a				***(c) provide advice in the implementation of this Regulation, in particular as regards the***

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				enforcement of rules on general purpose AI models; ***(d) contribute to the harmonisation of administrative practices in the Member States, including in relation to the derogation from the conformity assessment procedures referred to in Article 47, the functioning of regulatory sandboxes and testing in real world conditions referred to in Article 53, 54 and 54a;***
Article 58, first paragraph(e)				
G 565	(c) issue opinions, recommendations or written contributions on matters related to the implementation of this Regulation, in particular		(c) ~~*issue opinions,*~~ ***upon the request of the Commission or on its own initiative, issue*** recommendations ~~*or*~~***and*** written ~~*contributions on*~~ ***opinions on any relevant*** matters related to the implementation of this Regulation~~*, in particular*~~ ***and to its consistent and effective application, including:***	~~*(c)*~~***(e)*** ~~*issue opinions,*~~ ***upon the request of the Commission or on its own initiative, issue*** recommendations ~~*or*~~***and*** written ~~*contributions on*~~***opinions on any relevant*** matters related to the implementation of this Regulation ***and to its consistent and effective application, including:*** ~~*, in particular*~~
Article 58, first paragraph(e), point (i)				
G 566	(i) on technical specifications or existing standards regarding the requirements set out in Title III, Chapter 2,		(i) on technical specifications or existing standards regarding the requirements set out in Title III, Chapter 2,	(i) ***(i) on the development and application of codes of conduct and code of practice pursuant to this Regulation as well as the Commission's guidelines;***

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				(ii) the evaluation and review of this Regulation pursuant to Article 84, including as regards the serious incident reports referred to in Article 62 and the functioning of the database referred to in Article 60, the preparation of the delegated or implementing acts, and possible alignments of this Regulation with the legal acts listed in Annex II; ***(iii)*** on technical specifications or existing standards regarding the requirements set out in Title III, Chapter 2,
Article 58, first paragraph(e), point (ii)				
G 567	(ii) on the use of harmonised standards or common specifications referred to in Articles 40 and 41,		(ii) on the use of harmonised standards or common specifications referred to in Articles 40 and 41,	(~~ii~~***iv***) on the use of harmonised standards or common specifications referred to in Articles 40 and 41, G
Article 58, first paragraph(e), point (iii)				
G 568	(iii) on the preparation of guidance documents, including the guidelines concerning the setting of administrative fines referred to in Article 71.		(iii) on the preparation of guidance documents, including the guidelines concerning the setting of administrative fines referred to in Article 71~~.~~***:***	~~(iii)~~***(v) trends, such as European global competitiveness in artificial intelligence, the uptake of artificial intelligence in the Union and the development of digital skills;*** ***(via) trends*** on the ~~*preparation of guidance documents, including the guidelines concerning the setting of administrative fines referred to in Article 71.*~~***evolving typology of AI value chains, in particular on the*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				resulting implications in terms of accountability; ***(vi) on the potential need for amendment of Annex III in accordance with Article 7 and on the potential need for possible revision of Article 5 pursuant to Article 84, taking into account relevant available evidence and the latest developments in technology;***
Article 58, second paragraph, (new)				
G 568a		***2. The membership of the advisory forum shall represent a balanced selection of stakeholders, including industry, start-ups, SMEs, civil society, the social partners and academia. The membership of the advisory forum shall be balanced with regard to commercial and non-commercial interests and, within the category of commercial interests, with regards to SMEs and other undertakings.***		G
Article 58, third paragraph, (new)				
G 568b		***3. The management board shall appoint the members of the advisory forum in accordance with the selection procedure established in the AI Office's rules of procedure and taking into account***		G

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		the need for transparency and in accordance with the criteria set out in paragraph 2;		
Article 58, fourth paragraph, (new)				
G 568c		***4. The term of office of the members of the advisory forum shall be two years, which may be extended by up to no more than four years.***		G
Article 58, fifth paragraph, (new)				
G 568d		***5. The European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI) shall be permanent members of the Advisory Forum. The Joint Research Centre shall be permanent member, without voting rights.***		G
Article 58, sixth paragraph , (new)				
G 568e		***6. The advisory forum shall draw up its rules of procedure. It shall elect two co-Chairs from among its members, in accordance with criteria set out in paragraph 2. The term of office of the co-Chairs shall***		G

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		be two years, renewable once.		
Article 58, seventh paragraph, (new)				
G 568f		*7. The advisory forum shall hold meetings at least four times a year. The advisory forum may invite experts and other stakeholders to its meetings. The executive director may attend, ex officio, the meetings of the advisory forum.*		G
Article 58, eigth paragraph, (new)				
G 568g		*8. In fulfilling its role as set out in paragraph 1, the advisory forum may prepare opinions, recommendations and written contributions.*		G
Article 58, tenth paragraph, (new)				
G 568h		*(10) The advisory forum shall prepare an annual report of its activities. That report shall be made publicly available.*		G
Article 58 a (new)				
G 568i		*58 a Article 58 a Benchmarking The European authorities on benchmarking referred to in Article*		G

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		15 (1a) and the AI Office shall, in close cooperation with international partners, jointly develop cost-effective guidance and capabilities to measure and benchmark aspects of AI systems and AI components, and in particular of foundation models relevant to the compliance and enforcement of this Regulation based on the generally acknowledged state of the art, including as reflected in relevant harmonized standards.		
Article 58a, SECTION 5 - title				
G 568j		***(title) European Authorities on benchmarking***		G
Article 58, nineth paragraph, (new)				
G 568k		***9. The advisory forum may establish standing or temporary subgroups as appropriate for the purpose of examining specific questions related to the objectives of this Regulation.***		G
Article 58, first paragraph(e), point (iiia)				
G 568l				G
Article 58, first paragraph, point (ea)				
G 568m				G

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			(ca) advise the Commission on the potential need for amendment of Annex III in accordance with Articles 4 and 7, taking into account relevant available evidence and the latest develoments in technology;	*(f) support the Commission in promoting AI literacy, public awareness and understanding of the benefits, risks, safeguards and rights and obligations in relation to the use of AI systems;* *(g) facilitate the development of common criteria and a shared understanding among market operators and competent authorities of the relevant concepts provided for in this Regulation, including by contributing to the development of benchmarks;* *(h) cooperate, as appropriate, with other Union institutions, bodies, offices and agencies, as well as relevant Union expert groups and networks in particular in the fields of product safety, cybersecurity, competition, digital and media services, financial services, , consumer protection, data and fundamental rights protection;* *(i) contribute to the effective cooperation with the competent authorities of third countries and with international organisations;* *(j) assist national competent authorities and the Commission, in developing the organisational and technical expertise required for the*

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				implementation of this Regulation, including by contributing to the assessment of training needs for staff of Member States involved in implementing this Regulation; ***(j1) assist the AI Office in supporting national competent authorities in the establishment and development of regulatory sandboxes and facilitate cooperation and information-sharing among regulatory sandboxes;*** ***(k) contribute and provide relevant advice in the development of guidance documents;*** ***(l) advise the Commission in relation to international matters on artificial intelligence.*** ***(m) provide opinions to the Commission on the qualified alerts regarding general purpose AI models;*** ***(n) receive opinions by the Member states on the qualified alerts regarding general purpose AI models and on national experiences and practices on the monitoring and enforcement of the AI systems, in particular systems integrating the general purpose AI models.***
Article 58, first paragraph, point (cb)				

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G 568n			***(cb) advise the Commission during the preparation of delegated or implementing act pursuant to this Regulation;***	G
Article 58, first paragraph, point (cc)				
G 568o			***(cc) cooperate, as appropriate, with relevant EU bodies, experts groups and networks in particular in the fields of product safety, cybersecurity, competition, digital and media services, financial services, cryptocurrencies, consumer protection, data and fundamental rights protection;***	G
Article 58, first paragraph, point (cd)				
G 568p			***(cd) contribute and provide relevant advice to the Commission in the development of the guidance referred to in Article 58a or request the development of such guidance;***	G
Article 58, first paragraph, point (ce)				
G 568q			***(ce) assist the work of market surveillance authorities and, in cooperation and subject to agreement of the concerned market surveillance authorities, promote and support cross-border market***	G

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			surveillance investigations, including with respect to the emergence of risks of systemic nature that may stem from AI systems;	
Article 58, first paragraph, point (cf)				
G 568r			***(cf) contribute to the assessment of training needs for staff of Member States involved in implementing this Regulation;***	G
Article 58, first paragraph, point (cg)				
G 568s			***(cg) advise the Commission in relation to international matters on artificial intelligence.***	G
Chapter 1a				
G 568t			***Chapter 1a GUIDELINES FROM THE COMMISSION***	Text Origin: Council Mandate G
Article 58a				
G 568u			***Article 58a Guidelines from the Commission on the implementation of this Regulation***	Text Origin: Council Mandate G
Article 58a, first paragraph				

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G 568v			***Upon the request of the Member States or the Board, or on its own initiative, the Commission shall issue guidelines on the practical implementation of this Regulation, and in particular on:***	Text Origin: Council Mandate G
Article 58a, second paragraph				
G 568w			***(i) the application of the requirements referred to in Articles 8 - 15;*** ***(ii) the prohibited practices referred to in Article 5;*** ***(iii) the practical implementation of the provisions related to substantial modification;*** ***(iv) the practical implementation of uniform conditions referred to in Article 6, paragraph 3, including examples in relation to high risk AI systems referred to in Annex III;*** ***(v) the practical implementation of transparency obligations laid down in Article 52;*** ***(vi) the relationship of this Regulation with other relevant Union legislation, including as regards consistency in their enforcement.***	Text Origin: Council Mandate G
Article 58a, third paragraph				
G 568x			***When issuing such guidelines, the***	G

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			Commission shall pay particular attention to the needs of SMEs including start-ups, local public authorities and sectors most likely to be affected by this Regulation.	Text Origin: Council Mandate
Article 58b				
G 568y				***Article 58a*** ***Advisory forum*** ***1. An advisory forum shall be established to advise and provide technical expertise to the Board and the Commission to contribute to their tasks under this Regulation.*** ***2. The membership of the advisory forum shall represent a balanced selection of stakeholders, including industry, start-ups, SMEs, civil society and academia. The membership of the advisory forum shall be balanced with regard to commercial and non-commercial interests and, within the category of commercial interests, with regards to SMEs and other undertakings.*** ***3. The Commission shall appoint the members of the advisory forum, in accordance with the criteria set out in the previous paragraph, among stakeholders with recognised expertise in the field of AI.*** ***4. The term of office of the*** G

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				members of the advisory forum shall be two years, which may be extended by up to no more than four years. ***5. The Fundamental Rights Agency, European Union Agency for Cybersecurity, the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI) shall be permanent members of the advisory forum.*** ***6. The advisory forum shall draw up its rules of procedure. It shall elect two co-chairs from among its members, in accordance with criteria set out in paragraph 2. The term of office of the co-chairs shall be two years, renewable once.*** ***7. The advisory forum shall hold meetings at least two times a year. The advisory forum may invite experts and other stakeholders to its meetings.*** ***8. In fulfilling its role as set out in paragraph 1, the advisory forum may prepare opinions, recommendations and written contributions upon request of the Board or the Commission*** ***9. The advisory forum may establish standing or temporary subgroups as appropriate for the purpose of examining specific***

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				questions related to the objectives of this Regulation. ***10. The advisory forum shall prepare an annual report of its activities. That report shall be made publicly available.***
Chapter 1a				
G 568z				***Chapter 1a*** ***Scientific Panel of independent experts*** ***Article 58b*** ***Scientific panel of independent experts*** ***1. The Commission shall, by means of an implementing act, make provisions on the establishment of a scientific panel of independent experts (the 'scientific panel') intended to support the enforcement activities under this Regulation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).*** ***2. The scientific panel shall consist of experts selected by the Commission on the basis of up-to-date scientific or technical expertise in the field of artificial intelligence necessary for the tasks set out in*** G

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				paragraph 3, and shall be able to demonstrate meeting all of the following conditions: ***(a) particular expertise and competence and scientific or technical expertise in the field of artificial intelligence;*** ***(b) independence from any provider of AI systems or general purpose AI models or systems;*** ***(c) ability to carry out activities diligently, accurately and objectively.*** ***The Commission, in consultation with the AI Board, shall determine the number of experts in the panel in accordance with the required needs and shall ensure fair gender and geographical representation.*** ***3. The scientific panel shall advise and support the European AI Office, in particular with regard to the following tasks:*** ***(a) support the implementation and enforcement of this Regulation as regards general purpose AI models and systems, in particular by*** ***(i) alerting the AI Office of possible systemic risks at Union level of general purpose AI models, in accordance with Article [Alerts of systemic risks by the scientific panel];*** ***(ii) contributing to the development of tools and***

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				methodologies for evaluating capabilities of general purpose AI models and systems, including through benchmarks; ***(iii) providing advice on the classification of general purpose AI models with systemic risk;*** ***(iiii) providing advice on the classification of different general purpose AI models and systems;*** ***(iv) contributing to the development of tools and templates.*** ***(b) support the work of market surveillance authorities, at their request;*** ***(c) support cross-border market surveillance activities as referred to in Article 63(7a), without prejudice of the powers of market surveillance authorities;*** ***(d) support the AI Office when carrying out its duties in the context of the safeguard clause pursuant to Article 66;*** ***4. The experts shall perform their tasks with impartiality, objectivity and ensure the confidentiality of information and data obtained in carrying out their tasks and activities. They shall neither seek nor take instructions from anyone when exercising their tasks under paragraph 3. Each expert shall draw up a declaration of interests, which shall be made publicly available. The AI Office shall establish systems and***

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				procedures to actively manage and prevent potential conflicts of interest. ***5. The implementing act referred to in paragraph 1 shall include provisions on the conditions, procedure and modalities for the scientific panel and its members to issue alerts and request the assistance of the AI Office to the performance of its tasks.*** ***Article 58c*** ***Access to the pool of experts by the Member States*** ***1. Member States may call upon experts of the scientific panel to support their enforcement activities under this Regulation.*** ***2. The Member States may be required to pay fees for the advice and support by the experts. The structure and the level of fees as well as the scale and structure of recoverable costs shall be set out in the implementing act referred to in Article 58b(1), taking into account the objectives of the adequate implementation of this Regulation, cost-effectiveness and the necessity to ensure an effective access to experts by all Member States.*** ***3. The Commission shall facilitate timely access to the experts by the Member States, as needed, and ensure that the***

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				combination of support activities carried out by EU AI testing support pursuant to Article 68a and experts pursuant to this Article is efficiently organised and provides the best possible added value.
CHAPTER 2				
G 569	CHAPTER 2 national competent authorities	CHAPTER 2 national ~~competent~~***supervisory*** authorities	CHAPTER 2 National competent authorities	CHAPTER 2 national competent authorities Text Origin: Commission Proposal
Article 59				
G 570	Article 59 Designation of national competent authorities	Article 59 Designation of national ~~competent~~***supervisory*** authorities	Article 59 Designation of national competent authorities	Article 59 Designation of national competent authorities ***and single point of contact*** Text Origin: Commission Proposal
Article 59(1)				
G 571	1. National competent authorities shall be established or designated by each Member State for the purpose of ensuring the application and implementation of this Regulation. National competent authorities shall be organised so as to safeguard the objectivity and impartiality of their	1. ~~*National competent authorities*~~***Each Member State*** shall ~~*be established or designated by each Member State for the purpose of ensuring the application and implementation of this Regulation. National competent authorities shall be organised so as to safeguard the*~~	*deleted*	1. ~~*National competent authorities shall be established or designated by each Member State for the purpose of ensuring the application and implementation of this Regulation. National competent authorities shall be organised so as to safeguard the objectivity and impartiality of their*~~

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	activities and tasks.	~~objectivity and impartiality of their activities and tasks~~***designate one national supervisory authority, which shall be organised so as to safeguard the objectivity and impartiality of its activities and tasks by ...[three months after the date of entry into force of this Regulation]***.		~~activities and tasks.~~***deleted***
Article 59(2)				
G 572	2. Each Member State shall designate a national supervisory authority among the national competent authorities. The national supervisory authority shall act as notifying authority and market surveillance authority unless a Member State has organisational and administrative reasons to designate more than one authority.	2. ~~Each Member State~~***The national supervisory authority*** shall ~~designate a national supervisory authority among the national~~***ensure the application and implementation of this Regulation. With regard to high-risk AI systems, related to products to which legal acts listed in Annex II apply, the*** competent authorities~~. The national supervisory authority~~ ***designated under those legal acts*** shall ~~act as notifying authority and market surveillance authority unless a Member State has organisational and administrative reasons to designate more than one~~***continue to lead the administrative procedures. However, to the extent a case involves aspects exclusively covered by this Regulation, those competent authorities shall be bound by the measures related to those aspects issued by the national supervisory***	2. Each Member State shall ***establish or*** designate ~~a national supervisory~~***at least one notifying*** authority ~~among the~~ ***and at least one market surveillance authority for the purpose of this Regulation as*** national competent authorities. ~~The~~***These*** national ~~supervisory authority~~***competent authorities*** shall ~~act as notifying authority and market surveillance authority unless a Member State has organisational and administrative reasons to designate more than one authority~~***be organised so as to safeguard the priniciples of objectivity and impartiality of their activities and tasks. Provided that those prinicples are respected, such activities and tasks may be performed by one or several designated authorities, in accordance with the organisational needs of the Member State***.	2. ***2.*** Each Member State shall ***establish or*** designate ~~a national supervisory~~***at least one notifying authority and at least one market surveillance*** authority ~~among the~~ ***for the purpose of this Regulation as*** national competent authorities. ~~The~~***These*** national ~~supervisory authority~~***competent authorities*** shall ~~act as notifying authority and market surveillance authority unless a Member State has organisational and administrative reasons to designate more than one authority~~***exercise their powers independently, impartially and without bias so as to safeguard the principles of objectivity of their activities and tasks and to ensure the application and implementation of this Regulation. The members of these authorities shall refrain from any action incompatible with their duties. Provided that those*** G

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		authority designated under this Regulation. The national supervisory authority shall act as market surveillance authority.		***prinicples are respected, such activities and tasks may be performed by one or several designated authorities, in accordance with the organisational needs of the Member State***.
Article 59(3)				
G 573	3. Member States shall inform the Commission of their designation or designations and, where applicable, the reasons for designating more than one authority.	3. Member States shall ~~*inform the Commission of their designation or designations and, where applicable, the reasons for designating more than one authority*~~***make publicly available and communicate to the AI Office and the Commission the national supervisory authority and information on how it can be contacted, by… [three months after the date of entry into force of this Regulation]. The national supervisory authority shall act as single point of contact for this Regulation and should be contactable though electronic communications means***.	3. Member States shall inform the Commission of their designation or designations~~*and, where applicable, the reasons for designating more than one authority*~~.	3. Member States shall ~~*inform*~~***communicate to*** the Commission ***the identity of the notifying authorities and the market surveillance authorities and the tasks of those authorities and as well as any subsequent changes thereto. Member States shall make publicly available information on how competent authorities and single point of contact can be contacted***~~*of their designation or designations and, where applicable*~~, ***through electronic communication means by… [12 months after the date of entry into force of this Regulation]. Member States shall designate a market surveillance authority to act as single point of contact for this Regulation and notify the Commission of the identity of the single point of contact. The Commission shall make a list of the single points of contact publicly available***~~*the reasons for designating more than one authority*~~. G

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Article 59(4)				
574	4. Member States shall ensure that national competent authorities are provided with adequate financial and human resources to fulfil their tasks under this Regulation. In particular, national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements.	4. Member States shall ensure that ***the*** national ~~competent authorities are~~***supervisory authority is*** provided with adequate ***technical,*** financial and human resources***, and infrastructure*** to fulfil their tasks ***effectively*** under this Regulation. In particular, ***the*** national ~~competent authorities~~***supervisory authority*** shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, ***personal data protection, cybersecurity, competition law,*** fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. ***Member States shall assess and, if deemed necessary, update competence and resource requirements referred to in this paragraph on an annual basis.***	4. Member States shall ensure that national competent authorities are provided with adequate financial ***resources, technical equipment and well qualified*** ~~and~~ human resources to ***effectively*** fulfil their tasks under this Regulation. ~~*In particular, national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements.*~~	4. Member States shall ensure that ***the*** national competent ~~authorities are~~***authority is*** provided with adequate ***technical,*** financial and human resources***, and infrastructure*** to fulfil their tasks ***effectively*** under this Regulation. In particular, ***the*** national competent ~~authorities~~***authority*** shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, ***personal data protection, cybersecurity,*** fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. ***Member States shall assess and, if deemed necessary, update competence and resource requirements referred to in this paragraph on an annual basis.***
Article 59(4a)				
574a		***4a. Each national supervisory authority shall exercise their powers and carry out their duties***		

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		independently, impartially and without bias. The members of each national supervisory authority, in the performance of their tasks and exercise of their powers under this Regulation, shall neither seek nor take instructions from any body and shall refrain from any action incompatible with their duties.		
Article 59(4a)				
G 574b		***4b. National supervisory authorities shall satisfy the minimum cybersecurity requirements set out for public administration entities identified as operators of essential services pursuant to Directive (EU) 2022/2555.***		***4a. National competent authorities shall satisfy an adequate level of cybersecurity measures.*** G
Article 59(4b)				
G 574c		***4c. When performing their tasks, the national supervisory authority shall act in compliance with the confidentiality obligations set out in Article 70.***		***4c. When performing their tasks, the national competent authorities shall act in compliance with the confidentiality obligations set out in Article 70.*** Text Origin: EP Mandate G
Article 59(5)				
G 575	5. Member States shall report to the	5. Member States shall report to the	5. ~~Member States shall report to the~~	5. ***By one year after entry into*** G

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	Commission on an annual basis on the status of the financial and human resources of the national competent authorities with an assessment of their adequacy. The Commission shall transmit that information to the Board for discussion and possible recommendations.	Commission on an annual basis on the status of the financial and human resources of the national ~~competent authorities~~***supervisory authority*** with an assessment of their adequacy. The Commission shall transmit that information to the ~~Board~~***AI Office*** for discussion and possible recommendations.	~~Commission on an annual basis~~***By [one year after entry into force of this Regulation] and afterwards six months before the deadline referred to in Article 84(2) Member States shall inform the Commission*** on the status of the financial ***resources, technical equipment*** and human resources of the national competent authorities with an assessment of their adequacy. The Commission shall transmit that information to the Board for discussion and possible recommendations.	***force of this Regulation and once every two years thereafter*** Member States shall report to the Commission ~~on an annual basis~~ on the status of the financial and human resources of the national competent authorities with an assessment of their adequacy. The Commission shall transmit that information to the Board for discussion and possible recommendations.
Article 59(6)				
G 576	6. The Commission shall facilitate the exchange of experience between national competent authorities.	*deleted*	*6.* The Commission shall facilitate the exchange of experience between national competent authorities.	6. The Commission shall facilitate the exchange of experience between national competent authorities. Text Origin: Council Mandate G
Article 59(7)				
G 577	7. National competent authorities may provide guidance and advice on the implementation of this Regulation, including to small-scale providers. Whenever national competent authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the competent national authorities	7. National ~~competent~~***supervisory*** authorities may provide guidance and advice on the implementation of this Regulation, including to ~~small-scale providers~~***SMEs and start-ups, taking into account the AI Office or the Commission's guidance and advice***. Whenever ***the*** national ~~competent authorities~~***supervisory authority*** intend to provide guidance	7. National competent authorities may provide ~~guidance and~~ advice on the implementation of this Regulation, including ***tailored to SME***~~to small-scale~~ providers***, including start-ups***. Whenever national competent authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union legislation,	7. ***7.*** National competent authorities may provide guidance and advice on the implementation of this Regulation, ~~including to small-scale providers~~***in particular to SMEs including start-ups, taking into account the Board's and the Commission's guidance and advice, as appropriate***. Whenever national competent authorities intend to G

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	under that Union legislation shall be consulted, as appropriate. Member States may also establish one central contact point for communication with operators.	and advice with regard to an AI system in areas covered by other Union ~~legislation, the competent national authorities under that Union legislation~~***law, the guidance*** shall be ~~consulted, as appropriate. Member States may also establish one central contact point for communication with operators~~***drafted in consultation with the competent national authorities under that Union law, as appropriate***.	the competent national authorities under that Union legislation shall be consulted, as appropriate. Member States may also establish one central contact point for communication with operators.	provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the competent national authorities under that Union legislation shall be consulted, as appropriate. ~~Member States may also establish one central contact point for communication with operators.~~ Text Origin: Presidency2
Article 59(8)				
G 578	8. When Union institutions, agencies and bodies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as the competent authority for their supervision.	8. When Union institutions, agencies and bodies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as the competent authority for their supervision ***and coordination***.	8. When Union institutions, agencies and bodies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as the competent authority for their supervision.	8. When Union institutions, agencies and bodies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as the competent authority for their supervision. Text Origin: EP Mandate
Article 59a				
G 578a		***59 a. Cooperation mechanism between national supervisory authorities in cases involving two or more Member States*** ***1. Each national supervisory authority shall perform its tasks and powers conferred on in accordance with this Regulation on***		

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		the territory of its own Member State. ***2. In the event of a case involving two or more national supervisory authorities, the national supervisory authority of the Member State where the infringement took place shall be considered the lead supervisory authority.*** ***3. In the cases referred to in paragraph 2, the relevant supervisory authorities shall cooperate and exchange all relevant information in due time. National supervisory authorities shall cooperate in order to reach a consensus.***		
TITLE VII				
G 579	TITLE VII EU DATABASE FOR STAND-ALONE HIGH-RISK AI SYSTEMS	TITLE VII EU DATABASE FOR ~~*STAND-ALONE*~~ HIGH-RISK AI SYSTEMS	TITLE VII EU DATABASE FOR ~~*STAND-ALONE*~~ HIGH-RISK AI SYSTEMS ***LISTED IN ANNEX III***	TITLE VII EU DATABASE FOR ~~*STAND-ALONE*~~ HIGH-RISK AI SYSTEMS ***LISTED IN ANNEX III*** Text Origin: Council Mandate
Article 60				
G 580	Article 60 EU database for stand-alone high-risk AI systems	Article 60 EU database for ~~*stand-alone*~~ high-risk AI systems	Article 60 ***EU database for high-risk AI systems listed in Annex III***~~*EU database for stand-alone high-risk AI systems*~~	Article 60 ***EU database for high-risk AI systems listed in Annex III***~~*EU database for stand-alone high-risk AI systems*~~ Text Origin: Council Mandate

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Article 60(1)				
G 581	1. The Commission shall, in collaboration with the Member States, set up and maintain a EU database containing information referred to in paragraph 2 concerning high-risk AI systems referred to in Article 6(2) which are registered in accordance with Article 51.	1. The Commission shall, in collaboration with the Member States, set up and maintain a ***public*** EU database containing information referred to in ~~*paragraph 2*~~ ***paragraphs 2 and 2a*** concerning high-risk AI systems referred to in Article ~~*6(2)*~~***6 (2)*** which are registered in accordance with Article 51.	1. The Commission shall, in collaboration with the Member States, set up and maintain a EU database containing information referred to in paragraph 2 concerning ***relevant operators and*** high-risk AI systems ~~*referred to in Article 6(2)*~~***listed in Annex III*** which are registered in accordance with ~~*Article 51*~~***Articles 51 and 54a. When setting the fuctional specifications of such database, the Commission shall consult the AI Board***.	1. The Commission shall, in collaboration with the Member States, set up and maintain a EU database containing information referred to in ~~*paragraph 2*~~ ***paragraphs 2 and 2a*** concerning high-risk AI systems referred to in Article 6(2) which are registered in accordance with ~~*Article 51*~~***Articles 51 and 54a. When setting the functional specifications of such database, the Commission shall consult the relevant experts, and when updating the functional specifications of such database, the Commission shall consult the AI Board***. G
Article 60(2)				
G 582	2. The data listed in Annex VIII shall be entered into the EU database by the providers. The Commission shall provide them with technical and administrative support.	2. The data listed in Annex VIII***, Section A,*** shall be entered into the EU database by the providers. ~~*The Commission shall provide them with technical and administrative support.*~~	2. The data listed in Annex VIII***, Part I,*** shall be entered into the EU database by the providers***, authorised representatives and relevant users, as applicable, upon their registration***. ~~*The Commission*~~ ***The data listed in Annex VIII, Part II, 1 to 11,*** shall ~~*provide them with technical and administrative support*~~***be entered into the EU database by the providers, or where applicable by the authorised***	2. The data listed in Annex VIII***, Section A,*** shall be entered into the EU database by the ~~*providers. The Commission shall provide them with technical and administrative support*~~***provider or where applicable the authorised representative***. G

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			representative, in accordance with Article 51. The data referred in Annex VIII, Part II, 12 shall be automatically generated by the database based on the information provided by relevant users pursuant to Article 51(2). The data listed in Annex VIIIa shall be entered into the database by the prospective providers or providers in accordance with Article 54a.	
Article 60(2a)				
G 582a		***2a. The data listed in Annex VIII, Section B, shall be entered into the EU database by the deployers who are or who act on behalf of public authorities or Union institutions, bodies, offices or agencies and by deployers who are undertakings referred to in Article 51(1a) and (1b).***		***2a. The data listed in Annex VIII, Section B, shall be entered into the EU database by the deployer who is or who acts on behalf of public authorities, agencies or bodies, according to articles 51(1a) and (1b).***
Article 60(3)				
G 583	3. Information contained in the EU database shall be accessible to the public.	3. Information contained in the EU database shall be ~~accessible~~***freely available*** to the public***, user-friendly and accessible, easily navigable and machine-readable containing structured digital data based on a standardised protocol***.	*deleted*	3. ***With the exception of the section referred to in Article 51(1c) and Article 54a(5), the*** information contained in the EU database ***registered in accordance with Article 51*** shall be accessible ***and publicly available in a user friendly manner. The information should be easily navigable and machine-***

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				readable. The information registered in accordance with Article 54a shall be accessible only to market surveillance authorities and the Commission, unless the prospective provider or provider has given consent for making this information also accessible ~~to~~ the public.
Article 60(4)				
G 584	4. The EU database shall contain personal data only insofar as necessary for collecting and processing information in accordance with this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider.	4. The EU database shall contain personal data only insofar as necessary for collecting and processing information in accordance with this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider ***or the deployer which is a public authority or Union institution, body, office or agency or a deployer acting on their behalf or a deployer which is an undertaking referred to in Article 51(1a)(b) and (1b)***.	4. The EU database shall contain ***no*** personal data ~~only insofar as necessary for collecting and processing~~***, except for the*** information ***listed in Annex VIII, and*** ~~in accordance with this Regulation. That information~~ shall ~~include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider~~***be without prejudice to Article 70***.	4. The EU database shall contain personal data only insofar as necessary for collecting and processing information in accordance with this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider ***or the deployer, as applicable***. G
Article 60(5)				
G 585	5. The Commission shall be the controller of the EU database. It	5. The Commission shall be the controller of the EU database. It	5. The Commission shall be the controller of the EU database. It	5. The Commission shall be the controller of the EU database. It G

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	shall also ensure to providers adequate technical and administrative support.	shall also ensure to providers ***and deployers*** adequate technical and administrative support. ***The database shall comply with the accessibility requirements of Annex I to Directive (EU) 2019/882.***	shall ~~also ensure~~***make available*** to providers***, prospective providers and users*** adequate technical and administrative support.	shall ~~also ensure to~~***make available to providers, prospective*** providers ***and deployers*** adequate technical and administrative support. ***The database shall comply with the applicable accessibility requirements.***
Article 60(5a)				
G 585a			***5a. Information contained in the EU database registered in accordance with Article 51 shall be accessible to the public. The information registered in accordance with Article 54a shall be accessible only to market surveillance authorities and the Commission, unless the prospective provider or provider has given consent for making this information also accessible the public.***	G
TITLE VIII				
G 586	TITLE VIII POST-MARKET MONITORING, INFORMATION SHARING, MARKET SURVEILLANCE	TITLE VIII POST-MARKET MONITORING, INFORMATION SHARING, MARKET SURVEILLANCE	TITLE VIII POST-MARKET MONITORING, INFORMATION SHARING, MARKET SURVEILLANCE	TITLE VIII POST-MARKET MONITORING, INFORMATION SHARING, MARKET SURVEILLANCE Text Origin: Commission Proposal G
Chapter 1				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 587	Chapter 1 Post-market monitoring	Chapter 1 Post-market monitoring	Chapter 1 Post-market monitoring	Chapter 1 Post-market monitoring Text Origin: Commission Proposal G
Article 61				
G 588	Article 61 Post-market monitoring by providers and post-market monitoring plan for high-risk AI systems	Article 61 Post-market monitoring by providers and post-market monitoring plan for high-risk AI systems	Article 61 Post-market monitoring by providers and post-market monitoring plan for high-risk AI systems	Article 61 Post-market monitoring by providers and post-market monitoring plan for high-risk AI systems Text Origin: Commission Proposal G
Article 61(1)				
G 589	1. Providers shall establish and document a post-market monitoring system in a manner that is proportionate to the nature of the artificial intelligence technologies and the risks of the high-risk AI system.	1. Providers shall establish and document a post-market monitoring system in a manner that is proportionate to the nature of the artificial intelligence technologies and the risks of the high-risk AI system.	1. Providers shall establish and document a post-market monitoring system in a manner that is proportionate to the ~~*nature of the artificial intelligence technologies and the*~~ risks of the high-risk AI system.	1. Providers shall establish and document a post-market monitoring system in a manner that is proportionate to the nature of the artificial intelligence technologies and the risks of the high-risk AI system. Text Origin: Commission Proposal G
Article 61(2)				
G 590	2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by	2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by	2. ***In order to allow the provider to evaluate the compliance of AI systems with the requirements set out in Title III, Chapter 2***	2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data ***which may be*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	users or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.	~~users~~***deployers*** or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2. ***Where relevant, post-market monitoring shall include an analysis of the interaction with other AI systems environment, including other devices and software taking into account the rules applicable from areas such as data protection, intellectual property rights and competition law.***	***throughout their life cycle,*** the post-market monitoring system shall ~~actively and systematically~~ collect, document and analyse relevant data***, which may be*** provided by users or ***which may be*** collected through other sources on the performance of high-risk AI systems***. This obligation shall not cover sensitive operational data of users*** ~~throughout their lifetime, and allow the provider to evaluate the continuous compliance~~ of AI systems ~~with the requirements set out in Title III, Chapter 2~~***which are law enforcement authorities***.	provided by ~~users or~~ ***deployers or which may be*** collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2. ***Where relevant, post-market monitoring shall include an analysis of the interaction with other AI systems.*** ***This obligation shall not cover sensitive operational data of deployers which are law enforcement authorities.***
Article 61(3)				
G 591	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 an implementing act laying down detailed provisions establishing a template for the post-market monitoring plan and the list of elements to be included in the 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 an implementing act laying down detailed provisions establishing a template for the post-market monitoring plan and the list of elements to be included in the plan ***by [twelve months after the date of entry into force of this Regulation]***.	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 an implementing act laying down detailed provisions establishing a template for the post-market monitoring plan and the list of elements to be included in the 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 an implementing act laying down detailed provisions establishing a template for the post-market monitoring plan and the list of elements to be included in the plan ***by six months before the entry into application of this Regulation***. G
Article 61(4), first subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 592	4. For high-risk AI systems covered by the legal acts referred to in Annex II, where a post-market monitoring system and plan is already established under that legislation, the elements described in paragraphs 1, 2 and 3 shall be integrated into that system and plan as appropriate.	4. For high-risk AI systems covered by the legal acts referred to in Annex II, where a post-market monitoring system and plan is already established under that legislation, the elements described in paragraphs 1, 2 and 3 shall be integrated into that system and plan as appropriate.	4. For high-risk AI systems covered by the legal acts referred to in Annex II, ***Section A,*** where a post-market monitoring system and plan is already established under that legislation, the ~~*elements described in paragraphs 1, 2 and 3*~~***post-market monitoring documentation as prepared under that legislation*** shall be ~~*integrated into that system and plan as appropriate*~~***deemed sufficient, provided that the template referred to paragraph 3 is used***.	4. ***4.*** For high-risk AI systems covered by the legal acts referred to in Annex II, ***Section A,*** where a post-market monitoring system and plan is already established under that legislation, ***in order to ensure consistency, avoid duplications and minimise additional burdens, providers shall have a choice to integrate, as appropriate, the necessary*** ~~*the*~~ elements described in paragraphs 1, 2 and 3 ~~*shall be integrated into that*~~***using the template referred in paragraph 3 into already existing*** system and plan ~~*as appropriate*~~***under the Union harmonisation legislation listed in Annex II, Section A, provided it achieves an equivalent level of protection***.
Article 61(4), second subparagraph				
G 593	The first subparagraph shall also apply to high-risk AI systems referred to in point 5(b) of Annex III placed on the market or put into service by credit institutions regulated by Directive 2013/36/EU.	The first subparagraph shall also apply to high-risk AI systems referred to in point 5(b) of Annex III placed on the market or put into service by credit institutions regulated by Directive 2013/36/EU.	The first subparagraph shall also apply ~~*to*~~ high-risk AI systems referred to in point ~~*5(b)*~~***5*** of Annex III placed on the market or put into service by ~~*credit*~~***financial*** institutions ~~*regulated by Directive 2013/36/EU*~~***that are subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation***.	The first subparagraph shall also apply ~~*to*~~ high-risk AI systems referred to in point ~~*5(b)*~~***5*** of Annex III placed on the market or put into service by ~~*credit*~~***financial*** institutions ~~*regulated by Directive 2013/36/EU*~~***that are subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation***.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Chapter 2				
G 594	Chapter 2 Sharing of information on incidents and malfunctioning	Chapter 2 Sharing of information on incidents and malfunctioning	Chapter 2 ~~Sharing of information on incidents and malfunctioning~~***SHARING OF INFORMATION ON SERIOUS INCIDENTS***	Chapter 2 ~~Sharing of information on incidents and malfunctioning~~***SHARING OF INFORMATION ON SERIOUS INCIDENTS*** Text Origin: Council Mandate
Article 62				
G 595	Article 62 Reporting of serious incidents and of malfunctioning	Article 62 Reporting of serious incidents ~~and of malfunctioning~~	Article 62 ***Reporting of serious incidents*** ~~Reporting of serious incidents and of malfunctioning~~	Article 62 ***Reporting of serious incidents*** ~~Reporting of serious incidents and of malfunctioning~~ Text Origin: Council Mandate
Article 62(1), first subparagraph				
G 596	1. Providers of high-risk AI systems placed on the Union market shall report any serious incident or any malfunctioning of those systems which constitutes a breach of obligations under Union law intended to protect fundamental rights to the market surveillance authorities of the Member States where that incident or breach occurred.	1. Providers ***and, where deployers have identified a serious incident, deployers*** of high-risk AI systems placed on the Union market shall report any serious incident ~~or any malfunctioning~~ of those systems which constitutes a breach of obligations under Union law intended to protect fundamental rights to the ~~market surveillance authorities~~***national supervisory authority*** of the Member States where that incident or breach occurred.	1. Providers of high-risk AI systems placed on the Union market shall report any serious incident ~~or any malfunctioning of those systems which constitutes a breach of obligations under Union law intended to protect fundamental rights~~ to the market surveillance authorities of the Member States where that incident ~~or breach~~ occurred.	1. Providers of high-risk AI systems placed on the Union market shall report any serious incident ~~or any malfunctioning of those systems which constitutes a breach of obligations under Union law intended to protect fundamental rights to the market surveillance authorities~~***to the market surveillance authorities of the Member States where that incident occurred.*** ***1a. As a general rule, the period for***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				the reporting referred to in paragraph 1 shall take account of the ~~*Member States where that*~~***severity of the serious*** incident ~~*or breach occurred*~~.
Article 62(1), second subparagraph				
597	Such notification shall be made immediately after the provider has established a causal link between the AI system and the incident or malfunctioning or the reasonable likelihood of such a link, and, in any event, not later than 15 days after the providers becomes aware of the serious incident or of the malfunctioning.	Such notification shall be made ~~*immediately*~~***without undue delay*** after the provider***, or, where applicable the deployer,*** has established a causal link between the AI system and the incident or ~~*malfunctioning or*~~ the reasonable likelihood of such a link, and, in any event, not later than ~~*15 days*~~***72 hours*** after the ~~*providers becomes aware of the serious incident or*~~***provider or, where applicable, the deployer becomes aware*** of the ~~*malfunctioning*~~***serious incident***.	Such notification shall be made immediately after the provider has established a causal link between the AI system and the ***serious*** incident or ~~*malfunctioning or*~~ the reasonable likelihood of such a link, and, in any event, not later than 15 days after the providers becomes aware of the serious incident~~*or of the malfunctioning*~~.	~~*Such*~~***1b. The*** notification ***referred to in paragraph 1*** shall be made immediately after the provider has established a causal link between the AI system and the ***serious*** incident or ~~*malfunctioning or*~~ the reasonable likelihood of such a link, and, in any event, not later than 15 days after the ~~*providers*~~***provider or, where applicable, the deployer,*** becomes aware of the serious incident***.*** ***1c. Notwithstanding paragraph 1b, in the event of a widespread infringement or a serious incident as defined in Article 3(44) point (b) the report referred to in paragraph 1 shall be provided immediately, and not later than 2 days after the provider or, where applicable, the deployer becomes aware of that incident.*** ***1d. Notwithstanding paragraph 1b, in the event of death of a person the report shall be provided immediately after the provider or the deployer has established or as***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				soon as it suspects a causal relationship between the high-risk AI system and the serious incident but not later than 10 days after the date on which the provider or, where applicable, the deployer becomes aware of the serious incident. ***1e. Where necessary to ensure timely reporting, the provider or, where applicable, the deployer, may submit an initial report that is incomplete followed up by a complete report*** ~~*or of the malfunctioning*~~.
Article 62(1a)				
G 597a		***Upon establishing a causal link between the AI system and the serious incident or the reasonable likelihood of such a link, providers shall take appropriate corrective actions pursuant to Article 21.***		***1a. Following the reporting of a serious incident pursuant to the first subparagraph, the provider shall, without delay, perform the necessary investigations in relation to the serious incident and the AI system concerned. This shall include a risk assessment of the incident and corrective action. The provider shall co-operate with the competent authorities and where relevant with the notified body concerned during the investigations referred to in the first subparagraph and shall not perform any investigation which involves altering the AI system*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the competent authorities of such action. Text Origin: EP Mandate
Article 62(2)				
G 598	2. Upon receiving a notification related to a breach of obligations under Union law intended to protect fundamental rights, the market surveillance authority shall inform the national public authorities or bodies referred to in Article 64(3). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1. That guidance shall be issued 12 months after the entry into force of this Regulation, at the latest.	2. Upon receiving a notification related to a breach of obligations under Union law intended to protect fundamental rights, the ~~*market surveillance*~~***national supervisory*** authority shall inform the national public authorities or bodies referred to in Article 64(3). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1. That guidance shall be issued ~~*12 months after*~~ ***by [***the entry into force of this Regulation~~*, at the latest*~~***] and shall be assessed regularly***.	2. Upon receiving a notification related to a ~~*breach of obligations under Union law intended to protect fundamental rights, the*~~***serious incident referred to in Article 3(44)(c), the relevant*** market surveillance authority shall inform the national public authorities or bodies referred to in Article 64(3). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1. That guidance shall be issued 12 months after the entry into force of this Regulation, at the latest.	2. Upon receiving a notification related to a ~~*breach of obligations under Union law intended to protect fundamental rights, the*~~ ***serious incident referred to in Article 3(44)(c), the relevant*** market surveillance authority shall inform the national public authorities or bodies referred to in Article 64(3). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1. That guidance shall be issued 12 months after the entry into force of this Regulation, at the latest***, and shall be assessed regularly***. G
Article 62(2a)				
G 598a		***2a. The national supervisory authority shall take appropriate measures within 7 days from the date it received the notification referred to in paragraph 1. Where***		***2a. "2a. The market surveillance authority shall take appropriate measures, as provided in Article 19 of the Regulation 2019/1020, within 7 days from the date it received the*** G

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		the infringement takes place or is likely to take place in other Member States, the national supervisory authority shall notify the AI Office and the relevant national supervisory authorities of these Member States.		***notification referred to in paragraph 1 and follow the notification procedures as provided in the Regulation 2019/1020.*** Text Origin: Presidency2
Article 62(3)				
G 599	3. For high-risk AI systems referred to in point 5(b) of Annex III which are placed on the market or put into service by providers that are credit institutions regulated by Directive 2013/36/EU and for high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746, the notification of serious incidents or malfunctioning shall be limited to those that that constitute a breach of obligations under Union law intended to protect fundamental rights.	3. For high-risk AI systems referred to in ~~point 5(b) of~~ Annex III ~~which~~***that*** are placed on the market or put into service by providers that are ~~credit institutions regulated by Directive 2013/36/EU and for high-risk AI systems which are safety components of devices, or are themselves devices, covered by~~***subject to Union legislative instruments laying down reporting obligations equivalent to those set out in this*** Regulation ~~(EU) 2017/745 and Regulation (EU) 2017/746~~, the notification of serious incidents ~~or malfunctioning shall be limited to those that that constitute~~***constituting*** a breach of ~~obligations~~***fundamental rights*** under Union law ~~intended to protect fundamental rights~~***shall be transferred to the national supervisory authority***.	3. For high-risk AI systems referred to in point ~~5(b)~~***5*** of Annex III which are placed on the market or put into service by providers that are ~~credit~~***financial*** institutions ~~regulated by Directive 2013/36/EU and for high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746~~***that are subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation***, the notification of serious incidents ~~or malfunctioning~~ shall be limited to those ~~that that constitute a breach of obligations under Union law intended to protect fundamental rights~~***referred to in Article 3(44)(c)***.	3. For high-risk AI systems referred to in ~~point 5(b) of~~ Annex III ~~which~~***that*** are placed on the market or put into service by providers that are ~~credit institutions regulated by Directive 2013/36/EU and for high-risk AI systems which are safety components of devices, or are themselves devices, covered by~~***subject to Union legislative instruments laying down reporting obligations equivalent to those set out in this*** Regulation ~~(EU) 2017/745 and Regulation (EU) 2017/746~~, the notification of serious incidents ~~or malfunctioning~~ shall be limited to those ~~that that constitute a breach of obligations under Union law intended to protect fundamental rights~~***referred to in Article 3(44) (c)***. Text Origin: EP Mandate G
Article 62(3a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 599a			***3a. For high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746 the notification of serious incidents shall be limited to those referred to in Article 3(44)(c) and be made to the national competent authority chosen for this purpose by the Member States where that incident occurred.***	***3a. For high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746 the notification of serious incidents shall be limited to those referred to in Article 3(44)(c) and be made to the national competent authority chosen for this purpose by the Member States where that incident occurred.*** Text Origin: Council Mandate
Article 62(3b)				
G 599b		***3a. National supervisory authorities shall on an annual basis notify the AI Office of the serious incidents reported to them in accordance with this Article.***		***3a. National competent authorities shall immediately notify the Commission of any serious incident, whether or not it has taken action on it, in accordance with Article 20 of Regulation 2019/1020.*** Text Origin: Presidency2
Chapter 3				
G 600	Chapter 3 Enforcement	Chapter 3 Enforcement	Chapter 3 Enforcement	Chapter 3 Enforcement Text Origin: Commission Proposal

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 63				
601	Article 63 Market surveillance and control of AI systems in the Union market	Article 63 Market surveillance and control of AI systems in the Union market	Article 63 Market surveillance and control of AI systems in the Union market	Article 63 Market surveillance and control of AI systems in the Union market Text Origin: Commission Proposal
Article 63(1)				
602	1. Regulation (EU) 2019/1020 shall apply to AI systems covered by this Regulation. However, for the purpose of the effective enforcement of this Regulation:	1. Regulation (EU) 2019/1020 shall apply to AI systems ***and foundation models*** covered by this Regulation. However, for the purpose of the effective enforcement of this Regulation:	1. Regulation (EU) 2019/1020 shall apply to AI systems covered by this Regulation. However, for the purpose of the effective enforcement of this Regulation:	1. Regulation (EU) 2019/1020 shall apply to AI systems covered by this Regulation. However, for the purpose of the effective enforcement of this Regulation: Text Origin: EP Mandate
Article 63(1), point (a)				
603	(a) any reference to an economic operator under Regulation (EU) 2019/1020 shall be understood as including all operators identified in Title III, Chapter 3 of this Regulation;	(a) any reference to an economic operator under Regulation (EU) 2019/1020 shall be understood as including all operators identified in Title III, Chapter 3 of this Regulation;	(a) any reference to an economic operator under Regulation (EU) 2019/1020 shall be understood as including all operators identified in ~~*Title III, Chapter 3*~~ ***Article 2*** of this Regulation;	(a) any reference to an economic operator under Regulation (EU) 2019/1020 shall be understood as including all operators identified in ~~*Title III, Chapter 3*~~ ***Article 2(1)*** of this Regulation; Text Origin: Council Mandate
Article 63(1), point (b)				
604	(b) any reference to a product under Regulation (EU) 2019/1020 shall be understood as including all AI	(b) any reference to a product under Regulation (EU) 2019/1020 shall be understood as including all AI	(b) any reference to a product under Regulation (EU) 2019/1020 shall be understood as including all AI	(b) any reference to a product under Regulation (EU) 2019/1020 shall be understood as including all AI

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	systems falling within the scope of this Regulation.	systems falling within the scope of this Regulation.	systems falling within the scope of this Regulation.	systems falling within the scope of this Regulation. Text Origin: Commission Proposal
Article 63(1), point (ba)				
G 604a		***(ba) the national supervisory authorities shall act as market surveillance authorities under this Regulation and have the same powers and obligations as market surveillance authorities under Regulation (EU) 2019/1020.***		G
Article 63(2)				
G 605	2. The national supervisory authority shall report to the Commission on a regular basis the outcomes of relevant market surveillance activities. The national supervisory authority shall report, without delay, to the Commission and relevant national competition authorities any information identified in the course of market surveillance activities that may be of potential interest for the application of Union law on competition rules.	2. The national supervisory authority shall report to the Commission ~~on a regular basis~~***and the AI Office annually*** the outcomes of relevant market surveillance activities. The national supervisory authority shall report, without delay, to the Commission and relevant national competition authorities any information identified in the course of market surveillance activities that may be of potential interest for the application of Union law on competition rules.	2. ~~The national supervisory authority shall report to the Commission on a regular basis the outcomes of relevant~~ ***As part of their reporting obligations under Article 34(4) of Regulation (EU) 2019/1020, the*** market surveillance ~~activities. The national supervisory authority~~***authorities*** shall report~~, without delay,~~ to the Commission ~~and relevant national competition authorities any information identified in the course of~~ ***about the outcomes of relevant*** market surveillance activities ~~that may be of potential interest for the application of Union law on competition~~	2. ~~The national supervisory authority shall report to the Commission on a regular basis the outcomes of relevant~~ ***As part of their reporting obligations under Article 34(4) of Regulation (EU) 2019/1020, the*** market surveillance ~~activities. The national supervisory authority~~***authorities*** shall report~~, without delay~~ ***annually***, to the Commission and relevant national competition authorities any information identified in the course of market surveillance activities that may be of potential interest for the application of Union law on competition rules. ***They shall also*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			~~rules.~~***under this Regulation.***	***annually report to the Commission about the use of prohibited practices that occurred during that year and about the measures taken.*** Text Origin: Presidency2
Article 63(3)				
G 606	3. For high-risk AI systems, related to products to which legal acts listed in Annex II, section A apply, the market surveillance authority for the purposes of this Regulation shall be the authority responsible for market surveillance activities designated under those legal acts.	3. For high-risk AI systems, related to products to which legal acts listed in Annex II, section A apply, the market surveillance authority for the purposes of this Regulation shall be the authority responsible for market surveillance activities designated under those legal acts.	3. For high-risk AI systems, related to products to which legal acts listed in Annex II, section A apply, the market surveillance authority for the purposes of this Regulation shall be the authority responsible for market surveillance activities designated under those legal acts ***or, in justified circumstances and provided that coordination is ensured, another relevant authority identified by the Member State***.	3. For high-risk AI systems, related to products to which legal acts listed in Annex II, section A apply, the market surveillance authority for the purposes of this Regulation shall be the authority responsible for market surveillance activities designated under those legal acts. ***By derogation from the previous paragraph in justified circumstances, Member States may designate another relevant authority to act as a market surveillance authority provided that coordination is ensured with the relevant sectoral market surveillance authorities responsible for the enforcement of the legal acts listed in Annex II.*** Text Origin: Presidency2 G
Article 63(3a)				
G 606a			***3a. The procedures referred to in Articles 65, 66, 67 and 68 of this Regulation shall not apply to AI***	***3a. The procedures referred to in Articles 65, 66, 67 and 68 of this Regulation shall not apply to AI*** G

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			systems related to products, to which legal acts listed in Annex II, section A apply, when such legal acts already provide for procedures having the same objective. In such a case, these sectoral procedures shall apply instead.	***systems related to products, to which legal acts listed in Annex II, section A apply, when such legal acts already provide for procedures ensuring an equivalent level of protection and having the same objective. In such a case, these sectoral procedures shall apply instead*** Text Origin: Council Mandate
Article 63(3b)				
G 606b		***3a. For the purpose of ensuring the effective enforcement of this Regulation, national supervisory authorities may:*** ***(a) carry out unannounced on-site and remote inspections of high-risk AI systems;*** ***(b) acquire samples related to high-risk AI systems, including through remote inspections, to reverse-engineer the AI systems and to acquire evidence to identify non-compliance.***		***3b. Without prejudice to the powers of market surveillance authorities under Article 14 of Regulation 2019/1020, for the purpose of ensuring the effective enforcement of this Regulation, market surveillance authorities may exercise the powers referred to in Article 14(4)(d) and (j) of Regulation 2019/1020 remotely as appropriate.*** Text Origin: EP Mandate
Article 63(4)				
G 607	4. For AI systems placed on the market, put into service or used by financial institutions regulated by Union legislation on financial services, the market surveillance	4. For AI systems placed on the market, put into service or used by financial institutions regulated by Union legislation on financial services, the market surveillance	4. For ***high-risk*** AI systems placed on the market, put into service or used by financial institutions regulated by Union legislation on financial services, the market	4. For ***high-risk*** AI systems placed on the market, put into service or used by financial institutions regulated by Union legislation on financial services, the market

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	authority for the purposes of this Regulation shall be the relevant authority responsible for the financial supervision of those institutions under that legislation.	authority for the purposes of this Regulation shall be the relevant authority responsible for the financial supervision of those institutions under that legislation.	surveillance authority for the purposes of this Regulation shall be the relevant ***national*** authority responsible for the financial supervision of those institutions under that legislation ***in so far as the placement on the market, putting into service or the use of the AI system is in direct connection with the provision of those financial services***.	surveillance authority for the purposes of this Regulation shall be the relevant ***national*** authority responsible for the financial supervision of those institutions under that legislation ***in so far as the placement on the market, putting into service or the use of the AI system is in direct connection with the provision of those financial services***. Text Origin: Council Mandate
Article 63(4a), first subparagraph				
G 607a			***4a. By way of a derogation from the previous subparagraph, in justified circumstances and provided that coordination is ensured, another relevant authority may be identified by the Member State as market surveillance authority for the purposes of this Regulation.***	***4a. By way of a derogation from the previous subparagraph, in justified circumstances and provided that coordination is ensured, another relevant authority may be identified by the Member State as market surveillance authority for the purposes of this Regulation.*** Text Origin: Council Mandate
Article 63(4a), second subparagraph				
G 607b			***National market surveillance authorities supervising regulated credit institutions regulated under Directive 2013/36/EU, which are participating in the Single Supervisory Mechanism (SSM)***	***National market surveillance authorities supervising regulated credit institutions regulated under Directive 2013/36/EU, which are participating in the Single Supervisory Mechanism (SSM)***

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			established by Council Regulation No 1204/2013, should report, without delay, to the European Central Bank any information identified in the course of their market surveillance activities that may be of potential interest for the European Central Bank's prudential supervisory tasks as specified in that Regulation.	***established by Council Regulation No 1204/2013, should report, without delay, to the European Central Bank any information identified in the course of their market surveillance activities that may be of potential interest for the European Central Bank's prudential supervisory tasks as specified in that Regulation.*** Text Origin: Council Mandate
Article 63(5)				
G 608	5. For AI systems listed in point 1(a) in so far as the systems are used for law enforcement purposes, points 6 and 7 of Annex III, Member States shall designate as market surveillance authorities for the purposes of this Regulation either the competent data protection supervisory authorities under Directive (EU) 2016/680, or Regulation 2016/679 or the national competent authorities supervising the activities of the law enforcement, immigration or asylum authorities putting into service or using those systems.	5. For AI systems ~~*listed in point 1(a) in so far as the systems*~~***that*** are used for law enforcement purposes, ~~*points 6 and 7 of Annex III,*~~ Member States shall designate as market surveillance authorities for the purposes of this Regulation ~~*either*~~ the competent data protection supervisory authorities under Directive (EU) 2016/680~~*, or Regulation 2016/679 or the national competent authorities supervising the activities of the law enforcement, immigration or asylum authorities putting into service or using those systems*~~.	5. For ***high-risk*** AI systems listed in point 1(a) in so far as the systems are used for law enforcement purposes, points 6***, 7 and 8*** ~~*and 7*~~ of Annex III, Member States shall designate as market surveillance authorities for the purposes of this Regulation either the ***national authorities supervising the activities of the law enforcement, border control, immigration, asylum or judicial authorities, or the*** competent data protection supervisory authorities under Directive (EU) 2016/680, or Regulation 2016/679***. Market surveillance activities shall in no way affect the independence of judicial authorities or otherwise interfere with their activities when acting in their judicial capacity*** ~~*or the national competent authorities*~~	5. For ***high-risk*** AI systems listed in point ~~*1(a)*~~***1*** in so far as the systems are used for law enforcement purposes~~*,*~~ ***and for purposes listed in*** points 6***, 7 and 8*** ~~*and 7*~~ of Annex III, Member States shall designate as market surveillance authorities for the purposes of this Regulation either the competent data protection supervisory authorities under ***Regulation 2016/679, or*** Directive (EU) 2016/680~~*, or Regulation 2016/679 or the national competent authorities supervising the activities of the law enforcement, immigration or asylum authorities putting into service or using those systems.*~~ ***or any other authority designated pursuant to the same condictions laid down in Articles 1 to 44 of Directive or Directive (EU)*** G

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			~~*supervising the activities of the law enforcement, immigration or asylum authorities putting into service or using those systems*~~.	***2016/680. Market surveillance activities shall in no way affect the independence of judicial authorities or otherwise interfere with their activities when acting in their judicial capacity*** Text Origin: Council Mandate
Article 63(6)				
G 609	6. Where Union institutions, agencies and bodies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as their market surveillance authority.	6. Where Union institutions, agencies and bodies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as their market surveillance authority.	6. Where Union institutions, agencies and bodies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as their market surveillance authority.	6. Where Union institutions, agencies and bodies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as their market surveillance authority ***except in relation to the Court of Justice acting in its judicial capacity***. Text Origin: Commission Proposal
Article 63(7)				
G 610	7. Member States shall facilitate the coordination between market surveillance authorities designated under this Regulation and other relevant national authorities or bodies which supervise the application of Union harmonisation legislation listed in Annex II or other Union legislation that might be relevant for the high-risk AI systems referred to in Annex III.	7. ~~*Member States shall facilitate the coordination between market surveillance*~~***National supervisory*** authorities designated under this Regulation ~~*and*~~***shall coordinate with*** other relevant national authorities or bodies which supervise the application of Union harmonisation ~~*legislation*~~***law*** listed in Annex II or other Union ~~*legislation*~~***law*** that might be relevant for the high-risk	7. Member States shall facilitate the coordination between market surveillance authorities designated under this Regulation and other relevant national authorities or bodies which supervise the application of Union harmonisation legislation listed in Annex II or other Union legislation that might be relevant for the high-risk AI systems referred to in Annex III.	7. Member States shall facilitate the coordination between market surveillance authorities designated under this Regulation and other relevant national authorities or bodies which supervise the application of Union harmonisation legislation listed in Annex II or other Union legislation that might be relevant for the high-risk AI systems referred to in Annex III.

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		AI systems referred to in Annex III.		Text Origin: Commission Proposal
Article 63(7a)				
610a				***7a. Market surveillance authorities and the Commission shall be able to propose joint activities, including joint investigations, to be conducted by either market surveillance authorities or market surveillance authorities jointly with the Commission, that have the aim of promoting compliance, identifying non-compliance, raising awareness and providing guidance in relation to this Regulation with respect to specific categories of high-risk AI systems that are found to present a serious risk across several Member States in accordance with Article 9 of the 2019/1020. The AI Office shall provide coordination support for joint investigations.***
Article 63(7b)				
610b			***7a. Without prejudice to powers provided under Regulation (EU) 2019/1020, and where relevant and limited to what is necessary to fulfil their tasks, the market surveillance authorities shall be granted full access by the provider to the***	***7a. Without prejudice to powers provided under Regulation (EU) 2019/1020, and where relevant and limited to what is necessary to fulfil their tasks, the market surveillance authorities shall be granted full access by the provider to the***

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			documentation as well as the training, validation and testing datasets used for the development of the high-risk AI system, including, where appropriate and subject to security safeguards, through application programming interfaces ('API') or other relevant technical means and tools enabling remote access.	***documentation as well as the training, validation and testing datasets used for the development of the high-risk AI system, including, where appropriate and subject to security safeguards, through application programming interfaces ('API') or other relevant technical means and tools enabling remote access.*** Text Origin: Council Mandate
Article 63(7c)				
G 610c			***7b. Market surveillance authorities shall be granted access to the source code of the high-risk AI system upon a reasoned request and only when the following cumulative conditions are fulfilled:***	***7b. Market surveillance authorities shall be granted access to the source code of the high-risk AI system upon a reasoned request and only when the following cumulative conditions are fulfilled:*** Text Origin: Council Mandate
Article 63(7c), point (a)				
G 610d			***(a) access to source code is necessary to assess the conformity of a high-risk AI system with the requirements set out in Title III, Chapter 2, and***	***(a) access to source code is necessary to assess the conformity of a high-risk AI system with the requirements set out in Title III, Chapter 2, and*** Text Origin: Council Mandate
Article 63(7c), point (b)				

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G 610e			***(b) testing/auditing procedures and verifications based on the data and documentation provided by the provider have been exhausted or proved insufficient.***	***(b) testing/auditing procedures and verifications based on the data and documentation provided by the provider have been exhausted or proved insufficient.*** Text Origin: Council Mandate
Article 63(7d)				
G 610f			***7c. Any information and documentation obtained by market surveillance authorities shall be treated in compliance with the confidentiality obligations set out in Article 70.***	***7c. Any information and documentation obtained by market surveillance authorities shall be treated in compliance with the confidentiality obligations set out in Article 70.*** Text Origin: Council Mandate
Article 63(7e)				
G 610g			***7d. Complaints to the relevant market surveillance authority can be submitted by any natural or legal person having grounds to consider that there has been an infringement of the provisions of this Regulation.***	***7d.*** Now in cell 649a Text Origin: Council Mandate
Article 63(7d), second subparagraph				
G 610h			***In accordance with Article 11(3)(e) and (7)(a) of Regulation (EU) 2019/1020, complaints shall be taken into account for the purpose***	as above.

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			of conducting the market surveillance activities and be handled in line with the dedicated procedures established therefore by the market surveillance authorities.	Text Origin: Council Mandate
Article 63a				
G 610i				***Article 63a*** ***Mutual Assistance, market surveillance and control of general purpose AI systems*** ***1. Where an AI system is based on a general purpose AI model and the model and the system are developed by the same provider, the AI office shall have powers to monitor and supervise compliance of this AI system with the obligations of this Regulation. To carry monitoring and supervision tasks the AI Office shall have all the powers of a market surveillance authority within the meaning of the Regulation 2019/1020.*** ***2. Where the relevant market surveillance authorities have sufficient reasons to consider that general purpose AI systems that can be used directly by deployers for at least one purpose that is classified as high-risk pursuant to this Regulation, is non-compliant with the requirements*** G

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				laid down in this Regulation, it shall cooperate with the AI Office to carry out evaluation of compliance and inform the Board and other market surveillance authorities accordingly. ***3. When a national market surveillance authority is unable to conclude its investigation on the high-risk AI system because of its inability to access certain information related to the AI model despite having made all appropriate efforts to obtain that information, it may submit a reasoned request to the AI Office where access to this information can be enforced. In this case the AI Office shall supply to the applicant authority without delay, and in any event within 30 days, any information that the AI Office considers to be relevant in order to establish whether a high-risk AI system is non-compliant. National market authorities shall safeguard the confidentiality of the information they obtain in accordance with the Article 70. The procedure provided in Chapter VI of the Regulation (EU) 1020/2019 shall apply by analogy.***
Article 63b				
G 610j			***Article 63a*** ***Supervision of testing in real world***	***Article 63b*** G

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			conditions by market surveillance authorities	***Supervision of testing in real world conditions by market surveillance authorities***
Article 63c(1)				
G 610k			***1. Market surveillance authorities shall have the competence and powers to ensure that testing in real world conditions is in accordance with this Regulation.***	***1. Market surveillance authorities shall have the competence and powers to ensure that testing in real world conditions is in accordance with this Regulation.*** G
Article 63c(2)				
G 610l			***2. Where testing in real world conditions is conducted for AI systems that are supervised within an AI regulatory sandbox under Article 54, the market surveillance authorities shall verify the compliance with the provisions of Article 54a as part of their supervisory role for the AI regulatory sandbox. Those authorities may, as appropriate, allow the testing in real world conditions to be conducted by the provider or prospective provider in derogation to the conditions set out in Article 54a(4) (f) and (g).***	***2. Where testing in real world conditions is conducted for AI systems that are supervised within an AI regulatory sandbox under Article 54, the market surveillance authorities shall verify the compliance with the provisions of Article 54a as part of their supervisory role for the AI regulatory sandbox. Those authorities may, as appropriate, allow the testing in real world conditions to be conducted by the provider or prospective provider in derogation to the conditions set out in Article 54a(4) (f) and (g).*** G
Article 63c(3)				
G 610m			***3. Where a market surveillance***	***3. Where a market surveillance*** G

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			authority has been informed by the prospective provider, the provider or any third party of a serious incident or has other grounds for considering that the conditions set out in Articles 54a and 54b are not met, it may take any of the following decisions on its territory, as appropriate:	***authority has been informed by the prospective provider, the provider or any third party of a serious incident or has other grounds for considering that the conditions set out in Articles 54a and 54b are not met, it may take any of the following decisions on its territory, as appropriate:***
Article 63c(3), point (a)				
G 610n			***(a) suspend or terminate the testing in real world conditions;***	***(a) suspend or terminate the testing in real world conditions;***
Article 63c(3), point (b)				
G 610o			***(b) require the provider or prospective provider and user(s) to modify any aspect of the testing in real world conditions.***	***(b) require the provider or prospective provider and user(s) to modify any aspect of the testing in real world conditions.***
Article 63c(4)				
G 610p			***4. Where a market surveillance authority has taken a decision referred to in paragraph 3 of this Article or has issued an objection within the meaning of Article 54a(4)(b), the decision or the objection shall indicate the grounds thereof and the modalities and conditions for the provider or prospective provider to challenge***	***4. Where a market surveillance authority has taken a decision referred to in paragraph 3 of this Article or has issued an objection within the meaning of Article 54a(4)(b), the decision or the objection shall indicate the grounds thereof and the modalities and conditions for the provider or prospective provider to challenge***

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			the decision or objection.	***the decision or objection.***
Article 63c(5)				
G 610q			***5. Where applicable, where a market surveillance authority has taken a decision referred to in paragraph 3 of this Article, it shall communicate the grounds therefor to the market surveillance authorities of the other Member States in which the AI system has been tested in accordance with the testing plan.***	***5. Where applicable, where a market surveillance authority has taken a decision referred to in paragraph 3 of this Article, it shall communicate the grounds therefor to the market surveillance authorities of the other Member States in which the AI system has been tested in accordance with the testing plan.***
Article 64				
G 611	Article 64 Access to data and documentation	Article 64 Access to data and documentation	Article 64 ~~*Access to data and documentation*~~***Powers of authorities protecting fundamental rights***	Article 64 ~~*Access to data and documentation*~~***Powers of authorities protecting fundamental rights*** Text Origin: Council Mandate
Article 64(1)				
G 612	1. Access to data and documentation in the context of their activities, the market surveillance authorities shall be granted full access to the training, validation and testing datasets used by the provider, including through application programming interfaces ('API') or	1. ~~*Access to data and documentation*~~ In the context of their activities, ***and upon their reasoned request the national supervisory authority***~~*the market surveillance authorities*~~ shall be granted full access to the training, validation and testing datasets used by the provider,	*deleted*	

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	other appropriate technical means and tools enabling remote access.	~~including through application programming interfaces ('API') or other~~***or, where relevant, the deployer, that are relevant and strictly necessary for the purpose of its request through*** appropriate technical means and tools~~ enabling remote access~~.		
Article 64(2)				
G *613*	*2.* Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the market surveillance authorities shall be granted access to the source code of the AI system.	2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2***, after all other reasonable ways to verify conformity including paragraph 1 have been exhausted and have proven to be insufficient,*** and upon a reasoned request, the ~~market surveillance authorities~~***national supervisory authority*** shall be granted access to the ~~source code~~***training and trained models*** of the AI system***, including its relevant model parameters. All information in line with Article 70 obtained shall be treated as confidential information and shall be subject to existing Union law on the protection of intellectual property and trade secrets and shall be deleted upon the completion of the investigation for which the information was requested***.	*deleted*	G

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Article 64(2a)				
G *613a*		***2a. Paragraphs 1 and 2 are without prejudice to the procedural rights of the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020.***		G
Article 64(3)				
G 614	3. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights in relation to the use of high-risk AI systems referred to in Annex III shall have the power to request and access any documentation created or maintained under this Regulation when access to that documentation is necessary for the fulfilment of the competences under their mandate within the limits of their jurisdiction. The relevant public authority or body shall inform the market surveillance authority of the Member State concerned of any such request.	3. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights in relation to the use of high-risk AI systems referred to in Annex III shall have the power to request and access any documentation created or maintained under this Regulation when access to that documentation is necessary for the fulfilment of the competences under their mandate within the limits of their jurisdiction. The relevant public authority or body shall inform the ~~*market surveillance*~~***national supervisory*** authority of the Member State concerned of any such request.	3. 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,*** in relation to the use of high-risk AI systems referred to in Annex III shall have the power to request and access any documentation created or maintained under this Regulation when access to that documentation is necessary for the fulfilment of the competences under their mandate within the limits of their jurisdiction. The relevant public authority or body shall inform the market surveillance authority of the Member State concerned of any such request.	3. 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,*** in relation to the use of high-risk AI systems referred to in Annex III shall have the power to request and access any documentation created or maintained under this Regulation ***in accesible language and format*** when access to that documentation is necessary for ~~*the fulfilment of the competences under*~~***effectively fulfilling*** their mandate within the limits of their jurisdiction. The relevant public authority or body shall inform the market surveillance authority of the Member State concerned of any such request. Text Origin: Council Mandate G
Article 64(4)				

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G 615	4. By 3 months after the entering into force of this Regulation, each Member State shall identify the public authorities or bodies referred to in paragraph 3 and make a list publicly available on the website of the national supervisory authority. Member States shall notify the list to the Commission and all other Member States and keep the list up to date.	4. By ~~3~~***three*** months after the entering into force of this Regulation, each Member State shall identify the public authorities or bodies referred to in paragraph 3 and make a list publicly available on the website of the national supervisory authority. ~~*Member States*~~***National supervisory authorities*** shall notify the list to the Commission***, the AI Office,*** and all other ~~*Member States*~~***national supervisory authorities*** and keep the list up to date. ***The Commission shall publish in a dedicated website the list of all the competent authorities designated by the Member States in accordance with this Article.***	4. By 3 months after the entering into force of this Regulation, each Member State shall identify the public authorities or bodies referred to in paragraph 3 and make ~~*a*~~***the*** list publicly available~~*on the website of the national supervisory authority*~~. Member States shall notify the list to the Commission and all other Member States and keep the list up to date.	4. By ~~3~~***three*** months after the entering into force of this Regulation, each Member State shall identify the public authorities or bodies referred to in paragraph 3 and make a list publicly available~~*on the website of the national supervisory authority*~~. Member States shall notify the list to the Commission and all other Member States and keep the list up to date. Text Origin: EP Mandate
Article 64(5)				
G 616	5. Where the documentation referred to in paragraph 3 is insufficient to ascertain whether a breach of obligations under Union law intended to protect fundamental rights has occurred, the public authority or body referred to paragraph 3 may make a reasoned request to the market surveillance authority to organise testing of the high-risk AI system through technical means. The market surveillance authority shall organise the testing with the close	5. Where the documentation referred to in paragraph 3 is insufficient to ascertain whether a breach of obligations under Union law intended to protect fundamental rights has occurred, the public authority or body referred to ***in*** paragraph 3 may make a reasoned request to the ~~*market surveillance*~~***national supervisory*** authority***,*** to organise testing of the high-risk AI system through technical means. The ~~*market surveillance*~~***national supervisory***	5. Where the documentation referred to in paragraph 3 is insufficient to ascertain whether a breach of obligations under Union law intended to protect fundamental rights has occurred, the public authority or body referred to paragraph 3 may make a reasoned request to the market surveillance authority to organise testing of the high-risk AI system through technical means. The market surveillance authority shall organise the testing with the close	5. Where the documentation referred to in paragraph 3 is insufficient to ascertain whether a breach of obligations under Union law intended to protect fundamental rights has occurred, the public authority or body referred to ***in*** paragraph 3 may make a reasoned request to the market surveillance authority***,*** to organise testing of the high-risk AI system through technical means. The market surveillance authority shall organise the testing with the close

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	involvement of the requesting public authority or body within reasonable time following the request.	authority shall organise the testing with the close involvement of the requesting public authority or body within reasonable time following the request.	involvement of the requesting public authority or body within reasonable time following the request.	involvement of the requesting public authority or body within reasonable time following the request. Text Origin: EP Mandate
Article 64(6)				
G 617	6. Any information and documentation obtained by the national public authorities or bodies referred to in paragraph 3 pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.	6. Any information and documentation obtained by the national public authorities or bodies referred to in paragraph 3 pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.	6. Any information and documentation obtained by the national public authorities or bodies referred to in paragraph 3 pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.	6. Any information and documentation obtained by the national public authorities or bodies referred to in paragraph 3 pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70. Text Origin: Commission Proposal
Article 65				
G 618	Article 65 Procedure for dealing with AI systems presenting a risk at national level	Article 65 Procedure for dealing with AI systems presenting a risk at national level	Article 65 Procedure for dealing with AI systems presenting a risk at national level	Article 65 Procedure for dealing with AI systems presenting a risk at national level Text Origin: Council Mandate
Article 65(1)				
G 619	1. AI systems presenting a risk shall be understood as a product presenting a risk defined in Article 3, point 19 of Regulation (EU)	1. AI systems presenting a risk shall be understood as ~~a product presenting a risk defined in Article 3, point 19 of Regulation (EU)~~	1. AI systems presenting a risk shall be understood as a product presenting a risk defined in Article 3, point 19 of Regulation (EU)	1. AI systems presenting a risk shall be understood as a product presenting a risk defined in Article 3, point 19 of Regulation (EU)

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	2019/1020 insofar as risks to the health or safety or to the protection of fundamental rights of persons are concerned.	~~2019/1020 insofar as risks to the health or safety or to the protection of fundamental rights of persons~~***an AI system having the potential to affect adversely health and safety, fundamental rights of persons in general, including in the workplace, protection of consumers, the environment, public security, or democracy or the rule of law and other public interests, that are protected by the applicable Union harmonisation law, to a degree which goes beyond that considered reasonable and acceptable in relation to its intended purpose or under the normal or reasonably foreseeable conditions of use of the system*** are concerned***, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements***.	2019/1020 insofar as risks to the health or safety or to ~~the protection of~~ fundamental rights of persons are concerned.	2019/1020 insofar as risks to the health or safety or to ~~the protection of~~ fundamental rights of persons are concerned. Text Origin: Council Mandate
Article 65(2), first subparagraph				
G 620	2. Where the market surveillance authority of a Member State has sufficient reasons to consider that an AI system presents a risk as referred to in paragraph 1, they shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. When risks to the	2. Where the ~~market surveillance~~***national supervisory*** authority of a Member State has sufficient reasons to consider that an AI system presents a risk as referred to in paragraph 1, ~~they~~***it*** shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this	2. Where the market surveillance authority of a Member State has sufficient reasons to consider that an AI system presents a risk as referred to in paragraph 1, they shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. When risks to ~~the~~	2. Where the market surveillance authority of a Member State has sufficient reasons to consider that an AI system presents a risk as referred to in paragraph 1, ~~they~~***it*** shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. ~~When risks to the~~ G

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	protection of fundamental rights are present, the market surveillance authority shall also inform the relevant national public authorities or bodies referred to in Article 64(3). The relevant operators shall cooperate as necessary with the market surveillance authorities and the other national public authorities or bodies referred to in Article 64(3).	Regulation. When risks to ~~the protection of~~ fundamental rights are present, the ~~market surveillance~~***national supervisory*** authority shall also ***immediately*** inform ***and fully cooperate with*** the relevant national public authorities or bodies referred to in Article 64(3)***; Where there is sufficient reason to consider that that an AI system exploits the vulnerabilities of vulnerable groups or violates their rights intentionally or unintentionally, the national supervisory authority shall have the duty to investigate the design goals, data inputs, model selection, implementation and outcomes of the AI system*** . The relevant operators shall cooperate as necessary with the ~~market surveillance authorities~~***national supervisory authority*** and the other national public authorities or bodies referred to in Article 64(3)~~.~~***;***	~~protection of~~ fundamental rights are ~~present~~***identified***, the market surveillance authority shall also inform the relevant national public authorities or bodies referred to in Article 64(3). The relevant operators shall cooperate as necessary with the market surveillance authorities and the other national public authorities or bodies referred to in Article 64(3).	~~protection of~~***Particular attention shall be given to AI systems presenting a risk to vulnerable groups (referred to in Article 5). When risks to*** fundamental rights are ~~present~~***identified***, the market surveillance authority shall also inform ***and fully cooperate with*** the relevant national public authorities or bodies referred to in Article 64(3). The relevant operators shall cooperate as necessary with the market surveillance ~~authorities~~***authority*** and the other national public authorities or bodies referred to in Article 64(3)~~.~~***;*** Text Origin: EP Mandate
Article 65(2), second subparagraph				
G 621	Where, in the course of that evaluation, the market surveillance authority finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without delay require the relevant operator to take all appropriate	Where, in the course of that evaluation, the ~~market surveillance~~***national supervisory*** authority ***or, where relevant, the national public authority referred to in Article 64(3)*** finds that the AI system does not comply with the requirements and obligations laid	Where, in the course of that evaluation, the market surveillance authority finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without ***undue*** delay require the relevant operator to take all	Where, in the course of that evaluation, the market surveillance authority ***and where applicable in cooperation with the national public authority referred to in Article 64(3)*** finds that the AI system does not comply with the requirements and obligations laid G

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	corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.	down in this Regulation, it shall without delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe~~.~~ ***and in any event no later than fifteen working days or as provided for in the relevant Union harmonisation law as applicable***	appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it**,** within a ~~reasonable~~ period~~, commensurate with the nature of the risk, as~~ it may prescribe.	down in this Regulation, it shall without ***undue*** delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a ~~reasonable period, commensurate with the nature of the risk, as it may prescribe.~~***period it may prescribe and in any event no later than fifteen working days or as provided for in the relevant Union harmonisation law as applicable*** Text Origin: EP Mandate
Article 65(2), third subparagraph				
G 622	The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph.	***The national supervisory***~~The market surveillance~~ authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph.	The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph.	The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph. Text Origin: EP Mandate
Article 65(3)				
G 623	3. Where the market surveillance authority considers that non-compliance is not restricted to its national territory, it shall inform the Commission and the other Member States of the results of the evaluation	3. Where the ~~market surveillance~~***national supervisory*** authority considers that non-compliance is not restricted to its national territory, it shall inform the Commission***, the AI Office*** and the	3. Where the market surveillance authority considers that non-compliance is not restricted to its national territory, it shall inform the Commission and the other Member States ***without undue delay*** of the	3. Where the market surveillance authority considers that non-compliance is not restricted to its national territory, it shall inform the Commission**,** and the other Member States ***without undue delay*** of the

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	and of the actions which it has required the operator to take.	***national supervisory authority of the*** other Member States ***without undue delay*** of the results of the evaluation and of the actions which it has required the operator to take.	results of the evaluation and of the actions which it has required the operator to take.	results of the evaluation and of the actions which it has required the operator to take. Text Origin: EP Mandate
Article 65(4)				
G 624	4. The operator shall ensure that all appropriate corrective action is taken in respect of all the AI systems concerned that it has made available on the market throughout the Union.	4. The operator shall ensure that all appropriate corrective action is taken in respect of all the AI systems concerned that it has made available on the market throughout the Union.	4. The operator shall ensure that all appropriate corrective action is taken in respect of all the AI systems concerned that it has made available on the market throughout the Union.	
Article 65(5)				
G 625	5. Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market, to withdraw the product from that market or to recall it. That authority shall inform the Commission and the other Member States, without delay, of those measures.	5. Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the ~~market surveillance~~***national supervisory*** authority shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market ***or put into service***, to withdraw the ~~product~~***AI system*** from that market or to recall it. That authority shall ***immediately*** inform the Commission***, the AI Office*** and the ***national supervisory authority of the*** other Member States~~, without delay,~~ of those measures.	5. Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market, to withdraw the product from that market or to recall it. That authority shall ~~inform~~***notify*** the Commission and the other Member States, without ***undue*** delay, of those measures.	5. ***5.*** Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market ***or put into service***, to withdraw the product ***or the standalone AI system*** from that market or to recall it. That authority shall ~~inform~~***without undue delay notify*** the Commission and the other Member States~~, without delay,~~ of those measures. Text Origin: EP Mandate

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 65(6)				
626	6. The information referred to in paragraph 5 shall include all available details, in particular the data necessary for the identification of the non-compliant AI system, the origin of the AI system, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to one or more of the following:	6. The information referred to in paragraph 5 shall include all available details, in particular the data necessary for the identification of the non-compliant AI system, the origin of the AI system ***and the supply chain***, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant operator. In particular, the ~~*market surveillance authorities*~~***national supervisory authority*** shall indicate whether the non-compliance is due to one or more of the following:	6. The ~~*information*~~***notification*** referred to in paragraph 5 shall include all available details, in particular the ~~*data*~~***information*** necessary for the identification of the non-compliant AI system, the origin of the AI system, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to one or more of the following:	6. The ~~*information*~~***notification*** referred to in paragraph 5 shall include all available details, in particular the ~~*data*~~***information*** necessary for the identification of the non-compliant AI system, the origin of the AI system ***and the supply chain***, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant operator. In particular, ***(***the market surveillance authorities***)*** shall indicate whether the non-compliance is due to one or more of the following: Text Origin: Council Mandate
Article 65(6), point (-a)				
626a			***(-a) non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;***	***(-a) non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;*** Text Origin: Council Mandate
Article 65(6), point (a)				
627	(a) a failure of the AI system to meet requirements set out in Title	(a) a failure of the ***high-risk*** AI system to meet requirements set out	(a) a failure of ~~*the*~~***a high-risk*** AI system to meet requirements set out	(a) a failure of ~~*the*~~***a high-risk*** AI system to meet requirements set out

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	III, Chapter 2;	~~in Title III, Chapter 2~~***this Regulation***;	in Title III, Chapter 2;	in Title III, Chapter 2; Text Origin: Council Mandate
Article 65(6), point (b)				
G 628	(b) shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 conferring a presumption of conformity.	(b) shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 conferring a presumption of conformity.	(b) shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 conferring a presumption of conformity~~.~~***;***	G
Article 65(6), point (ba)				
G 628a			***(ba) non-compliance with provisions set out in Article 52;***	***(ba) non-compliance with provisions set out in Article 52;*** Text Origin: Council Mandate G
Article 65(6), point (ba)				
G 628b		***(ba) non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;***		G
Article 65(6), point (bb)				
G 628c			***(bb) non-compliance of general purpose AI systems with the requirements and obligations referred to in Article 4a.***	***(bb)*** Text Origin: Council Mandate G
Article 65(6), point (bb)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 628d		***(bb) non-compliance with provisions set out in Article 52.***		G
Article 65(7)				
G 629	7. The market surveillance authorities of the Member States other than the market surveillance authority of the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the AI system concerned, and, in the event of disagreement with the notified national measure, of their objections.	7. The ~~market surveillance~~***national supervisory*** authorities of the Member States other than the ~~market surveillance~~***national supervisory*** authority of the Member State initiating the procedure shall without delay inform the Commission***, the AI Office*** and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the AI system concerned, and, in the event of disagreement with the notified national measure, of their objections.	7. The market surveillance authorities of the Member States other than the market surveillance authority of the Member State initiating the procedure shall without ***undue*** delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the AI system concerned, and, in the event of disagreement with the notified national measure, of their objections.	7. The market surveillance authorities of the Member States other than the market surveillance authority of the Member State initiating the procedure shall without ***undue*** delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the AI system concerned, and, in the event of disagreement with the notified national measure, of their objections. Text Origin: EP Mandate	G
Article 65(8)				
G 630	8. Where, within three months of receipt of the information referred to in paragraph 5, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified. This is without prejudice to the procedural rights of the concerned operator in	8. Where, within three months of receipt of the information referred to in paragraph 5, no objection has been raised by either a ***national supervisory authority of a*** Member State or the Commission in respect of a provisional measure taken by a ***national supervisory authority of another*** Member State, that measure shall be deemed justified. This is	8. Where, within three months of receipt of the ~~information~~***notification*** referred to in paragraph 5, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified. This is without prejudice to the procedural rights of	8. Where, within three months of receipt of the ~~information~~***notification*** referred to in paragraph 5, no objection has been raised by either ***a market surveillance authority of*** a Member State or the Commission in respect of a provisional measure taken by a ***market surveillance authority of another*** Member State, that measure	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	accordance with Article 18 of Regulation (EU) 2019/1020.	without prejudice to the procedural rights of the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020. ***The period referred to in the first sentence of this paragraph shall be reduced to thirty days in the event of non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5.***	the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020. ***The period referred to in the first sentence of this paragraph shall be reduced to 30 days in the case of non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5.***	shall be deemed justified. This is without prejudice to the procedural rights of the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020. ***The period referred to in the first sentence of this paragraph shall be reduced to thirty days in the event of non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5.*** Text Origin: EP Mandate
Article 65(9)				
G 631	9. The market surveillance authorities of all Member States shall ensure that appropriate restrictive measures are taken in respect of the product concerned, such as withdrawal of the product from their market, without delay.	9. The ~~*market surveillance*~~***national supervisory*** authorities of all Member States shall ensure that appropriate restrictive measures are taken in respect of the ~~*product*~~***AI system*** concerned, such as withdrawal of the ~~*product*~~***AI system*** from their market, without delay.	9. The market surveillance authorities of all Member States shall ***then*** ensure that appropriate restrictive measures are taken in respect of the ~~*product*~~***AI system*** concerned, such as withdrawal of the product from their market, without ***undue*** delay.	9. The market surveillance authorities of all Member States shall ensure that appropriate restrictive measures are taken in respect of the product ***or the AI system*** concerned, such as withdrawal of the product ***or the AI system*** from their market, without ***undue*** delay. Text Origin: EP Mandate
Article 65(9a)				
G 631a		***9a. National supervisory authorities shall annually report to the AI Office about the use of prohibited practices that occurred during that year and about the***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		measures taken to eliminate or mitigate the risks in accordance with this Article.		
Article 65a				
G 631b				***Article 65a*** ***Procedure for dealing with AI systems classified by the provider as a not high-risk in application of Annex III*** Text Origin: Presidency2 G
Article 65a(1)				
G 631c				***1. Where a market surveillance authority has sufficient reasons to consider that an AI system classified by the provider as non high-risk in application of Annex III is high-risk, they market surveillance authority shall carry out an evaluation of the AI system concerned in respect of its classification as a high-risk AI system based on the conditions set out in Annex III and the Commission guidelines.*** Text Origin: Presidency2 G
Article 65a(2)				
G 631d				***2. Where, in the course of that*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				evaluation, the market surveillance authority finds that the AI system concerned is high-risk, it shall without undue delay require the relevant provider to take all necessary actions to bring the AI system into compliance with the requirements and obligations laid down in this Regulation as well as take appropriate corrective action within a period it may prescribe. Text Origin: Presidency2
Article 65a(3)				
G 631e				***3. Where the market surveillance authority considers that the use of the AI system concerned is not restricted to its national territory, it shall inform the Commission and the other Member States without undue delay of the results of the evaluation and of the actions which it has required the provider to take.*** Text Origin: Presidency2
Article 65a(4)				
G 631f				***4. The provider shall ensure that all necessary action is taken to bring the AI system into compliance with the requirements and obligations laid down in this Regulation. Where the provider of***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				an AI system concerned does not bring the AI system into compliance with the requirements and obligations of this Regulation within the period referred to in paragraph 2, the provider shall be subject to fines in accordance with Article 71. Text Origin: Presidency2
Article 65a(5)				
G 631g				***5. The provider shall ensure that all appropriate corrective action is taken in respect of all the AI systems concerned that it has made available on the market throughout the Union.*** Text Origin: Presidency2
Article 65a(6)				
G 631h				***6. Where the provider of the AI system concerned does not take adequate corrective action within the period referred to in paragraph 2, then the provisions of Article 65 paragraphs 5 to 9 apply.*** Text Origin: Presidency2
Article 65a(7)				
G 631i				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				7. Where, in the course of that evaluation pursuant to paragraph 1, the market surveillance authority establishes that the AI system was misclassified by the provider as not high-risk to circumvent the application of requirements in Title III, Chapter 2, the provider shall be subject to fines in accordance with Article 71. Text Origin: Presidency2
Article 65a(8)				
631j				***8. In exercising their power to monitor the application of this article and in accordance with Article 11 of Regulation (EU) 2019/1020, market surveillance authorities may perform appropriate checks, taking into account in particular information stored in the EU database referred to in Article 60.*** Text Origin: Presidency2
Article 66				
632	Article 66 Union safeguard procedure	Article 66 Union safeguard procedure	Article 66 Union safeguard procedure	
Article 66(1)				
633				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	1. Where, within three months of receipt of the notification referred to in Article 65(5), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall without delay enter into consultation with the relevant Member State and operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not within 9 months from the notification referred to in Article 65(5) and notify such decision to the Member State concerned.	1. Where, within three months of receipt of the notification referred to in Article 65(5), ***or 30 days in the case of non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5,*** objections are raised by ***the national supervisory authority of*** a Member State against a measure taken by another ~~*Member State*~~***national supervisory authority***, or where the Commission considers the measure to be contrary to Union law, the Commission shall without delay enter into consultation with the ***national supervisory authority of the*** relevant Member State and operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not within ~~*9*~~***three*** months***, or 60 days in the case of non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5, starting*** from the notification referred to in Article 65(5) and notify such decision to the ***national supervisory authority of the*** Member State concerned. ***The Commission shall also inform all other national***	1. Where, within three months of receipt of the notification referred to in Article 65(5), ***or 30 days in the case of non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5,*** objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall without ***undue*** delay enter into consultation with the relevant Member State***'s market surveillance authority*** and operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not within 9 months***, or 60 days in the case of non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5, starting*** from the notification referred to in Article 65(5)***. It shall*** and notify such decision to the Member State concerned. ***The Commission shall also inform all other Member States of such decision.***	1. Where, within three months of receipt of the notification referred to in Article 65(5), ***or 30 days in the case of non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5,*** objections are raised by ***the market surveillance authority of*** a Member State against a measure taken by another ~~*Member State*~~***market surveillance authority***, or where the Commission considers the measure to be contrary to Union law, the Commission shall without ***undue*** delay enter into consultation with the ***market surveillance authority of the*** relevant Member State and operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not within ~~*9*~~***six*** months***, or 60 days in the case of non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5, starting*** from the notification referred to in Article 65(5) and notify such decision to the ***market surveillance authority of the*** Member State concerned. ***The Commission shall also inform all other market surveillance authorities of such decision.*** Text Origin: EP Mandate

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 66(2)				
634	2. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant AI system is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.	2. If the national measure is considered justified, all ~~Member States~~***national supervisory authorities designated under this Regulation*** shall take the measures necessary to ensure that the non-compliant AI system is withdrawn from their market ***without delay***, and shall inform the Commission ***and the AI Office*** accordingly. If the national measure is considered unjustified, ***the national supervisory authority of*** the Member State concerned shall withdraw the measure.	2. If the ~~national measure~~***measure taken by the relevant Member State's market surveillance authority*** is considered justified ***by the Commission, the market surveillance authorities of*** ~~,~~ all Member States shall ~~take the~~***ensure that appropriate restrictive*** measures ~~necessary to ensure that the non-compliant~~***are taken in respect of the*** AI system ~~is withdrawn~~***concerned, such as withdrawal of the AI system*** from their market ***without undue delay***, and shall inform the Commission accordingly. If the national measure is considered unjustified ***by the Commission, the market surveillance authority of the*** ~~, the~~ Member State concerned shall withdraw the measure ***and inform the Commission accordingly***.	2. If the ~~national measure~~***measure taken by the relevant Member States*** is considered justified ***by the Commission***, all Member States shall ~~take the~~***ensure that appropriate restrictive*** measures ~~necessary to ensure that the non-compliant~~***are taken in respect of the*** AI system ~~is withdrawn~~***concerned, such as withdrawal of the AI system*** from their market ***without undue delay***, and shall inform the Commission accordingly. If the national measure is considered unjustified ***by the Commission***, the Member State concerned shall withdraw the measure ***and inform the Commission accordingly***. Text Origin: Council Mandate
Article 66(2a)				
634a		***66 a Joint investigations Where a national supervisory authority has reasons to suspect that the infringement by a provider or a deployer of a high-risk AI system or foundation model to this Regulation amount to a widespread***		***66 a*** Text Origin: EP Mandate

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		infringement with a Union dimension, or affects or is likely affect at least 45 million individuals, in more than one Member State, that national supervisory authority shall inform the AI Office and may request the national supervisory authorities of the Member States where such infringement took place to start a joint investigation. The AI Office shall provide central coordination to the joint investigation. Investigation powers shall remain within the competence of the national supervisory authorities.		
Article 66(3)				
G 635	3. Where the national measure is considered justified and the non-compliance of the AI system is attributed to shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.	3. Where the national measure is considered justified and the non-compliance of the AI system is attributed to shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.	3. Where the national measure is considered justified and the non-compliance of the AI system is attributed to shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.	3. Where the national measure is considered justified and the non-compliance of the AI system is attributed to shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012. Text Origin: Commission Proposal
Article 67				
G 636				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 67 Compliant AI systems which present a risk	Article 67 Compliant AI systems which present a risk	Article 67 ***Compliant high-risk or general purpose AI systems which present a risk***~~Compliant AI systems which present a risk~~	Article 67 Compliant AI systems which present a risk Text Origin: Commission Proposal
Article 67(1)				
G 637	1. Where, having performed an evaluation under Article 65, the market surveillance authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons, to the compliance with obligations under Union or national law intended to protect fundamental rights or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.	1. Where, having performed an evaluation under Article 65, ***in full cooperation with the relevant national public authority referred to in Article 64(3), the national supervisory***~~the market surveillance~~ authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a ***serious*** risk to the health or safety of persons, to the compliance with obligations under Union or national law intended to protect fundamental rights***, or the environment or the democracy and rule of law*** or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk~~, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe~~.	1. Where, having performed an evaluation under Article 65, the market surveillance authority of a Member State finds that although ~~an~~***a high-risk or general purpose*** AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons~~, to the compliance with obligations under Union or national law intended to protect~~ ***or to*** fundamental rights~~or to other aspects of public interest protection~~, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it ~~within a reasonable period, commensurate with the nature of the risk, as~~***without undue delay, within a period*** it may prescribe.	1. Where, having performed an evaluation under Article 65, ***after consulting the relevant national public authority referred to in Article 64(3),*** the market surveillance authority of a Member State finds that although ~~an~~***a high-risk*** AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons, ~~to the compliance with obligations under Union or national law intended to protect~~ fundamental rights***,*** or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk~~, to withdraw the AI system from the market or to recall it~~ ***without undue delay,*** within a ~~reasonable~~ period~~, commensurate with the nature of the risk, as~~ it may prescribe. Text Origin: Presidency2

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 67(2)				
G 638	2. The provider or other relevant operators shall ensure that corrective action is taken in respect of all the AI systems concerned that they have made available on the market throughout the Union within the timeline prescribed by the market surveillance authority of the Member State referred to in paragraph 1.	2. The provider or other relevant operators shall ensure that corrective action is taken in respect of all the AI systems concerned that they have made available on the market throughout the Union within the timeline prescribed by the ~~*market surveillance*~~***national supervisory authority*** authority of the Member State referred to in paragraph 1.	2. The provider or other relevant operators shall ensure that corrective action is taken in respect of all the AI systems concerned that they have made available on the market throughout the Union within the timeline prescribed by the market surveillance authority of the Member State referred to in paragraph 1.	2. The provider or other relevant operators shall ensure that corrective action is taken in respect of all the AI systems concerned that they have made available on the market throughout the Union within the timeline prescribed by the market surveillance authority of the Member State referred to in paragraph 1. Text Origin: EP Mandate
Article 67(2a)				
G 638a		***2a. Where the provider or other relevant operators fail to take corrective action as referred to in paragraph 2 and the AI system continues to present a risk as referred to in paragraph 1, the national supervisory authority may require the relevant operator to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk.***		***2a.*** Text Origin: EP Mandate
Article 67(3)				
G 639	3. The Member State shall immediately inform the Commission	3. The ~~*Member State*~~***national supervisory authority*** shall	3. The Member State shall immediately inform the Commission	3. The Member ~~*State*~~***States*** shall immediately inform the Commission

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.	immediately inform the Commission***, the AI Office*** and the other ~~*Member States*~~***national supervisory authorities***. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.	and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.	and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken. Text Origin: EP Mandate
Article 67(4)				
G 640	4. The Commission shall without delay enter into consultation with the Member States and the relevant operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.	4. The Commission***, in consultation with the AI Office*** shall without delay enter into consultation with the ~~*Member States*~~***national supervisory authorities concerned*** and the relevant operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the ~~*Commission*~~***AI Office*** shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.	4. The Commission shall without ***undue*** delay enter into consultation with the Member States ***concerned*** and the relevant operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.	4. The Commission shall without ***undue*** delay enter into consultation with the Member States ***concerned*** and the relevant operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not and, where necessary, propose appropriate measures. G
Article 67(5)				
G 641	5. The Commission shall address its decision to the Member States.	5. The Commission***, in consultation with the AI Office*** shall ~~*address*~~***immediately communicate*** its decision to the ***national***	5. The Commission shall address its decision to the Member States ***concerned, and inform all other Member States***.	5. The Commission shall ~~*address*~~***immediately communicate*** its decision to the Member States ***concerned and to the relevant*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		supervisory authorities of the Member States ***concerned and to the relevant operators. It shall also inform the decision to all other national supervisory authorities***.		***operators***. ***It shall also inform of the decision all other Member States.***
Article 67(5a)				
G 641a		***5a. The Commission shall adopt guidelines to help national competent authorities to identify and rectify, where necessary, similar problems arising in other AI systems.***		***5a.*** Text Origin: EP Mandate
Article 68				
G 642	Article 68 Formal non-compliance	Article 68 Formal non-compliance	Article 68 Formal non-compliance	
Article 68(1)				
G 643	1. Where the market surveillance authority of a Member State makes one of the following findings, it shall require the relevant provider to put an end to the non-compliance concerned:	1. Where the ~~*market surveillance*~~***national supervisory*** authority of a Member State makes one of the following findings, it shall require the relevant provider to put an end to the non-compliance concerned:	1. Where the market surveillance authority of a Member State makes one of the following findings, it shall require the relevant provider to put an end to the non-compliance concerned***, within a period it may prescribe***:	1. Where the market surveillance authority of a Member State makes one of the following findings, it shall require the relevant provider to put an end to the non-compliance concerned***, within a period it may prescribe***: Text Origin: Council Mandate
Article 68(1), point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 644	(a) the conformity marking has been affixed in violation of Article 49;	(a) the ~~conformity~~***CE*** marking has been affixed in violation of Article 49;	(a) the conformity marking has been affixed in violation of Article 49;	(a) the ~~conformity~~***CE*** marking has been affixed in violation of Article 49; Text Origin: EP Mandate
Article 68(1), point (b)				
G 645	(b) the conformity marking has not been affixed;	(b) the ~~conformity~~***CE*** marking has not been affixed;	(b) the conformity marking has not been affixed;	(b) the ~~conformity~~***CE*** marking has not been affixed; Text Origin: EP Mandate
Article 68(1), point (c)				
G 646	(c) the EU declaration of conformity has not been drawn up;	(c) the EU declaration of conformity has not been drawn up;	(c) the EU declaration of conformity has not been drawn up;	
Article 68(1), point (d)				
G 647	(d) the EU declaration of conformity has not been drawn up correctly;	(d) the EU declaration of conformity has not been drawn up correctly;	(d) the EU declaration of conformity has not been drawn up correctly;	
Article 68(1), point (e)				
G 648	(e) the identification number of the notified body, which is involved in the conformity assessment procedure, where applicable, has not been affixed;	(e) the identification number of the notified body, which is involved in the conformity assessment procedure, where applicable, has not been affixed;	(e) the identification number of the notified body, which is involved in the conformity assessment procedure, where applicable, has not been affixed~~;~~.	
Article 68(1), point (ea)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 648a		***(ea) the registration in the EU database has not been carried out;***		***(ea) the registration in the EU database has not been carried out;*** Text Origin: EP Mandate
Article 68(1), point (eb)				
G 648b		***(eb) where applicable, the authorised representative has not been appointed.***		***(eb) where applicable, the authorised representative has not been appointed.*** Text Origin: EP Mandate
Article 68(1), point (ec)				
G 648c		***(ec) the technical documentation is not available***		***(ec) the technical documentation is not available*** Text Origin: EP Mandate
Article 68(2)				
G 649	2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the high-risk AI system being made available on the market or ensure that it is recalled or withdrawn from the market.	2. Where the non-compliance referred to in paragraph 1 persists, the ***national supervisory authority of the*** Member State concerned shall take ~~all~~ appropriate ***and proportionate*** measures to restrict or prohibit the high-risk AI system being made available on the market or ensure that it is recalled or withdrawn from the market ***without delay. The national supervisory authority of the Member State***	2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the high-risk AI system being made available on the market or ensure that it is recalled or withdrawn from the market.	2. Where the non-compliance referred to in paragraph 1 persists, the ***market surveillance authority of the*** Member State concerned shall take ~~all appropriate~~***appropriate and proportionate*** measures to restrict or prohibit the high-risk AI system being made available on the market or ensure that it is recalled or withdrawn from the market ***without delay***.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		concerned shall immediately inform the AI Office of the non-compliance and the measures taken.		
Article 68a				
G 649a			*Article 68a* *Union testing facilities in the area of artificial intelligence*	*Article 68a* *EU AI testing support structures in the area of artificial intelligence* Text Origin: Council Mandate
Article 68a(1)				
G 649b			*1. The Commission shall designate one or more Union testing facilities pursuant to Article 21 of Regulation (EU) 1020/2019 in the area of artificial intelligence.*	*1. The Commission shall designate one or more EU AI testing support structures to perform the tasks listed under Article 21(6) of Regulation (EU) 1020/2019 in the area of artificial intelligence.* Text Origin: Presidency2
Article 68a(2)				
G 649c			*2. Without prejudice to the activities of Union testing facilities referred to in Article 21(6) of Regulation (EU) 1020/2019, Union testing facilities referred to in paragraph 1 shall also provide independent technical or scientific advice at the request of the Board or market surveillance authorities.*	*2. Without prejudice to the tasks referred to in paragraph 1, EU AI testing support structure shall also provide independent technical or scientific advice at the request of the Board, the Commission, or market surveillance authorities.* Text Origin: Presidency2

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 68 – Chapter 3b (new)				
G 649d		***Chapter 3a(new)*** ***Remedies***		***Chapter 3b(new)*** ***Remedies*** Text Origin: EP Mandate G
Article 68 – Chapter 3a (new)				
G 649e		***Article 68 a*** ***Right to lodge a complaint with a national supervisory authority*** ***1. Without prejudice to any other administrative or judicial remedy, every natural persons or groups of natural persons shall have the right to lodge a complaint with a national supervisory authority, in particular in the Member State of his or her habitual residence, place of work or place of the alleged infringement if they consider that the AI system relating to him or her infringes this Regulation.*** ***2. The national supervisory authority with which the complaint has been lodged shall inform the complainant on the progress and the outcome of the complaint including the possibility of a judicial remedy pursuant to Article 78.***		***Article 68 a*** ***Right to lodge a complaint with a market surveillance authority*** ***1. Without prejudice to other administrative or judicial remedies, complaints to the relevant market surveillance authority may be submitted by any natural or legal person having grounds to consider that there has been an infringement of the provisions of this Regulation.*** ***In accordance with Regulation (EU) 2019/1020, complaints shall be taken into account for the purpose of conducting the market surveillance activities and be handled in line with the dedicated procedures established therefore by the market surveillance authorities*** Text Origin: EP Mandate G
Chapter I				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 649f				***Chapter I*** ***Supervision, investigation, enforcement and monitoring in respect of providers of general purpose AI Models*** ***Article A*** ***Enforcement of obligations on providers of general purpose AI models*** ***1. The Commission shall have exclusive powers to supervise and enforce Chapter/Title [general purpose AI models] taking into account the procedural guarantees by virtue of Article H. The Commission shall entrust the implementation of these tasks to the European AI Office, without prejudice to the powers of organisation of the Commission and the division of competences between Member States and the Union based on the Treaties.*** ***2. Without prejudice to Article 63a paragraph 3, market surveillance authorities may request to the Commission to exercise the powers laid down in this Chapter, where this is necessary and proportionate to assist with the fulfilment of their tasks under this Regulation.*** ***Article B*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Monitoring actions ***For the purposes of carrying out the tasks assigned to it under this Chapter, the AI Office may take the necessary actions to monitor the effective implementation and compliance with this Regulation by providers of general purpose AI models, including adherence to approved codes of practice.*** ***2. Downstream providers shall have the right to lodge a complaint alleging an infringement of this Regulation. A complaint shall be duly reasoned and at least indicate:*** ***(a) the point of contact of the provider of the general purpose AI model concerned;*** ***(b) description of the relevant facts, the provisions of this Regulation concerned and the reason why the downstream provider considers that the provider of the general purpose AI model concerned infringed this Regulation;*** ***(c) any other information that the downstream provider that sent the request considers relevant, including, where appropriate, information gathered on its own initiative.*** ***Article C*** ***Alerts of systemic risks by the scientific panel*** ***1. The scientific panel may***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				provide a qualified alert to the AI Office where it has reason to suspect that ***(a) a general purpose AI model poses concrete identifiable risk at Union level; or*** ***(b) a general purpose AI model meets the requirements referred to in Article [Classification of general purpose AI models with systemic risk…].*** ***2. Upon such qualified alert, the Commission, through the AI Office and after having informed the AI Board, may exercise the powers laid down in this Chapter for the purpose of assessing the matter. The AI Office shall inform the Board of any measure according to Articles [D-H].*** ***3. A qualified alert shall be duly reasoned and at least indicate:*** ***(a) the point of contact of the provider of the general purpose AI model with systemic risk concerned;*** ***(b) a description of the relevant facts and reasons for the suspicion of the scientific panel;*** ***(c) any other information that the scientific panel considers relevant, including, where appropriate, information gathered on its own initiative.*** ***Article D*** ***Power to request documentation and information***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				1. The Commission may request the provider of the general purpose AI model concerned to provide the documentation drawn up by the provider according to Article [Obligations for providers of general purpose AI models] and [Obligations on providers of general purpose AI models with systemic risk] or any additional information that is necessary for the purpose of assessing compliance of the provider with this Regulation. ***2. Before the request for information is sent, the AI Office may initiate a structured dialogue with the provider of the general purpose AI model.*** ***3. Upon a duly substantiated request from the scientific panel, the Commission may issue a request for information to a provider of a general purpose AI model, where the access to information is necessary and proportionate for the fulfilment of the tasks of the scientific panel according to Article [Scientific panel](2).*** ***4. The request for information shall state the legal basis and the purpose of the request, specifying what information is required and set the period within which the information is to be provided, and the fines provided for in Article***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				[fines] for supplying incorrect, incomplete or misleading information. ***5. The provider of the general purpose AI model concerned or their representatives and, in the case of legal persons, companies or firms, or where they have no legal personality, the persons authorised to represent them by law or by their constitution shall supply the information requested on behalf of the provider of the general purpose AI model concerned. Lawyers duly authorised to act may supply the information on behalf of their clients. The latter shall remain fully responsible if the information supplied is incomplete, incorrect or misleading.*** ***Article E*** ***Power to conduct evaluations*** ***1. The AI Office, after consulting the Board, may conduct evaluations of the general purpose AI model concerned*** ***(a) to assess compliance of the provider with the obligations under this Regulation, where the information gathered pursuant to Article D [Power to request information] is insufficient; or*** ***(b) to investigate systemic risks at Union level of general purpose AI models with systemic risk, in particular following a qualified***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				report from the scientific panel in accordance with point (c) of Article [Enforcement of obligations on providers of general purpose AI models and general purpose AI models with systemic risk](3) . ***2. The Commission may decide to appoint independent experts to carry out evaluations on its behalf, including from the scientific panel pursuant to Article [scientific panel of independent experts]. All independent experts appointed for this task shall meet the criteria outlined in Article 58b, paragraph 2.*** ***3. For the purpose of paragraph 1, the Commission may request access to the general purpose AI model concerned through application programming interfaces ('API') or further appropriate technical means and tools, including through source code.*** ***4. The request for access shall state the legal basis, the purpose and reasons of the request and set the period within which the access is to be provided, and the fines provided for in Article [fines] for failure to provide access.*** ***5. The providers of the general purpose AI model concerned and, in the case of legal persons, companies or firms, or where they have no legal***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				personality, the persons authorised to represent them by law or by their constitution shall provide the access requested on behalf of the provider of the general purpose AI model concerned. ***6. The modalities and the conditions of the evaluations, including the modalities for involving independent experts and the procedure for the selection of the latter, shall be set out in implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article xx(x).*** ***7. Prior to requesting access to the general purpose AI model concerned, the AI Office may initiate a structured dialogue with the provider of the general purpose AI model to gather more information on the internal testing of the model, internal safeguards for preventing systemic risks, and other internal procedures and measures the provider has taken to mitigate such risks.*** ***Article F*** ***Power to request measures*** ***1. Where necessary and appropriate, the Commission may request providers to*** ***(a) take appropriate measures to comply with the obligations set out***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				in Title/Chapter [Obligations for provider of general purpose AI models]; ***(b) require a provider to implement mitigation measures, where the evaluation carried out in accordance with Article [Power to conduct evaluations] has given rise to serious and substantiated concern of a systemic risk at Union level;*** ***(c) restrict the making available on the market, withdraw or recall the model.*** ***2. Before a measure is requested, the AI Office may initiate a structured dialogue with the provider of the general purpose AI model.*** ***3. If, during the structured dialogue under paragraph 2, the provider of the general purpose AI model with systemic risk offers commitments to implement mitigation meausres to address a systemic risk at Union level, the Commission may by decision make these commitments binding and declare that there are no further grounds for action.*** ***Article H*** ***Procedural rights of economic operators of the general purpose AI model*** ***Article 18 of the Regulation (EU)***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				2019/1020 apply by analogy to the providers of the general purpose AI model without prejudice to more specific procedural rights provided for in this Regulation.
Article 68 b (new)				
G 649g		***Article 68 b*** ***Right to an effective judicial remedy against a national supervisory authority*** ***1. Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to an effective judicial remedy against a legally binding decision of a national supervisory authority concerning them.*** ***2. Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to a an effective judicial remedy where the national supervisory authority which is competent pursuant to Articles 59 does not handle a complaint or does not inform the data subject within three months on the progress or outcome of the complaint lodged pursuant to Article 68a.*** ***3. Proceedings against a national supervisory authority shall be brought before the courts of the***		G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Member State where the national supervisory authority is established. ***4. Where proceedings are brought against a decision of a national supervisory authority which was preceded by an opinion or a decision of the Commission in the union safeguard procedure, the supervisory authority shall forward that opinion or decision to the court.***		
Article 68b				
G 649h			***Article 68b*** ***Central pool of independent experts***	G
Article 68b(1)				
G 649i			***1. Upon request of the AI Board, the Commission shall, by means of an implementing act, make provisions on the creation, maintenance and financing of a central pool of independent experts to support the enforcement activities under this Regulation.***	G
Article 68b(2)				
G 649j			***2. Experts shall be selected by the Commission and included in the central pool on the basis of up-to-date scientific or technical expertise***	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			in the field of artificial intelligence, having due regard to the technical areas covered by the requirements and obligations in this Regulation and the activities of market surveillance authorities pursuant to Article 11 of Regulation (EU) 1020/2019. The Commission shall determine the number of experts in the pool in accordance with the required needs.	
Article 68b(3)				
G 649k			***3. Experts may have the following tasks:***	G
Article 68b(3), point (a)				
G 649l			***(a) provide advice to and support the work of market surveillance authorities, at their request;***	G
Article 68b(3), point (b)				
G 649m			***(b) support cross-border market surveillance investigations as referred to in Article 58(h), without prejudice of the powers of market surveillance authorities;***	G
Article 68b(3), point (c)				
G 649n				G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			(c) advise and support the Commission when carrying out its duties in the context of the safeguard clause pursuant to Article 66.	
Article 68b(4)				
G 649o			*4. The experts shall perform their tasks with impartiality, objectivity and ensure the confidentiality of information and data obtained in carrying out their tasks and activities. Each expert shall draw up a declaration of interests, which shall be made publicly available. The Commission shall establish systems and procedures to actively manage and prevent potential conflicts of interest.*	G
Article 68b(5)				
G 649p			*5. The Member States may be required to pay fees for the advice and support by the experts. The structure and the level of fees as well as the scale and structure of recoverable costs shall be adopted by the Commission by means of the implementing act referred to in paragraph 1, taking into account the objectives of the adequate implementation of this Regulation, cost-effectiveness and the necessity*	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			to ensure an effective access to experts by all Member States.	
Article 68b(6)				
G 649q			*6. The Commission shall facilitate timely access to the experts by the Member States, as needed, and ensure that the combination of support activities carried out by Union testing facilities pursuant to Article 68a and experts pursuant to this Article is efficiently organised and provides the best possible added value.*	G
Article 68 – Chapter 3a (new)				
G 649r		*Article 68 c* *A right to explanation of individual decision-making* *1. Any affected person subject to a decision which is taken by the deployer on the basis of the output from an high-risk AI system which produces legal effects or similarly significantly affects him or her in a way that they consider to adversely impact their health, safety, fundamental rights, socio-economic well-being or any other of the rights deriving from the obligations laid down in this Regulation, shall have the right to request from the deployer clear and meaningful*		*Article 68 c* *A right to explanation of individual decision-making* *1. Any affected person subject to a decision which is taken by the deployer on the basis of the output from an high-risk AI system listed in Annex III, with the exception of systems listed under point 2, and which produces legal effects or similarly significantly affects him or her in a way that they consider to adversely impact their health, safety and fundamental rights shall have the right to request from the deployer clear and meaningful* G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		explanation pursuant to Article 13(1) on the role of the AI system in the decision-making procedure, the main parameters of the decision taken and the related input data. *2. Paragraph 1 shall not apply to the use of AI systems for which exceptions from, or restrictions to, the obligation under paragraph 1 follow from Union or national law are provided in so far as such exception or restrictions respect the essence of the fundamental rights and freedoms and is a necessary and proportionate measure in a democratic society.* *3. This Article shall apply without prejudice to Articles 13, 14, 15, and 22 of the Regulation 2016/679.*		*explanations on the role of the AI system in the decision-making procedure and the main elements of the decision taken.* *2. Paragraph 1 shall not apply to the use of AI systems for which exceptions from, or restrictions to, the obligation under paragraph 1 follow from Union or national law in compliance with Union law.* *3. . This Article shall only apply to the extent that the right referred to in paragraph 1 is not already provided for under Union legislation.* Text Origin: EP Mandate
Article 68 – Chapter 3a (new)				
G 649s		*Article 68 d* *Amendment to Directive (EU) 2020/1828* *In Annex I to Directive (EU) 2020/1828 of the European Parliament and of the Council [1a], the following point is added:* *"(67a) Regulation xxxx/xxxx of the European Parliament and of the Council [laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts (OJ L ...)]".*		*Article 68 d* *Amendment to Directive (EU) 2020/1828* *In Annex I to Directive (EU) 2020/1828 of the European Parliament and of the Council [1a], the following point is added:* *"(67a) Regulation xxxx/xxxx of the European Parliament and of the Council [laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts (OJ L ...)]".* G

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		[1a] Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC (OJ L 409, 4.12.2020, p. 1).		***[1a] Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC (OJ L 409, 4.12.2020, p. 1).*** Text Origin: EP Mandate
Article 68 – Chapter 3a (new)				
G 649t		***Article 68 e*** ***Reporting of breaches and protection of reporting persons*** ***Directive (EU) 2019/1937 of the European Parliament and of the Council shall apply to the reporting of breaches of this Regulation and the protection of persons reporting such breaches.***		***Article 68 e*** ***Reporting of breaches and protection of reporting persons*** ***Directive (EU) 2019/1937 of the European Parliament and of the Council shall apply to the reporting of breaches of this Regulation and the protection of persons reporting such breaches.*** Text Origin: EP Mandate
TITLE IX				
G 650	TITLE IX CODES OF CONDUCT	TITLE IX CODES OF CONDUCT	TITLE IX CODES OF CONDUCT	TITLE IX CODES OF CONDUCT Text Origin: Commission Proposal
Article 69				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 651	Article 69 Codes of conduct	Article 69 Codes of conduct	Article 69 ***Codes of conduct for voluntary application of specific requirements***~~Codes of conduct~~	Article 69 ***Codes of conduct for voluntary application of specific requirements***~~Codes of conduct~~ Text Origin: Council Mandate
Article 69(1)				
G 652	1. The Commission and the Member States shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to AI systems other than high-risk AI systems of the requirements set out in Title III, Chapter 2 on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems.	1. The Commission***, the AI Office*** and the Member States shall encourage and facilitate the drawing up of codes of conduct intended***, including where they are drawn up in order to demonstrate how AI systems respect the principles set out in Article 4a and can thereby be considered trustworthy,*** to foster the voluntary application to AI systems other than high-risk AI systems of the requirements set out in Title III, Chapter 2 on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems.	1. The Commission***,*** and the Member States shall~~ encourage and~~ facilitate the drawing up of codes of conduct intended to ~~foster~~***encourage*** the voluntary application to AI systems other than high-risk AI systems of ***one or more of*** the requirements set out in Title III, Chapter 2 ~~on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems~~***of this Regulation to the best extent possible, taking into account the available, technical solutions allowing for the application of such requirements***.	1. The ~~Commission~~***AI Office,*** and the Member States shall encourage and facilitate the drawing up of codes of conduct***, including related governance mechanisms,*** intended to foster the voluntary application to AI systems other than high-risk AI systems of ***some or all of*** the requirements set out in Title III, Chapter 2 ~~on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems~~***of this Regulation taking into account the available technical solutions and industry best practices allowing for the application of such requirements***.
Article 69(2)				
G 653	2. The Commission and the Board shall encourage and facilitate the drawing up of codes of conduct	2. ***Codes of conduct intended to foster the voluntary compliance with the principles underpinning***	2. The Commission and the ~~Board shall encourage and~~***Member States shall*** facilitate the drawing up of	2. The ~~Commission~~***AI Office*** and the ~~Board~~***Member States*** shall ~~encourage and~~ facilitate the drawing

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	intended to foster the voluntary application to AI systems of requirements related for example to environmental sustainability, accessibility for persons with a disability, stakeholders participation in the design and development of the AI systems and diversity of development teams on the basis of clear objectives and key performance indicators to measure the achievement of those objectives.	***trustworthy AI systems,***~~*The Commission and the Board*~~ shall***, in particular:*** ***(a) aim for a sufficient level of AI literacy among their staff and other persons dealing with the operation and use of AI systems in order to observe such principles;*** ***(b) assess to what extent their***~~*encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to*~~ AI systems ~~*of requirements related for example to environmental sustainability, accessibility for*~~***may affect vulnerable persons or groups of persons, including children, the elderly, migrants and*** persons with ~~*a disability, stakeholders participation in the design and development of the*~~***disabilities or whether measures could be put in place in order to increase accessibility, or otherwise support such persons or groups of persons;*** ***(c) consider the way in which the use of their AI systems may have an impact or can increase diversity, gender balance and equality;*** ***(d) have regard to whether their*** AI systems ***can be used in a way that, directly or indirectly, may residually or significantly reinforce existing biases or inequalities;*** ***(e) reflect on the need and relevance of having in place diverse***	codes of conduct intended to ~~*foster*~~***encourage*** the voluntary application to ***all*** AI systems of ***specific*** requirements related***,*** for example***,*** to environmental sustainability, ***including as regards energy-efficient programming,*** accessibility for persons with a disability, stakeholders participation in the design and development of the AI systems and diversity of development teams on the basis of clear objectives and key performance indicators to measure the achievement of those objectives. ***The Commission and the Member States shall also facilitate, where appropriate, the drawing of codes of conduct applicable on a voluntary basis with regard to users' obligations in relation to AI systems.***	up of codes of conduct ~~*intended to foster*~~***concerning*** the voluntary application***, including by deployers, of specific requirements to all*** ~~*to*~~ AI systems***, on the basis of clear objectives and key performance indicators to measure the achievement of those objectives, including elements such as, but not limited to:*** ***(a) applicable elements foreseen in European ethic guidelines for trustworthy AI;*** ***(b) assessing and minimizing the impact of AI systems on*** ~~*of requirements related for example to*~~ environmental sustainability, ~~*accessibility for persons with a disability, stakeholders participation in the design and development of the*~~***including as regards energy-efficient programming and techniques for efficient design, training and use of AI;*** ***(c) promoting AI literacy, in particular of persons dealing with the development, operation and use of AI;*** ***(d) facilitating an inclusive and diverse design of*** AI systems***, including through the establishment of inclusive and diverse*** ~~*and diversity of*~~ development teams ~~*on the basis of clear objectives and key performance indicators to measure*~~

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		~~and diversity of~~ development teams ~~on the basis of clear objectives and key performance indicators to measure the achievement of those objectives~~***in view of securing an inclusive design of their systems;*** ***(f) give careful consideration to whether their systems can have a negative societal impact, notably concerning political institutions and democratic processes;*** ***(g) evaluate how AI systems can contribute to environmental sustainability and in particular to the Union's commitments under the European Green Deal and the European Declaration on Digital Rights and Principles***.		~~the achievement of those objectives~~***and the promotion of stakeholders' participation in that process;*** ***(e) assessing and preventing the negative impact of AI systems on vulnerable persons or groups of persons, including as regards accessibility for persons with a disability, as well as on gender equality***.
Article 69(3)				
G 654	3. Codes of conduct may be drawn up by individual providers of AI systems or by organisations representing them or by both, including with the involvement of users and any interested stakeholders and their representative organisations. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems.	3. Codes of conduct may be drawn up by individual providers of AI systems or by organisations representing them or by both, including with the involvement of users and any interested stakeholders***, including scientific researchers,*** and their representative organisations***, in particular trade unions, and consumer organisations***. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems. ***Providers adopting codes***	3. Codes of conduct ***applicable on a voluntary basis*** may be drawn up by individual providers of AI systems or by organisations representing them or by both, including with the involvement of users and any interested stakeholders and their representative organisations***, or, where appropriate, by users with regard to their obligations***. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems.	3. Codes of conduct may be drawn up by individual providers ***or deployers*** of AI systems or by organisations representing them or by both, including with the involvement of ~~users~~***deployers*** and any interested stakeholders and their representative organisations***, including civil society organisations and academia***. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems. G

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		of conduct will designate at least one natural person responsible for internal monitoring.		
Article 69(4)				
655	4. The Commission and the Board shall take into account the specific interests and needs of the small-scale providers and start-ups when encouraging and facilitating the drawing up of codes of conduct.	4. The Commission and the ~~Board~~***AI Office*** shall take into account the specific interests and needs of ~~the small-scale providers~~***SMEs*** and start-ups when encouraging and facilitating the drawing up of codes of conduct.	4. The Commission and the ~~Board~~***Member States*** shall take into account the specific interests and needs of ~~the small-scale~~***SME*** providers***, including*** ~~and~~ start-ups***,*** when encouraging and facilitating the drawing up of codes of conduct ***referred to in this Article***.	4. The ~~Commission~~***AI Office,*** and the ~~Board~~***Member States*** shall take into account the specific interests and needs of ~~the small-scale providers and~~***SMEs, including*** start-ups***,*** when encouraging and facilitating the drawing up of codes of conduct.
TITLE X				
656	TITLE X CONFIDENTIALITY AND PENALTIES	TITLE X CONFIDENTIALITY AND PENALTIES	TITLE X CONFIDENTIALITY AND PENALTIES	TITLE X CONFIDENTIALITY AND PENALTIES Text Origin: Commission Proposal
Article 70				
657	Article 70 Confidentiality	Article 70 Confidentiality	Article 70 Confidentiality	Article 70 Confidentiality Text Origin: Commission Proposal
Article 70(1)				
658				

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	1. National competent authorities and notified bodies involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:	1. ***The Commission,*** national competent authorities and notified bodies***, the AI Office and any other natural or legal person*** involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular~~:~~**;**	1. National competent authorities ~~and~~**,** notified bodies***, the Commission, the Board, and any other natural or legal person*** involved in the application of this Regulation shall***, in accordance with Union or national law, put appropriate technical and organisational measures in place to ensure*** ~~respect~~ the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:	1. ~~National competent~~***The Commission, market surveillance*** authorities and notified bodies ***and any other natural or legal person*** involved in the application of this Regulation shall***, in accordance with Union or national law,*** respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular~~:~~**;**
Article 70(1), point (a)				
G 659	(a) intellectual property rights, and confidential business information or trade secrets of a natural or legal person, including source code, except the cases referred to in Article 5 of Directive 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure apply.	(a) intellectual property rights, and confidential business information or trade secrets of a natural or legal person, ***in accordance with the provisions of Directives 2004/48/EC and 2016/943/EC,*** including source code, except the cases referred to in Article 5 of Directive 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure apply~~.~~**;**	(a) intellectual property rights, and confidential business information or trade secrets of a natural or legal person, including source code, except the cases referred to in Article 5 of Directive 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure apply~~.~~**;**	(a) intellectual property rights, and confidential business information or trade secrets of a natural or legal person, including source code, except the cases referred to in Article 5 of Directive 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure apply~~.~~**;** Text Origin: EP Mandate
Article 70(1), point (b)				
G 660	(b) the effective implementation of this Regulation, in particular for the	(b) the effective implementation of this Regulation, in particular for the	(b) the effective implementation of this Regulation, in particular for the	(b) the effective implementation of this Regulation, in particular for the

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	purpose of inspections, investigations or audits;(c) public and national security interests;	purpose of inspections, investigations or audits;(c) public and national security interests;	purpose of inspections, investigations or audits;~~(c) public and national security interests;~~	purpose of inspections, investigations or audits;~~(c) public and national security interests;~~
Article 70(1), point (ba)				
G 660a		***(ba) public and national security interests***		***(ba) public and national security interests*** G
Article 70(1), point (c)				
G 661	(c) integrity of criminal or administrative proceedings.	(c) integrity of criminal or administrative proceedings.	(c) ~~*integrity of criminal or administrative proceedings.*~~***public and national security interests;***	(c) integrity of criminal or administrative proceedings. G
Article 70(1), point (d)				
G 662	(d) THIS POINT IS MISSING. THANK YOU FOR USING ANOTHER LANGUAGE.	(d) THIS POINT IS MISSING. THANK YOU FOR USING ANOTHER LANGUAGE.	(d) ~~*THIS POINT IS MISSING. THANK YOU FOR USING ANOTHER LANGUAGE.*~~***integrity of criminal or administrative proceedings;***	G
Article 70(1), point (da)				
G 662a			***(da) the integrity of information classified in accordance with Union or national law.***	***(da) the integrity of information classified in accordance with Union or national law.*** G
Article 70(1), point (db)				
G 662b		***1a. The authorities involved in the***		***(db) 1a. The authorities involved in*** G

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		application of this Regulation pursuant to paragraph 1 shall minimise the quantity of data requested for disclosure to the data that is strictly necessary for the perceived risk and the assessment of that risk. They shall delete the data as soon as it is no longer needed for the purpose it was requested for. They shall put in place adequate and effective cybersecurity, technical and organisational measures to protect the security and confidentiality of the information and data obtained in carrying out their tasks and activities;		***the application of this Regulation pursuant to paragraph 1 shall only request data that is strictly necessary for the assessment of the risk posed by the AI system and for the exercise of their powers in compliance with this Regulation and Regulation 2019/1020. They shall put in place adequate and effective cybersecurity measures to protect the security and confidentiality of the information and data obtained and shall delete the data collected as soon as it is no longer needed for the purpose it was requested for, in accordance with applicable national or European legislation .***
Article 70(2), first subparagraph				
G 663	2. Without prejudice to paragraph 1, information exchanged on a confidential basis between the national competent authorities and between national competent authorities and the Commission shall not be disclosed without the prior consultation of the originating national competent authority and the user when high-risk AI systems referred to in points 1, 6 and 7 of Annex III are used by law enforcement, immigration or asylum authorities, when such disclosure would jeopardise public and national	2. Without prejudice to ~~paragraph 1~~***paragraphs 1 and 1a***, information exchanged on a confidential basis between the national competent authorities and between national competent authorities and the Commission shall not be disclosed without the prior consultation of the originating national competent authority and the ~~user~~***deployer*** when high-risk AI systems referred to in points 1, 6 and 7 of Annex III are used by law enforcement, immigration or asylum authorities, when such disclosure would	2. Without prejudice to paragraph 1, information exchanged on a confidential basis between the national competent authorities and between national competent authorities and the Commission shall not be disclosed without the prior consultation of the originating national competent authority and the user when high-risk AI systems referred to in points 1, 6 and 7 of Annex III are used by law enforcement, ***border control,*** immigration or asylum authorities, when such disclosure would	2. Without prejudice to paragraph 1 ***and 1a***, information exchanged on a confidential basis between the national competent authorities and between national competent authorities and the Commission shall not be disclosed without the prior consultation of the originating national competent authority and the ~~user~~***deployer*** when high-risk AI systems referred to in points 1, 6 and 7 of Annex III are used by law enforcement, ***border control,*** immigration or asylum authorities, when such disclosure would G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	security interests.	jeopardise public ~~and~~***or*** national security ~~interests~~.	jeopardise public and national security interests. ***This obligation to exchange information shall not cover sensitive operational data in relation to the activities of law enforcement, border control, immigration or asylum authorities.***	jeopardise public and national security interests. ***This exchange of information shall not cover sensitive operational data in relation to the activities of law enforcement, border control, immigration or asylum authorities.*** Text Origin: Auxiliary 1
Article 70(2), second subparagraph				
G 664	When the law enforcement, immigration or asylum authorities are providers of high-risk AI systems referred to in points 1, 6 and 7 of Annex III, the technical documentation referred to in Annex IV shall remain within the premises of those authorities. Those authorities shall ensure that the market surveillance authorities referred to in Article 63(5) and (6), as applicable, can, upon request, immediately access the documentation or obtain a copy thereof. Only staff of the market surveillance authority holding the appropriate level of security clearance shall be allowed to access that documentation or any copy thereof.	When the law enforcement, immigration or asylum authorities are providers of high-risk AI systems referred to in points 1, 6 and 7 of Annex III, the technical documentation referred to in Annex IV shall remain within the premises of those authorities. Those authorities shall ensure that the market surveillance authorities referred to in Article 63(5) and (6), as applicable, can, upon request, immediately access the documentation or obtain a copy thereof. Only staff of the market surveillance authority holding the appropriate level of security clearance shall be allowed to access that documentation or any copy thereof.	When the law enforcement, immigration or asylum authorities are providers of high-risk AI systems referred to in points 1, 6 and 7 of Annex III, the technical documentation referred to in Annex IV shall remain within the premises of those authorities. Those authorities shall ensure that the market surveillance authorities referred to in Article 63(5) and (6), as applicable, can, upon request, immediately access the documentation or obtain a copy thereof. Only staff of the market surveillance authority holding the appropriate level of security clearance shall be allowed to access that documentation or any copy thereof.	When the law enforcement, immigration or asylum authorities are providers of high-risk AI systems referred to in points 1, 6 and 7 of Annex III, the technical documentation referred to in Annex IV shall remain within the premises of those authorities. Those authorities shall ensure that the market surveillance authorities referred to in Article 63(5) and (6), as applicable, can, upon request, immediately access the documentation or obtain a copy thereof. Only staff of the market surveillance authority holding the appropriate level of security clearance shall be allowed to access that documentation or any copy thereof. Text Origin: Commission Proposal
Article 70(3)				

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G 665	3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to the exchange of information and the dissemination of warnings, nor the obligations of the parties concerned to provide information under criminal law of the Member States.	3. Paragraphs 1***, 1a*** and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to the exchange of information and the dissemination of warnings, nor the obligations of the parties concerned to provide information under criminal law of the Member States~~.~~***;***	3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and ***their relevant authorities, as well as*** notified bodies***,*** with regard to the exchange of information and the dissemination of warnings***, including in the context of cross-border cooperation***, nor the obligations of the parties concerned to provide information under criminal law of the Member States.	3. Paragraphs 1***, [1a]*** and 2 shall not affect the rights and obligations of the Commission, Member States and ***their relevant authorities, as well as*** notified bodies***,*** with regard to the exchange of information and the dissemination of warnings***, including in the context of cross-border cooperation***, nor the obligations of the parties concerned to provide information under criminal law of the Member States.
Article 70(4)				
G 666	4. The Commission and Member States may exchange, where necessary, confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of confidentiality.	4. The Commission and Member States may exchange, where ***strictly*** necessary ***and in accordance with relevant provisions of international and trade agreements***, confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of confidentiality.	4. The Commission and Member States may exchange, where necessary, confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of confidentiality.	4. The Commission and Member States may exchange, where necessary ***and in accordance with relevant provisions of international and trade agreements***, confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of confidentiality.
Article 71				
G 667	Article 71 Penalties	Article 71 Penalties	Article 71 Penalties	Article 71 Penalties Text Origin: Commission Proposal

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 71(1)				
668	1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests of small-scale providers and start-up and their economic viability.	1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, ~~including administrative fines,~~ applicable to infringements of this Regulation ***by any operator,*** and shall take all measures necessary to ensure that they are properly and effectively implemented ***and aligned with the guidelines issued by the Commission and the AI Office pursuant to Article 82b***. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into ~~particular~~ account the interests of ~~small-scale providers and start-up~~***SMEs and start-ups*** and their economic viability~~.~~***;***	1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the ***size and*** interests of ~~small-scale~~***SME*** providers***, including start-ups,*** ~~and start-up~~ and their economic viability. ***They shall also take into account whether the use of the AI system is in the context of personal non-professional activity.***	1. In compliance 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***~~, including administrative fines~~, applicable to infringements of this Regulation ***by operators,*** and shall take all measures necessary to ensure that they are properly and effectively implemented ***and taking into account the guidelines issued by the Commission pursuant to Article 82b***. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into ~~particular~~ account the interests of ~~small-scale providers and start-up~~***SMEs including start-ups*** and their economic viability.
Article 71(2)				
669	2. The Member States shall notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.	2. The Member States shall notify the Commission ***and the Office by [12 months after the date of entry into force of this Regulation]*** of those rules and of those measures and shall notify ~~it~~***them***, without delay, of any subsequent amendment	2. The Member States shall ***without delay*** notify the Commission of those rules and of those measures and ~~shall notify it, without delay,~~ of any subsequent amendment affecting them.	2. The Member States shall ***without delay*** notify the Commission ***and at the latest by the date of entry into application*** of those ***respective*** rules and of those ***respective*** measures and shall notify ~~it~~***them***, without delay, of any subsequent amendment affecting

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		affecting them.		them.
Article 71(3)				
G 670	3. The following infringements shall be subject to administrative fines of up to 30 000 000 EUR or, if the offender is company, up to 6 % of its total worldwide annual turnover for the preceding financial year, whichever is higher:	3. ***Non compliance with the prohibition of the artificial intelligence practices referred to in Article 5***~~The following infringements~~ shall be subject to administrative fines of up to ~~30 000 000~~***40 000 000*** EUR or, if the offender is ***a*** company, up to ~~6~~***7*** % of its total worldwide annual turnover for the preceding financial year, whichever is higher:	3. ***Non-compliance with any of the prohibitions of the artificial intelligence practices referred to in Article 5***~~The following infringements~~ shall be subject to administrative fines of up to 30 000 000 EUR or, if the offender is company, up to 6 % of its total worldwide annual turnover for the preceding financial year, whichever is higher~~:~~***. In case of SMEs, including start-ups, these fines shall be up to 3% of their worldwide annual turnover for the preceding financial year.***	3. ***Non compliance with the prohibition of the artificial intelligence practices referred to in Article 5***~~The following infringements~~ shall be subject to administrative fines of up to ~~30 000 000~~***35 000 000*** EUR or, if the offender is ***a*** company, up to ~~6~~***7*** % of its total worldwide annual turnover for the preceding financial year, whichever is higher:
Article 71(3), point (a)				
G 671	(a) non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;	*deleted*	*deleted*	
Article 71(3), point (b)				
G *672*	*(b)* non-compliance of the AI system with the requirements laid down in Article 10.	*deleted*	*deleted*	
Article 71(3a)				

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G 672a		***3a. Non-compliance of the AI system with the requirements laid down in Article 10 and 13 shall be subject to administrative fines of up to EUR 20 000 000 or, if the offender is a company, up to 4% of its total worldwide annual turnover for the preceding financial year, whichever is the higher.***		G
Article 71(4)				
G 673	4. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to 20 000 000 EUR or, if the offender is a company, up to 4 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.	4. ~~The~~ Non-compliance of the AI system ***or foundation model*** with any requirements or obligations under this Regulation, other than those laid down in Articles 5***, 10 and 13*** ~~and 10~~, shall be subject to administrative fines of up to ~~20 000 000~~ EUR ***10 000 000*** or, if the offender is a company, up to ~~4 %~~***2%*** of its total worldwide annual turnover for the preceding financial year, whichever is higher~~.~~***;***	4. ~~The non-compliance~~***Infringements*** of the ~~AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10~~***following provisions related to operators or notified bodies***, shall be subject to administrative fines of up to 20 000 000 EUR or, if the offender is a company, up to 4 % of its total worldwide annual turnover for the preceding financial year, whichever is higher~~.~~***:***	4. ~~The~~ Non-compliance of ~~the~~***an*** AI system with any ~~requirements or obligations under this Regulation~~***of the following provisions related to operators or notified bodies***, other than those laid down in Articles 5 ~~and 10~~, shall be subject to administrative fines of up to ~~20 000 000~~***15 000 000*** EUR or, if the offender is a company, up to ~~4 %~~***3%*** of its total worldwide annual turnover for the preceding financial year, whichever is higher~~.~~***:*** Text Origin: Presidency1	G
Article 71(4), point (a)				
G 673a			***(a) obligations of providers pursuant to Articles 4b and 4c;***	***(a)*** Text Origin: Council Mandate	G

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Article 71(4), point (b)				
G 673b			***(b) obligations of providers pursuant to Article 16;***	***(b) obligations of providers pursuant to Article 16;*** Text Origin: Council Mandate
Article 71(4), point (c)				
G 673c			***(c) obligations for certain other persons pursuant to Article 23a;***	***(c)*** Text Origin: Council Mandate
Article 71(4), point (d)				
G 673d			***(d) obligations of authorised representatives pursuant to Article 25;***	***(d) obligations of authorised representatives pursuant to Article 25;*** Text Origin: Council Mandate
Article 71(4), point (e)				
G 673e			***(e) obligations of importers pursuant to Article 26;***	***(e) obligations of importers pursuant to Article 26;*** Text Origin: Council Mandate
Article 71(4), point (f)				
G 673f			***(f) obligations of distributors pursuant to Article 27;***	***(f) obligations of distributors pursuant to Article 27;*** Text Origin: Council Mandate

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 71(4), point (g)				
G 673g			*(g) obligations of users pursuant to Article 29, paragraphs 1 to 6a;*	*(g) obligations of deployers pursuant to Article 29, paragraphs 1 to 6a;* Text Origin: Council Mandate
Article 71(4), point (h)				
G 673h			*(h) requirements and obligations of notified bodies pursuant to Article 33, 34(1), 34(3), 34(4), 34a;*	*(h) requirements and obligations of notified bodies pursuant to Article 33, 34(1), 34(3), 34(4), 34a;* Text Origin: Council Mandate
Article 71(4), point (i)				
G 673i			*(i) transparency obligations for providers and users pursuant to Article 52.*	*(i) transparency obligations for providers and users pursuant to Article 52.* Text Origin: Council Mandate
Article 71(4a)				
G 673j			*4a. In case of SMEs, including start-ups, these fines shall be up to 2% of their worldwide annual turnover for the preceding financial year.*	*4a.* Text Origin: Council Mandate
Article 71(5)				
G 674				

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	5. The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to 10 000 000 EUR or, if the offender is a company, up to 2 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.	5. The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to ~~10 000 000~~***5 000 000*** EUR or, if the offender is a company, up to ~~2~~***1*** % of its total worldwide annual turnover for the preceding financial year, whichever is higher.	5. The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to 10 000 000 EUR or, if the offender is a company, up to 2 % of its total worldwide annual turnover for the preceding financial year, whichever is higher. ***In case of SMEs, including start-ups, these fines shall be up to 1% of their worldwide annual turnover for the preceding financial year.***	5. The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to ~~10 000 000~~***7 500 000*** EUR or, if the offender is a company, up to ~~2~~***1*** % of its total worldwide annual turnover for the preceding financial year, whichever is higher. ***5a. In case of SMEs, including start-ups, each fine referred to in this Article shall be up to the percentages or amount referred to paragraphs 3, 4 and 5, whichever of the two is lower.***
Article 71(6)				
G 675	6. When deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:	6. ***Fines may be imposed in addition to or instead of non-monetary measures such as orders or warnings.*** When deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following~~:~~***;***	6. When deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:	6. When deciding ***whether to impose an administrative fine and*** on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and***, as appropriate,*** ~~due~~ regard shall be given to the following:
Article 71(6), point (a)				
G 676	(a) the nature, gravity and duration	(a) the nature, gravity and duration	(a) the nature, gravity and duration	(a) the nature, gravity and duration

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	of the infringement and of its consequences;	of the infringement and of its consequences***, taking into account the purpose of the AI system, as well as, where appropriate, the number of affected persons and the level of damage suffered by them***;	of the infringement and of its consequences;	of the infringement and of its consequences***, taking into account the purpose of the AI system, as well as, where appropriate, the number of affected persons and the level of damage suffered by them***;
Article 71(6), point (aa)				
G 676a			***(aa) the intentional or negligent character of the infringement;***	***(aa)***
Article 71(6), point (ab)				
G 676b			***(ab) any action taken by the operator in order to remedy the infringement and mitigate the possible adverse effects of the infringement;***	***(ab)***
Article 71(6), point (b)				
G 677	(b) whether administrative fines have been already applied by other market surveillance authorities to the same operator for the same infringement.	(b) whether administrative fines have been already applied by other ~~market surveillance~~***national supervisory*** authorities ***of one or more Member States*** to the same operator for the same infringement~~.~~***;***	(b) whether administrative fines have been already applied by other market surveillance authorities ***in other Member States*** to the same operator for the same infringement~~.~~***;***	(b) whether administrative fines have been already applied by other market surveillance authorities ***of one or more Member States*** to the same operator for the same infringement~~.~~***;*** Text Origin: Auxiliary 1
Article 71(6), point (ba)				
G 677a				

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			(ba) whether administrative fines have been already applied by other authorities to the same operator for infringements of other Union or national law, when such infringements result from the same activity or omission constituting a relevant infringement of this Act;	***(ba) whether administrative fines have been already applied by other authorities to the same operator for infringements of other Union or national law, when such infringements result from the same activity or omission constituting a relevant infringement of this Act;*** Text Origin: Auxiliary 1
Article 71(6), point (c)				
G 678	(c) the size and market share of the operator committing the infringement;	(c) the size and ~~market share~~***annual turnover*** of the operator committing the infringement;	(c) the size***, the annual turnover*** and market share of the operator committing the infringement;	(c) the size***, the annual turnover*** and market share of the operator committing the infringement; Text Origin: Auxiliary 1
Article 71(6), point (ca)				
G 678a			***(ca) any other aggravating or mitigating factor applicable to the circumstances of the case, such as financial benefits gained, or losses avoided, directly or indirectly, from the infringement.***	***(ca) any other aggravating or mitigating factor applicable to the circumstances of the case, such as financial benefits gained, or losses avoided, directly or indirectly, from the infringement.*** Text Origin: Council Mandate
Article 71(6), point (cb)				
G 678b		***(ca) the degree of cooperation with the national competent authorities, in order to remedy the infringement***		***(ca) the degree of cooperation with the national competent authorities, in order to remedy the infringement***

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		and mitigate the possible adverse effects of the infringement;		***and mitigate the possible adverse effects of the infringement;*** Text Origin: Auxiliary 1
Article 71(6), point (cc)				
G 678c		***(cb) the degree of responsibility of the operator taking into account the technical and organisational measures implemented by them;***		***(cb) the degree of responsibility of the operator taking into account the technical and organisational measures implemented by them;*** Text Origin: Auxiliary 1
Article 71(6), point (cd)				
G 678d		***(cc) adherence to approved codes of conduct or approved certification mechanisms;***		***(cc)*** Text Origin: EP Mandate
Article 71(6), point (cd)				
G 678e		***(cd) any relevant previous infringements by the operator;***		
Article 71(6), point (ce)				
G 678f		***(ce) the manner in which the infringement became known to the national competent authorities, in particular whether, and if so to what extent, the operator notified the infringement;***		***(ce) the manner in which the infringement became known to the national competent authorities, in particular whether, and if so to what extent, the operator notified the infringement;***

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				Text Origin: Auxiliary 1
Article 71(6), point (cf)				
678g		***(cf) the intentional or negligent character of the infringement;***		***(cf) the intentional or negligent character of the infringement;*** Text Origin: EP Mandate
Article 71(6), point (cg)				
678h		***(cg) any action taken by the operator to mitigate the harm of damage suffered by the affected persons;***		***(cg) any action taken by the operator to mitigate the harm of damage suffered by the affected persons;*** Text Origin: EP Mandate
Article 71(7)				
679	7. Each Member State shall lay down rules on whether and to what extent administrative fines may be imposed on public authorities and bodies established in that Member State.	7. each Member State shall lay down rules on ~~*whether and to what extent*~~ administrative fines ~~*may*~~***to*** be imposed on public authorities and bodies established in that Member State~~.~~***;***	7. Each Member State shall lay down rules on whether and to what extent administrative fines may be imposed on public authorities and bodies established in that Member State.	7. Each Member State shall lay down rules on ~~*whether and*~~ to what extent administrative fines may be imposed on public authorities and bodies established in that Member State. Text Origin: Auxiliary 1
Article 71(8)				
680	8. Depending on the legal system of the Member States, the rules on administrative fines may be applied	8. Depending on the legal system of the Member States, the rules on administrative fines may be applied	8. Depending on the legal system of the Member States, the rules on administrative fines may be applied	8. Depending on the legal system of the Member States, the rules on administrative fines may be applied

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	in such a manner that the fines are imposed by competent national courts of other bodies as applicable in those Member States. The application of such rules in those Member States shall have an equivalent effect.	in such a manner that the fines are imposed by competent national courts of other bodies as applicable in those Member States. The application of such rules in those Member States shall have an equivalent effect.	in such a manner that the fines are imposed by competent national courts ~~of~~***or*** other bodies as applicable in those Member States. The application of such rules in those Member States shall have an equivalent effect.	in such a manner that the fines are imposed by competent national courts ~~of~~***or*** other bodies as applicable in those Member States. The application of such rules in those Member States shall have an equivalent effect. Text Origin: Auxiliary 1
Article 71(8a)				
G 680a			***8a. The exercise by the market surveillance authority of its powers under this Article shall be subject to appropriate procedural safeguards in accordance with Union and Member State law, including effective judicial remedy and due process.***	***8a. The exercise by the market surveillance authority of its powers under this Article shall be subject to appropriate procedural safeguards in accordance with Union and Member State law, including effective judicial remedy and due process.*** Text Origin: Auxiliary 1
Article 71(8a)				
G 680b		***8a. The penalties referred to in this article as well as the associated litigation costs and indemnification claims may not be the subject of contractual clauses or other form of burden-sharing agreements between providers and distributors, importers, deployers, or any other third parties;***		

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Article 71(8b)				
680c		***8b. National supervisory authorities shall, on an annual basis, report to the AI Office about the fines they have issued during that year, in accordance with this Article;***		***8b. Member States shall, on an annual basis, report to the Commission about the administrative fines they have issued during that year, in accordance with this Article, and any related litigation or judicial proceedings;*** Text Origin: Auxiliary 1
Article 71(8c)				
680d		***8c. The exercise by competent authorities of their powers under this Article shall be subject to appropriate procedural safeguards in accordance with Union and national law, including judicial remedy and due process;***		
Article 72				
681	Article 72 Administrative fines on Union institutions, agencies and bodies	Article 72 Administrative fines on Union institutions, agencies and bodies	Article 72 Administrative fines on Union institutions, agencies and bodies	Article 72 Administrative fines on Union institutions, agencies and bodies Text Origin: Commission Proposal
Article 72(1)				
682	1. The European Data Protection	1. The European Data Protection	1. The European Data Protection	1. The European Data Protection

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	Supervisor may impose administrative fines on Union institutions, agencies and bodies falling within the scope of this Regulation. When deciding whether to impose an administrative fine and deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:	Supervisor may impose administrative fines on Union institutions, agencies and bodies falling within the scope of this Regulation. When deciding whether to impose an administrative fine and deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:	Supervisor may impose administrative fines on Union institutions, agencies and bodies falling within the scope of this Regulation. When deciding whether to impose an administrative fine and deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:	Supervisor may impose administrative fines on Union institutions, agencies and bodies falling within the scope of this Regulation. When deciding whether to impose an administrative fine and deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following: Text Origin: Commission Proposal
Article 72(1), point (a)				
G 683	(a) the nature, gravity and duration of the infringement and of its consequences;	(a) the nature, gravity and duration of the infringement and of its consequences;***, taking into account the purpose of the AI system concerned as well as the number of affected persons and the level of damage suffered by them, and any relevant previous infringement;***	(a) the nature, gravity and duration of the infringement and of its consequences;	(a) the nature, gravity and duration of the infringement and of its consequences;***, taking into account the purpose of the AI system concerned as well as the number of affected persons and the level of damage suffered by them, and any relevant previous infringement;*** Text Origin: EP Mandate
Article 72(1), point (aa)				
G 683a		***(aa) the degree of responsibility of the Union institution, agency or body, taking into account technical and organisational measures***		***(aa) the degree of responsibility of the Union institution, agency or body, taking into account technical and organisational measures***

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		implemented by them;		***implemented by them;*** Text Origin: Auxiliary 1
Article 72(1), point (ab)				
683b		***(ab) any action taken by the Union institution, agency or body to mitigate the damage suffered by affected persons;***		***(ab) any action taken by the Union institution, agency or body to mitigate the damage suffered by affected persons;*** Text Origin: Auxiliary 1
Article 72(1), point (b)				
684	(b) the cooperation with the European Data Protection Supervisor in order to remedy the infringement and mitigate the possible adverse effects of the infringement, including compliance with any of the measures previously ordered by the European Data Protection Supervisor against the Union institution or agency or body concerned with regard to the same subject matter;	(b) the ***degree of*** cooperation with the European Data Protection Supervisor in order to remedy the infringement and mitigate the possible adverse effects of the infringement, including compliance with any of the measures previously ordered by the European Data Protection Supervisor against the Union institution or agency or body concerned with regard to the same subject matter;	(b) the cooperation with the European Data Protection Supervisor in order to remedy the infringement and mitigate the possible adverse effects of the infringement, including compliance with any of the measures previously ordered by the European Data Protection Supervisor against the Union institution or agency or body concerned with regard to the same subject matter;	(b) the ***degree of*** cooperation with the European Data Protection Supervisor in order to remedy the infringement and mitigate the possible adverse effects of the infringement, including compliance with any of the measures previously ordered by the European Data Protection Supervisor against the Union institution or agency or body concerned with regard to the same subject matter; Text Origin: Auxiliary 1
Article 72(1), point (c)				
685	(c) any similar previous infringements by the Union institution, agency or body;	(c) any similar previous infringements by the Union institution, agency or body;	(c) any similar previous infringements by the Union institution, agency or body~~;~~.	(c) any similar previous infringements by the Union institution, agency or body;

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Article 72(1), point (ca)				
G 685a		***(ca) the manner in which the infringement became known to the European Data Protection Supervisor, in particular whether, and if so to what extent, the Union institution or body notified the infringement;***		***(ca) the manner in which the infringement became known to the European Data Protection Supervisor, in particular whether, and if so to what extent, the Union institution or body notified the infringement;*** G Text Origin: Auxiliary 1
Article 72(1), point (cb)				
G 685b		***(cb) the annual budget of the body;***		***(cb) the annual budget of the body;*** G Text Origin: Auxiliary 1
Article 72(2)				
G 686	2. The following infringements shall be subject to administrative fines of up to 500 000 EUR:	2. ***Non compliance with the prohibition of the artificial intelligence practices referred to in Article 5*** ~~*The following infringements*~~ shall be subject to administrative fines of up to ~~*500 000 EUR:*~~ ***EUR 1 500 000.***	2. ***Non-compliance with any of the prohibitions of the artificial intelligence practices referred to in Article 5*** ~~*The following infringements*~~ shall be subject to administrative fines of up to 500 000 EUR~~:~~.	2. ***Non compliance with the prohibition of the artificial intelligence practices referred to in Article 5*** ~~*The following infringements*~~ shall be subject to administrative fines of up to ~~*500 000 EUR:*~~ ***EUR 1 500 000.*** G Text Origin: Auxiliary 1
Article 72(2), point (-a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 686a				G
Article 72(2), point (a)				
G 687	(a) non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;	*deleted*	*deleted*	(a) ~~*non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;*~~***deleted*** G
Article 72(2), point (aa)				
G 687a		***2 a non-compliance of the AI system with the requirements laid down in Article 10 shall be subject to administrative fines of up to 1 000 000 EUR.***		***(aa) deleted*** Text Origin: Auxiliary 1 G
Article 72(2), point (b)				
G 688	(b) non-compliance of the AI system with the requirements laid down in Article 10.	(b) non-compliance of the AI system with the requirements laid down in Article 10.	*deleted*	(b) ~~*non-compliance of the AI system with the requirements laid down in Article 10.*~~***deleted*** Text Origin: Auxiliary 1 G
Article 72(3)				
G 689	3. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to 250 000	3. the non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to ~~*250 000*~~	3. ~~*The*~~ Non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to 250 000	3. the non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5~~*and 10*~~, shall be subject to administrative fines of up to ~~*250 000*~~ G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	EUR.	EUR ***750 000***.	EUR.	EUR ***750 000***. Text Origin: Auxiliary 1
Article 72(4)				
G 690	4. Before taking decisions pursuant to this Article, the European Data Protection Supervisor shall give the Union institution, agency or body which is the subject of the proceedings conducted by the European Data Protection Supervisor the opportunity of being heard on the matter regarding the possible infringement. The European Data Protection Supervisor shall base his or her decisions only on elements and circumstances on which the parties concerned have been able to comment. Complainants, if any, shall be associated closely with the proceedings.	4. Before taking decisions pursuant to this Article, the European Data Protection Supervisor shall give the Union institution, agency or body which is the subject of the proceedings conducted by the European Data Protection Supervisor the opportunity of being heard on the matter regarding the possible infringement. The European Data Protection Supervisor shall base his or her decisions only on elements and circumstances on which the parties concerned have been able to comment. Complainants, if any, shall be associated closely with the proceedings.	4. Before taking decisions pursuant to this Article, the European Data Protection Supervisor shall give the Union institution, agency or body which is the subject of the proceedings conducted by the European Data Protection Supervisor the opportunity of being heard on the matter regarding the possible infringement. The European Data Protection Supervisor shall base his or her decisions only on elements and circumstances on which the parties concerned have been able to comment. Complainants, if any, shall be associated closely with the proceedings.	4. Before taking decisions pursuant to this Article, the European Data Protection Supervisor shall give the Union institution, agency or body which is the subject of the proceedings conducted by the European Data Protection Supervisor the opportunity of being heard on the matter regarding the possible infringement. The European Data Protection Supervisor shall base his or her decisions only on elements and circumstances on which the parties concerned have been able to comment. Complainants, if any, shall be associated closely with the proceedings. Text Origin: Commission Proposal
Article 72(5)				
G 691	5. The rights of defense of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the European Data Protection Supervisor's file, subject to the	5. The rights of defense of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the European Data Protection Supervisor's file, subject to the	5. The rights of defense of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the European Data Protection Supervisor's file, subject to the	5. The rights of defense of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the European Data Protection Supervisor's file, subject to the

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	legitimate interest of individuals or undertakings in the protection of their personal data or business secrets.	legitimate interest of individuals or undertakings in the protection of their personal data or business secrets.	legitimate interest of individuals or undertakings in the protection of their personal data or business secrets.	legitimate interest of individuals or undertakings in the protection of their personal data or business secrets. Text Origin: Commission Proposal
Article 72(6)				
G 692	6. Funds collected by imposition of fines in this Article shall be the income of the general budget of the Union.	6. Funds collected by imposition of fines in this Article shall ~~be the income~~***contribute to the general budget*** of the ~~general budget~~***Union. The fines shall not affect the effective operation*** of the Union ***institution, body or agency fined***.	6. Funds collected by imposition of fines in this Article shall be the income of the general budget of the Union.	6. Funds collected by imposition of fines in this Article shall ~~be the income~~***contribute to the general budget*** of the ~~general budget~~***Union. The fines shall not affect the effective operation*** of the Union ***institution, body or agency fined***. Text Origin: Auxiliary 1
Article 72(6a)				
G 692a		***6a. the European Data Protection Supervisor shall, on an annual basis, notify the AI Office of the fines it has imposed pursuant to this Article.***		***6a. the European Data Protection Supervisor shall, on an annual basis, notify the Commission of the administrative fines it has imposed pursuant to this Article and any litigation or judicial proceedings;*** ***Article 72a*** ***Fines for providers of general purpose AI models***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				1. The Commission may impose on providers of general purpose AI models fines not exceeding 3% of its total worldwide turnover in the preceding financial year or 15 million EUR whichever is higher. Fines should be imposed one year after the entry into application of the relevant provisions in this Regulation in order to allow providers sufficient time to adapt when the Commission finds that the provider intentionally or negligently: ***(a) infringes the relevant provisions of this Regulation;*** ***(b) fails to comply with a request for document or information pursuant to Article [Power to request documentation and information], or supply of incorrect, incomplete or misleading information;*** ***(b) fails to comply with a measure requested under Article [Power to request measures];*** ***(c) fails to make available to the Commission access to the general purpose AI model or general purpose AI model with systemic risk with a view to conduct an evaluation pursuant to Article [Power to conduct evaluations].***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				In fixing the amount of the fine or periodic penalty payment, regard shall be had to the nature, gravity and duration of the infringement, taking due account of the principles of proportionality and appropriateness. The Commission shall also into account commitments made in accordance with Article F(3) or in relevant codes of practice in accordance with Article [Codes of practice]. ***2. Before adopting the decision pursuant to paragraph 1 of this Article, the Commission shall communicate its preliminary findings to the provider of the general purpose AI model or general purpose AI model with systemic risk and give opportunity to be heard.*** ***2a. Fines imposed in accordance with this article shall be proportionate, dissuasive and effective.*** ***2b. The information on the fines shall be also communicated to the Board as appropriate.*** ***3. The Court of Justice of the European Union shall have unlimited jurisdiction to review decisions whereby the Commission***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				has fixed a fine. It may cancel, reduce or increase the fine imposed. ***4. The Commission shall adopt implementing*** ***acts concerning the modalities and practical arrangements for the proceedings in view of possible adoptions of decisions pursuant to paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article xx(x).*** Text Origin: Auxiliary 1
TITLE XI				
G 693	TITLE XI DELEGATION OF POWER AND COMMITTEE PROCEDURE	TITLE XI DELEGATION OF POWER AND COMMITTEE PROCEDURE	TITLE XI DELEGATION OF POWER AND COMMITTEE PROCEDURE	TITLE XI DELEGATION OF POWER AND COMMITTEE PROCEDURE Text Origin: Commission Proposal
Article 73				
G 694	Article 73 Exercise of the delegation	Article 73 Exercise of the delegation	Article 73 Exercise of the delegation	Article 73 Exercise of the delegation Text Origin: Commission Proposal
Article 73(1)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 695	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article. Text Origin: Commission Proposal
Article 73(2)				
G 696	2. The delegation of power referred to in Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall be conferred on the Commission for an indeterminate period of time from [entering into force of the Regulation].	2. The ~~delegation of power~~***power to adopt delegated acts*** referred to in Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall be conferred on the Commission for ~~an indeterminate~~***a*** period of ~~time from~~ ***five years from …*** [~~entering~~***the date of entry*** into force of the Regulation].***The Commission shall draw up a report in respect of the delegation of power not later than 9 months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***	2. The delegation of power referred to in Article ~~4~~***7(1)***, Article ~~7(1)~~***7(3)***, Article 11(3), Article 43(5) and (6) and Article 48(5) shall be conferred on the Commission for ~~an indeterminate~~***a*** period of ~~time~~***five years*** from [***entering into force of the Regulation***~~entering into force of the Regulation~~].	2. The ~~delegation of power~~***power to adopt delegated acts*** referred to in ***[***Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5)***]*** shall be conferred on the Commission for ~~an indeterminate~~***a*** period of ~~time from~~ ***five years from …*** [~~entering~~***the date of entry*** into force of the Regulation].***The Commission shall draw up a report in respect of the delegation of power not later than 9 months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*** Text Origin: Auxiliary 1
Article 73(2a)				
G 696a				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			2a. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the 5 year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.	covered above.
Article 73(3)				
G 697	3. The delegation of power referred to in Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following that of its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	3. The delegation of power referred to in Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following that of its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	3. The delegation of power referred to in Article ~~4~~***7(1)***, Article ~~7(1)~~***7(3)***, Article 11(3), Article 43(5) and (6) and Article 48(5) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following that of its publication in the ***Official Journal of the European Union***~~Official Journal of the European Union~~ or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	3. The delegation of power referred to in ***{***Article ~~4~~***7(1)***, Article ~~7(1)~~***7(3)***, Article 11(3), Article 43(5) and (6) and Article 48(5)***]*** may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following that of its publication in the ***Official Journal of the European Union***~~Official Journal of the European Union~~ or at a later date specified therein. It shall not affect the validity of any delegated acts already in force. Text Origin: Auxiliary 1
Article 73(3a)				
G 697a				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		3a. Before adopting a delegated act, the Commission shall consult with the relevant institutions, the Office, the Advisory Forum and other relevant stakeholders in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. ***Once the Commission decides to draft a delegated act, it shall notify the European Parliament of this fact. This notification does not place an obligation on the Commission to adopt the said act.***		
Article 73(4)				
G 698	4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council. Text Origin: Commission Proposal
Article 73(5)				
G 699	5. Any delegated act adopted pursuant to Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall enter into force only if no objection has been expressed by either the European Parliament or the Council within a	5. Any delegated act adopted pursuant to Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall enter into force only if no objection has been expressed by either the European Parliament or the Council within a	5. Any delegated act adopted pursuant to Article ~~4~~***7(1)***, Article ~~7(1)~~***7(3)***, Article 11(3), Article 43(5) and (6) and Article 48(5) shall enter into force only if no objection has been expressed by either the European Parliament or the Council	5. Any delegated act adopted pursuant to ***[***Article 4***]***, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall enter into force only if no objection has been expressed by either the European Parliament or the Council within a

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.	period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.	within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.	period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council. Text Origin: Commission Proposal
Article 74				
G 700	Article 74 Committee procedure	Article 74 Committee procedure	Article 74 Committee procedure	Article 74 Committee procedure Text Origin: Commission Proposal
Article 74(1)				
G 701	1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011. Text Origin: Commission Proposal
Article 74(2)				
G 702				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. Text Origin: Commission Proposal
TITLE XII				
703	TITLE XII FINAL PROVISIONS	TITLE XII FINAL PROVISIONS	TITLE XII FINAL PROVISIONS	TITLE XII FINAL PROVISIONS Text Origin: Commission Proposal
Article 75				
704	Article 75 Amendment to Regulation (EC) No 300/2008	Article 75 Amendment to Regulation (EC) No 300/2008	Article 75 Amendment to Regulation (EC) No 300/2008	Article 75 Amendment to Regulation (EC) No 300/2008 Text Origin: Commission Proposal
Article 75, first paragraph				
705	In Article 4(3) of Regulation (EC) No 300/2008, the following subparagraph is added:	In Article 4(3) of Regulation (EC) No 300/2008, the following subparagraph is added:	In Article 4(3) of Regulation (EC) No 300/2008, the following subparagraph is added:	In Article 4(3) of Regulation (EC) No 300/2008, the following subparagraph is added: Text Origin: Commission Proposal
Article 75, first paragraph, amending provision, first paragraph				
706				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	“ When adopting detailed measures related to technical specifications and procedures for approval and use of security equipment concerning Artificial Intelligence systems in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Chapter 2, Title III of that Regulation shall be taken into account.”	“ When adopting detailed measures related to technical specifications and procedures for approval and use of security equipment concerning Artificial Intelligence systems in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Chapter 2, Title III of that Regulation shall be taken into account.”	“ “When adopting detailed measures related to technical specifications and procedures for approval and use of security equipment concerning Artificial Intelligence systems in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Chapter 2, Title III of that Regulation shall be taken into account.”	“ When adopting detailed measures related to technical specifications and procedures for approval and use of security equipment concerning Artificial Intelligence systems in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Chapter 2, Title III of that Regulation shall be taken into account.” Text Origin: Commission Proposal
Article 75, first paragraph, amending provision, second paragraph				
G 707	_____	_____	_____	_____ Text Origin: Commission Proposal G
Article 75, first paragraph, amending provision, third paragraph				
G 708	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).” “	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).” “	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).” “	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).” “ Text Origin: Commission Proposal G
Article 76				
G 709	Article 76	Article 76	Article 76	Article 76 G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Amendment to Regulation (EU) No 167/2013	Amendment to Regulation (EU) No 167/2013	Amendment to Regulation (EU) No 167/2013	Amendment to Regulation (EU) No 167/2013 Text Origin: Commission Proposal
Article 76, first paragraph				
G 710	In Article 17(5) of Regulation (EU) No 167/2013, the following subparagraph is added:	In Article 17(5) of Regulation (EU) No 167/2013, the following subparagraph is added:	In Article 17(5) of Regulation (EU) No 167/2013, the following subparagraph is added:	In Article 17(5) of Regulation (EU) No 167/2013, the following subparagraph is added: Text Origin: Commission Proposal
Article 76, first paragraph, amending provision, first paragraph				
G 711	“ When adopting delegated acts pursuant to the first subparagraph concerning artificial intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.	“ When adopting delegated acts pursuant to the first subparagraph concerning artificial intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.	“ “When adopting delegated acts pursuant to the first subparagraph concerning artificial intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.	“ When adopting delegated acts pursuant to the first subparagraph concerning artificial intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account. Text Origin: Commission Proposal
Article 76, first paragraph, amending provision, second paragraph				
G 712				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	_____	_____	_____	_____ Text Origin: Commission Proposal
Article 76, first paragraph, amending provision, third paragraph				
G 713	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …). ”	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …). ”	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).” ”	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …). ” Text Origin: Commission Proposal G
Article 77				
G 714	Article 77 Amendment to Regulation (EU) No 168/2013	Article 77 Amendment to Regulation (EU) No 168/2013	Article 77 Amendment to Regulation (EU) No 168/2013	Article 77 Amendment to Regulation (EU) No 168/2013 Text Origin: Commission Proposal G
Article 77, first paragraph				
G 715	In Article 22(5) of Regulation (EU) No 168/2013, the following subparagraph is added:	In Article 22(5) of Regulation (EU) No 168/2013, the following subparagraph is added:	In Article 22(5) of Regulation (EU) No 168/2013, the following subparagraph is added:	In Article 22(5) of Regulation (EU) No 168/2013, the following subparagraph is added: Text Origin: Commission Proposal G
Article 77, first paragraph, amending provision, first paragraph				
G 716	“	“	“	“ G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	When adopting delegated acts pursuant to the first subparagraph concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX on [Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.	When adopting delegated acts pursuant to the first subparagraph concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX on [Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.	"When adopting delegated acts pursuant to the first subparagraph concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX on [Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.	When adopting delegated acts pursuant to the first subparagraph concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX on [Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account. Text Origin: Commission Proposal
Article 77, first paragraph, amending provision, second paragraph				
G 717	_____	_____	_____	_____ Text Origin: Commission Proposal G
Article 77, first paragraph, amending provision, third paragraph				
G 718	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …). "	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …). "	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …)." "	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …). " Text Origin: Commission Proposal G
Article 78				
G 719	Article 78 Amendment to Directive	Article 78 Amendment to Directive	Article 78 Amendment to Directive	Article 78 Amendment to Directive G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	2014/90/EU	2014/90/EU	2014/90/EU	2014/90/EU Text Origin: Commission Proposal
Article 78, first paragraph				
G 720	In Article 8 of Directive 2014/90/EU, the following paragraph is added:	In Article 8 of Directive 2014/90/EU, the following paragraph is added:	In Article 8 of Directive 2014/90/EU, the following paragraph is added:	In Article 8 of Directive 2014/90/EU, the following paragraph is added: Text Origin: Commission Proposal
Article 78, first paragraph, amending provision, first subparagraph				
G 721	" 4. "For Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, when carrying out its activities pursuant to paragraph 1 and when adopting technical specifications and testing standards in accordance with paragraphs 2 and 3, the Commission shall take into account the requirements set out in Title III, Chapter 2 of that Regulation.	" 4. "For Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, when carrying out its activities pursuant to paragraph 1 and when adopting technical specifications and testing standards in accordance with paragraphs 2 and 3, the Commission shall take into account the requirements set out in Title III, Chapter 2 of that Regulation.	" 4. "**4.** For Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, when carrying out its activities pursuant to paragraph 1 and when adopting technical specifications and testing standards in accordance with paragraphs 2 and 3, the Commission shall take into account the requirements set out in Title III, Chapter 2 of that Regulation.	" 4. "For Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, when carrying out its activities pursuant to paragraph 1 and when adopting technical specifications and testing standards in accordance with paragraphs 2 and 3, the Commission shall take into account the requirements set out in Title III, Chapter 2 of that Regulation. Text Origin: Commission Proposal

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 78, first paragraph, amending provision, first subparagraph, first paragraph				
722	_____	_____	_____	_____ Text Origin: Commission Proposal
Article 78, first paragraph, amending provision, first subparagraph, second paragraph				
723	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”. "	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”. "	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”. "	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”. " Text Origin: Commission Proposal
Article 79				
724	Article 79 Amendment to Directive (EU) 2016/797	Article 79 Amendment to Directive (EU) 2016/797	Article 79 Amendment to Directive (EU) 2016/797	Article 79 Amendment to Directive (EU) 2016/797 Text Origin: Commission Proposal
Article 79, first paragraph				
725	In Article 5 of Directive (EU) 2016/797, the following paragraph is added:	In Article 5 of Directive (EU) 2016/797, the following paragraph is added:	In Article 5 of Directive (EU) 2016/797, the following paragraph is added:	In Article 5 of Directive (EU) 2016/797, the following paragraph is added: Text Origin: Commission Proposal
Article 79, first paragraph, amending provision, first subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 726	" 12. “When adopting delegated acts pursuant to paragraph 1 and implementing acts pursuant to paragraph 11 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.	" 12. “When adopting delegated acts pursuant to paragraph 1 and implementing acts pursuant to paragraph 11 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.	" 12. “***12.*** When adopting delegated acts pursuant to paragraph 1 and implementing acts pursuant to paragraph 11 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.	" 12. “When adopting delegated acts pursuant to paragraph 1 and implementing acts pursuant to paragraph 11 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account. Text Origin: Commission Proposal
Article 79, first paragraph, amending provision, first subparagraph, first paragraph				
G 727	_____	_____	_____	_____ Text Origin: Commission Proposal
Article 79, first paragraph, amending provision, first subparagraph, second paragraph				
G 728	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”. "	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”. "	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”. "	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”. " Text Origin: Commission Proposal
Article 80				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 729	Article 80 Amendment to Regulation (EU) 2018/858	Article 80 Amendment to Regulation (EU) 2018/858	Article 80 Amendment to Regulation (EU) 2018/858	Article 80 Amendment to Regulation (EU) 2018/858 Text Origin: Commission Proposal
Article 80, first paragraph				
G 730	In Article 5 of Regulation (EU) 2018/858 the following paragraph is added:	In Article 5 of Regulation (EU) 2018/858 the following paragraph is added:	In Article 5 of Regulation (EU) 2018/858 the following paragraph is added:	In Article 5 of Regulation (EU) 2018/858 the following paragraph is added: Text Origin: Commission Proposal
Article 80, first paragraph, amending provision, first subparagraph				
G 731	" 4. "When adopting delegated acts pursuant to paragraph 3 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council *, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.	" 4. "When adopting delegated acts pursuant to paragraph 3 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council *, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.	" 4. "***4.*** When adopting delegated acts pursuant to paragraph 3 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council *, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.	" 4. "When adopting delegated acts pursuant to paragraph 3 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council *, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account. Text Origin: Commission Proposal
Article 80, first paragraph, amending provision, first subparagraph, first paragraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 732	_____		_____	_____ Text Origin: Commission Proposal
Article 80, first paragraph, amending provision, first subparagraph, second paragraph				
G 733	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”. "	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”. "	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”. "	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”. " Text Origin: Commission Proposal
Article 81				
G 734	Article 81 Amendment to Regulation (EU) 2018/1139	Article 81 Amendment to Regulation (EU) 2018/1139	Article 81 Amendment to Regulation (EU) 2018/1139	Article 81 Amendment to Regulation (EU) 2018/1139 Text Origin: Commission Proposal
Article 81, first paragraph				
G 735	Regulation (EU) 2018/1139 is amended as follows:	Regulation (EU) 2018/1139 is amended as follows:	Regulation (EU) 2018/1139 is amended as follows:	Regulation (EU) 2018/1139 is amended as follows: Text Origin: Commission Proposal
Article 81, first paragraph, point (1)				
G 736	(1) In Article 17, the following	(1) In Article 17, the following	(1) In Article 17, the following	(1) In Article 17, the following

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	paragraph is added:	paragraph is added:	paragraph is added:	paragraph is added: Text Origin: Commission Proposal
Article 81, first paragraph, point (1), amending provision, first subparagraph				
G 737	" 3. "Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 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 in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 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 in the meaning of Regulation (EU) YYY/XX [***on Artificial Intelligence***~~on Artificial Intelligence~~] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 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 in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account. Text Origin: Commission Proposal
Article 81, first paragraph, point (1), amending provision, first subparagraph, first paragraph				
G 738	_____		_____	_____ Text Origin: Commission Proposal
Article 81, first paragraph, point (1), amending provision, first subparagraph, second paragraph				
G 739	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …)." "	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …)." "	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …)." "	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …)." "

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Article 81, first paragraph, point (2)				
G 740	(2) In Article 19, the following paragraph is added:	(2) In Article 19, the following paragraph is added:	(2) In Article 19, the following paragraph is added:	(2) In Article 19, the following paragraph is added: Text Origin: Commission Proposal
Article 81, first paragraph, point (2), amending provision, numbered paragraph (4)				
G 741	“ 4. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account. ”	“ 4. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account. ”	“ 4. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.” ”	“ 4. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account. ” Text Origin: Commission Proposal
Article 81, first paragraph, point (3)				
G 742	(3) In Article 43, the following paragraph is added:	(3) In Article 43, the following paragraph is added:	(3) In Article 43, the following paragraph is added:	(3) In Article 43, the following paragraph is added: Text Origin: Commission

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Proposal
Article 81, first paragraph, point (3), amending provision, numbered paragraph (4)				
G 743	“ 4. When adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account. ”	“ 4. When adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account. ”	“ 4. When adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.” ”	“ 4. When adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account. ” Text Origin: Commission Proposal
Article 81, first paragraph, point (4)				
G 744	(4) In Article 47, the following paragraph is added:	(4) In Article 47, the following paragraph is added:	(4) In Article 47, the following paragraph is added:	(4) In Article 47, the following paragraph is added: Text Origin: Commission Proposal
Article 81, first paragraph, point (4), amending provision, numbered paragraph (3)				
G 745	“ 3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety	“ 3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety	“ 3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety	“ 3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account. ”	components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account. ”	components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.” ”	components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account. ” Text Origin: Commission Proposal
Article 81, first paragraph, point (5)				
G 746	(5) In Article 57, the following paragraph is added:	(5) In Article 57, the following paragraph is added:	(5) In Article 57, the following paragraph is added:	(5) In Article 57, the following paragraph is added: Text Origin: Commission Proposal
Article 81, first paragraph, point (5), amending provision, first paragraph				
G 747	“ When adopting those implementing acts concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account. ”	“ When adopting those implementing acts concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account. ”	“ When adopting those implementing acts concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.” ”	“ When adopting those implementing acts concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account. ” Text Origin: Commission Proposal

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 81, first paragraph, point (6)				
748	(6) In Article 58, the following paragraph is added:	(6) In Article 58, the following paragraph is added:	(6) In Article 58, the following paragraph is added:	(6) In Article 58, the following paragraph is added: Text Origin: Commission Proposal
Article 81, first paragraph, point (6), amending provision, numbered paragraph (3)				
749	" 3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] , the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.. "	" 3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] , the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.. "	" 3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] , the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.". "	" 3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] , the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.. " Text Origin: Commission Proposal
Article 81a (new)				
749a		***Article 81a*** ***Amendment to Regulation (EU) 2019/1020*** ***Regulation (EU) 2019/1020 is amended as follows:*** ***in Article 14(4), the following paragraph is added:***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		"(l). the power to implement the powers provided for in this Article remotely, where applicable;"		
Article 82				
750	Article 82 Amendment to Regulation (EU) 2019/2144	Article 82 Amendment to Regulation (EU) 2019/2144	Article 82 Amendment to Regulation (EU) 2019/2144	Article 82 Amendment to Regulation (EU) 2019/2144 Text Origin: Commission Proposal
Article 82a (new)				
750a		*Article 82a* *Better Regulation* *in taking into account the requirements of this Regulation pursuant to the Amendments in Articles 75, 76, 77, 78, 79, 80, 81, and 82, the Commission shall conduct an analysis and consult relevant stakeholders to determine potential gaps as well as overlaps between existing sectoral legislation and the provisions of this Regulation.*		
Article 82b (new)				
750b		*Article 82b* *Guidelines from the Commission*		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		on the implementation of this Regulation ***1. The Commission shall develop, in consultation with the AI office, guidelines on the practical implementation of this Regulation, and in particular on:*** ***(a) the application of the requirements referred to in Articles 8 - 15 and Article 28 to 28b;*** ***(b) the prohibited practices referred to in Article 5;*** ***(c) the practical implementation of the provisions related to substantial modification;*** ***(d) the practical circumstances where the output of an AI system referred to in Annex III would pose a significant risk of harm to the health, safety or fundamental rights of natural persons as referred to in Article 6, paragraph 2, including examples in relation to high risk AI systems referred to in Annex III;*** ***(e) the practical implementation of transparency obligations laid down in Article 52;*** ***(f) the development of codes of conduct referred to in Article 69;*** ***(g) the relationship of this Regulation with other relevant Union law, including as regards consistency in their enforcement.*** ***(h) the practical implementation of Article 12, Article 28b on environmental impact of***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		foundation models and Annex IV 3(b), particularly the measurement and logging methods to enable calculations and reporting of the environmental impact of systems to comply with the obligations in this Regulation, including carbon footprint and energy efficiency, taking into account state-of-the-art methods and economies of scale. When issuing such guidelines, the Commission shall pay particular attention to the needs of SMEs including start-ups, local public authorities and sectors most likely to be affected by this Regulation. 2. Upon request of the Member States or the AI Office, or on its own initiative, the Commission shall update already adopted guidelines when deemed necessary.		
Article 82, first paragraph				
G 751	In Article 11 of Regulation (EU) 2019/2144, the following paragraph is added:	In Article 11 of Regulation (EU) 2019/2144, the following paragraph is added:	In Article 11 of Regulation (EU) 2019/2144, the following paragraph is added:	In Article 11 of Regulation (EU) 2019/2144, the following paragraph is added: Text Origin: Commission Proposal G
Article 82, first paragraph, amending provision, first subparagraph				
G 752	” 3. “When adopting the	” 3. “When adopting the	” 3. “When adopting the	” 3. “When adopting the G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	implementing acts pursuant to paragraph 2, concerning artificial intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.	implementing acts pursuant to paragraph 2, concerning artificial intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.	implementing acts pursuant to paragraph 2, concerning artificial intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.	implementing acts pursuant to paragraph 2, concerning artificial intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account. Text Origin: Commission Proposal
Article 82, first paragraph, amending provision, first subparagraph, first paragraph				
G 753	_____	_____	_____	_____ Text Origin: Commission Proposal G
Article 82, first paragraph, amending provision, first subparagraph, second paragraph				
G 754	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).. ”	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).. ”	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”. ”	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).. ” Text Origin: Commission Proposal G
Article 82a				
754a				***Article 82a*** ***Guidelines from the Commission on the implementation of this***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Regulation
Article 82a(1), first subparagraph				
754b				***1. The Commission shall develop guidelines on the practical implementation of this Regulation, and in particular on:***
Article 82a(1), first subparagraph, point (a)				
754c				***(a) the application of the requirements and obligations referred to in Articles 8 - 15 and Article 28;***
Article 82a(1), first subparagraph, point (b)				
754d				***(b) the prohibited practices referred to in Article 5;***
Article 82a(1), first subparagraph, point (c)				
754e				***(c) the practical implementation of the provisions related to substantial modification;***
Article 82a(1), first subparagraph, point (d)				
754f				***(d) the practical implementation of transparency obligations laid down in Article 52;***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 82a(1), first subparagraph, point (e)				
754g				***(e) detailed information on the relationship of this Regulation with the legislation referred to in Annex II of this Regulation as well as other relevant Union law, including as regards consistency in their enforcement;***
Article 82a(1), first subparagraph, point (f)				
754h				***(f) the application of the definition of an AI system as set out in Article 3(1).***
Article 82a(1), second subparagraph				
754i				***When issuing such guidelines, the Commission shall pay particular attention to the needs of SMEs including start-ups, local public authorities and sectors most likely to be affected by this Regulation.***
Article 82a(1), third subparagraph				
754j				***The guidelines referred to in the first subparagraph shall take due account of the generally acknowledged state of the art on AI, as well as of relevant harmonised***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				standards and common specifications that are referred to in Articles 40 and 41, or of those harmonised standards or technical specifications that are set out pursuant to Union harmonisation law.
Article 82a(2)				
754k				***2. Upon request of the Member States or the AI Office, or on its own initiative, the Commission shall update already adopted guidelines when deemed necessary.***
Article 83				
G 755	Article 83 AI systems already placed on the market or put into service	Article 83 AI systems already placed on the market or put into service	Article 83 AI systems already placed on the market or put into service	Article 83 AI systems already placed on the market or put into service Text Origin: Commission Proposal G
Article 83(1), first subparagraph				
G 756	1. This Regulation shall not apply to the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before [12 months after the	1. ~~This Regulation shall not apply to~~***Operators of*** the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service ~~before [12 months after~~ ***prior***	1. This Regulation shall not apply to the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before ***[12 months after the***	1. ~~This Regulation shall not apply to the~~ ***Without prejudice to the application of Article 5 as referred in Article 85 (3) (-aa)*** AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	date of application of this Regulation referred to in Article 85(2)], unless the replacement or amendment of those legal acts leads to a significant change in the design or intended purpose of the AI system or AI systems concerned.	***to … [***the date of ~~application~~***entry into force*** of this Regulation***] shall take the necessary steps to comply with the requirements laid down in this Regulation by … [four years after the date of entry into force of this Regulation]*** ~~referred to in Article 85(2)], unless the replacement or amendment of those legal acts leads to a significant change in the design or intended purpose of the AI system or AI systems concerned~~.	***date of application of this Regulation referred to in Article 85(2)]***~~[12 months after the date of application of this Regulation referred to in Article 85(2)]~~, unless the replacement or amendment of those legal acts leads to a significant change in the design or intended purpose of the AI system or AI systems concerned.	have been placed on the market or put into service before ~~[~~12 months after the date of application of this Regulation referred to in Article 85(2)~~], unless the replacement or amendment of those legal acts leads to a significant change in the design or intended purpose of the AI system or AI systems concerned~~ ***shall be brought into compliance with this Regulation by end of 2030***.
Article 83(1), second subparagraph				
G 757	The requirements laid down in this Regulation shall be taken into account, where applicable, in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts.	The requirements laid down in this Regulation shall be taken into account~~, where applicable,~~ in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts ***and whenever those legal acts are replaced or amended***.	The requirements laid down in this Regulation shall be taken into account, where applicable, in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts.	The requirements laid down in this Regulation shall be taken into account~~, where applicable,~~ in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts ***and whenever those legal acts are replaced or amended***. Text Origin: Auxiliary 1 G
Article 83(2)				
G 758	2. This Regulation shall apply to the high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of	2. This Regulation shall apply to ~~the~~***operators of*** high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into	2. This Regulation shall apply to the high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [***date of***	2. ***Without prejudice to the application of Article 5 as referred in Article 85 (3) (-aa)*** this Regulation shall apply to ~~the~~***operators of*** high-risk AI G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	application of this Regulation referred to in Article 85(2)], only if, from that date, those systems are subject to significant changes in their design or intended purpose.	service before [date of application of this Regulation referred to in Article 85(2)], only if, from that date, those systems are subject to ~~significant changes in their design or~~***substantial modifications as defined in Article 3(23). In the case of high-risk AI systems*** intended ~~purpose~~***to be used by public authorities, providers and deployers of such systems shall take the necessary steps to comply with the requirements of the present Regulation [two years after the date of entry into force of this Regulation]***.	***application of this Regulation referred to in Article 85(2)***~~date of application of this Regulation referred to in Article 85(2)~~], only if, from that date, those systems are subject to significant changes in their design or intended purpose.	systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], only if, from that date, those systems are subject to significant changes in their ~~design or~~***designs. In the case of high-risk AI systems*** intended ~~purpose~~***to be used by public authorities, providers and deployers of such systems shall take the necessary steps to comply with the requirements of the present Regulation four years after the date of entry into application of this Regulation.*** ***3. Providers of general-purpose AI models that have been placed on the market before [date of application of this Regulation referred to in point a) Article 85(3)] shall take the necessary steps in order to comply with the obligations laid down in this Regulation by [2 years after the date of entry into application of this Regulation referred to in point a) of 85(3)]***. Text Origin: Auxiliary 1
Article 84				
759	Article 84 Evaluation and review	Article 84 Evaluation and review	Article 84 Evaluation and review	Article 84 Evaluation and review

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Article 84(1)				
G 760	1. The Commission shall assess the need for amendment of the list in Annex III once a year following the entry into force of this Regulation.	1. ***After consulting the AI Office,*** the Commission shall assess the need for amendment of the list in Annex III***, including the extension of existing area headings or addition of new area headings in that Annex, the list of prohibited AI practices in Article 5, and the list of AI systems requiring additional transparency measures in Article 52*** once a year following the entry into force of this Regulation ***and following a recommendation of the Office***. ***The Commission shall submit the findings of that assessment to the European Parliament and the Council.***	1. The Commission shall assess the need for amendment of the list in Annex III ~~once a year~~***every 24 months*** following the entry into force of this Regulation ***and until the end of the period of the delegation of power. The findings of that assessment shall be presented to the European Parliament and the Council***.	1. The Commission shall assess the need for amendment of the list in Annex III***, the list of prohibited AI practices in Article 5,*** once a year following the entry into force of this Regulation***, and until the end of the period of the delegation of power***. ***The Commission shall submit the findings of that assessment to the European Parliament and the Council.*** Text Origin: EP Mandate
Article 84(2)				
G 761	2. By [three years after the date of application of this Regulation referred to in Article 85(2)] and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The	2. By ***…*** [~~three~~***two*** years after the date of application of this Regulation referred to in Article 85(2)] and every ~~four~~***two*** years thereafter, the Commission***, together with the AI office,*** shall submit a report on the evaluation and review of this Regulation to the European	2. By [***three years after the date of application of this Regulation referred to in Article 85(2)***~~three years after the date of application of this Regulation referred to in Article 85(2)~~] and every four years thereafter, the Commission shall submit a report on the evaluation and	2. By ~~[~~***two years after the date of application of this Regulation referred to in Article 85(2) and every four years thereafter, the Commission shall evaluate and report to the European Parliament and to the Council on the need for amendment of the following:***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	reports shall be made public.	Parliament and to the Council. The reports shall be made public.	review of this Regulation to the European Parliament and to the Council. The reports shall be made public.	***- the need for extension of existing area headings or addition of new area headings in Annex III,*** ***- the list of AI systems requiring additional transparency measures in Article 52*** ***- effectiveness of the supervision and governance system*** ***2a. By*** three years after the date of application of this Regulation referred to in Article ~~*85(2)]*~~***85(3)*** and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council***. This report shall include an assessment with regard to the structure of enforcement and the possible need for an Union agency to resolve any identified shortcomings. On the basis of the findings that report shall, where appropriate, be accompanied by a proposal for amendment of this Regulation***. The reports shall be made public. Text Origin: Auxiliary 1
Article 84(3)				
G 762	3. The reports referred to in paragraph 2 shall devote specific attention to the following:	3. The reports referred to in paragraph 2 shall devote specific attention to the following:	3. The reports referred to in paragraph 2 shall devote specific attention to the following:	3. The reports referred to in paragraph 2 shall devote specific attention to the following: G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Article 84(3), point (a)				
G 763	(a) the status of the financial and human resources of the national competent authorities in order to effectively perform the tasks assigned to them under this Regulation;	(a) the status of the financial, ***technical*** and human resources of the national competent authorities in order to effectively perform the tasks assigned to them under this Regulation;	(a) the status of the financial ***resources, technical equipment*** and human resources of the national competent authorities in order to effectively perform the tasks assigned to them under this Regulation;	(a) the status of the financial, ***technical*** and human resources of the national competent authorities in order to effectively perform the tasks assigned to them under this Regulation; Text Origin: Auxiliary 1
Article 84(3), point (b)				
G 764	(b) the state of penalties, and notably administrative fines as referred to in Article 71(1), applied by Member States to infringements of the provisions of this Regulation.	(b) the state of penalties, and notably administrative fines as referred to in Article 71(1), applied by Member States to infringements of the provisions of this Regulation.	(b) the state of penalties, and notably administrative fines as referred to in Article 71(1), applied by Member States to infringements of the provisions of this Regulation.	(b) the state of penalties, and notably administrative fines as referred to in Article 71(1), applied by Member States to infringements of the provisions of this Regulation. Text Origin: Commission Proposal
Article 84(3), point (ba)				
G 764a		***(ba) the level of the development of harmonised standards and common specifications for Artificial Intelligence;***		***(ba) ba) adopted harmonised standards and common specifications developed to support this Regulation.*** ***bb) the number of companies that enter the market after the enter into***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				application of the regulation and how many of them are SMEs. Text Origin: Auxiliary 1
Article 84(3), point (bb)				
764b		***(bb) the levels of investments in research, development and application of AI systems throughout the Union;***		
Article 84(3), point (bc)				
764c		***(bc) the competitiveness of the aggregated European AI sector compared to AI sectors in third countries;***		
Article 84(3), point (bd)				
764d		***(bd) the impact of the Regulation with regards to the resource and energy use, as well as waste production and other environmental impact;***		
Article 84(3), point (be)				
764e		***(be) the implementation of the coordinated plan on AI, taking into account the different level of progress among Member States and***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		identifying existing barriers to innovation in AI;		
Article 84(3), point (bf)				
764f		***(bf) the update of the specific requirements regarding the sustainability of AI systems and foundation models, building on the reporting and documentation requirement in Annex IV and in Article 28b;***		
Article 84(3), point (bg)				
764g		***(bg) the legal regime governing foundation models;***		
Article 84(3), point (bh)				
764h		***(bh) the list of unfair contractual terms within Article 28a taking into account new business practices if necessary;***		
Article 84(3), point (bb)				
764i		***3a. By ... [two years after the date of entry into application of this Regulation referred to in Article 85(2)] the Commission shall evaluate the functioning of the AI office, whether the office has been***		***(bb) By ... [two years after the date of entry into application of this Regulation referred to in Article 85(2)] the Commission shall evaluate the functioning of the AI office, whether the office has been***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		given sufficient powers and competences to fulfil its tasks and whether it would be relevant and needed for the proper implementation and enforcement of this Regulation to upgrade the Office and its enforcement competences and to increase its resources. The Commission shall submit this evaluation report to the European Parliament and to the Council.		***given sufficient powers and competences to fulfil its tasks and whether it would be relevant and needed for the proper implementation and enforcement of this Regulation to upgrade the Office and its enforcement competences and to increase its resources. The Commission shall submit this evaluation report to the European Parliament and to the Council.***
Article 84(3a)				
764j				***3a. By two years [after the date of application of this Regulation referred to in Article 85(2)] and every four years thereafter, the Commission shall submit a report on the review of the progress on the development of standardization deliverables on energy efficient development of general-purpose models and asses the need for further measures or actions, including binding measures or actions. The report shall be submitted to the European Parliament and to the Council and it shall be made public.***
Article 84(4)				
765	4. Within [three years after the date	4. Within ***…*** [~~*three years*~~***one year***	4. Within [***three years after the date***	4. Within ***…*** [~~*three years*~~***two year***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	of application of this Regulation referred to in Article 85(2)] and every four years thereafter, the Commission shall evaluate the impact and effectiveness of codes of conduct to foster the application of the requirements set out in Title III, Chapter 2 and possibly other additional requirements for AI systems other than high-risk AI systems.	after the date of application of this Regulation referred to in Article 85(2)] and every ~~four~~***two*** years thereafter, the Commission shall evaluate the impact and effectiveness of codes of conduct to foster the application of the requirements set out in Title III, Chapter 2 and possibly other additional requirements for AI systems other than high-risk AI systems~~.~~***;***	***of application of this Regulation referred to in Article 85(2)*** ~~three years after the date of application of this Regulation referred to in Article 85(2)~~] and every four years thereafter, ***where appropriate,*** the Commission shall evaluate the impact and effectiveness of ***voluntary*** codes of conduct to foster the application of the requirements set out in Title III, Chapter 2 ***for AI systems other than high-risk AI systems*** and possibly other additional requirements for AI systems***, including as regards environmental sustainability*** ~~other than high-risk AI systems~~.	after the date of application of this Regulation referred to in Article 85(2)] and every ~~four~~***three*** years thereafter, the Commission shall evaluate the impact and effectiveness of ***voluntary*** codes of conduct to foster the application of the requirements set out in Title III, Chapter 2 ***for AI systems other than high-risk AI systems*** and possibly other additional requirements for AI systems other than high-risk AI systems~~.~~***, including as regards environmental sustainability;*** Text Origin: EP Mandate
Article 84(5)				
G 766	5. For the purpose of paragraphs 1 to 4 the Board, the Member States and national competent authorities shall provide the Commission with information on its request.	5. For the purpose of paragraphs 1 to 4 the ~~Board~~***AI Office***, the Member States and national competent authorities shall provide the Commission with information on its request ***without undue delay***.	5. For the purpose of paragraphs ~~1~~***1a*** to 4 the Board, the Member States and national competent authorities shall provide the Commission with information on its request.	5. ***5.*** For the purpose of paragraphs 1 to 4 the Board, the Member States and national competent authorities shall provide the Commission with information on its request~~.~~***, without undue delay*** Text Origin: Auxiliary 1
Article 84(6)				
G 767	6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions	6. in carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions	6. In carrying out the evaluations and reviews referred to in paragraphs ~~1~~***1a*** to 4 the Commission shall take into account the positions	6. ***6.*** In carrying out the evaluations and reviews referred to in paragraphs 1~~-~~ to 4 the Commission shall take into account the positions

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	and findings of the Board, of the European Parliament, of the Council, and of other relevant bodies or sources.	and findings of the ~~Board,~~ ***-AI Office*** of the European Parliament, of the Council, and of other relevant bodies or sources ***and shall consult relevant stakeholders. The result of such consultation shall be attached to the report;***	and findings of the Board, of the European Parliament, of the Council, and of other relevant bodies or sources.	and findings of the Board, of the European Parliament, of the Council, and of other relevant bodies or sources. Text Origin: Auxiliary 1
Article 84(7)				
G 768	7. The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology and in the light of the state of progress in the information society.	7. the Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology***, the effect of AI systems on health and safety, fundamental rights, the environment, equality, and accessibility for persons with disabilities, democracy and rule of law*** and in the light of the state of progress in the information society.	7. The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology and in the light of the state of progress in the information society.	7. The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology***, the effect of AI systems on health and safety, fundamental rights*** and in the light of the state of progress in the information society. Text Origin: Presidency3 G
Article 84(7a)				
G 768a		***7a. To guide the evaluations and reviews referred to in paragraphs 1 to 4 of this Article, the Office shall undertake to develop an objective and participative methodology for the evaluation of risk level based on the criteria outlined in the relevant articles and inclusion of new systems in: the list in Annex III, including the extension of existing***		***7a. To guide the evaluations and reviews referred to in paragraphs 1 to 4 of this Article, the Office shall undertake to develop an objective and participative methodology for the evaluation of risk level based on the criteria outlined in the relevant articles and inclusion of new systems in: the list in Annex III, including the extension of existing*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		area headings or addition of new area headings in that Annex; the list of prohibited practices laid down in Article 5; and the list of AI systems requiring additional transparency measures pursuant to Article 52.		***area headings or addition of new area headings in that Annex; the list of prohibited practices laid down in Article 5; and the list of AI systems requiring additional transparency measures pursuant to Article 52.*** Text Origin: EP Mandate
Article 84(7b)				
G 768b		***7b. Any amendment to this Regulation pursuant to paragraph 7 of this Article, or relevant future delegated or implementing acts, which concern sectoral legislation listed in Annex II Ssection B, shall take into account the regulatory specificities of each sector, and existing governance, conformity assessment and enforcement mechanisms and authorities established therein.***		***7b. Any amendment to this Regulation pursuant to paragraph 7 of this Article, or relevant future delegated or implementing acts, which concern sectoral legislation listed in Annex II Section B, shall take into account the regulatory specificities of each sector, and existing governance, conformity assessment and enforcement mechanisms and authorities established therein.*** Text Origin: Auxiliary 1
Article 84(7c)				
G 768c		***7c. By … [five years from the date of application of this Regulation], the Commission shall carry out an assessment of the enforcement of this Regulation and shall report it to the European Parliament, the Council and the European***		***7c. By … [five years from the date of application of this Regulation], the Commission shall carry out an assessment of the enforcement of this Regulation and shall report it to the European Parliament, the Council and the European***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Economic and Social Committee, taking into account the first years of application of the Regulation. On the basis of the findings that report shall, where appropriate, be accompanied by a proposal for amendment of this Regulation with regard to the structure of enforcement and the need for an Union agency to resolve any identified shortcomings.		***Economic and Social Committee, taking into account the first years of application of the Regulation. On the basis of the findings that report shall, where appropriate, be accompanied by a proposal for amendment of this Regulation with regard to the structure of enforcement and the need for an Union agency to resolve any identified shortcomings.*** Text Origin: Presidency1
Article 85				
G 769	Article 85 Entry into force and application	Article 85 Entry into force and application	Article 85 Entry into force and application	Article 85 Entry into force and application Text Origin: Commission Proposal
Article 85(1)				
G 770	1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	1. This Regulation shall enter into force on the twentieth day following that of its publication in the ***Official Journal of the European Union***~~*Official Journal of the European Union*~~.	1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. Text Origin: Commission Proposal
Article 85(2)				
G 771	2. This Regulation shall apply from	2. This Regulation shall apply from	2. This Regulation shall apply from	2. This Regulation shall apply from

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	[24 months following the entering into force of the Regulation].	[24 months following the entering into force of the Regulation].	[~~24~~***36*** months following the entering into force of the Regulation].	[24 months following the entering into force of the Regulation]. ***With regard to the obligation referred to in Article 53(1), this obligation shall include either that at least one regulatory sandbox per Member State shall be operational on this day or that the Member State participates in the sandbox of another Member State ****
Article 85(3)				
G 772	3. By way of derogation from paragraph 2:	3. By way of derogation from paragraph 2:	3. By way of derogation from paragraph 2:	3. By way of derogation from paragraph 2: Text Origin: Commission Proposal
Article 85(3),				
G 773	(a) Title III, Chapter 4 and Title VI shall apply from [three months following the entry into force of this Regulation];	(a) Title III, Chapter 4 and Title VI shall apply from [three months following the entry into force of this Regulation];	(a) Title III, Chapter 4~~–~~ and Title VI shall apply from [~~three~~***twelve*** months following the entry into force of this Regulation];	~~(a)~~ ***(-a) Title I and II [Prohibitions] shall apply from [six months following the entry into force of this Regulation];*** ***(a)*** Title III~~,~~ Chapter 4~~ and~~***,*** Title VI ***, Title VIIIa [GPAI], Title X [Penalties]*** shall apply from [~~three~~***twelve*** months following the entry into force of this Regulation];
Article 85(3), point (b)				
G 774				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(b) Article 71 shall apply from [twelve months following the entry into force of this Regulation].	(b) Article 71 shall apply from [twelve months following the entry into force of this Regulation].	(b) Article 71 shall apply from [twelve months following the entry into force of this Regulation].	(b) Article ~~71~~***6(1) and the corresponding obligations in this Regulation*** shall apply from [~~twelve~~***36*** months following the entry into force of this Regulation]. Text Origin: Commission Proposal
Article 85, fourth paragraph -a				
G 774a				***Codes of practices shall be ready at the latest nine months after the entry into force of this Regulation. The AI Office shall take the necessary steps, including inviting providers pursuant to Article 52e paragraph 5.*** G
Article 85, fourth paragraph				
G 775	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.	This Regulation shall be binding in its entirety and directly applicable in all Member States. Text Origin: Commission Proposal G
Formula				
G 776	Done at Brussels,	Done at Brussels,	Done at Brussels,	Done at Brussels, Text Origin: Commission Proposal G

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Formula				
777	For the European Parliament	For the European Parliament	For the European Parliament	For the European Parliament Text Origin: Commission Proposal
Formula				
778	The President	The President	The President	The President Text Origin: Commission Proposal
Formula				
779	For the Council	For the Council	For the Council	For the Council Text Origin: Commission Proposal
Formula				
780	The President	The President	The President	The President Text Origin: Commission Proposal
Annex I				
781	Annex I ARTIFICIAL INTELLIGENCE TECHNIQUES AND APPROACHESreferred to in Article 3, point 1	*deleted*	*deleted*	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex I, first paragraph				
G *782*	*(a)* Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning;	*deleted*	*deleted*	G
Annex I, second paragraph				
G *783*	*(b)* Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;	*deleted*	*deleted*	G
Annex I, third paragraph				
G *784*	*(c)* Statistical approaches, Bayesian estimation, search and optimization methods.	*deleted*	*deleted*	G
Annex II				
G *785*	*Annex II* LIST OF UNION HARMONISATION LEGISLATION	Annex II LIST OF UNION HARMONISATION LEGISLATION	Annex II LIST OF UNION HARMONISATION LEGISLATION	Annex II LIST OF UNION HARMONISATION LEGISLATION Text Origin: Commission Proposal G
Annex II, Part I				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 786	Part I Section A. List of Union harmonisation legislation based on the New Legislative Framework	Part I Section A. List of Union harmonisation legislation based on the New Legislative Framework	Part I Section A~~.~~ – List of Union harmonisation legislation based on the New Legislative Framework	Part I Section A. List of Union harmonisation legislation based on the New Legislative Framework Text Origin: Commission Proposal
Annex II, point 1.				
G 787	1. 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) [as repealed by the Machinery Regulation];	1. 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) [as repealed by the Machinery Regulation];	1. 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) [as repealed by the Machinery Regulation];	1. 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) [as repealed by the Machinery Regulation]; Text Origin: Commission Proposal
Annex II, point 2.				
G 788	2. 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);	2. 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);	2. 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);	2. 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); Text Origin: Commission Proposal
Annex II, point 3.				
G 789	3. Directive 2013/53/EU of the European Parliament and of the	3. Directive 2013/53/EU of the European Parliament and of the	3. Directive 2013/53/EU of the European Parliament and of the	3. Directive 2013/53/EU of the European Parliament and of the

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	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);	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);	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);	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); Text Origin: Commission Proposal
Annex II, point 4.				
G 790	4. 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);	4. 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);	4. 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);	4. 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); Text Origin: Commission Proposal
Annex II, point 5.				
G 791	5. Directive 2014/34/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 equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309);	5. Directive 2014/34/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 equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309);	5. Directive 2014/34/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 equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309);	5. Directive 2014/34/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 equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309); Text Origin: Commission Proposal

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Annex II, point 6.				
G 792	6. 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);	6. 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);	6. 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);	6. 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); Text Origin: Commission Proposal G
Annex II, point 7.				
G 793	7. 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);	7. 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);	7. 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);	7. 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); Text Origin: Commission Proposal G
Annex II, point 8.				
G 794	8. 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,	8. 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,	8. 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,	8. 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, G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	31.3.2016, p. 1);	31.3.2016, p. 1);	31.3.2016, p. 1);	31.3.2016, p. 1); Text Origin: Commission Proposal
Annex II, point 9.				
G 795	9. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);	9. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);	9. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);	9. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51); Text Origin: Commission Proposal
Annex II, point 10.				
G 796	10. 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);	10. 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);	10. 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);	10. 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); Text Origin: Commission Proposal
Annex II, point 11.				
G 797	11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive	11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive	11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive	11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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;	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;	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;	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; Text Origin: Commission Proposal
Annex II, point 12.				
G 798	12. 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).	12. 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).	12. 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).	12. 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). Text Origin: Commission Proposal
Annex II, Part II				
G 799	Part II Section B. List of other Union harmonisation legislation	Part II Section B. List of other Union harmonisation legislation	Part II Section B. List of other Union harmonisation legislation	Part II Section B. List of other Union harmonisation legislation Text Origin: Commission Proposal
Annex II, point 13.				
G 800	13. Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on	13. Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on	13. Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on	13. Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on

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	common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72).	common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72).	common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72).	common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72). Text Origin: Commission Proposal
Annex II, point 14.				
G 801	14. Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52);	14. Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52);	14. Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52);	14. Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52); Text Origin: Commission Proposal
Annex II, point 15.				
G 802	15. Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1);	15. Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1);	15. Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1);	15. Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1); Text Origin: Commission Proposal
Annex II, point 16.				
G 803	16. Directive 2014/90/EU of the	16. Directive 2014/90/EU of the	16. Directive 2014/90/EU of the	16. Directive 2014/90/EU of the

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	European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146);	European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146);	European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146);	European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146); Text Origin: Commission Proposal
Annex II, point 17.				
G 804	17. Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44).	17. Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44).	17. Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44)~~.~~;	17. Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44). Text Origin: Commission Proposal
Annex II, point 18.				
G 805	18. Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1); 3. Regulation (EU) 2019/2144 of the European Parliament and of the	18. Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1); 3. Regulation (EU) 2019/2144 of the European Parliament and of the	18. Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1);~~ 3.~~ Regulation (EU) 2019/2144 of the	18. Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1);~~ 3~~

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	Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1);	Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1);	European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1);	***18a***. Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1); Text Origin: Commission Proposal
Annex II, point 19.				
G 806	19. Regulation (EU) 2018/1139 of	19. Regulation (EU) 2018/1139 of	19. Regulation (EU) 2018/1139 of	19. Regulation (EU) 2018/1139 of G

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	the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1), in so far as the design, production and placing on the market of aircrafts referred to in points (a) and (b) of Article 2(1) thereof, where it concerns unmanned aircraft and their engines, propellers, parts and equipment to control them remotely, are concerned.	the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1), in so far as the design, production and placing on the market of aircrafts referred to in points (a) and (b) of Article 2(1) thereof, where it concerns unmanned aircraft and their engines, propellers, parts and equipment to control them remotely, are concerned.	the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1), in so far as the design, production and placing on the market of aircrafts referred to in points (a) and (b) of Article 2(1) thereof, where it concerns unmanned aircraft and their engines, propellers, parts and equipment to control them remotely, are concerned.	the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1), in so far as the design, production and placing on the market of aircrafts referred to in points (a) and (b) of Article 2(1) thereof, where it concerns unmanned aircraft and their engines, propellers, parts and equipment to control them remotely, are concerned. Text Origin: Commission Proposal
Annex IIa				
G 806a				***ANNEX IIa List of criminal offences referred to in Article 5 (1)(iii)*** ***- terrorism,*** G

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				- trafficking in human beings, ***- sexual exploitation of children and child pornography,*** ***- illicit trafficking in narcotic drugs and psychotropic substances,*** ***- illicit trafficking in weapons, munitions and explosives,*** ***- murder, grievous bodily injury,*** ***- illicit trade in human organs and tissue,*** ***- illicit trafficking in nuclear or radioactive materials,*** ***- kidnapping, illegal restraint and hostage-taking,*** ***- crimes within the jurisdiction of the International Criminal Court,*** ***- unlawful seizure of aircraft/ships*** ***- rape*** ***- environmental crime,*** ***- organised or armed robbery,*** ***- sabotage,*** ***- participation in a criminal organisation involved in one or more offences listed above.***
Annex III				
G 807	Annex III HIGH-RISK AI SYSTEMS REFERRED TO IN ARTICLE 6(2)	Annex III HIGH-RISK AI SYSTEMS REFERRED TO IN ARTICLE 6(2)	Annex III HIGH-RISK AI SYSTEMS REFERRED TO IN ARTICLE ~~6(2)~~***6(3)***	Annex III HIGH-RISK AI SYSTEMS REFERRED TO IN ARTICLE 6(2) Text Origin: EP Mandate
Annex III, first paragraph				
G 808				

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	High-risk AI systems pursuant to Article 6(2) are the AI systems listed in any of the following areas:	***The AI systems specifically refered to in under points 1 to 8a stand for critical use cases and are each considered to be*** high-risk AI systems pursuant to Article 6(2)***, provided that they fulfil the criteria set out in that Article*** ~~are the AI systems listed in any of the following areas~~:	~~High-risk~~***In each of the areas listed under points 1-8, the*** AI systems ~~pursuant to Article 6(2) are the AI systems listed in any of the following areas~~***specifically mentioned under each letter are considered to be high-risk AI systems pursuant to Article 6(3)***:	High-risk AI systems pursuant to Article 6(2) are the AI systems listed in any of the following areas: Text Origin: Commission Proposal
Annex III, second paragraph				
G 809	1. Biometric identification and categorisation of natural persons:	1. Biometric ~~identification and categorisation of natural persons:~~***and biometrics-based systems***	1. ~~Biometric identification and categorisation of natural persons~~***Biometrics***:	1. ~~Biometric identification and categorisation of natural persons:~~***Biometrics, insofar as their use is permitted under relevant Union or national law*** Text Origin: Council Mandate
Annex III, second paragraph, point (a)				
G 810	(a) AI systems intended to be used for the 'real-time' and 'post' remote biometric identification of natural persons;	(a) AI systems intended to be used for ~~the 'real-time' and 'post' remote biometric identification of natural persons~~***biometric identification of natural persons, with the exception of those mentioned in Article 5***;	(a) ~~AI systems intended to be used for the 'real-time' and 'post'~~ Remote biometric identification ~~of natural persons;~~***systems.***	(a) ***Remote biometric identification systems.*** ***This shall not include*** AI systems intended to be used for ~~the 'real-time' and 'post' remote biometric identification of~~***biometric verification whose sole purpose is to confirm that a specific*** natural ~~persons~~***person is the person he or she claims to be***; Text Origin: Council Mandate

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Annex III, second paragraph, point (aa)				
G 810a		***(aa) AI systems intended to be used to make inferences about personal characteristics of natural persons on the basis of biometric or biometrics-based data, including emotion recognition systems, with the exception of those mentioned in Article 5;*** ***Point 1 shall not include AI systems intended to be used for biometric verification whose sole purpose is to confirm that a specific natural person is the person he or she claims to be.***		***(aa) AI systems intended to be used for biometric categorisation, according to sensitive or protected attributes or characteristics based on the inference of those attributes or characteristics.*** ***(ab) AI systems intended to be used for emotion recognition;*** G
Annex III, third paragraph				
G 811	2. Management and operation of critical infrastructure:	2. Management and operation of critical infrastructure:	2. ~~*Management and operation of*~~ Critical infrastructure:	2. ~~*Management and operation of*~~ Critical infrastructure: Text Origin: Council Mandate G
Annex III, third paragraph, point (a)				
G 812	(a) AI systems intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity.	(a) AI systems intended to be used as safety components in the management and operation of road***, rail and air traffic unless they are regulated in harmonisation or sectoral law*** ~~*traffic and the supply of water, gas, heating and electricity*~~.	(a) AI systems intended to be used as safety components in the management and operation of ***critical digital infrastructure,*** road traffic and the supply of water, gas, heating and electricity.	(a) AI systems intended to be used as safety components in the management and operation of ***critical digital infrastructure,*** road traffic and the supply of water, gas, heating and electricity. G
Annex III, first paragraph, point 2 - point (aa)				

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G 812a		***(aa) AI systems intended to be used as safety components in the management and operation of the supply of water, gas, heating, electricity and critical digital infrastructure;***		
Annex III, fourth paragraph				
G 813	3. Education and vocational training:	3. Education and vocational training:	3. Education and vocational training:	3. Education and vocational training: Text Origin: Commission Proposal
Annex III, fourth paragraph, point (a)				
G 814	(a) AI systems intended to be used for the purpose of determining access or assigning natural persons to educational and vocational training institutions;	(a) AI systems intended to be used for the purpose of determining access or ***materially influence decisions on admission or*** assigning natural persons to educational and vocational training institutions;	(a) AI systems intended to be used ~~for the purpose of determining access or assigning~~***to determine access, admission or to assign*** natural persons to educational and vocational training institutions ***or programmes at all levels***;	(a) AI systems intended to be used ~~for the purpose of determining access or assigning~~***to determine access or admission or to assign*** natural persons to educational and vocational training institutions ***at all levels***; Text Origin: Council Mandate
Annex III, fourth paragraph, point (b)				
G 815	(b) AI systems intended to be used for the purpose of assessing students in educational and vocational training institutions and for assessing participants in tests commonly	(b) AI systems intended to be used for the purpose of assessing students in educational and vocational training institutions and for assessing participants in tests commonly	(b) AI systems intended to be used ~~for the purpose of assessing students in educational and vocational training institutions and for assessing participants in tests~~	(b) AI systems intended to be used ~~for the purpose of assessing students in educational and vocational training institutions and for assessing participants in tests~~

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	required for admission to educational institutions.	required for admission to ~~educational~~***those*** institutions~~.~~***;***	~~commonly required for admission to educational institutions~~***to evaluate learning outcomes, including when those outcomes are used to steer the learning process of natural persons in educational and vocational training institutions or programmes at all levels***.	~~commonly required for admission to educational institutions~~***to evaluate learning outcomes, including when those outcomes are used to steer the learning process of natural persons in educational and vocational training institutions at all levels***. Text Origin: Council Mandate
Annex III, fourth paragraph, point (ba)				
G 815a		***(ba) AI systems intended to be used for the purpose of assessing the appropriate level of education for an individual and materially influencing the level of education and vocational training that individual will receive or will be able to access;***		***(ba) AI systems intended to be used for the purpose of assessing the appropriate level of education that individual will receive or will be able to access, in the context of/within education and vocational training institution;*** Text Origin: EP Mandate
Annex III, fourth paragraph, point (bb)				
G 815b		***(bb) AI systems intended to be used for monitoring and detecting prohibited behaviour of students during tests in the context of/within education and vocational training institutions;***		***(bb) AI systems intended to be used for monitoring and detecting prohibited behaviour of students during tests in the context of/within education and vocational training institutions;*** Text Origin: EP Mandate
Annex III, fifth paragraph				
G 816				

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	4. Employment, workers management and access to self-employment:	4. Employment, workers management and access to self-employment:	4. Employment, workers management and access to self-employment:	4. Employment, workers management and access to self-employment: Text Origin: Commission Proposal
Annex III, fifth paragraph, point (a)				
G 817	(a) AI systems intended to be used for recruitment or selection of natural persons, notably for advertising vacancies, screening or filtering applications, evaluating candidates in the course of interviews or tests;	(a) AI systems intended to be used for recruitment or selection of natural persons, notably for ~~advertising vacancies,~~***placing targeted job advertisements*** screening or filtering applications, evaluating candidates in the course of interviews or tests;	(a) AI systems intended to be used for recruitment or selection of natural persons, notably ~~for advertising vacancies, screening or filtering applications, evaluating candidates in the course of interviews or tests~~***to place targeted job advertisements, to analyse and filter job applications, and to evaluate candidates***;	(a) AI systems intended to be used for recruitment or selection of natural persons, notably ~~for advertising vacancies, screening or filtering applications, evaluating candidates in the course of interviews or tests~~***to place targeted job advertisements, to analyse and filter job applications, and to evaluate candidates***; Text Origin: EP Mandate
Annex III, fifth paragraph, point (b)				
G 818	(b) AI intended to be used for making decisions on promotion and termination of work-related contractual relationships, for task allocation and for monitoring and evaluating performance and behavior of persons in such relationships.	(b) AI ***systems*** intended to be used ~~for making~~***to make or materially influence*** decisions ~~on~~***affecting the initiation,*** promotion and termination of work-related contractual relationships, ~~for~~ task allocation ~~and~~***based on individual behaviour or personal traits or characteristics, or*** for monitoring and evaluating performance and behavior of persons in such relationships~~.~~***;***	(b) AI intended to be used ~~for making~~***to make*** decisions on promotion and termination of work-related contractual relationships, ~~for task allocation and for monitoring and evaluating~~***to allocate tasks based on individual behavior or personal traits or characteristics and to monitor and evaluate*** performance and behavior of persons in such relationships.	(b) AI intended to be used ~~for making~~***to make*** decisions ~~on~~***affecting terms of the work related relationships,*** promotion and termination of work-related contractual relationships, ~~for task allocation and for monitoring and evaluating~~***to allocate tasks based on individual behavior or personal traits or characteristics and to monitor and evaluate*** performance and behavior of persons in such

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				relationships.
Annex III, sixth paragraph				
G 819	5. Access to and enjoyment of essential private services and public services and benefits:	5. Access to and enjoyment of essential private services and public services and benefits:	5. Access to and enjoyment of essential private services and ***essential*** public services and benefits:	5. Access to and enjoyment of essential private services and ***essential*** public services and benefits: Text Origin: Council Mandate
Annex III, sixth paragraph, point (a)				
G 820	(a) AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for public assistance benefits and services, as well as to grant, reduce, revoke, or reclaim such benefits and services;	(a) AI systems intended to be used by ~~public authorities~~ or on behalf of public authorities to evaluate the eligibility of natural persons for public assistance benefits and services, ***including healthcare services and essential services, including but not limited to housing, electricity, heating/cooling and internet,*** as well as to grant, reduce, revoke, ***increase*** or reclaim such benefits and services;	(a) AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for ***essential*** public assistance benefits and services, as well as to grant, reduce, revoke, or reclaim such benefits and services;	(a) AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for ***essential*** public assistance benefits and ***services, including healthcare*** services, as well as to grant, reduce, revoke, or reclaim such benefits and services;
Annex III, sixth paragraph, point (b)				
G 821	(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems put into service by small scale providers for their own use;	(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems ~~put into service by small scale providers for their own~~	(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems put into service ~~by small scale providers~~ ***by providers that are***	(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems ~~put into service by small scale providers for their own~~

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		~~use~~***used for the purpose of detecting financial fraud***;	***micro and small-sized enterprises as defined in the Annex of Commission Recommendation 2003/361/EC*** for their own use;	~~use~~***used for the purpose of detecting financial fraud***; Text Origin: EP Mandate
Annex III, sixth paragraph, point (ba)				
821a		***(ba) AI systems intended to be used for making decisions or materially influencing decisions on the eligibility of natural persons for health and life insurance;***		
Annex III, sixth paragraph, point (c)				
822	(c) AI systems intended to be used to dispatch, or to establish priority in the dispatching of emergency first response services, including by firefighters and medical aid.	(c) AI systems intended to ***evaluate and classify emergency calls by natural persons or to*** be used to dispatch, or to establish priority in the dispatching of emergency first response services, including by ***police and law enforcement,*** firefighters and medical aid~~.~~***, as well as of emergency healthcare patient triage systems;***	(c) AI systems intended to be used to dispatch, or to establish priority in the dispatching of emergency first response services, including by firefighters and medical aid~~.~~***;***	(c) AI systems intended to ***evaluate and classify emergency calls by natural persons or to*** be used to dispatch, or to establish priority in the dispatching of emergency first response services, including by ***police,*** firefighters and medical aid~~.~~***, as well as of emergency healthcare patient triage systems;*** Text Origin: EP Mandate
Annex III, sixth paragraph, point (ca)				
822a			***(ca) AI systems intended to be used for risk assessment and pricing in relation to natural persons in the case of life and health insurance with the exception of AI systems put***	***(ca) AI systems intended to be used for risk assessment and pricing in relation to natural persons in the case of life and health insurance.*** Text Origin: Council Mandate

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			into service by providers that are micro and small-sized enterprises as defined in the Annex of Commission Recommendation 2003/361/EC for their own use.	
Annex III, seventh paragraph				
G 823	6. Law enforcement:	6. Law enforcement:	6. Law enforcement:	6. Law enforcement~~:~~***, insofar as their use is permitted under relevant Union or national law*** Text Origin: Commission Proposal
Annex III, seventh paragraph, point (a)				
G 824	(a) AI systems intended to be used by law enforcement authorities for making individual risk assessments of natural persons in order to assess the risk of a natural person for offending or reoffending or the risk for potential victims of criminal offences;	*deleted*	(a) AI systems intended to be used by law enforcement authorities ~~*for making individual risk assessments of natural persons in order*~~***or on their behalf*** to assess the risk of a natural person for offending or reoffending or the risk for ***a natural person to become a*** potential ~~*victims*~~***victim*** of criminal offences;	(a) AI systems intended to be used by ***or on behalf of*** law enforcement authorities***, or by Union institutions, agencies, offices or bodies in support of law enforcement authorities or on their behalf*** ~~*for making individual risk assessments of natural persons in order*~~ to assess the risk of a natural person ~~*for offending or reoffending or the risk for potential victims*~~***to become a victim*** of criminal offences;
Annex III, seventh paragraph, point (b)				
G 825	(b) AI systems intended to be used by law enforcement authorities as	(b) AI systems intended to be used by ***or on behalf of law enforcement***	(b) AI systems intended to be used by law enforcement authorities ***or on***	(b) AI systems intended to be used by ***or on behalf of*** law enforcement

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	polygraphs and similar tools or to detect the emotional state of a natural person;	***authorities, or by Union agencies, offices or bodies in support of*** law enforcement authorities as polygraphs and similar tools***, insofar as their use is permitted under relevant Union and national law*** ~~or to detect the emotional state of a natural person~~;	***their behalf*** as polygraphs and similar tools or to detect the emotional state of a natural person;	authorities ~~as polygraphs and similar tools or to detect the emotional state of a natural person~~***or by Union institutions, bodies and agencies in support of Law enforcement authorities as polygraphs and similar tools*** ;
Annex III, seventh paragraph, point (c)				
G 826	(c) AI systems intended to be used by law enforcement authorities to detect deep fakes as referred to in article 52(3);	*deleted*	*deleted*	(c) ~~AI systems intended to be used by law enforcement authorities to detect deep fakes as referred to in article 52(3);~~***deleted***
Annex III, seventh paragraph, point (d)				
G 827	(d) AI systems intended to be used by law enforcement authorities for evaluation of the reliability of evidence in the course of investigation or prosecution of criminal offences;	(d) AI systems intended to be used by ***or on behalf of*** law enforcement authorities***, or by Union agencies, offices or bodies in support of law enforcement authorities to evaluate*** ~~for evaluation of~~ the reliability of evidence in the course of investigation or prosecution of criminal offences;	(d) AI systems intended to be used by law enforcement authorities ~~for evaluation of~~***or on their behalf to evaluate*** the reliability of evidence in the course of investigation or prosecution of criminal offences;	(d) AI systems intended to be used by ***or on behalf of*** law enforcement authorities***, or by Union institutions, agencies, offices or bodies in support of law enforcement authorities to evaluate*** ~~for evaluation of~~ the reliability of evidence in the course of investigation or prosecution of criminal offences; Text Origin: EP Mandate
Annex III, seventh paragraph, point (e)				
G 828	(e) AI systems intended to be used		(e) AI systems intended to be used	(e) AI systems intended to be used

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	by law enforcement authorities for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups;	*deleted*	by law enforcement authorities ~~for predicting the~~ ***or on their behalf to predict the*** occurrence~~–~~ or reoccurrence of an actual or potential criminal offence based on profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 or ~~assessing~~***to assess*** personality traits and characteristics or past criminal behaviour of natural persons or groups;	by law enforcement authorities ***or on their behalf or by Union institutions, agencies, offices or bodies in support of law enforcement authorities for assessing the risk of a natural person of offending or re-offending not solely***~~for predicting the occurrence or reoccurrence of an actual or potential criminal offence~~ based on profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 or ~~assessing~~***to assess*** personality traits and characteristics or past criminal behaviour of natural persons or groups;
Annex III, seventh paragraph, point (f)				
G 829	(f) AI systems intended to be used by law enforcement authorities for profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of detection, investigation or prosecution of criminal offences;	(f) AI systems intended to be used by ***or on behalf of law enforcement authorities or by Union agencies, offices or bodies in support of*** law enforcement authorities for profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of detection, investigation or prosecution of criminal offences ***or, in the case of Union agencies, offices or bodies, as referred to in Article 3(5) of Regulation (EU) 2018/1725***;	(f) AI systems intended to be used by law enforcement authorities ~~for profiling of~~***or on their behalf to profile*** natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of detection, investigation or prosecution of criminal offences~~;~~**.**	(f) AI systems intended to be used by ***or on behalf of law enforcement authorities or by Union agencies institutions, agencies, offices or bodies in support of*** law enforcement authorities for profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of detection, investigation or prosecution of criminal offences~~;~~**.** Text Origin: EP Mandate
Annex III, seventh paragraph, point (g)				

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G 830	(g) AI systems intended to be used for crime analytics regarding natural persons, allowing law enforcement authorities to search complex related and unrelated large data sets available in different data sources or in different data formats in order to identify unknown patterns or discover hidden relationships in the data.	(g) AI systems intended to be used ***by or on behalf of law enforcement authorities or by Union agencies, offices or bodies in support of law enforcement authorities*** for crime analytics regarding natural persons, allowing law enforcement authorities to search complex related and unrelated large data sets available in different data sources or in different data formats in order to identify unknown patterns or discover hidden relationships in the data.	*deleted*	(g) ~~*AI systems intended to be used for crime analytics regarding natural persons, allowing law enforcement authorities to search complex related and unrelated large data sets available in different data sources or in different data formats in order to identify unknown patterns or discover hidden relationships in the data.*~~***Deleted*** G
Annex III, eighth paragraph				
G 831	7. Migration, asylum and border control management:	7. Migration, asylum and border control management:	7. Migration, asylum and border control management:	7. Migration, asylum and border control management***, insofar as their use is permitted under relevant Union or national law***: Text Origin: Commission Proposal G
Annex III, eighth paragraph, point (a)				
G 832	(a) AI systems intended to be used by competent public authorities as polygraphs and similar tools or to detect the emotional state of a natural person;	(a) AI systems intended to be used by ***or on behalf of*** competent public authorities ***or by Union agencies, offices or bodies*** as polygraphs and similar tools ~~*or to detect the emotional state of a natural person;*~~***insofar as their use is***	(a) AI systems intended to be used by competent public authorities ***or on their behalf*** as polygraphs and similar tools or to detect the emotional state of a natural person;	(a) AI systems intended to be used by competent public authorities as polygraphs and similar tools~~*or to detect the emotional state of a natural person;*~~***;*** G

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		permitted under relevant Union or national law		
Annex III, eighth paragraph, point (b)				
833	(b) AI systems intended to be used by competent public authorities to assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;	(b) AI systems intended to be used by ***or on behalf of*** competent public authorities ***or by Union agencies, offices or bodies*** to assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;	(b) AI systems intended to be used by competent public authorities ***or on their behalf*** to assess a risk, including a security risk, a risk of irregular ~~immigration~~***migration***, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;	(b) AI systems intended to be used by ***or on behalf of*** competent public authorities ***or by Union agencies, offices or bodies*** to assess a risk, including a security risk, a risk of irregular ~~immigration~~***migration***, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State; Text Origin: EP Mandate
Annex III, eighth paragraph, point (c)				
834	(c) AI systems intended to be used by competent public authorities for the verification of the authenticity of travel documents and supporting documentation of natural persons and detect non-authentic documents by checking their security features;	(c) AI systems intended to be used by ***or on behalf of*** competent public authorities ***or by Union agencies, offices or bodies*** for the verification of the authenticity of travel documents and supporting documentation of natural persons and detect non-authentic documents by checking their security features;	*deleted*	(c) ~~*AI systems intended to be used by competent public authorities for the verification of the authenticity of travel documents and supporting documentation of natural persons and detect non-authentic documents by checking their security features;*~~***deleted***
Annex III, eighth paragraph, point (d)				
835	(d) AI systems intended to assist competent public authorities for the	(d) AI systems intended to ***be used by or on behalf of competent public***	(d) AI systems intended to ~~*assist*~~***be used by*** competent public authorities	(d) AI systems intended to ***be used by or on behalf of competent public***

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	examination of applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.	***authorities or by Union agencies, offices or bodies to*** assist competent public authorities for the examination ***and assessment of the veracity of evidence in relation to*** ~~of~~ applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status~~.~~***;***	~~for the examination of~~***or on their behalf to examine*** applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.	***authorities or by Union agencies, offices or bodies to*** assist competent public authorities for the examination of applications~~-~~ for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status~~.~~***, including related assessment of the reliability of evidence;*** Text Origin: EP Mandate
Annex III, eighth paragraph, point (da)				
G 835a		***(da) AI systems intended to be used by or on behalf of competent public authorities or by Union agencies, offices or bodies in migration, asylum and border control management to monitor, surveil or process data in the context of border management activities, for the purpose of detecting, recognising or identifying natural persons;***		***(da) AI systems intended to be used by or on behalf of competent public authorities, including Union agencies, offices or bodies, in the context of migration, asylum and border control management, for the purpose of detecting, recognising or identifying natural persons with the exception of verification of travel documents;*** G
Annex III, eighth paragraph, point (db)				
G 835b		***(db) AI systems intended to be used by or on behalf of competent public authorities or by Union agencies, offices or bodies in migration, asylum and border control management for the forecasting or***		***(db)*** G

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		prediction of trends related to migration movement and border crossing;		
Annex III, ninth paragraph				
G 836	8. Administration of justice and democratic processes:	8. Administration of justice and democratic processes:	8. Administration of justice and democratic processes:	8. Administration of justice and democratic processes: Text Origin: Commission Proposal
Annex III, ninth paragraph, point (a)				
G 837	(a) AI systems intended to assist a judicial authority in researching and interpreting facts and the law and in applying the law to a concrete set of facts.	(a) AI systems intended to ***be used by a judicial authority ot administrative body or on their behalf to*** assist a judicial authority ***or administrative body*** in researching and interpreting facts and the law and in applying the law to a concrete set of facts ***or used in a similar way in alternative dispute resolution***.	(a) AI systems intended to ~~assist~~***be used by*** a judicial authority ~~in researching and interpreting~~***or on their behalf to interpret*** facts ~~and~~***or*** the law and ~~in applying~~***to apply*** the law to a concrete set of facts.	(a) AI systems intended to ***be used by a judicial authority or on their behalf to*** assist a judicial authority in researching and interpreting facts and the law and in applying the law to a concrete set of facts~~.~~ ***or used in a similar way in alternative dispute resolution*** Text Origin: EP Mandate
Annex III, ninth paragraph, point (aa), first subparagraph				
G 837a		***(aa) AI systems intended to be used for influencing the outcome of an election or referendum or the voting behaviour of natural persons in the exercise of their vote in elections or referenda. This does not include AI systems whose***		***(aa) AI systems intended to be used for influencing the outcome of an election or referendum or the voting behaviour of natural persons in the exercise of their vote in elections or referenda. This does not include AI systems whose***

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		output natural persons are not directly exposed to, such as tools used to organise, optimise and structure political campaigns from an administrative and logistic point of view.		***output natural persons are not directly exposed to, such as tools used to organise, optimise and structure political campaigns from an administrative and logistic point of view.***
Annex III, ninth paragraph, point (aa), second subparagraph				
G 837b				G
Annex III, ninth paragraph, point (aa), third subparagraph				
G 837c		***(ab) AI systems intended to be used by social media platforms that have been designated as very large online platforms within the meaning of Article 33 of Regulation EU 2022/2065, in their recommender systems to recommend to the recipient of the service user-generated content available on the platform.***		***deleted*** G
Annex IV				
G 838	Annex IV TECHNICAL DOCUMENTATION referred to in Article 11(1)	Annex IV TECHNICAL DOCUMENTATION referred to in Article 11(1)	Annex IV TECHNICAL DOCUMENTATION referred to in Article 11(1)	Annex IV TECHNICAL DOCUMENTATION referred to in Article 11(1) Text Origin: Commission Proposal G
Annex IV, first paragraph				

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G 839	The technical documentation referred to in Article 11(1) shall contain at least the following information, as applicable to the relevant AI system:	The technical documentation referred to in Article 11(1) shall contain at least the following information, as applicable to the relevant AI system:	The technical documentation referred to in Article 11(1) shall contain at least the following information, as applicable to the relevant AI system:	The technical documentation referred to in Article 11(1) shall contain at least the following information, as applicable to the relevant AI system: Text Origin: Commission Proposal
Annex IV, second paragraph				
G 840	1. A general description of the AI system including:	1. A general description of the AI system including:	1. A general description of the AI system including:	1. A general description of the AI system including: Text Origin: Commission Proposal
Annex IV, second paragraph, point (a)				
G 841	(a) its intended purpose, the person/s developing the system the date and the version of the system;	(a) its intended purpose, the ~~person/s developing the system the date~~***name of the provider*** and the version of the system ***reflecting its relation to previous and, where applicable, more recent, versions in the succession of revisions***;	(a) its intended purpose, the person/s developing the system the date and the version of the system;	(a) its intended purpose, the ~~person/s developing the system the date~~***name of the provider*** and the version of the system ***reflecting its relation to previous versions*** ; Text Origin: EP Mandate
Annex IV, second paragraph, point (aa)				
G 841a		***(aa) the nature of data likely or intended to be processed by the system and, in the case of personal data, the categories of natural persons and groups likely or***		

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		intended to be affected;		
Annex IV, second paragraph, point (b)				
842	(b) how the AI system interacts or can be used to interact with hardware or software that is not part of the AI system itself, where applicable;	(b) how the AI system ~~interacts~~***can interact*** or can be used to interact with hardware or software***, including other AI systems, that are*** ~~that is~~ not part of the AI system itself, where applicable;	(b) how the AI system interacts or can be used to interact with hardware or software that is not part of the AI system itself, where applicable;	(b) how the AI system interacts or can be used to interact with hardware or software***, including other AI systems, that are*** ~~that is~~ not part of the AI system itself, where applicable;
Annex IV, second paragraph, point (c)				
843	(c) the versions of relevant software or firmware and any requirement related to version update;	(c) the versions of relevant software or firmware and***, where applicable, information for the deployer on*** any requirement related to version update;	(c) the versions of relevant software or firmware and any requirement related to version update;	(c) the versions of relevant software or firmware and any requirement related to version update;
Annex IV, second paragraph, point (d)				
844	(d) the description of all forms in which the AI system is placed on the market or put into service;	(d) the description of ~~all forms in which~~***the various configurations and variants of*** the AI system ~~is~~***which are intended to be*** placed on the market or put into service;	(d) the description of all forms in which the AI system is placed on the market or put into service ***(e.g. software package embedded into hardware, downloadable, API etc.)***;	(d) the description of all forms in which the AI system is placed on the market or put into service ***(e.g. software package embedded into hardware, downloadable, API etc.)***;
Annex IV, second paragraph, point (e)				
845	(e) the description of hardware on which the AI system is intended to run;	(e) the description of hardware on which the AI system is intended to run;	(e) the description of hardware on which the AI system is intended to run;	(e) the description of hardware on which the AI system is intended to run;

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				Text Origin: Commission Proposal
Annex IV, second paragraph, point (f)				
G 846	(f) where the AI system is a component of products, photographs or illustrations showing external features, marking and internal layout of those products;	(f) where the AI system is a component of products, photographs or illustrations showing external features, marking and internal layout of those products;	(f) where the AI system is a component of products, photographs or illustrations showing external features, marking and internal layout of those products;	(f) where the AI system is a component of products, photographs or illustrations showing external features, marking and internal layout of those products; G Text Origin: Commission Proposal
Annex IV, second paragraph, point (fa)				
G 846a		***(fa) the description of the deployer interface;***		***(fa) a basic description of the user-interface provided to the deployer;*** G
Annex IV, second paragraph, point (g)				
G 847	(g) instructions of use for the user and, where applicable installation instructions;	(g) instructions of use for the ~~user~~***deployer in accordance with Article 13(2) and (3) as well as 14(4)(e)*** and, where applicable installation instructions;	(g) instructions of use for the user and, where applicable installation instructions;	(g) instructions of use for the ~~user and~~,***deployer and a basic description of the user-interface provided to the deployer*** where applicable~~ installation instructions~~; G
Annex IV, second paragraph, point (ga)				
G 847a		***(ga) a detailed and easily intellegible description of the system's main optimisation goal or goals;***		G

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Annex IV, second paragraph, point (gb)				
G 847b		***(gb) a detailed and easily intellegible description of the system's expected output and expected output quality;***		G
Annex IV, second paragraph, point (gc)				
G 847c		***(gc) detailed and easily intellegible instructions for interpreting the system's output;***		G
Annex IV, second paragraph, point (gd)				
G 847d		***(gd) examples of scenarios for which the system should not be used;***		G
Annex IV, third paragraph				
G 848	2. A detailed description of the elements of the AI system and of the process for its development, including:	2. A detailed description of the elements of the AI system and of the process for its development, including:	2. A detailed description of the elements of the AI system and of the process for its development, including:	2. A detailed description of the elements of the AI system and of the process for its development, including: Text Origin: Commission Proposal G
Annex IV, third paragraph, point (a)				
G 849	(a) the methods and steps performed for the development of the AI	(a) the methods and steps performed for the development of the AI	(a) the methods and steps performed for the development of the AI	(a) the methods and steps performed for the development of the AI G

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	system, including, where relevant, recourse to pre-trained systems or tools provided by third parties and how these have been used, integrated or modified by the provider;	system, including, where relevant, recourse to pre-trained systems or tools provided by third parties and how these have been used, integrated or modified by the provider;	system, including, where relevant, recourse to pre-trained systems or tools provided by third parties and how these have been used, integrated or modified by the provider;	system, including, where relevant, recourse to pre-trained systems or tools provided by third parties and how these have been used, integrated or modified by the provider; Text Origin: Commission Proposal
Annex IV, third paragraph, point (b)				
G 850	(b) the design specifications of the system, namely the general logic of the AI system and of the algorithms; the key design choices including the rationale and assumptions made, also with regard to persons or groups of persons on which the system is intended to be used; the main classification choices; what the system is designed to optimise for and the relevance of the different parameters; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Title III, Chapter 2;	(b) ***a description of the architecture,*** ~~the~~ design specifications***, algorithms and the data structures including a decomposition of its components and interfaces, how they relate to one another and how they provide for the overall processing or logic*** ~~*of the system, namely the general logic of the AI system and*~~ of the ~~*algorithms*~~***AI system***; the key design choices including the rationale and assumptions made, also with regard to persons or groups of persons on which the system is intended to be used; the main classification choices; what the system is designed to optimise for and the relevance of the different parameters; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Title III, Chapter 2;	(b) the design specifications of the system, namely the general logic of the AI system and of the algorithms; the key design choices including the rationale and assumptions made, also with regard to persons or groups of persons on which the system is intended to be used; the main classification choices; what the system is designed to optimise for and the relevance of the different parameters; the ***description of the expected output of the system; the*** decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Title III, Chapter 2;	(b) the design specifications of the system, namely the general logic of the AI system and of the algorithms; the key design choices including the rationale and assumptions made, also with regard to persons or groups of persons on which the system is intended to be used; the main classification choices; what the system is designed to optimise for and the relevance of the different parameters; the ***description of the expected output and output quality of the system; the*** decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Title III, Chapter 2; G

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Annex IV, third paragraph, point (c)				
G 851	(c) the description of the system architecture explaining how software components build on or feed into each other and integrate into the overall processing; the computational resources used to develop, train, test and validate the AI system;	*deleted*	*(c)* the description of the system architecture explaining how software components build on or feed into each other and integrate into the overall processing; the computational resources used to develop, train, test and validate the AI system;	(c) the description of the system architecture explaining how software components build on or feed into each other and integrate into the overall processing; the computational resources used to develop, train, test and validate the AI system; Text Origin: Council Mandate
Annex IV, third paragraph, point (d)				
G 852	(d) where relevant, the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used, including information about the provenance of those data sets, their scope and main characteristics; how the data was obtained and selected; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection);	(d) where relevant, the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used, including information about the provenance of those data sets, their scope and main characteristics; how the data was obtained and selected; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection);	(d) where relevant, the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used, including ~~*information about the provenance of those*~~***a general description of these*** data sets, ***information about*** their ***provenance,*** scope and main characteristics; how the data was obtained and selected; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection);	(d) where relevant, the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used, including ~~*information about the provenance of those*~~***a general description of these*** data sets, ***information about*** their ***provenance,*** scope and main characteristics; how the data was obtained and selected; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection); Text Origin: Council Mandate
Annex IV, third paragraph, point (e)				
G 853				

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	(e) assessment of the human oversight measures needed in accordance with Article 14, including an assessment of the technical measures needed to facilitate the interpretation of the outputs of AI systems by the users, in accordance with Articles 13(3)(d);	(e) assessment of the human oversight measures needed in accordance with Article 14, including an assessment of the technical measures needed to facilitate the interpretation of the outputs of AI systems by the ~~users~~***deployers***, in accordance with Articles 13(3)(d);	(e) assessment of the human oversight measures needed in accordance with Article 14, including an assessment of the technical measures needed to facilitate the interpretation of the outputs of AI systems by the users, in accordance with Articles 13(3)(d);	(e) assessment of the human oversight measures needed in accordance with Article 14, including an assessment of the technical measures needed to facilitate the interpretation of the outputs of AI systems by the ~~users~~***deployers***, in accordance with Articles 13(3)(d); Text Origin: EP Mandate
Annex IV, third paragraph, point (f)				
G 854	(f) where applicable, a detailed description of pre-determined changes to the AI system and its performance, together with all the relevant information related to the technical solutions adopted to ensure continuous compliance of the AI system with the relevant requirements set out in Title III, Chapter 2;	(f) where applicable, a detailed description of pre-determined changes to the AI system and its performance, together with all the relevant information related to the technical solutions adopted to ensure continuous compliance of the AI system with the relevant requirements set out in Title III, Chapter 2;	(f) where applicable, a detailed description of pre-determined changes~~–~~ to the AI system and its performance, together with all the relevant information related to the technical solutions adopted to ensure continuous compliance of the AI system with the relevant requirements set out in Title III, Chapter 2;	(f) where applicable, a detailed description of pre-determined changes to the AI system and its performance, together with all the relevant information related to the technical solutions adopted to ensure continuous compliance of the AI system with the relevant requirements set out in Title III, Chapter 2; Text Origin: Commission Proposal
Annex IV, third paragraph, point (g)				
G 855	(g) the validation and testing procedures used, including information about the validation and testing data used and their main characteristics; metrics used to measure accuracy, robustness,	(g) the validation and testing procedures used, including information about the validation and testing data used and their main characteristics; metrics used to measure accuracy, robustness~~,~~	(g) the validation and testing procedures used, including information about the validation and testing data used and their main characteristics; metrics used to measure accuracy, robustness,	(g) the validation and testing procedures used, including information about the validation and testing data used and their main characteristics; metrics used to measure accuracy, robustness~~,~~

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	cybersecurity and compliance with other relevant requirements set out in Title III, Chapter 2 as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point (f).	~~cybersecurity~~ and compliance with other relevant requirements set out in Title III, Chapter 2 as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point (f).	cybersecurity and compliance with other relevant requirements set out in Title III, Chapter 2 as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point (f).	~~cybersecurity~~ and compliance with other relevant requirements set out in Title III, Chapter 2 as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point (f). Text Origin: EP Mandate
Annex IV, third paragraph, point (ga)				
G 855a		***(ga) cybersecurity measures put in place.***		***(ga) cybersecurity measures put in place.*** Text Origin: EP Mandate
Annex IV, fourth paragraph				
G 856	3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system;	3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system;	3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system;	3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system;

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate;	the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the ~~users~~***deployers***; specifications on input data, as appropriate;	the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate;	the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the ~~users~~***deployers***; specifications on input data, as appropriate; Text Origin: EP Mandate
Annex IV, fourth paragraph a				
G 856a		***A description of the appropriateness of the performance metrics for the specific AI system;***		***3. A description of the appropriateness of the performance metrics for the specific AI system;*** Text Origin: EP Mandate
Annex IV, fifth paragraph				
G 856b		***Information about the energy consumption of the AI system during the development phase and the expected energy consumption during use, taking into account, where applicable, relevant Union and national law;***		
Annex IV, fifth paragraph				
G 857	4. A detailed description of the risk management system in accordance with Article 9;	4. A detailed description of the risk management system in accordance with Article 9;	4. A detailed description of the risk management system in accordance with Article 9;	4. A detailed description of the risk management system in accordance with Article 9;

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Annex IV, sixth paragraph				
G 858	5. A description of any change made to the system through its lifecycle;	5. A description of any ***relevant*** change made ***by providers*** to the system through its lifecycle ;	5. A description of ~~any change made~~***relevant changes made by the provider*** to the system through its lifecycle;	5. A description of ~~any change made~~***relevant changes made by the provider*** to the system through its lifecycle; Text Origin: Council Mandate
Annex IV, seventh paragraph				
G 859	6. A list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union; where no such harmonised standards have been applied, a detailed description of the solutions adopted to meet the requirements set out in Title III, Chapter 2, including a list of other relevant standards and technical specifications applied;	6. A list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union; where no such harmonised standards have been applied, a detailed description of the solutions adopted to meet the requirements set out in Title III, Chapter 2, including a list of other relevant standards ~~and technical~~***or common*** specifications applied;	6. A list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union; where no such harmonised standards have been applied, a detailed description of the solutions adopted to meet the requirements set out in Title III, Chapter 2, including a list of other relevant standards and technical specifications applied;	6. A list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union; where no such harmonised standards have been applied, a detailed description of the solutions adopted to meet the requirements set out in Title III, Chapter 2, including a list of other relevant standards and technical specifications applied; Text Origin: Council Mandate
Annex IV, eighth paragraph				
G 860	7. A copy of the EU declaration of conformity;	7. A copy of the EU declaration of conformity;	7. A copy of the EU declaration of conformity;	7. A copy of the EU declaration of conformity; Text Origin: Commission Proposal

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex IV, ninth paragraph				
861	8. A detailed description of the system in place to evaluate the AI system performance in the post-market phase in accordance with Article 61, including the post-market monitoring plan referred to in Article 61(3).	8. A detailed description of the system in place to evaluate the AI system performance in the post-market phase in accordance with Article 61, including the post-market monitoring plan referred to in Article 61(3).	8. A detailed description of the system in place to evaluate the AI system performance in the post-market phase in accordance with Article 61, including the post-market monitoring plan referred to in Article 61(3).	8. A detailed description of the system in place to evaluate the AI system performance in the post-market phase in accordance with Article 61, including the post-market monitoring plan referred to in Article 61(3). Text Origin: Commission Proposal
Annex V				
862	Annex V EU DECLARATION OF CONFORMITY	Annex V EU DECLARATION OF CONFORMITY	Annex V EU DECLARATION OF CONFORMITY	Annex V EU DECLARATION OF CONFORMITY Text Origin: Commission Proposal
Annex V, first paragraph				
863	The EU declaration of conformity referred to in Article 48, shall contain all of the following information:	The EU declaration of conformity referred to in Article 48, shall contain all of the following information:	The EU declaration of conformity referred to in Article 48, shall contain all of the following information:	The EU declaration of conformity referred to in Article 48, shall contain all of the following information: Text Origin: Commission Proposal
Annex V, second paragraph				
864	1. AI system name and type and any	1. AI system name and type and any	1. AI system name and type and any	1. AI system name and type and any

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	additional unambiguous reference allowing identification and traceability of the AI system;	additional unambiguous reference allowing identification and traceability of the AI system;	additional unambiguous reference allowing identification and traceability of the AI system;	additional unambiguous reference allowing identification and traceability of the AI system; Text Origin: Commission Proposal
Annex V, third paragraph				
G 865	2. Name and address of the provider or, where applicable, their authorised representative;	2. Name and address of the provider or, where applicable, their authorised representative;	2. Name and address of the provider or, where applicable, their authorised representative;	2. Name and address of the provider or, where applicable, their authorised representative; Text Origin: Commission Proposal
Annex V, fourth paragraph				
G 866	3. A statement that the EU declaration of conformity is issued under the sole responsibility of the provider;	3. A statement that the EU declaration of conformity is issued under the sole responsibility of the provider;	3. A statement that the EU declaration of conformity is issued under the sole responsibility of the provider;	3. A statement that the EU declaration of conformity is issued under the sole responsibility of the provider; Text Origin: Commission Proposal
Annex V, fifth paragraph				
G 867	4. A statement that the AI system in question is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity;	4. A statement that the AI system in question is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity;	4. A statement that the AI system in question is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity;	4. A statement that the AI system in question is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity; Text Origin: Commission

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Proposal
Annex V, fifth paragraph a				
G 867a		***4 a. Where an AI system involves the processing of personal data, a statement that that AI system complies with Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680.***		***4. 4a. Where an AI system involves the processing of personal data, a statement that that AI system complies with Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680.*** Text Origin: EP Mandate
Annex V, sixth paragraph				
G 868	5. References to any relevant harmonised standards used or any other common specification in relation to which conformity is declared;	5. References to any relevant harmonised standards used or any other common specification in relation to which conformity is declared;	5. References to any relevant harmonised standards used or any other common specification in relation to which conformity is declared;	5. References to any relevant harmonised standards used or any other common specification in relation to which conformity is declared; Text Origin: Commission Proposal
Annex V, seventh paragraph				
G 869	6. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate issued;	6. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate issued;	6. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate issued;	6. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate issued; Text Origin: Commission Proposal

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex V, eighth paragraph				
G 870	7. Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.	7. Place and date of issue of the declaration, ***signature,*** name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.	7. Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.	7. Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature. G
Annex VI				
G 871	Annex VI CONFORMITY ASSESSMENT PROCEDURE BASED ON INTERNAL CONTROL	Annex VI CONFORMITY ASSESSMENT PROCEDURE BASED ON INTERNAL CONTROL	Annex VI CONFORMITY ASSESSMENT PROCEDURE BASED ON INTERNAL CONTROL	Annex VI CONFORMITY ASSESSMENT PROCEDURE BASED ON INTERNAL CONTROL Text Origin: Commission Proposal G
Annex VI, point 1.				
G 872	1. The conformity assessment procedure based on internal control is the conformity assessment procedure based on points 2 to 4.	1. The conformity assessment procedure based on internal control is the conformity assessment procedure based on points 2 to 4.	1. The conformity assessment procedure based on internal control is the conformity assessment procedure based on points 2 to 4.	1. The conformity assessment procedure based on internal control is the conformity assessment procedure based on points 2 to 4. Text Origin: Commission Proposal G
Annex VI, point 2.				
G 873	2. The provider verifies that the established quality management system is in compliance with the requirements of Article 17.	2. The provider verifies that the established quality management system is in compliance with the requirements of Article 17.	2. The provider verifies that the established quality management system is in compliance with the requirements of Article 17.	2. The provider verifies that the established quality management system is in compliance with the requirements of Article 17. G

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	
					Text Origin: Commission Proposal	
Annex VI, point 3.						
G	874	3. The provider examines the information contained in the technical documentation in order to assess the compliance of the AI system with the relevant essential requirements set out in Title III, Chapter 2.	3. The provider examines the information contained in the technical documentation in order to assess the compliance of the AI system with the relevant essential requirements set out in Title III, Chapter 2.	3. The provider examines the information contained in the technical documentation in order to assess the compliance of the AI system with the relevant essential requirements set out in Title III, Chapter 2.	3. The provider examines the information contained in the technical documentation in order to assess the compliance of the AI system with the relevant essential requirements set out in Title III, Chapter 2. Text Origin: Commission Proposal	G
Annex VI, point 4.						
G	875	4. The provider also verifies that the design and development process of the AI system and its post-market monitoring as referred to in Article 61 is consistent with the technical documentation.	4. The provider also verifies that the design and development process of the AI system and its post-market monitoring as referred to in Article 61 is consistent with the technical documentation.	4. The provider also verifies that the design and development process of the AI system and its post-market monitoring as referred to in Article 61 is consistent with the technical documentation.	4. The provider also verifies that the design and development process of the AI system and its post-market monitoring as referred to in Article 61 is consistent with the technical documentation. Text Origin: Commission Proposal	G
Annex VII						
G	876	Annex VII CONFORMITY BASED ON ASSESSMENT OF QUALITY MANAGEMENT SYSTEM AND ASSESSMENT OF TECHNICAL DOCUMENTATION	Annex VII CONFORMITY BASED ON ASSESSMENT OF QUALITY MANAGEMENT SYSTEM AND ASSESSMENT OF TECHNICAL DOCUMENTATION	Annex VII CONFORMITY BASED ON ASSESSMENT OF QUALITY MANAGEMENT SYSTEM AND ASSESSMENT OF TECHNICAL DOCUMENTATION	Annex VII CONFORMITY BASED ON ASSESSMENT OF QUALITY MANAGEMENT SYSTEM AND ASSESSMENT OF TECHNICAL DOCUMENTATION	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Annex VII, point 1., first subparagraph				
G 877	1. Introduction	1. Introduction	1. Introduction	1. Introduction Text Origin: Commission Proposal
Annex VII, point 1., second subparagraph				
G 878	Conformity based on assessment of quality management system and assessment of the technical documentation is the conformity assessment procedure based on points 2 to 5.	Conformity based on assessment of quality management system and assessment of the technical documentation is the conformity assessment procedure based on points 2 to 5.	Conformity based on assessment of quality management system and assessment of the technical documentation is the conformity assessment procedure based on points 2 to 5.	Conformity based on assessment of quality management system and assessment of the technical documentation is the conformity assessment procedure based on points 2 to 5. Text Origin: Commission Proposal
Annex VII, point 2., first subparagraph				
G 879	2. Overview	2. Overview	2. Overview	2. Overview Text Origin: Commission Proposal
Annex VII, point 2., second subparagraph				
G 880	The approved quality management system for the design, development and testing of AI systems pursuant to	The approved quality management system for the design, development and testing of AI systems pursuant to	The approved quality management system for the design, development and testing of AI systems pursuant to	The approved quality management system for the design, development and testing of AI systems pursuant to

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 17 shall be examined in accordance with point 3 and shall be subject to surveillance as specified in point 5. The technical documentation of the AI system shall be examined in accordance with point 4.	Article 17 shall be examined in accordance with point 3 and shall be subject to surveillance as specified in point 5. The technical documentation of the AI system shall be examined in accordance with point 4.	Article 17 shall be examined in accordance with point 3 and shall be subject to surveillance as specified in point 5. The technical documentation of the AI system shall be examined in accordance with point 4.	Article 17 shall be examined in accordance with point 3 and shall be subject to surveillance as specified in point 5. The technical documentation of the AI system shall be examined in accordance with point 4. Text Origin: Commission Proposal
Annex VII, point 3.				
G 881	3. Quality management system	3. Quality management system	3. Quality management system	3. Quality management system Text Origin: Commission Proposal
Annex VII, first paragraph				
G 882	3.1. The application of the provider shall include:	3.1. The application of the provider shall include:	3.1. The application of the provider shall include:	3.1. The application of the provider shall include: Text Origin: Commission Proposal
Annex VII, first paragraph, point (a)				
G 883	(a) the name and address of the provider and, if the application is lodged by the authorised representative, their name and address as well;	(a) the name and address of the provider and, if the application is lodged by the authorised representative, their name and address as well;	(a) the name and address of the provider and, if the application is lodged by the authorised representative, their name and address as well;	(a) the name and address of the provider and, if the application is lodged by the authorised representative, their name and address as well; Text Origin: Commission Proposal

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex VII, first paragraph, point (b)				
884	(b) the list of AI systems covered under the same quality management system;	(b) the list of AI systems covered under the same quality management system;	(b) the list of AI systems covered under the same quality management system;	(b) the list of AI systems covered under the same quality management system; Text Origin: Commission Proposal
Annex VII, first paragraph, point (c)				
885	(c) the technical documentation for each AI system covered under the same quality management system;	(c) the technical documentation for each AI system covered under the same quality management system;	(c) the technical documentation for each AI system covered under the same quality management system;	(c) the technical documentation for each AI system covered under the same quality management system; Text Origin: Commission Proposal
Annex VII, first paragraph, point (d)				
886	(d) the documentation concerning the quality management system which shall cover all the aspects listed under Article 17;	(d) the documentation concerning the quality management system which shall cover all the aspects listed under Article 17;	(d) the documentation concerning the quality management system which shall cover all the aspects listed under Article 17;	(d) the documentation concerning the quality management system which shall cover all the aspects listed under Article 17; Text Origin: Commission Proposal
Annex VII, first paragraph, point (e)				
887	(e) a description of the procedures in place to ensure that the quality management system remains adequate and effective;	(e) a description of the procedures in place to ensure that the quality management system remains adequate and effective;	(e) a description of the procedures in place to ensure that the quality management system remains adequate and effective;	(e) a description of the procedures in place to ensure that the quality management system remains adequate and effective;

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Annex VII, first paragraph, point (f)				
G 888	(f) a written declaration that the same application has not been lodged with any other notified body.	(f) a written declaration that the same application has not been lodged with any other notified body.	(f) a written declaration that the same application has not been lodged with any other notified body.	(f) a written declaration that the same application has not been lodged with any other notified body. Text Origin: Commission Proposal
Annex VII, third paragraph				
G 889	3.2. The quality management system shall be assessed by the notified body, which shall determine whether it satisfies the requirements referred to in Article 17.	3.2. The quality management system shall be assessed by the notified body, which shall determine whether it satisfies the requirements referred to in Article 17.	3.2. The quality management system shall be assessed by the notified body, which shall determine whether it satisfies the requirements referred to in Article 17.	3.2. The quality management system shall be assessed by the notified body, which shall determine whether it satisfies the requirements referred to in Article 17. Text Origin: Commission Proposal
Annex VII, fourth paragraph				
G 890	The decision shall be notified to the provider or its authorised representative.	The decision shall be notified to the provider or its authorised representative.	The decision shall be notified to the provider or its authorised representative.	The decision shall be notified to the provider or its authorised representative. Text Origin: Commission Proposal
Annex VII, fifth paragraph				
G 891				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	The notification shall contain the conclusions of the assessment of the quality management system and the reasoned assessment decision.	The notification shall contain the conclusions of the assessment of the quality management system and the reasoned assessment decision.	The notification shall contain the conclusions of the assessment of the quality management system and the reasoned assessment decision.	The notification shall contain the conclusions of the assessment of the quality management system and the reasoned assessment decision. Text Origin: Commission Proposal
Annex VII, sixth paragraph				
G 892	3.3. The quality management system as approved shall continue to be implemented and maintained by the provider so that it remains adequate and efficient.	3.3. The quality management system as approved shall continue to be implemented and maintained by the provider so that it remains adequate and efficient.	3.3. The quality management system as approved shall continue to be implemented and maintained by the provider so that it remains adequate and efficient.	3.3. The quality management system as approved shall continue to be implemented and maintained by the provider so that it remains adequate and efficient. Text Origin: Commission Proposal
Annex VII, eighth paragraph				
G 893	3.4. Any intended change to the approved quality management system or the list of AI systems covered by the latter shall be brought to the attention of the notified body by the provider.	3.4. Any intended change to the approved quality management system or the list of AI systems covered by the latter shall be brought to the attention of the notified body by the provider.	3.4. Any intended change to the approved quality management system or the list of AI systems covered by the latter shall be brought to the attention of the notified body by the provider.	3.4. Any intended change to the approved quality management system or the list of AI systems covered by the latter shall be brought to the attention of the notified body by the provider. Text Origin: Commission Proposal
Annex VII, ninth paragraph				
G 894	The proposed changes shall be examined by the notified body, which shall decide whether the	The proposed changes shall be examined by the notified body, which shall decide whether the	The proposed changes shall be examined by the notified body, which shall decide whether the	The proposed changes shall be examined by the notified body, which shall decide whether the

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	modified quality management system continues to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.	modified quality management system continues to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.	modified quality management system continues to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.	modified quality management system continues to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary. Text Origin: Commission Proposal
Annex VII, tenth paragraph				
G 895	The notified body shall notify the provider of its decision. The notification shall contain the conclusions of the examination of the changes and the reasoned assessment decision.	The notified body shall notify the provider of its decision. The notification shall contain the conclusions of the examination of the changes and the reasoned assessment decision.	The notified body shall notify the provider of its decision. The notification shall contain the conclusions of the examination of the changes and the reasoned assessment decision.	The notified body shall notify the provider of its decision. The notification shall contain the conclusions of the examination of the changes and the reasoned assessment decision. Text Origin: Commission Proposal
Annex VII, point 4.				
G 896	4. Control of the technical documentation.	4. Control of the technical documentation.	4. Control of the technical documentation.	4. Control of the technical documentation. Text Origin: Commission Proposal
Annex VII, eleventh paragraph				
G 897	4.1. In addition to the application referred to in point 3, an application with a notified body of their choice shall be lodged by the provider for the assessment of the technical	4.1. In addition to the application referred to in point 3, an application with a notified body of their choice shall be lodged by the provider for the assessment of the technical	4.1. In addition to the application referred to in point 3, an application with a notified body of their choice shall be lodged by the provider for the assessment of the technical	4.1. In addition to the application referred to in point 3, an application with a notified body of their choice shall be lodged by the provider for the assessment of the technical

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	documentation relating to the AI system which the provider intends to place on the market or put into service and which is covered by the quality management system referred to under point 3.	documentation relating to the AI system which the provider intends to place on the market or put into service and which is covered by the quality management system referred to under point 3.	documentation relating to the AI system which the provider intends to place on the market or put into service and which is covered by the quality management system referred to under point 3.	documentation relating to the AI system which the provider intends to place on the market or put into service and which is covered by the quality management system referred to under point 3. Text Origin: Commission Proposal
Annex VII, twelfth paragraph				
G 898	4.2. The application shall include:	4.2. The application shall include:	4.2. The application shall include:	4.2. The application shall include: Text Origin: Commission Proposal
Annex VII, twelfth paragraph, point (a)				
G 899	(a) the name and address of the provider;	(a) the name and address of the provider;	(a) the name and address of the provider;	(a) the name and address of the provider; Text Origin: Commission Proposal
Annex VII, twelfth paragraph, point (b)				
G 900	(b) a written declaration that the same application has not been lodged with any other notified body;	(b) a written declaration that the same application has not been lodged with any other notified body;	(b) a written declaration that the same application has not been lodged with any other notified body;	(b) a written declaration that the same application has not been lodged with any other notified body; Text Origin: Commission Proposal
Annex VII, twelfth paragraph, point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 901	(c) the technical documentation referred to in Annex IV.	(c) the technical documentation referred to in Annex IV.	(c) the technical documentation referred to in Annex IV.	(c) the technical documentation referred to in Annex IV. Text Origin: Commission Proposal
Annex VII, thirteenth paragraph				
G 902	4.3. The technical documentation shall be examined by the notified body. To this purpose, the notified body shall be granted full access to the training and testing datasets used by the provider, including through application programming interfaces (API) or other appropriate means and tools enabling remote access.	4.3. The technical documentation shall be examined by the notified body. To this purpose, the notified body shall be granted full access to the training and testing datasets used by the provider, including through application programming interfaces (API) or other appropriate means and tools enabling remote access.	4.3. The technical documentation shall be examined by the notified body. ***Where relevant and limited to what is necessary to fulfil their tasks***~~To this purpose~~, the notified body shall be granted full access to the training***, validation,*** and testing datasets used***, including, where appropriate and subject to security safeguards,*** ~~by the provider, including~~ through application programming interfaces (API) or other ~~appropriate~~***relevant technical*** means and tools enabling remote access.	4.3. The technical documentation shall be examined by the notified body. ***Where relevant and limited to what is necessary to fulfil their tasks***~~To this purpose~~, the notified body shall be granted full access to the training***, validation,*** and testing datasets used***, including, where appropriate and subject to security safeguards,*** ~~by the provider, including~~ through application programming interfaces (API) or other ~~appropriate~~***relevant technical*** means and tools enabling remote access.
Annex VII, fourteenth paragraph				
G 903	4.4. In examining the technical documentation, the notified body may require that the provider supplies further evidence or carries out further tests so as to enable a proper assessment of conformity of the AI system with the requirements set out in Title III, Chapter 2.	4.4. In examining the technical documentation, the notified body may require that the provider supplies further evidence or carries out further tests so as to enable a proper assessment of conformity of the AI system with the requirements set out in Title III, Chapter 2.	4.4. In examining the technical documentation, the notified body may require that the provider supplies further evidence or carries out further tests so as to enable a proper assessment of conformity of the AI system with the requirements set out in Title III, Chapter 2.	4.4. In examining the technical documentation, the notified body may require that the provider supplies further evidence or carries out further tests so as to enable a proper assessment of conformity of the AI system with the requirements set out in Title III, Chapter 2.

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	Whenever the notified body is not satisfied with the tests carried out by the provider, the notified body shall directly carry out adequate tests, as appropriate.	Whenever the notified body is not satisfied with the tests carried out by the provider, the notified body shall directly carry out adequate tests, as appropriate.	Whenever the notified body is not satisfied with the tests carried out by the provider, the notified body shall directly carry out adequate tests, as appropriate.	Whenever the notified body is not satisfied with the tests carried out by the provider, the notified body shall directly carry out adequate tests, as appropriate. Text Origin: Commission Proposal
Annex VII, fifteenth paragraph				
904	4.5. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the notified body shall also be granted access to the source code of the AI system.	4.5. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2***, after all other reasonable ways to verify conformity have been exhausted and have proven to be insufficient,*** and upon a reasoned request, the notified body shall also be granted access to the ~~source code~~***training and trained models*** of the AI system***, including its relevant parameters. Such access shall be subject to existing Union law on the protection of intellectual property and trade secrets. They shall take technical and organisational measures to ensure the protection of intellectual property and trade secrets***.	4.5. ~~*Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and*~~***Notified bodies shall be granted access to the source code of the AI system*** upon a reasoned request~~*, the notified body shall also be granted access to the source code of the AI system.*~~ ***and only when the following cumulative conditions are fulfilled:***	4.5. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2***, after all other reasonable ways to verify conformity have been exhausted and have proven to be insufficient,*** and upon a reasoned request, the notified body shall also be granted access to the ~~source code~~***training and trained models*** of the AI system***, including its relevant parameters. Such access shall be subject to existing Union law on the protection of intellectual property and trade secrets.*** Text Origin: EP Mandate
Annex VII, fifteenth paragraph, point (a)				
904a			***(a) access to source code is***	

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			necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2, and	
Annex VII, fifteenth paragraph, point (b)				
G 904b			***(b) testing/auditing procedures and verifications based on the data and documentation provided by the provider have been exhausted or proved insufficient.***	G
Annex VII, seventeenth paragraph				
G 905	4.6. The decision shall be notified to the provider or its authorised representative. The notification shall contain the conclusions of the assessment of the technical documentation and the reasoned assessment decision.	4.6. The decision shall be notified to the provider or its authorised representative. The notification shall contain the conclusions of the assessment of the technical documentation and the reasoned assessment decision.	4.6. The decision shall be notified to the provider or its authorised representative. The notification shall contain the conclusions of the assessment of the technical documentation and the reasoned assessment decision.	4.6. The decision shall be notified to the provider or its authorised representative. The notification shall contain the conclusions of the assessment of the technical documentation and the reasoned assessment decision. Text Origin: Commission Proposal G
Annex VII, eighteenth paragraph				
G 906	Where the AI system is in conformity with the requirements set out in Title III, Chapter 2, an EU technical documentation assessment certificate shall be issued by the notified body. The certificate shall	Where the AI system is in conformity with the requirements set out in Title III, Chapter 2, an EU technical documentation assessment certificate shall be issued by the notified body. The certificate shall	Where the AI system is in conformity with the requirements set out in Title III, Chapter 2, an EU technical documentation assessment certificate shall be issued by the notified body. The certificate shall	Where the AI system is in conformity with the requirements set out in Title III, Chapter 2, an EU technical documentation assessment certificate shall be issued by the notified body. The certificate shall G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	indicate the name and address of the provider, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for the identification of the AI system.	indicate the name and address of the provider, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for the identification of the AI system.	indicate the name and address of the provider, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for the identification of the AI system.	indicate the name and address of the provider, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for the identification of the AI system. Text Origin: Commission Proposal
Annex VII, nineteenth paragraph				
G 907	The certificate and its annexes shall contain all relevant information to allow the conformity of the AI system to be evaluated, and to allow for control of the AI system while in use, where applicable.	The certificate and its annexes shall contain all relevant information to allow the conformity of the AI system to be evaluated, and to allow for control of the AI system while in use, where applicable.	The certificate and its annexes shall contain all relevant information to allow the conformity of the AI system to be evaluated, and to allow for control of the AI system while in use, where applicable.	The certificate and its annexes shall contain all relevant information to allow the conformity of the AI system to be evaluated, and to allow for control of the AI system while in use, where applicable. Text Origin: Commission Proposal
Annex VII, twentieth paragraph				
G 908	Where the AI system is not in conformity with the requirements set out in Title III, Chapter 2, the notified body shall refuse to issue an EU technical documentation assessment certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.	Where the AI system is not in conformity with the requirements set out in Title III, Chapter 2, the notified body shall refuse to issue an EU technical documentation assessment certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.	Where the AI system is not in conformity with the requirements set out in Title III, Chapter 2, the notified body shall refuse to issue an EU technical documentation assessment certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.	Where the AI system is not in conformity with the requirements set out in Title III, Chapter 2, the notified body shall refuse to issue an EU technical documentation assessment certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal. Text Origin: Commission Proposal

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex VII, twenty-first paragraph				
G 909	Where the AI system does not meet the requirement relating to the data used to train it, re-training of the AI system will be needed prior to the application for a new conformity assessment. In this case, the reasoned assessment decision of the notified body refusing to issue the EU technical documentation assessment certificate shall contain specific considerations on the quality data used to train the AI system, notably on the reasons for non-compliance.	Where the AI system does not meet the requirement relating to the data used to train it, re-training of the AI system will be needed prior to the application for a new conformity assessment. In this case, the reasoned assessment decision of the notified body refusing to issue the EU technical documentation assessment certificate shall contain specific considerations on the quality data used to train the AI system, notably on the reasons for non-compliance.	Where the AI system does not meet the requirement relating to the data used to train it, re-training of the AI system will be needed prior to the application for a new conformity assessment. In this case, the reasoned assessment decision of the notified body refusing to issue the EU technical documentation assessment certificate shall contain specific considerations on the quality data used to train the AI system, notably on the reasons for non-compliance.	Where the AI system does not meet the requirement relating to the data used to train it, re-training of the AI system will be needed prior to the application for a new conformity assessment. In this case, the reasoned assessment decision of the notified body refusing to issue the EU technical documentation assessment certificate shall contain specific considerations on the quality data used to train the AI system, notably on the reasons for non-compliance. Text Origin: Commission Proposal
Annex VII, 11 paragraph				
G 910	4.7. Any change to the AI system that could affect the compliance of the AI system with the requirements or its intended purpose shall be approved by the notified body which issued the EU technical documentation assessment certificate. The provider shall inform such notified body of its intention to introduce any of the above-mentioned changes or if it becomes otherwise aware of the occurrence of such changes. The intended changes shall be assessed by the notified	4.7. Any change to the AI system that could affect the compliance of the AI system with the requirements or its intended purpose shall be approved by the notified body which issued the EU technical documentation assessment certificate. The provider shall inform such notified body of its intention to introduce any of the above-mentioned changes or if it becomes otherwise aware of the occurrence of such changes. The intended changes shall be assessed by the notified	4.7. Any change to the AI system that could affect the compliance of the AI system with the requirements or its intended purpose shall be approved by the notified body which issued the EU technical documentation assessment certificate. The provider shall inform such notified body of its intention to introduce any of the above-mentioned changes or if it becomes otherwise aware of the occurrence of such changes. The intended changes shall be assessed by the notified	4.7. Any change to the AI system that could affect the compliance of the AI system with the requirements or its intended purpose shall be approved by the notified body which issued the EU technical documentation assessment certificate. The provider shall inform such notified body of its intention to introduce any of the above-mentioned changes or if it becomes otherwise aware of the occurrence of such changes. The intended changes shall be assessed by the notified

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	body which shall decide whether those changes require a new conformity assessment in accordance with Article 43(4) or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the provider of its decision and, where the changes are approved, issue to the provider a supplement to the EU technical documentation assessment certificate.	body which shall decide whether those changes require a new conformity assessment in accordance with Article 43(4) or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the provider of its decision and, where the changes are approved, issue to the provider a supplement to the EU technical documentation assessment certificate.	body which shall decide whether those changes require a new conformity assessment in accordance with Article 43(4) or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the provider of its decision and, where the changes are approved, issue to the provider a supplement to the EU technical documentation assessment certificate.	body which shall decide whether those changes require a new conformity assessment in accordance with Article 43(4) or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the provider of its decision and, where the changes are approved, issue to the provider a supplement to the EU technical documentation assessment certificate. Text Origin: Commission Proposal
Annex VII, point 5.				
G 911	5. Surveillance of the approved quality management system.	5. Surveillance of the approved quality management system.	5. Surveillance of the approved quality management system.	5. Surveillance of the approved quality management system. Text Origin: Commission Proposal G
Annex VII, 8 paragraph				
G 912	5.1. The purpose of the surveillance carried out by the notified body referred to in Point 3 is to make sure that the provider duly fulfils the terms and conditions of the approved quality management system.	5.1. The purpose of the surveillance carried out by the notified body referred to in Point 3 is to make sure that the provider duly fulfils the terms and conditions of the approved quality management system.	5.1. The purpose of the surveillance carried out by the notified body referred to in Point 3 is to make sure that the provider duly fulfils the terms and conditions of the approved quality management system.	5.1. The purpose of the surveillance carried out by the notified body referred to in Point 3 is to make sure that the provider duly fulfils the terms and conditions of the approved quality management system. G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Annex VII, 2 paragraph				
G 913	5.2. For assessment purposes, the provider shall allow the notified body to access the premises where the design, development, testing of the AI systems is taking place. The provider shall further share with the notified body all necessary information.	5.2. For assessment purposes, the provider shall allow the notified body to access the premises where the design, development, testing of the AI systems is taking place. The provider shall further share with the notified body all necessary information.	5.2. For assessment purposes, the provider shall allow the notified body to access the premises where the design, development, testing of the AI systems is taking place. The provider shall further share with the notified body all necessary information.	5.2. For assessment purposes, the provider shall allow the notified body to access the premises where the design, development, testing of the AI systems is taking place. The provider shall further share with the notified body all necessary information. Text Origin: Commission Proposal
Annex VII, 3 paragraph				
G 914	5.3. The notified body shall carry out periodic audits to make sure that the provider maintains and applies the quality management system and shall provide the provider with an audit report. In the context of those audits, the notified body may carry out additional tests of the AI systems for which an EU technical documentation assessment certificate was issued.	5.3. The notified body shall carry out periodic audits to make sure that the provider maintains and applies the quality management system and shall provide the provider with an audit report. In the context of those audits, the notified body may carry out additional tests of the AI systems for which an EU technical documentation assessment certificate was issued.	5.3. The notified body shall carry out periodic audits to make sure that the provider maintains and applies the quality management system and shall provide the provider with an audit report. In the context of those audits, the notified body may carry out additional tests of the AI systems for which an EU technical documentation assessment certificate was issued.	5.3. The notified body shall carry out periodic audits to make sure that the provider maintains and applies the quality management system and shall provide the provider with an audit report. In the context of those audits, the notified body may carry out additional tests of the AI systems for which an EU technical documentation assessment certificate was issued. Text Origin: Commission Proposal
Annex VIII				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 915	Annex VIII INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF HIGH-RISK AI SYSTEMS IN ACCORDANCE WITH ARTICLE 51	Annex VIII INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF HIGH-RISK AI SYSTEMS IN ACCORDANCE WITH ARTICLE 51	Annex VIII INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF ***OPERATORS AND*** HIGH-RISK AI SYSTEMS IN ACCORDANCE WITH ARTICLE 51	Annex VIII INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF HIGH-RISK AI SYSTEMS IN ACCORDANCE WITH ARTICLE 51 Text Origin: Commission Proposal
Annex VIII, first paragraph				
G 916	The following information shall be provided and thereafter kept up to date with regard to high-risk AI systems to be registered in accordance with Article 51.	***Section A -*** The following information shall be provided and thereafter kept up to date with regard to high-risk AI systems to be registered in accordance with Article 51 ***(1)***.	~~The following information~~***Providers, authorised representatives and users that are public authorities, agencies or bodies*** shall ~~be provided and thereafter kept up to date with regard to~~***submit the information referred to in Part I. Providers or, when applicable, authorised representatives shall ensure that the information on their*** high-risk AI systems ***referred to in Part II, 1 to 11 is complete, correct and kept up-to-date. Information laid down in II.12 shall be automatically generated by the database***~~to be registered in accordance with Article 51~~.	***Section A -*** The following information shall be provided and thereafter kept up to date with regard to high-risk AI systems to be registered in accordance with Article 51 ***(1)***.
Annex VIII, first paragraph a				
G 916a			***1. Type of operator (provider, authorised representative or user);***	Text Origin: Council Mandate

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex VIII, Part I				
916b			***Part I Information related to operators (upon operators'registration)***	
Annex VIII, point 1.				
917	1. Name, address and contact details of the provider;	1. Name, address and contact details of the provider;	1. Name, address and contact details of the provider;	1. Name, address and contact details of the provider; Text Origin: Commission Proposal
Annex VIII, point 2.				
918	2. Where submission of information is carried out by another person on behalf of the provider, the name, address and contact details of that person;	2. Where submission of information is carried out by another person on behalf of the provider, the name, address and contact details of that person;	2. Where submission of information is carried out by another person on behalf of the ~~provider~~***operator***, the name, address and contact details of that person;	2. Where submission of information is carried out by another person on behalf of the provider, the name, address and contact details of that person; Text Origin: Commission Proposal
Annex VIII, Part II				
918a			***Part II Information related to the high-risk AI system***	
Annex VIII, point 3.				
919	3. Name, address and contact details of the authorised representative,	3. Name, address and contact details of the authorised representative,	3. Name, address and contact details of the ~~authorised representative,~~	3. Name, address and contact details of the authorised representative,

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	where applicable;	where applicable;	~~where applicable;~~***provider***	where applicable; Text Origin: Commission Proposal
Annex VIII, point 3a.				
919a			***3a. Name, address and contact details of the authorised representative, where applicable;***	
Annex VIII, point 4.				
920	4. AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system;	4. AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system;	4. AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system;	4. AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system; Text Origin: Commission Proposal
Annex VIII, point 4a.				
920a		***4a. Foundation model trade name and any additional unambiguous refernce allowing identification and traceability***		***4a.*** Text Origin: EP Mandate
Annex VIII, point 5.				
921	5. Description of the intended purpose of the AI system;	5. ***A simple and comprehensible*** description of ***a.*** the intended purpose of the AI system;	5. Description of the intended purpose of the AI system;	5. Description of the intended purpose of the AI system ***and of the components and functions supported through this AI system***;

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		b. the components and functions supported through AI; ***c. a basic explanation of the logic of the AI system***		***5a A basic and concise description of the information used by the system (data, inputs) and its operating logic.***
Annex VIII, point 5a (new).				
G 921a		***5a. where applicable, the categories and nature of data likely or foreseen to be processed by the AI system.***		G
Annex VIII, point 6.				
G 922	6. Status of the AI system (on the market, or in service; no longer placed on the market/in service, recalled);	6. Status of the AI system (on the market, or in service; no longer placed on the market/in service, recalled);	6. Status of the AI system (on the market, or in service; no longer placed on the market/in service, recalled);	6. Status of the AI system (on the market, or in service; no longer placed on the market/in service, recalled); Text Origin: Commission Proposal G
Annex VIII, point 7.				
G 923	7. Type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body, when applicable;	7. Type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body, when applicable;	7. Type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body, when applicable;	7. Type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body, when applicable; Text Origin: Commission Proposal G
Annex VIII, point 8.				

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G 924	8. A scanned copy of the certificate referred to in point 7, when applicable;	8. A scanned copy of the certificate referred to in point 7, when applicable;	8. A scanned copy of the certificate referred to in point 7, when applicable;	8. A scanned copy of the certificate referred to in point 7, when applicable; Text Origin: Commission Proposal
Annex VIII, point 9.				
G 925	9. Member States in which the AI system is or has been placed on the market, put into service or made available in the Union;	9. Member States in which the AI system is or has been placed on the market, put into service or made available in the Union;	9. Member States in which the AI system is or has been placed on the market, put into service or made available in the Union;	9. Member States in which the AI system is or has been placed on the market, put into service or made available in the Union; Text Origin: Commission Proposal
Annex VIII, point 10.				
G 926	10. A copy of the EU declaration of conformity referred to in Article 48;	10. A copy of the EU declaration of conformity referred to in Article 48;	10. A copy of the EU declaration of conformity referred to in Article 48;	10. A copy of the EU declaration of conformity referred to in Article 48; Text Origin: Commission Proposal
Annex VIII, point 11.				
G 927	11. Electronic instructions for use; this information shall not be provided for high-risk AI systems in the areas of law enforcement and migration, asylum and border control management referred to in Annex III, points 1, 6 and 7.	*deleted*	11. Electronic instructions for use; ~~*this information shall not be provided for high-risk AI systems in the areas of law enforcement and migration, asylum and border control management referred to in Annex III, points 1, 6 and 7.*~~	11. Electronic instructions for use; this information shall not be provided for high-risk AI systems in the areas of law enforcement and migration, asylum and border control management referred to in Annex III, points 1, 6 and 7.

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				Text Origin: Commission Proposal
Annex VIII, point 12.				
G 928	12. URL for additional information (optional).	12. URL for additional information (optional).	12. URL for additional information (optional)~~.~~;	12. URL for additional information (optional). Text Origin: Commission Proposal
Annex VIII, point 12a.				
G 928a			***12a. Name, address and contact details of users.***	
Annex VIII - SECTION B (new)				
G 928b		***Annex VIII SECTION B The following information shall be provided and thereafter kept up to date with regard to high-risk AI systems to be registered in accordance with Article 51 (1a) (a) and (1b).*** ***1. the name, address and contact details of the deployer ;*** ***2. the name, address and contact details of the person submitting information on behalf of the deployer ;*** ***3. the high risk AI system trade name and any additional unambiguous reference allowing identification and traceability of the***		***Annex VIII SECTION B The following information shall be provided and thereafter kept up to date with regard to high-risk AI systems to be registered in accordance with Article 51.*** ***1. the name, address and contact details of the deployer;*** ***2. the name, address and contact details of the person submitting information on behalf of the deployer ;*** ***5. a summary of the findings of the fundamental rights impact assessment conducted in accordance with Article 29a*** ***6. The URL of the entry of the AI***

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		AI system used; *4. a) A simple and comprehensible description of the intended use of the AI system, including the specific outcomes sought through the use of the systemn, the geographic and temporal scope of application* *b. Where applicable, the categories and nature of data to be processed by the AI system;* *c. Arrangements for human oversight and governance* *d. Where relevant, the bodies or natural persons responsible for decisions taken or supported by the AI system;* *5. a summary of the findings of the fundamental rights impact assessment conducted in accordance with Article 29a* *6. The URL of the entry of the AI system in the EU database by its provider* *7. A summary of the data protection impact assessment carried out in accordance with Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680 as specified in paragraph 6 of Article 29 of this Regulation, where applicable.*		*system in the EU database by its provider.* *7. A summary of the data protection impact assessment carried out in accordance with Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680 as specified in paragraph 6 of Article 29 of this Regulation, where applicable.* *ANNEX VIII SECTION C INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF HIGH-RISK AI SYSTEMS IN ACCORDANCE WITH ARTICLE 51* *The following information shall be provided and thereafter kept up to date with regard to AI systems to be registered in accordance with Article 51(1a).* *1. Name, address and contact details of the provider;* *1. Where submission of information is carried out by another person on behalf of the provider, the name, address and contact details of that person;* *2. Name, address and contact details of the authorised representative, where applicable;* *3. AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system;*

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				4. Description of the intended purpose of the AI system; ***5. Based on which criterion or criteria provided in Article 6(2a) the AI system is considered as not high-risk;*** ***6. Short summary of the grounds for considering the AI system as not high-risk in application of the procedure under Article 6(2a);*** ***7. Status of the AI system (on the market, or in service; no longer placed on the market/in service, recalled);*** ***Member States in which the AI system is or has been placed on the market, put into service or made available in the Union.*** Text Origin: EP Mandate
Annex VIII - SECTION B (new)				
G 928c			***Annex VIIIa INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF HIGH-RISK AI SYSTEMS LISTED IN ANNEX III IN RELATION TO TESTING IN REAL WORLD CONDITIONS IN ACCORDANCE WITH ARTICLE 54a*** ***The following information shall be provided and thereafter kept up to date with regard to testing in real***	***Annex VIIIa INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF HIGH-RISK AI SYSTEMS LISTED IN ANNEX III IN RELATION TO TESTING IN REAL WORLD CONDITIONS IN ACCORDANCE WITH ARTICLE 54a*** ***The following information shall be provided and thereafter kept up to date with regard to testing in real*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			world conditions to be registered in accordance with Article 54a: ***1. Union-wide unique single identification number of the testing in real world conditions;*** ***2. Name and contact details of the provider or prospective provider and users involved in the testing in real world conditions;*** ***3. A brief description of the AI system, its intended purpose and other information necessary for the identification of the system;*** ***4. A summary of the main characteristics of the plan for testing in real world conditions;*** ***5. Information on the suspension or termination of the testing in real world conditions.***	***world conditions to be registered in accordance with Article 54a:*** ***1. Union-wide unique single identification number of the testing in real world conditions;*** ***2. Name and contact details of the provider or prospective provider and users involved in the testing in real world conditions;*** ***3. A brief description of the AI system, its intended purpose and other information necessary for the identification of the system;*** ***4. A summary of the main characteristics of the plan for testing in real world conditions;*** ***5. Information on the suspension or termination of the testing in real world conditions.*** Text Origin: Council Mandate
Annex VIII SECTION C - (new)				
G 928d		***Annex VIII Section C The following information shall be provided and thereafter kept up to date with regard to foundation models to be registered in accordance with Article 28b (e).*** ***1. Name, address and contact details of the provider;*** ***2. Where submission of information is carried out by another person on behalf of the***		G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		provider, the name, address and contact details of that person; ***3. Name, address and contact details of the authorised representative, where applicable;*** ***4. Trade name and any additional unambiguous reference allowing the identification of the foundation model*** ***5. Description of the data sources used in the development of the foundational model*** ***6. Description of the capabilities and limitations of the foundation model, including the reasonably foreseeable risks and the measures that have been taken to mitigate them as well as remaining non-mitigated risks with an explanation on the reason why they cannot be mitigated*** ***7. Description of the training resources used by the foundation model including computing power required, training time, and other relevant information related to the size and power of the model 8. Description of the model's performance, including on public benchmarks or state of the art industry benchmarks*** ***8. Description of the results of relevant internal and external testing and optimisation of the model*** ***9. Member States in which the foundation model is or has been***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		placed on the market, put into service or made available in the Union; ***10. URL for additional information (optional).***		
Annex VIIIb				
928e				
Annex VIIId				
928f				
Annex IX				
929	Annex IX Union legislation ON large-scale IT systems in the area of Freedom, Security and Justice	Annex IX Union legislation ON large-scale IT systems in the area of Freedom, Security and Justice	Annex IX Union legislation ON large-scale IT systems in the area of Freedom, Security and Justice	Annex IX Union legislation ON large-scale IT systems in the area of Freedom, Security and Justice Text Origin: Commission Proposal
Annex IX, point 1.				
930	1. Schengen Information System	1. Schengen Information System	1. Schengen Information System	1. Schengen Information System Text Origin: Commission Proposal
Annex IX, point 1.(a)				
931	(a) Regulation (EU) 2018/1860 of the European Parliament and of the Council of 28 November 2018 on	(a) Regulation (EU) 2018/1860 of the European Parliament and of the Council of 28 November 2018 on	(a) Regulation (EU) 2018/1860 of the European Parliament and of the Council of 28 November 2018 on	(a) Regulation (EU) 2018/1860 of the European Parliament and of the Council of 28 November 2018 on

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	the use of the Schengen Information System for the return of illegally staying third-country nationals (OJ L 312, 7.12.2018, p. 1).	the use of the Schengen Information System for the return of illegally staying third-country nationals (OJ L 312, 7.12.2018, p. 1).	the use of the Schengen Information System for the return of illegally staying third-country nationals (OJ L 312, 7.12.2018, p. 1).	the use of the Schengen Information System for the return of illegally staying third-country nationals (OJ L 312, 7.12.2018, p. 1). Text Origin: Commission Proposal
Annex IX, point 1.(b)				
G 932	(b) Regulation (EU) 2018/1861 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of border checks, and amending the Convention implementing the Schengen Agreement, and amending and repealing Regulation (EC) No 1987/2006 (OJ L 312, 7.12.2018, p. 14)	(b) Regulation (EU) 2018/1861 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of border checks, and amending the Convention implementing the Schengen Agreement, and amending and repealing Regulation (EC) No 1987/2006 (OJ L 312, 7.12.2018, p. 14)	(b) Regulation (EU) 2018/1861 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of border checks, and amending the Convention implementing the Schengen Agreement, and amending and repealing Regulation (EC) No 1987/2006 (OJ L 312, 7.12.2018, p. 14)	(b) Regulation (EU) 2018/1861 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of border checks, and amending the Convention implementing the Schengen Agreement, and amending and repealing Regulation (EC) No 1987/2006 (OJ L 312, 7.12.2018, p. 14) Text Origin: Commission Proposal
Annex IX, point 1.(c)				
G 933	(c) Regulation (EU) 2018/1862 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of police cooperation and judicial cooperation in criminal matters, amending and	(c) Regulation (EU) 2018/1862 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of police cooperation and judicial cooperation in criminal matters, amending and	(c) Regulation (EU) 2018/1862 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of police cooperation and judicial cooperation in criminal matters, amending and	(c) Regulation (EU) 2018/1862 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of police cooperation and judicial cooperation in criminal matters, amending and

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	repealing Council Decision 2007/533/JHA, and repealing Regulation (EC) No 1986/2006 of the European Parliament and of the Council and Commission Decision 2010/261/EU (OJ L 312, 7.12.2018, p. 56).	repealing Council Decision 2007/533/JHA, and repealing Regulation (EC) No 1986/2006 of the European Parliament and of the Council and Commission Decision 2010/261/EU (OJ L 312, 7.12.2018, p. 56).	repealing Council Decision 2007/533/JHA, and repealing Regulation (EC) No 1986/2006 of the European Parliament and of the Council and Commission Decision 2010/261/EU (OJ L 312, 7.12.2018, p. 56).	repealing Council Decision 2007/533/JHA, and repealing Regulation (EC) No 1986/2006 of the European Parliament and of the Council and Commission Decision 2010/261/EU (OJ L 312, 7.12.2018, p. 56). Text Origin: Commission Proposal
Annex IX, point 2.				
G 934	2. Visa Information System	2. Visa Information System	2. Visa Information System	2. Visa Information System Text Origin: Commission Proposal
Annex IX, point 2.(a)				
G 935	(a) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 767/2008, Regulation (EC) No 810/2009, Regulation (EU) 2017/2226, Regulation (EU) 2016/399, Regulation XX/2018 [Interoperability Regulation], and Decision 2004/512/EC and repealing Council Decision 2008/633/JHA - COM(2018) 302 final. To be updated once the Regulation is adopted (April/May 2021) by the co-legislators.	(a) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 767/2008, Regulation (EC) No 810/2009, Regulation (EU) 2017/2226, Regulation (EU) 2016/399, Regulation XX/2018 [Interoperability Regulation], and Decision 2004/512/EC and repealing Council Decision 2008/633/JHA - COM(2018) 302 final. To be updated once the Regulation is adopted (April/May 2021) by the co-legislators.	(a) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 767/2008, Regulation (EC) No 810/2009, Regulation (EU) 2017/2226, Regulation (EU) 2016/399, Regulation XX/2018 [Interoperability Regulation], and Decision 2004/512/EC and repealing Council Decision 2008/633/JHA - COM(2018) 302 final. To be updated once the Regulation is adopted (April/May 2021) by the co-legislators.	(a) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 767/2008, Regulation (EC) No 810/2009, Regulation (EU) 2017/2226, Regulation (EU) 2016/399, Regulation XX/2018 [Interoperability Regulation], and Decision 2004/512/EC and repealing Council Decision 2008/633/JHA - COM(2018) 302 final. To be updated once the Regulation is adopted (April/May 2021) by the co-legislators.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Annex IX, point 3.				
G 936	3. Eurodac	3. Eurodac	3. Eurodac	3. Eurodac Text Origin: Commission Proposal
Annex IX, point 3.(a)				
G 937	(a) Amended proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the establishment of 'Eurodac' for the comparison of biometric data for the effective application of Regulation (EU) XXX/XXX [Regulation on Asylum and Migration Management] and of Regulation (EU) XXX/XXX [Resettlement Regulation], for identifying an illegally staying third-country national or stateless person and on requests for the comparison with Eurodac data by Member States' law enforcement authorities and Europol for law enforcement purposes and amending Regulations (EU) 2018/1240 and (EU) 2019/818 – COM(2020) 614 final.	(a) Amended proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the establishment of 'Eurodac' for the comparison of biometric data for the effective application of Regulation (EU) XXX/XXX [Regulation on Asylum and Migration Management] and of Regulation (EU) XXX/XXX [Resettlement Regulation], for identifying an illegally staying third-country national or stateless person and on requests for the comparison with Eurodac data by Member States' law enforcement authorities and Europol for law enforcement purposes and amending Regulations (EU) 2018/1240 and (EU) 2019/818 – COM(2020) 614 final.	(a) Amended proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the establishment of 'Eurodac' for the comparison of biometric data for the effective application of Regulation (EU) XXX/XXX [Regulation on Asylum and Migration Management] and of Regulation (EU) XXX/XXX [Resettlement Regulation], for identifying an illegally staying third-country national or stateless person and on requests for the comparison with Eurodac data by Member States' law enforcement authorities and Europol for law enforcement purposes and amending Regulations (EU) 2018/1240 and (EU) 2019/818 – COM(2020) 614 final.	(a) Amended proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the establishment of 'Eurodac' for the comparison of biometric data for the effective application of Regulation (EU) XXX/XXX [Regulation on Asylum and Migration Management] and of Regulation (EU) XXX/XXX [Resettlement Regulation], for identifying an illegally staying third-country national or stateless person and on requests for the comparison with Eurodac data by Member States' law enforcement authorities and Europol for law enforcement purposes and amending Regulations (EU) 2018/1240 and (EU) 2019/818 – COM(2020) 614 final. Text Origin: Commission Proposal

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex IX, point 4.				
G 938	4. Entry/Exit System	4. Entry/Exit System	4. Entry/Exit System	4. Entry/Exit System Text Origin: Commission Proposal
Annex IX, point 4.(a)				
G 939	(a) Regulation (EU) 2017/2226 of the European Parliament and of the Council of 30 November 2017 establishing an Entry/Exit System (EES) to register entry and exit data and refusal of entry data of third-country nationals crossing the external borders of the Member States and determining the conditions for access to the EES for law enforcement purposes, and amending the Convention implementing the Schengen Agreement and Regulations (EC) No 767/2008 and (EU) No 1077/2011 (OJ L 327, 9.12.2017, p. 20).	(a) Regulation (EU) 2017/2226 of the European Parliament and of the Council of 30 November 2017 establishing an Entry/Exit System (EES) to register entry and exit data and refusal of entry data of third-country nationals crossing the external borders of the Member States and determining the conditions for access to the EES for law enforcement purposes, and amending the Convention implementing the Schengen Agreement and Regulations (EC) No 767/2008 and (EU) No 1077/2011 (OJ L 327, 9.12.2017, p. 20).	(a) Regulation (EU) 2017/2226 of the European Parliament and of the Council of 30 November 2017 establishing an Entry/Exit System (EES) to register entry and exit data and refusal of entry data of third-country nationals crossing the external borders of the Member States and determining the conditions for access to the EES for law enforcement purposes, and amending the Convention implementing the Schengen Agreement and Regulations (EC) No 767/2008 and (EU) No 1077/2011 (OJ L 327, 9.12.2017, p. 20).	(a) Regulation (EU) 2017/2226 of the European Parliament and of the Council of 30 November 2017 establishing an Entry/Exit System (EES) to register entry and exit data and refusal of entry data of third-country nationals crossing the external borders of the Member States and determining the conditions for access to the EES for law enforcement purposes, and amending the Convention implementing the Schengen Agreement and Regulations (EC) No 767/2008 and (EU) No 1077/2011 (OJ L 327, 9.12.2017, p. 20). Text Origin: Commission Proposal
Annex IX, point 5.				
G 940	5. European Travel Information and Authorisation System	5. European Travel Information and Authorisation System	5. European Travel Information and Authorisation System	5. European Travel Information and Authorisation System

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Annex IX, point 5.(a)				
G 941	(a) Regulation (EU) 2018/1240 of the European Parliament and of the Council of 12 September 2018 establishing a European Travel Information and Authorisation System (ETIAS) and amending Regulations (EU) No 1077/2011, (EU) No 515/2014, (EU) 2016/399, (EU) 2016/1624 and (EU) 2017/2226 (OJ L 236, 19.9.2018, p. 1).	(a) Regulation (EU) 2018/1240 of the European Parliament and of the Council of 12 September 2018 establishing a European Travel Information and Authorisation System (ETIAS) and amending Regulations (EU) No 1077/2011, (EU) No 515/2014, (EU) 2016/399, (EU) 2016/1624 and (EU) 2017/2226 (OJ L 236, 19.9.2018, p. 1).	(a) Regulation (EU) 2018/1240 of the European Parliament and of the Council of 12 September 2018 establishing a European Travel Information and Authorisation System (ETIAS) and amending Regulations (EU) No 1077/2011, (EU) No 515/2014, (EU) 2016/399, (EU) 2016/1624 and (EU) 2017/2226 (OJ L 236, 19.9.2018, p. 1).	(a) Regulation (EU) 2018/1240 of the European Parliament and of the Council of 12 September 2018 establishing a European Travel Information and Authorisation System (ETIAS) and amending Regulations (EU) No 1077/2011, (EU) No 515/2014, (EU) 2016/399, (EU) 2016/1624 and (EU) 2017/2226 (OJ L 236, 19.9.2018, p. 1). Text Origin: Commission Proposal
Annex IX, point 5.(b)				
G 942	(b) Regulation (EU) 2018/1241 of the European Parliament and of the Council of 12 September 2018 amending Regulation (EU) 2016/794 for the purpose of establishing a European Travel Information and Authorisation System (ETIAS) (OJ L 236, 19.9.2018, p. 72).	(b) Regulation (EU) 2018/1241 of the European Parliament and of the Council of 12 September 2018 amending Regulation (EU) 2016/794 for the purpose of establishing a European Travel Information and Authorisation System (ETIAS) (OJ L 236, 19.9.2018, p. 72).	(b) Regulation (EU) 2018/1241 of the European Parliament and of the Council of 12 September 2018 amending Regulation (EU) 2016/794 for the purpose of establishing a European Travel Information and Authorisation System (ETIAS) (OJ L 236, 19.9.2018, p. 72).	(b) Regulation (EU) 2018/1241 of the European Parliament and of the Council of 12 September 2018 amending Regulation (EU) 2016/794 for the purpose of establishing a European Travel Information and Authorisation System (ETIAS) (OJ L 236, 19.9.2018, p. 72). Text Origin: Commission Proposal
Annex IX, point 6.				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 943	6. European Criminal Records Information System on third-country nationals and stateless persons	6. European Criminal Records Information System on third-country nationals and stateless persons	6. European Criminal Records Information System on third-country nationals and stateless persons	6. European Criminal Records Information System on third-country nationals and stateless persons Text Origin: Commission Proposal
Annex IX, point 6.(a)				
G 944	(a) Regulation (EU) 2019/816 of the European Parliament and of the Council of 17 April 2019 establishing a centralised system for the identification of Member States holding conviction information on third-country nationals and stateless persons (ECRIS-TCN) to supplement the European Criminal Records Information System and amending Regulation (EU) 2018/1726 (OJ L 135, 22.5.2019, p. 1).	(a) Regulation (EU) 2019/816 of the European Parliament and of the Council of 17 April 2019 establishing a centralised system for the identification of Member States holding conviction information on third-country nationals and stateless persons (ECRIS-TCN) to supplement the European Criminal Records Information System and amending Regulation (EU) 2018/1726 (OJ L 135, 22.5.2019, p. 1).	(a) Regulation (EU) 2019/816 of the European Parliament and of the Council of 17 April 2019 establishing a centralised system for the identification of Member States holding conviction information on third-country nationals and stateless persons (ECRIS-TCN) to supplement the European Criminal Records Information System and amending Regulation (EU) 2018/1726 (OJ L 135, 22.5.2019, p. 1).	(a) Regulation (EU) 2019/816 of the European Parliament and of the Council of 17 April 2019 establishing a centralised system for the identification of Member States holding conviction information on third-country nationals and stateless persons (ECRIS-TCN) to supplement the European Criminal Records Information System and amending Regulation (EU) 2018/1726 (OJ L 135, 22.5.2019, p. 1). Text Origin: Commission Proposal
Annex IX, point 7.				
G 945	7. Interoperability	7. Interoperability	7. Interoperability	7. Interoperability Text Origin: Commission Proposal
Annex IX, point 7.(a)				
G 946				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(a) Regulation (EU) 2019/817 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of borders and visa (OJ L 135, 22.5.2019, p. 27).	(a) Regulation (EU) 2019/817 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of borders and visa (OJ L 135, 22.5.2019, p. 27).	(a) Regulation (EU) 2019/817 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of borders and visa (OJ L 135, 22.5.2019, p. 27).	(a) Regulation (EU) 2019/817 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of borders and visa (OJ L 135, 22.5.2019, p. 27). Text Origin: Commission Proposal
Annex IX, point 7.(b)				
G 947	(b) Regulation (EU) 2019/818 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of police and judicial cooperation, asylum and migration (OJ L 135, 22.5.2019, p. 85).	(b) Regulation (EU) 2019/818 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of police and judicial cooperation, asylum and migration (OJ L 135, 22.5.2019, p. 85).	(b) Regulation (EU) 2019/818 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of police and judicial cooperation, asylum and migration (OJ L 135, 22.5.2019, p. 85).	(b) Regulation (EU) 2019/818 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of police and judicial cooperation, asylum and migration (OJ L 135, 22.5.2019, p. 85). Text Origin: Commission Proposal
Annex IXa				
G 947a				***Annex IXa TECHNICAL DOCUMENTATION referred to in Article C(1a): technical documentation for providers of general-purpose AI models:*** ***Section 1: Information to be***

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				provided by all providers of general-purpose AI models ***The technical documentation referred to in Article X (b) shall contain at least the following information as appropriate to the size and risk profile of the model:*** ***1. A general description of the general-purpose AI model including:*** ***a) the tasks that the model is intended to perform and the type and nature of AI systems in which it can be integrated;*** ***b) acceptable use policies applicable;*** ***c) the date of release and methods of distribution;*** ***d) the architecture and number of parameters;*** ***e) modality (e.g. text, image) and format of inputs and outputs;*** ***f) the license;*** ***2. A detailed description of the elements of the model refered to in paragraph 1, and relevant information of the process for the development, including the following elements:*** ***a) the technical means (e.g. instructions of use, infrastructure, tools) required for the general-purpose AI model to be integrated in AI systems;*** ***b) the design specifications of the model and training process,***

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				including training methodologies and techniques, the key design choices including the rationale and assumptions made; what the model is designed to optimise for and the relevance of the different parameters, as applicable; ***c) information on the data used for training, testing and validation, where applicable, including type and provenance of data and curation methodologies (e.g. cleaning, filtering etc), the number of data points, their scope and main characteristics; how the data was obtained and selected as well as all other measures to detect the unsuitability of data sources and methods to detect identifiable biases, where applicable;*** ***d) the computational resources used to train the model (e.g. number of floating point operations – FLOPs-), training time, and other relevant details related to the training;*** ***e) known or estimated energy consumption of the model; in case not known, this could be based on information about computational resources used ;*** ***Section 2: Additional information to be provided by providers of general-purpose AI model with systemic risk***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				3. Detailed description of the evaluation strategies, including evaluation results, on the basis of available public evaluation protocols and tools or otherwise of other evaluation methodologies. Evaluation strategies shall include evaluation criteria, metrics and the methodology on the identification of limitations. ***4. Where applicable, detailed description of the measures put in place for the purpose of conducting internal and/or external adversarial testing (e.g., red teaming), model adaptations, including alignment and fine-tuning.*** ***Where applicable, detailed description of the system architecture explaining how software components build or feed into each other and integrate into the overall processing.***
Annex IXb				
G 947b				***Annex IXb TRANSPARENCY INFORMATION referred to in Article C(1b): technical documentation for providers of general-purpose AI models to downstream providers that integrate the model into their AI system*** ***The information referred to in*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Article X(c) shall contain at least the following: ***1. A general description of the general-purpose AI model including:*** ***a) the tasks that the model is intended to perform and the type and nature of AI systems in which it can be integrated;*** ***b) acceptable use policies applicable;*** ***c) the date of release and methods of distribution;*** ***d) how the model interacts or can be used to interact with hardware or software that is not part of the model itself, where applicable;*** ***e) the versions of relevant software related to the use of the general purpose AI model, where applicable;*** ***f) architecture and number of parameters,*** ***g) modality (e.g., text, image) and format of inputs and outputs;*** ***h) the license for the model;*** ***2. A description of the elements of the model and of the process for its development, including:*** ***a) the technical means (e.g.,instructions of use, infrastructure, tools) required for the general-purpose AI model to be***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				integrated in AI systems. ***b) modality (e.g., text, image, etc.) and format of the inputs and outputs and their maximum size (e.g., context window length, etc.);*** ***c) information on the data used for training, testing and validation, where applicable, including, type and provenance of data and curation methodologies***
Annex IXc				
G 947c				***Annex IXc For the purpose of determining that a general purpose AI model has capabilities or impact equivalent to those of points a) and b) in Article A, the Commission shall take into account the following criteria:*** ***a. number of parameters of the model;*** ***b. quality or size of the data set, for example measured through tokens;*** ***c. the amount of compute used for training the model, measured in FLOPs or indicated by a combination of other variables such as estimated cost of training, estimated time required for the training, or estimated energy consumption for the training;*** ***d. input and output modalities of the model, such as text to text (large language models), text to image, multi-modality, and the state-of-the-*** G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				art thresholds for determining high-impact capabilities for each modality, and the specific type of inputs and outputs (e.g. biological sequences); ***e. benchmarks and evaluations of capabilities of the model, including considering the number of tasks without additional training, adaptability to learn new, distinct tasks, its degree of autonomy and scalability, the tools it has access to;*** ***f. it has a high impact on the internal market due to its reach, which shall be presumed when it has been made available to at least 10 000 registered business users established in the Union;*** ***g. number of registered end-users.***