



Council of the
European Union

Brussels, 24 November 2023
(OR. en)

15688/23

**Interinstitutional File:
2021/0106(COD)**

LIMITE

**TELECOM 344
JAI 1528
COPEN 404
CYBER 296
DATAPROTECT 324
EJUSTICE 59
COSI 229
IXIM 221
ENFOPOL 501
RELEX 1353
MI 1008
COMPET 1143
CODEC 2205**

NOTE

From:	Presidency
To:	Permanent Representatives Committee
No. prev. doc.:	13921/23
No. Cion doc.:	8115/21
Subject:	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 - Preparation for the trilogue

I. INTRODUCTION

1. The Commission adopted the proposal for a Regulation laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) on 21 April 2021.
2. The Council unanimously adopted its General Approach on the proposal on 6 December 2022.
3. The European Parliament (hereinafter: the EP) confirmed its position in a plenary vote on 14 June 2023.

4. Also on 14 June 2023, immediately after the vote in the EP, the co-legislators and the Commission held the first political trilogue on the AI Act, during which all three institutions outlined their priorities for the negotiations and the technical level was given a broad mandate to work on the entire proposal.
5. On 18 July 2023 the second political trilogue was held, during which some of the less controversial parts of the proposal were agreed and compromise was found on most elements of the chapter concerning measures in support of innovation.
6. On 2 and 3 October 2023 the third political trilogue took place in Strasbourg, during which further less controversial parts of the proposal were endorsed. In addition to this, the intention of the Presidency was to come to an agreement with the EP on three more controversial topics, namely the mechanism for the classification of AI systems as high-risk, the list of high-risk AI use cases, as well as subject matter and scope. However, talks on these topics proved inconclusive and no agreements were reached.
7. On 24 October 2023 the fourth political trilogue was held in Brussels. The co-legislators used this meeting to come to an agreement on the mechanism for classification of AI systems as high-risk, and to further explore potential landing zones with regard to foundation models and general purpose AI systems, governance, as well the prohibitions and law enforcement package. However, no agreements were made on any of these topics at that stage.
8. Since then six technical meetings with the EP have taken place, as well as numerous informal contacts, in order to prepare all the remaining provisions for agreement at the political level during the fifth political trilogue, which will take place on 6 December 2023 in Brussels.
9. Between 9 November and 23 November 2023, the Presidency consulted the delegations, both during the meetings of the Working Party on Telecommunications and Information Society (hereinafter: WP TELECOM), and in writing through questionnaires, on the compromise proposals and potential landing zones for agreement that are going to be discussed during the fifth political trilogue on 6 December 2023, and it has addressed most concerns in the final wording of the compromise proposals. The first part of these proposals is presented in the Annex to this note. The remaining compromise proposals will be presented in a separate note which will be disseminated prior to the second meeting of the Committee of Permanent Representatives devoted to preparation for the fifth AI Act trilogue, scheduled for 1 December 2023.

II. CONFIRMATION OF ARTICLES PROVISIONALLY AGREED (PART 1 – Articles 1 – 55a, with the exception of EP’s Article 4b and Article 52)

10. At the second and third trilogues, a significant number of articles were provisionally agreed: Articles 8-12, Articles 16-27 (with the exception of Articles 23a and 24), Articles 30-55a (with the exception of Articles 47 and 52) and Articles 60-85 (with the exception of Article 69). Some of them were **greened**, but some remained in **yellow** or had some elements in brackets, subject to additional final checks.
11. During the technical meetings held until now, all outstanding articles have been discussed and prepared for confirmation (**green**) or decision (**red**) at political level at the fifth trilogue on 6 December 2023.
12. In the Annex to this note, delegations will find draft agreement text and compromise proposals on **Articles 1-55a¹**, with the exception of EP’s Article 4b and Article 52. Provisions to be confirmed are indicated in **green** and can be found in the fourth column ("Draft Agreement") of the table. As compared to the Commission's proposal, changes are marked as ***bold italics*** (additions) and ~~striketrough~~ (deletions). Some rows are marked in **red**, which means that they will be updated after the fifth trilogue, subject to solutions on higher-level political issues listed in point 13 below.

The Presidency considers the compromise proposals in **green** in the articles mentioned above to fall within the Council’s General Approach from 6 December 2022, as amended by the revised mandate obtained from the Permanent Representatives Committee during its meetings on 14 July 2023, 19 September and 20 October, but **it intends to ask the Committee for confirmation during its meeting on 29 November 2023**.

III. POLITICAL ISSUES FOR POTENTIAL AGREEMENT DURING THE FIFTH TRILOGUE (PART 1)

13. The co-legislators intend to discuss the following twelve topics with a view to reaching a provisional agreement at political level during the fifth trilogue:

¹ Articles 56-85 will be included in Part 2, which will be prepared by the Permanent Representatives Committee on 1 December 2023 and will be presented in a separate note (doc. 15695/23 to follow).

- **Testing high-risk AI systems in real world conditions outside AI regulatory sandboxes**
- **Fundamental rights impact assessment**
- **Prohibitions**
- **Law enforcement exceptions**
- **National security exception**
- **Derogation from conformity assessment**

- *Foundation models/General purpose AI systems**
- *Governance**
- *Access to source code**
- *Fines**
- *Entry into force**
- *Delegated acts/implementing acts**

** These elements (Part 2) will be prepared by the Permanent Representatives Committee on 1 December 2023 and will be presented in a separate note (doc. 15695/23 to follow)*

The relevant rows in the 4-column document are indicated in red and appear either in the 4th column (draft agreement) or in the additional fifth column (compromise proposals).

14. **Testing high-risk AI systems in real world conditions outside AI regulatory sandboxes**
[Articles 54a and 54b, rows 541b – 541aa]

As regards the first topic above, **testing high-risk AI systems in real world conditions outside AI regulatory sandboxes** (Articles 54a and 54b), the compromise proposal, as set out in Annex I to this note, is based on elements taken from the General Approach of the Council from 6 December 2022, but it contains some additional safeguards which the Presidency considers necessary in order to reach an agreement with the EP on this topic. The Presidency obtained a revised mandate and some flexibilities on this element from the Permanent Representatives Committee on 20 October 2023, and the intention is to approach the negotiations with the EP on 6 December 2023 based on that mandate (document 13921/23, Annex I). The only new safeguard that has been added since then is in **Article 54b(1) [row 541z]**, and it concerns situations where, in the case of law enforcement, the

seeking of informed consent would prevent the AI system from being tested. In such a case the provider would need to ensure that the testing itself and the outcome of the testing in the real world conditions should not have any negative effect on the subject and the related data should be deleted after the test is performed.

Question 1: Delegations are requested to indicate whether they can accept this additional safeguard, subject to the EP's agreement to include in the text the possibility to conduct testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes, as currently provided in Articles 54a and 54b.

15. **Fundamental rights impact assessment [Article 29a, row 388e]**

Concerning the second topic listed above, namely **the fundamental rights impact assessment (Article 29a)**, this is a new obligation introduced by the EP for deployers of high-risk AI systems, who would have to conduct such an assessment prior to putting an AI system into use. The Council's position does not include such an obligation. However, the Presidency considers that in order to reach an overall agreement with the EP on the entire text, it is absolutely necessary to include some form of the fundamental rights impact assessment. It is also important to note that this element is closely linked to the topics of prohibitions and exceptions for law enforcement authorities. Therefore the Presidency's proposal is to include it in the text, subject to some modifications which would make the obligation relatively light and easy to comply with. Firstly, the Fundamental Rights Impact Assessment should only be conducted by deployers that are bodies governed by public law or private actors providing services of general interest. Additionally, it would only need to be carried out for aspects not covered by other legal obligations, such as Data Protection Impact Assessment under the GDPR and should be procedurally aligned with existing processes avoiding any overlap and additional burden. Moreover, with regard to obligations already established for the provider in Articles 9, 10 and 13 of the AI Act, the deployer would only be required to verify whether they have been complied with and to focus on residual risks that have not been mitigated by the provider. Finally, the Presidency considers that it could also be envisaged that there would be no obligation for public sector users to hold a six-week consultation, which could be replaced by a simple notification of the results of the assessment to the market surveillance authority, using a template provided in the Annex to the Regulation.

Question 2: Delegations are asked to indicate whether they would be open to the possibility of including a light version of the Fundamental Rights Impact Assessment in the AI Act, as described above, and as set out in in Article 29a in the Annex to this note.

16. **Artificial intelligence practices that should be prohibited in the Union [Article 5, rows 179- 196] + Annex III [row 810a]**

As regards the third topic listed above, which is the list of **artificial intelligence practices that should be prohibited in the Union** (Article 5), the EP has introduced a number of far reaching modifications in its position by adding several prohibitions (biometric categorisation, predictive policing, untargeted scraping of facial images from internet or CCTV footage, emotion recognition systems and ‘post’ remote biometric identification systems) and by removing any exceptions to the prohibition to use real-time biometric identification as well broadening its scope. The Presidency is aware of the very limited flexibilities of the Member States on this topic and for this reason it proposes to limit the additional prohibitions proposed by the EP, only accepting untargeted scraping of facial images, emotion recognition but only at the workplace and in educational institutions, a very limited prohibition of categorization based on certain beliefs or characteristics, as well as including individual predictive policing in a limited and targeted way. In the spirit of compromise, the Presidency also proposes to consider as high-risk those prohibitions that have not been accepted. This would mean adding biometric categorisation systems, emotion recognition systems and ‘post’ remote biometric identification systems to Annex III (subject to further limitations of their scope). Finally, with regard to real-time biometric identification by law enforcement authorities in publicly accessible spaces, the Presidency’s compromise proposal is to limit the scope of the prohibition and add a range of safeguards, which include monitoring and oversight measures and limited reporting obligations at EU level.

Question 3: Delegations are requested to indicate their flexibility with regard to the limited extension of the list of prohibitions and the addition of some safeguards for real-time biometric identification by law enforcement authorities in publicly accessible spaces, as described above, and as set out in in Article 5 in the Annex to this note. Delegations are also requested to indicate whether they can accept the inclusion of some of the prohibitions proposed by the EP in the list of high-risk AI use cases, as set out in Annex III to the AI Act in the Annex to this note.

17. **Law enforcement exceptions**

- **Article 14(5)**
- **Article 29(4)**
- **Article 29(4)**
- **Article 29(5a)**
- **Article 47 (1a) and (2)**
- **Article 51**
- **Article 52(2)**
- **Article 61(2)**
- **Article 63(5)**
- **Article 70(2)**
- **Article 83(1)**

Concerning the fourth topic listed above, namely **law enforcement exceptions**, the Presidency proposes to keep almost all of them in the Council's revised mandate, as law enforcement authorities must be able to continue to use artificial intelligence in their vital work. This includes **Article 14** on human oversight, **Article 29(4)**, **Article 61(2)** and **Article 70(2)** that exclude sensitive operational data, **Articles 47 (1a) and (2)** concerning derogation from conformity assessment procedure for law enforcement authorities in cases of urgency, and **Article 52(2)** containing a derogation from the obligation to inform people about the use of emotion recognition and biometric categorisation systems. At the same time the Presidency considers that it would be appropriate to introduce some safeguards to ensure that our fundamental rights will be sufficiently protected against any misuses of artificial intelligence. For this reason, the Presidency proposes to modify slightly **Article 51** concerning registration and **Article 83(1)** concerning large-scale AI systems. The registration of high risk AI systems by law enforcement authorities would be subject to slight modifications: they would need to be registered, but in a secure non-public database with limited amount of information. On the other hand, large-scale IT systems would benefit from a very long adaptation period before being required to show compliance with the requirements of the AI Act, until 2030.

Question 4: Delegations are requested to indicate whether they have flexibility to agree to a slight modification of the exceptions for law enforcement authorities referred to above, as set out in in Articles 51(1) and 83(1) in the Annex to this note.

18. **National security exception [Article 2(3), row 123]**

The Presidency is aware of the importance of the **national security exception** for the Member States and it agrees that it is imperative to spell out this exception in the AI Act as some doubts may persist regarding the exact content of this concept. Nevertheless, the EP appears to have no flexibility to accept the wording of this exception as proposed in the Council's General Approach. For this reason, the Presidency proposes to modify this wording by splitting the text in two parts. The first one focuses on the competences of the Member States concerning public security or national security and takes very limited elements of the recently adopted Data Act. The second one, on the exclusion of activities related to military and defense, remains identical to the Council's General Approach.

Question 5: Delegations are asked to indicate whether they would have the flexibility to accept the revised wording concerning the national security exception as set out in in Article 2(3) in the Annex to this note.

19. **Derogation from conformity assessment [Article 47(1)-(5), rows 486 – 490]**

As for the sixth topic listed above, **the derogation from conformity assessment**, the Presidency's intention has been to maintain the wording of the General Approach. However, the EP now insists subjecting the derogation from conformity assessment for public security reasons to a judicial authorisation. Since this would not be acceptable for the Council, as a compromise solution the Presidency proposes to keep the wording regarding this derogation in Article 47(1) and also the related exemption (urgency procedure) for law enforcement authorities. In exchange, the Presidency proposes to the delegations to consider re-introducing the wording regarding the control of the authorisation process by the Commission, as provided in points 3, 4 and 5 of Article 47 (previously deleted in the General Approach).

Question 6: Delegations are asked to indicate whether they would have the flexibility to reinstate points 3, 4 and 5 of Article 47 concerning the control by the Commission of the process of authorizing derogations from conformity assessment by market surveillance authorities.

IV. CONCLUSION

20. In light of the above, and with a view to obtaining a revised mandate (Part 1) for trilogue negotiations on the AI Act on 6 December 2023, the Permanent Representatives Committee is invited to:

- **confirm agreement with green lines in Articles 1-55a as presented in the Annex to this note;**
 - **indicate their flexibility with regard to the questions 1-6 presented in Part III of this note,**
-

**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
2021/0106(COD)**

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
TITLE I					
G 101	TITLE I GENERAL PROVISIONS	TITLE I GENERAL PROVISIONS	TITLE I GENERAL PROVISIONS	TITLE I GENERAL PROVISIONS Text Origin: Commission Proposal	
Article 1					
G 102	Article 1 Subject matter	Article 1 Subject matter	Article 1 Subject matter	Article 1 Subject matter Text Origin: Commission Proposal	
Article 1, first paragraph -a					
R 102a		<u>The purpose of this Regulation is to promote the uptake of human-</u>		<u>(1) The purpose of this Regulation is to improve the functioning of the</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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;</u>		<u>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 sustainability against harmful effects of artificial intelligence systems in the Union and supporting innovation.</u>	
Article 1, first paragraph					
103	This Regulation lays down:	This Regulation lays down:	This Regulation lays down:	This Regulation lays down: Text Origin: Commission Proposal	
Article 1, first paragraph, point (a)					
104	(a) harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems') in the Union;	(a) harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems') in the Union;	(a) harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems') in the Union;	(a) harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems') in the Union;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				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	(d) harmonised transparency rules for AI systems intended to interact with natural persons, emotion recognition systems and biometric categorisation systems, and <u>certain</u> AI	(d) harmonised transparency rules for AI systems intended to interact with natural persons, emotion recognition systems and biometric categorisation systems, and <u>certain</u> AI	(d) harmonised transparency rules for AI systems intended to interact with natural persons, emotion recognition systems and biometric categorisation systems, and <u>certain</u> AI	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	used to generate or manipulate image, audio or video content;	systems used to generate or manipulate image, audio or video content;	systems used to generate or manipulate image, audio or video content;	systems used to generate or manipulate image, audio or video content; Text Origin: EP Mandate	
Article 1, first paragraph, point (e)					
108	(e) rules on market monitoring and surveillance.	(e) rules on market monitoring, <u>market surveillance governance and enforcement;</u> and surveillance.	(e) rules on market monitoring, <u>market surveillance and governance;</u> and surveillance.	(e) rules on market monitoring, <u>market surveillance governance and enforcement;</u> and surveillance. Text Origin: EP Mandate	
Article 1, first paragraph, point (ea)					
108a			<u>(ea) measures in support of innovation.</u>		
Article 1, first paragraph a, point (ea new)					
108b		<u>(ea) measures to support innovation, with a particular focus on SMEs and start-ups, including on setting up regulatory sandboxes and targeted</u>		<u>(ea) measures to support innovation, with a particular focus on SMEs, including start-ups;</u> Text Origin: EP Mandate	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>measures to reduce the regulatory burden on SMEs's and start-ups;</u>			
Article 1, first paragraph, point (ea)					
R	108c	<u>(eb) rules for the establishment and functioning of the Union's Artificial Intelligence Office (AI Office).</u>			<u>(eb) rules for the establishment and functioning of the Union's Artificial Intelligence Office (AI Office).</u>
Article 2					
G	109	Article 2 Scope	Article 2 Scope	Article 2 Scope Text Origin: Commission Proposal	
Article 2(1)					
G	110	1. This Regulation applies to:	1. This Regulation applies to:	1. This Regulation applies to: Text Origin: Commission Proposal	
Article 2(1), point (a)					
G	111				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	(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 <u>physically present or</u> 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 <u>or who are located</u> within the Union or in a third country; Text Origin: Council Mandate	
Article 2(1), point (b)					
112	(b) users of AI systems located within the Union;	(b) users <u>deployers</u> of AI systems <u>that have their place of establishment or who are</u> located within the Union;	(b) users of AI systems located <u>who are physically present or established</u> within the Union;	(b) users <u>deployers</u> of AI systems <u>that have their place of establishment or who are</u> located within the Union; Text Origin: EP Mandate	
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 <u>deployers</u> of AI systems that <u>have their place of establishment or who</u> are located in a third country, where <u>either Member State law applies</u>	(c) providers and users of AI systems that are located <u>who are physically present or established</u> in a third country, where the output produced by the system is used in the	(c) providers and users <u>deployers</u> of AI systems that <u>have their place of establishment or who</u> are located in a third country, where the output produced by the system is	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>by virtue of a public international law or</u> the output produced by the system is <u>intended to be</u> used in the Union;	Union;	used in the Union; Text Origin: EP Mandate	
	Article 2(1), point (ca)				
G	113a		<u>(ca) importers and distributors of AI systems;</u>	<u>(ca) importers and distributors of AI systems;</u> Text Origin: Council Mandate	G
	Article 2(1), point (ca)				
R	113b	<u>(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;</u>			<u>(ca) deleted</u> R
	Article 2(1), point (cb)				
G	113c		<u>(cb) product manufacturers placing on the market or putting into service an AI system</u>	<u>(cb) product manufacturers placing on the market or putting into service an AI system</u>	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>together with their product and under their own name or trademark;</u>	<u>together with their product and under their own name or trademark;</u> Text Origin: Council Mandate	
Article 2(1), point (cb new)					
G 113d		<u>(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;</u>			
Article 2(1), point (cc)					
G 113e			<u>(cc) authorised representatives of providers, which are established in the Union.</u>	<u>(cc) authorised representatives of providers, which are established in the Union.</u> Text Origin: Council Mandate	
Article 2(1), point (cc new)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
113f		<u>(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.</u>		<u>(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 used within the Union.</u> Text Origin: EP Mandate	
Article 2(2)					
114	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 <u>full</u> , within the scope of the following <u>acts harmonisation legislation listed in Annex II - Section B</u> , 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 <u>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</u> only Article 84 of this Regulation shall apply. <u>Article 53 shall</u>	2. <u>2.</u> For high-risk AI systems that are safety components of products or systems, or which are themselves <u>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</u> only Article 84 of this Regulation shall apply. <u>Article 53 shall</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>apply only insofar as the requirements for high-risk AI systems under this Regulation have been integrated under that Union harmonisation legislation.</u>	<u>apply only insofar as the requirements for high-risk AI systems under this Regulation have been integrated under that Union harmonisation legislation.</u>	
	Article 2(2), point (a)				
G	115	(a) Regulation (EC) 300/2008;	<i>deleted</i>	<i>deleted</i>	
	Article 2(2), point (b)				
G	116	(b) Regulation (EU) No 167/2013;	<i>deleted</i>	<i>deleted</i>	
	Article 2(2), point (c)				
G	117	(c) Regulation (EU) No 168/2013;	<i>deleted</i>	<i>deleted</i>	
	Article 2(2), point (d)				
G	118	(d) Directive 2014/90/EU;	<i>deleted</i>	(d) Directive 2014/90/EU; <u>deleted</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3	
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)						
R	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		3. This Regulation does not apply to areas that fall outside the scope of Union law and in any event shall not affect the competences of the Member States	R

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>without modification of such systems 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.</u> <u>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.</u>		<u>concerning public security or national security, regardless of the type of entity entrusted by the Member States to carry out tasks in relation to those competences.</u> <u>In any event,</u> this Regulation shall not apply to AI systems developed or used exclusively for <u>if and insofar placed on the market, put into service, or used with or without modification of such systems or 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 purposes or defence, regardless of the type of entity carrying out those activities.</u>
	Article 2(4)				
124					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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 <u>cooperation or</u> agreements for law enforcement and judicial cooperation with the Union or with one or more Member States: <u>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</u>	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 <u>cooperation or</u> agreements for law enforcement and judicial cooperation with the Union or with one or more Member States: <u>under the condition that this third country or international organisations provide adequate safeguards with respect to the protection of privacy and fundamental rights and freedoms of individuals;</u> Text Origin: EP Mandate	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>and freedoms of individuals;</u>			
Article 2(5)					
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 Council¹ [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 Council¹ [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 IV⁴ of Directive 2000/31/EC of the European Parliament and of the Council¹ [<u>as to be replaced by the corresponding provisions of the Digital Services Act</u> as to be replaced by the corresponding provisions of the Digital Services Act]. 1. <u>[II]</u> 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 IV⁴ of Directive 2000/31/EC of the European Parliament and of the Council¹ [<u>as to be replaced by the corresponding provisions of the Digital Services Act</u> as to be replaced by the corresponding provisions of the Digital Services Act]. 1. <u>[II]</u> 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). Text Origin: Council Mandate	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	Article 2(5a)				
G 125a			<u>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.</u>	<u>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.</u> Text Origin: Council Mandate	
	Article 2(5a) new				
G 125b		<u>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</u>		<u>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</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>prejudice to arrangements provided for in Article 10(5) and Article 54 of this Regulation.;</u>		<u>prejudice to arrangements provided for in Article 10(5) and Article 54 of this Regulation;</u> Text Origin: EP Mandate	
Article 2(5b)					
G 125c			<u>5b. This Regulation shall not apply to any research and development activity regarding AI systems.</u>	<u>5b. This Regulation shall not apply to any research, testing and development activity regarding AI systems prior to these systems or models 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.</u> Text Origin: Council Mandate	G
Article 2(5b) new					
G 125d		<u>5b. This Regulation is without prejudice to the</u>		<u>5b. This Regulation is without prejudice to the</u>	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>rules laid down by other Union legal acts related to consumer protection and product safety;</u>		<u>rules laid down by other Union legal acts related to consumer protection and product safety.</u> Text Origin: EP Mandate	
Article 2(5c)					
125e			<u>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.</u>	<u>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.</u> Text Origin: Council Mandate	
Article 2(5c) new					
125f		<u>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</u>		<u>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</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>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.</u>		<u>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.</u> Member states remain free to legislate on any AI systems in employment, whether high risk or not. Text Origin: Presidency2	
Article 2(5d) new					
125g		<u>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</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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 the governance of research and development pursuant to Article 56, also aiming to coordinate its application by the national supervisory authorities;</u>			
Article 2(5a)					
R 125h		<u>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</u>		<u>5f. [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</u>	<u>5f. This Regulation shall not apply to [widely available] AI components provided [or- alternative--: 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 as a high-risk</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u><i>IV. This exemption shall not apply to foundation models as defined in Art 3.</i></u>		<u><i>IV.] [This exemption shall not apply to foundation models as defined in Art 3.]</i></u> Text Origin: Presidency2	<u><i>AI system itself, or as a high impact foundation model as defined in Art 3.</i></u>
Article 3					
126	Article 3 Definitions	Article 3 Definitions	Article 3 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,	(1) ‘artificial intelligence system’ (AI system) means software <u>a machine-based system</u> 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 <u>designed to operate with varying levels of</u>	(1) ‘artificial intelligence system’ (AI system) means software <u>a system</u> that is developed with one or more of the techniques and approaches listed in Annex I and can, for <u>designed to operate with elements of autonomy and that, based on machine and/or</u>	(1) ‘artificial intelligence <u>An AI system</u> ² (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 <u>is a machine-based system designed to</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	recommendations, or decisions influencing the environments they interact with;	<u>autonomy and that can, for explicit or implicit</u> objectives, generate outputs such as content , predictions, recommendations, or decisions, <u>that influence physical or virtual environments influencing the environments they interact with</u> ;	<u>human-provided data and inputs, infers how to achieve</u> a given set of human-defined objectives , <u>generate objectives using machine learning and/or logic- and knowledge based approaches, and produces system-generated</u> outputs such as content (<u>generative AI systems</u>), predictions, recommendations, or decisions, <u>influencing the environments they interact with with which the AI system interacts</u> ;	<u>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</u> generate outputs such as content , <u>predictions</u> , <u>content</u> , recommendations, or decisions influencing the that can influence physical or virtual environments. - they interact with ;	
Article 3, first paragraph, point (1a)					
128a			<u>(1a) 'life cycle of an AI system' means the duration of an AI 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</u>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>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.</u>		
Article 3, first paragraph, point (1a new)					
G	128b	<u>(1a) 'risk' means the combination of the probability of an occurrence of harm and the severity of that harm;</u>		<u>(1a) 'risk' means the combination of the probability of an occurrence of harm and the severity of that harm;</u>	G
Article 3, first paragraph, point (1b)					
R	128c		<u>(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</u>		R

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>software - is intended by the provider to perform generally applicable functions such as image and speech recognition, audio and video 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;</u>		
Article 3, first paragraph, point (1b new)					
128d		<u>(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;</u>			
Article 3, first paragraph, point (1c new)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
R	128e	<u>(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;</u>			R
Article 3, first paragraph, point (1d new)					
R	128f	<u>(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 designed;</u>			R
Article 3, first paragraph, point (1e new)					
G	128g	<u>(1e) 'large training runs' means the production process of a powerful AI model that require computing resources above a very high threshold;</u>			G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 3, first paragraph, point (2)					
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 <u>and places that system</u> on the market or putting <u>puts</u> 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 <u>and places that system</u> on the market or putting <u>puts</u> it 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)					
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 ; 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).	<i>deleted</i>	<i>deleted</i>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	Article 3, first paragraph, point (3a)				
130a			(3a) <u>'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;</u>		
	Article 3, first paragraph, point (4)				
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' <u>deployer</u> 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, <u>including a</u> public authority, agency or other body using an AI system, under its <u>whose</u> authority, except where the AI the system is used in the course of a personal non-professional activity;	(4) 'user' <u>deployer</u> 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)				
132	(5) 'authorised	(5) 'authorised	(5) 'authorised	(5) 'authorised	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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 procedures established by this Regulation;	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 procedures established by this Regulation;	representative' means any natural or legal person <u>physically present or established in the Union</u> who has received <u>and accepted</u> a written mandate from a provider of an AI system to, respectively, perform and carry out on its behalf the obligations and procedures established by this Regulation;	representative' means any natural or legal person <u>located or</u> established in the Union who has received <u>and accepted</u> a written mandate from a provider of an AI system to, respectively, perform and carry out on its behalf the obligations and procedures established by this Regulation; Text Origin: Council Mandate	
Article 3, first paragraph, point (5a)					
132a			<u>(5a) 'product manufacturer' means a manufacturer within the meaning of any of the Union harmonisation legislation listed in Annex II;</u>		
Article 3, first paragraph, point (6)					
133	(6) 'importer' means any natural or legal person established in the Union that places on the market	(6) 'importer' means any natural or legal person established in the Union that places on the market	(6) 'importer' means any natural or legal person <u>physically present or</u> established in the Union	(6) 'importer' means any natural or legal person <u>located or</u> established in the Union that places on	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	or puts into service an AI system that bears the name or trademark of a natural or legal person established outside the Union;	or puts into service an AI system that bears the name or trademark of a natural or legal person established outside 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;	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	
Article 3, first paragraph, point (7)					
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 ; Text Origin: Council Mandate	
Article 3, first paragraph, point (8)					
135	(8) ‘operator’ means the provider, the user, the authorised representative, the importer and the distributor;	(8) ‘operator’ means the provider, the user <u>deployer</u> , the authorised representative, the importer and the distributor;	(8) ‘operator’ means the provider, the <u>product manufacturer, the</u> user, the authorised representative, the importer and <u>or</u> the distributor;	(8) ‘operator’ means the provider, the user <u>product manufacturer, the deployer</u> , the authorised representative, the importer and <u>or</u> the distributor;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				Text Origin: Council Mandate	
Article 3, first paragraph, point (8a new)					
135a		<u>(8a) ‘affected person’ means any natural person or group of persons who are subject to or otherwise affected by an AI system;</u>			
Article 3, first paragraph, point (9)					
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 on the Union market; Text Origin: Commission Proposal	
Article 3, first paragraph, point (10)					
137	(10) ‘making available on the market’ means any supply of an AI system for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;	(10) ‘making available on the market’ means any supply of an AI system for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;	(10) ‘making available on the market’ means any supply of an AI system for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;	(10) ‘making available on the market’ means any supply of an AI system for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				Text Origin: Commission Proposal	
Article 3, first paragraph, point (11)					
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 <u>deployer</u> 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 <u>in</u> 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 <u>deployer</u> or for own use on <u>in</u> the Union market for its intended purpose; Text Origin: Council Mandate	
Article 3, first paragraph, point (12)					
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	(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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	documentation;	documentation;	documentation;	documentation; Text Origin: Commission Proposal	
Article 3, first paragraph, point (13)					
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 <u>as indicated in instructions for use established by the provider</u> , but which may result from reasonably foreseeable human behaviour or interaction with other <u>systems, including other AI systems</u> ;	(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 <u>as indicated in instructions for use established by the provider</u> , but which may result from reasonably foreseeable human behaviour or interaction with other <u>systems, including other AI systems</u> ; Text Origin: EP Mandate	
Article 3, first paragraph, point (14)					
141	(14) ‘safety component of a product or system’ means a component of a product or of a system which fulfils	(14) ‘safety component of a product or system’ means <u>in line with Union harmonisation law listed</u>	(14) ‘safety component of a product or system’ means a component of a product or of a system which fulfils	(14) ‘safety component of a product or system’ means a component of a product or of a system which fulfils	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	a safety function for that product or system or the failure or malfunctioning of which endangers the health and safety of persons or property;	<u>in Annex II</u> , 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 ;	a safety function for that product or system or the failure or malfunctioning of which endangers the health and safety of persons or property;	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)					
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 used;	(15) ‘instructions for use’ means the information provided by the provider to inform the user <u>deployer</u> of in particular an AI system’s intended purpose and proper use, <u>as well as information on any precautions to be taken</u> ; inclusive of the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used;	(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 used ;	(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 used ; Text Origin: Council Mandate	
Article 3, first paragraph, point (16)					
143	(16) ‘recall of an AI	(16) ‘recall of an AI	(16) ‘recall of an AI	(16) ‘recall of an AI	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	system' means any measure aimed at achieving the return to the provider of an AI system made available to users;	system' means any measure aimed at achieving the return to the provider of an AI system <u>that has been</u> made available to users <u>deployers</u> ;	system' means any measure aimed at achieving the return to the provider <u>or taking it out of service or disabling the use</u> of an AI system made available to users;	system' means any measure aimed at achieving the return to the provider <u>or taking it out of service or disabling the use</u> of an AI system made available to users <u>deployers</u> ; 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 <u>an AI system in the supply chain being made available on the market</u> the distribution, display and offer of an AI system;	(17) 'withdrawal of an AI system' means any measure aimed at preventing <u>an AI system in the supply chain being made available on the market</u> 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	(18) 'performance of an AI system' means the ability of an AI system to	(18) 'performance of an AI system' means the ability of an AI system to	(18) 'performance of an AI system' means the ability of an AI system to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	achieve its intended purpose;	achieve its intended purpose;	achieve its intended purpose;	achieve its intended purpose; Text Origin: Commission Proposal	
Article 3, first paragraph, point (19)					
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)					
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 <u>demonstrating</u> whether the requirements set out in Title III, Chapter 2 of this Regulation relating to an AI system	(20) ‘conformity assessment’ means the process of verifying whether the requirements set out in Title III, Chapter 2 of this Regulation relating to an <u>a high-risk</u> AI system have been	(20) ‘conformity assessment’ means the process of verifying <u>demonstrating</u> whether the requirements set out in Title III, Chapter 2 of this Regulation relating to an <u>a high-risk</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		have been fulfilled;	fulfilled;	AI system have been fulfilled; Text Origin: Council Mandate	
Article 3, first paragraph, point (21)					
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	
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
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 <u>modification or a series of modifications of</u> the AI system following after its placing on the market or putting into service which affects <u>is not foreseen or planned in the initial risk assessment by the provider and as a result of which</u> the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation <u>is affected</u> 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. <u>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 constitute a</u>	(23) ‘substantial modification’ means a change to the AI system following after its placing on the market or putting into service which affects <u>is not foreseen or planned in the initial conformity assessment by the provider and as a result of which</u> the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation <u>is affected</u> 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	Presidency ³
			<u>substantial modification</u> ;		
Article 3, first paragraph, point (24)					
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 <u>physical or digital</u> marking by which a provider indicates that an <u>AI system or a product with an embedded</u> 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 <u>or in Article 4b</u> of this Regulation and other applicable Union legislation <u>legal act</u> 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 <u>or in Article 4b</u> 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	
Article 3, first paragraph, point (25)					
152	(25) ‘post-market monitoring’ means all activities carried out by providers of AI systems to proactively collect and review experience gained	(25) ‘post-market monitoring’ means all activities carried out by providers of AI systems to proactively collect and review experience gained	(25) ‘post-market monitoring <u>system</u> ’ means all activities carried out by providers of AI systems to proactively collect and review experience gained	(25) ‘post-market monitoring <u>system</u> ’ means all activities carried out by providers of AI systems to proactively collect and review experience gained	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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;	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;	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;	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	
Article 3, first paragraph, point (26)					
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)					
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				Text Origin: Commission Proposal	
Article 3, first paragraph, point (28)					
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 <u>specification</u> ’ means a document, other than a standard, containing technical solutions providing a set of <u>technical specifications, as defined in point 4 of Article 2 of Regulation (EU) No 1025/2012</u> providing means to, comply with certain requirements and obligations established under this Regulation;	(28) ‘common specifications <u>specification</u> ’ means a document, other than a standard, containing technical solutions providing a set of <u>technical specifications, as defined in point 4 of Article 2 of Regulation (EU) No 1025/2012</u> providing means to, comply with certain requirements and obligations established under this Regulation; Text Origin: Council Mandate	
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				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 <u>underfitting or</u> 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 <u>underfitting or</u> 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	(31) ‘testing data’ means data used for providing an independent evaluation of the trained and validated AI system in order to confirm the expected	(31) ‘testing data’ means data used for providing an independent evaluation of the trained and validated AI system in order to confirm the expected	(31) ‘testing data’ means data used for providing an independent evaluation of the trained and validated AI system in order to confirm the expected	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	performance of that system before its placing on the market or putting into service;	performance of that system before its placing on the market or putting into service;	performance of that system before its placing on the market or putting into service;	performance of that system before its placing on the market or putting into service; Text Origin: Commission Proposal	
Article 3, first paragraph, point (32)					
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	
Article 3, first paragraph, point (33)					
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	(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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	facial images or dactyloscopic data;	as facial images or dactyloscopic data <u>biometric data as defined in Article 4, point (14) of Regulation (EU) 2016/679;</u>	as facial images or dactyloscopic data;	as facial images or dactyloscopic data; Text Origin: EP Mandate	
Article 3, first paragraph, point (33a new)					
160a		<u>(33a) 'biometric-based data' means data resulting from specific technical processing relating to physical, physiological or behavioural signals of a natural person;</u>			
Article 3, first paragraph, point (33b new)					
160b		<u>(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</u>		<u>(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</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>individuals in a database (one-to-many identification);</u>		<u>individuals in a database;</u>	
Article 3, first paragraph, point (33c new)					
G	160c	<u>(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);</u>			
Article 3, first paragraph, point (33a)					
R	160d	<u>(33d) 'special categories of personal data' means the categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679;</u>			In law enforcement pack
Article 3, first paragraph, point (34)					
G	161	(34) 'emotion recognition system' means an AI	(34) 'emotion recognition system' means an AI	(34) 'emotion recognition system' means an AI	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric data;	system for the purpose of identifying or inferring emotions, <u>thoughts, states of mind</u> or intentions of natural persons <u>individuals or groups</u> on the basis of their biometric <u>and biometric-based</u> data;	system for the purpose of identifying or inferring <u>psychological states</u> , emotions or intentions of natural persons on the basis of their biometric data;	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)					
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 biometric data;	(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 biometric <u>or inferring their characteristics and attributes on the basis of their biometric or biometric-based data, or which can be inferred from such</u> data;	(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 biometric data;	(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 biometric data; Text Origin: Council Mandate	Linked to Law enforcement package.
Article 3, first paragraph, point (36)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
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 <u>deployer</u> of the AI system whether the person will be present and can be identified, <u>excluding verification systems</u> ;	(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons <u>typically</u> at a distance, <u>without their active involvement</u> , 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 <u>data repository</u> ;	(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons, <u>without with their active involvement, typically</u> 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 ; Text Origin: Commission Proposal	
Article 3, first paragraph, point (37)					
R 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.	(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.	(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 .	(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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	This comprises not only instant identification, but also limited short delays in order to avoid circumvention.	This comprises not only instant identification, but also limited short delays in order to avoid circumvention-;	This comprises not only instant identification, but also limited short delays in order to avoid circumvention- <u>instantaneo</u> <u>usly or near</u> <u>instantaneously;</u>	This comprises not only instant identification, but also limited short delays in order to avoid circumvention. Text Origin: Commission Proposal	
Article 3, first paragraph, point (38)					
R 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 <u>publicly or privately owned</u> physical place accessible to the public, regardless of whether certain conditions for access may apply, <u>and regardless of the potential</u>	(39) ‘publicly accessible space’ means any <u>publicly or privately owned</u> physical place accessible to the public, <u>an undetermined number of natural persons</u> regardless of whether certain	(39) ‘publicly accessible space’ means any <u>publicly or privately owned</u> physical place accessible to the public, <u>an undetermined number of natural persons</u> , regardless of whether certain conditions	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>capacity restrictions</u> ;	conditions <u>or circumstances</u> for access may apply <u>have been predetermined, and regardless of the potential capacity restrictions</u> ;	for access may apply, <u>and regardless of the potential capacity restrictions</u> ; Text Origin: Commission Proposal	
Article 3, first paragraph, point (40)					
167	(40) 'law enforcement authority' means:	(40) 'law enforcement authority' means:	(40) 'law enforcement authority' means:	(40) 'law enforcement authority' means: Text Origin: Commission Proposal	
Article 3, first paragraph, point (40)(a)					
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)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
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)					
170	(41) ‘law enforcement’ means 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;	(41) ‘law enforcement’ means activities carried out by law enforcement authorities <u>or on their behalf</u> 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	(41) ‘law enforcement’ means activities carried out by law enforcement authorities <u>or on their behalf</u> 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	(41) ‘law enforcement’ means activities carried out by law enforcement authorities <u>or on their behalf</u> 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		security;	security;	security; Text Origin: Council Mandate	
Article 3, first paragraph, point (42)					
R 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 <u>public</u> 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 <u>in the management Board of the AI Office</u> ;	deleted		
Article 3, first paragraph, point (43)					
G 172	(43) ‘national competent authority’ means the national supervisory authority, the notifying	(43) ‘national competent authority’ means <u>any of</u> the national supervisory authority, the notifying	(43) ‘national competent authority’ means the national supervisory authority, <u>any of the</u>	(43) ‘national competent authority’ means the national supervisory authority, <u>any of the</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	authority and the market surveillance authority;	authority and the market surveillance authority <u>authorities which are responsible for the enforcement of this Regulation</u> ;	<u>following:</u> the notifying authority and the market surveillance authority. <u>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</u> ;	<u>following:</u> the notifying authority and the market surveillance authority. <u>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</u> ; 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 <u>or malfunctioning of an AI system</u> 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 <u>or malfunctioning of an AI system that directly or indirectly leads</u> to any of the following:	(44) ‘serious incident’ means any incident that directly or indirectly leads, might have led or might lead <u>or malfunctioning of an AI system that directly or indirectly leads</u> to any of the following:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				Text Origin: Council Mandate	
Article 3, first paragraph, point (44)(a)					
174	(a) the death of a person or serious damage to a person's health, to property or the environment,	(a) the death of a person or serious damage to a person's health, to property or the environment,	(a) the death of a person or serious damage to a person's health, to property or the environment,	(a) the death of a person or serious 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			<u>(ba) breach of obligations under Union law intended to protect fundamental rights;</u>	<u>(ba) breach of obligations under Union law intended to protect fundamental rights;</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				Text Origin: Council Mandate	
	Article 3, first paragraph, point (44)(ba new)				
G	175b	<u>(ba) a breach of fundamental rights protected under Union law,</u>			G
	Article 3, first paragraph, point (44)(bb)				
G	175c		<u>(bb) serious damage to property or the environment.</u>	<u>(bb) serious damage to property or the environment.</u> Text Origin: Council Mandate	G
	Article 3, first paragraph, point (44)(bb new)				
G	175d	<u>(bb) serious damage to property or the environment.</u>			G
	Article 3, first paragraph, point (44a new)				
G	175e	<u>(44a) 'personal data' means personal data as defined in Article 4, point</u>		<u>(44a) 'personal data' means personal data as defined in Article 4, point</u>	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>(1) of Regulation (EU) 2016/679;</u>		<u>(1) of Regulation (EU) 2016/679;</u> Text Origin: EP Mandate	
Article 3, first paragraph, point (44a)					
175f			<u>(44a) ‘non-personal data’ means data other than personal data as defined in point (1) of Article 4 of Regulation (EU) 2016/679;</u>	<u>(44c) ‘non-personal data’ means data other than personal data as defined in point (1) of Article 4 of Regulation (EU) 2016/679;</u> Text Origin: Council Mandate	
Article 3, first paragraph, point (44b)					
175g			<u>(44b) ‘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</u>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>of critical entities;</u>		
Article 3, first paragraph, point (44c new)					
175h		<u>(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;</u>		<u>(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;</u>	
Article 3, first paragraph, point (44a)					
175i			<u>(44c) ‘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</u>		<u>(44c) ‘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</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>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;</u>		<u>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;</u>
Article 3, first paragraph, point (44a)(a)					
G 175j			<u>(44f) ‘subject’ for the purpose of real world testing means a natural person who participates in testing in real world conditions;</u>	<u>(bh) ‘subject’ for the purpose of real world testing means a natural person who participates in testing in real world conditions;</u>	<u>(bh) ‘subject’ for the purpose of real world testing means a natural person who participates in testing in real world conditions;</u>
Article 3, first paragraph, point (44a)(b)					
R 175k			<u>(44g) ‘informed consent’</u>	<u>(bi) ‘informed consent’</u>	<u>(bi) ‘informed consent’</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>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;</u>	<u>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;</u>	<u>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;</u>
Article 3, first paragraph, point (44a)(c)					
1751		<u>(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;</u>		<u>(bf) "deep fake" means manipulated 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 truthful</u>	linked to art 52

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	Article 3, first paragraph, point (44e)				
175m			<u>(44e) ‘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;</u>	<u>(bg) ‘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;</u> <u>(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.</u>	
	Article 3, first paragraph, point (44h)				
175n			<u>(44h) ‘AI regulatory sandbox’ means a concrete framework set up by a national competent</u>	<u>(bi) ‘AI regulatory sandbox’ means a concrete and controlled framework set up by a</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>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.</u>	<u>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.</u>	
	Article 3, first paragraph, point (44d)				
G	175o		<u>(44d) 'personal data' means data as defined in point (1) of Article 4 of Regulation (EU) 2016/679;</u>		G
	Article 3, first paragraph, point (44b new)				
G	175p	<u>(44d) 'non-personal data' means data other than personal data;</u>			G
	Article 3, first paragraph, point (44b)				
R	175q	<u>(44e) 'widespread</u>			<u>(44e) 'widespread</u> R

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u><i>infringement' means any act or omission contrary to Union law that protects the interest of individuals:</i></u>			<u><i>infringement' means any act or omission contrary to Union law that protects the interest of individuals:</i></u>
	Article 3, first paragraph, point (44e)(a new)				
175r		<u><i>(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:</i></u>			<u><i>(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:</i></u>
	Article 3, first paragraph, point (44e)(a)(i new)				
175s		<u><i>(i) the act or omission originated or took place;</i></u>			<u><i>(i) the act or omission originated or took place;</i></u>
	Article 3, first paragraph, point (44e)(a)(i new)				
175t		<u><i>(ii) the provider concerned, or, where applicable, its authorised representative is established; or,</i></u>			<u><i>(ii) the provider concerned, or, where applicable, its authorised representative is established; or,</i></u>
	Article 3, first paragraph, point (44e)(a)(i new)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
R 175u		<u>(iii) the deployer is established, when the infringement is committed by the deployer;</u>			<u>(iii) the deployer is established, when the infringement is committed by the deployer;</u>
Article 3, first paragraph, point (44e)(a new)					
R 175v		<u>(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;</u>			<u>(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;</u>
Article 3, first paragraph, point (44c)					
R 175w		<u>(44f) 'widespread infringement with a Union dimension' means a widespread infringement that has harmed or is</u>			<u>(44f) 'widespread infringement with a Union dimension' means a widespread infringement that has harmed or is</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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;</u>			<u>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;</u>
Article 3, first paragraph, point (44g new)					
175x		<u>(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 under regulatory supervision;</u>			
Article 3, first paragraph, point (44h new)					
175y		<u>(44h) 'critical infrastructure' means an asset, a facility,</u>		<u>(44h) 'critical infrastructure' means an asset, a facility,</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>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;</u>		<u>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;</u> Text Origin: EP Mandate	
Article 3, first paragraph, point (44k new)					
175z		<u>(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;</u>			
Article 3, first paragraph, point (44l new)					
175aa		<u>(44l) 'social behaviour' means the way a natural person interacts with and influences other natural persons or society;</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
Article 3, first paragraph, point (44m new)					
G	175ab		<u>(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;</u>		G
Article 3, first paragraph, point (44n new)					
R	175ac		<u>(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;</u>		R
Article 4					
R	176	Article 4 Amendments to Annex I	deleted	Article 4 Amendments to Annex I <u>Implementing acts</u>	R

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	Article 4, first paragraph				
177	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.	<i>deleted</i>	The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and <u>In order to ensure uniform conditions for the implementation of this Regulation as regards machine learning approaches and logic- and knowledge based approaches listed in Annex I, in order to update that list to</u> <u>referred to in Article 3(1), the Commission may adopt implementing acts to specify the technical elements of those approaches, taking into account</u> market and technological developments. <u>Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2)</u> on the basis of characteristics that are similar to the techniques and approaches listed		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<i>therein.</i>		
Title Ia					
R 177a			<u><i>Title Ia</i></u> <u><i>GENERAL PURPOSE AI</i></u> <u><i>SYSTEMS</i></u>		R
Article 4a new					
R 177b		<u><i>Article 4a</i></u> <u><i>General principles</i></u> <u><i>applicable to all AI</i></u> <u><i>systems</i></u>			R <u><i>Article 4a</i></u> <u><i>General principles</i></u> <u><i>applicable to all AI</i></u> <u><i>systems</i></u>
Article 4a, first paragraph new					
R 177c		<u><i>1. All operators falling</i></u> <u><i>under this Regulation</i></u> <u><i>shall make their best</i></u> <u><i>efforts to develop and use</i></u> <u><i>AI systems or foundation</i></u> <u><i>models in accordance with</i></u> <u><i>the following general</i></u> <u><i>principles establishing a</i></u> <u><i>high-level framework that</i></u> <u><i>promotes a coherent</i></u> <u><i>human-centric European</i></u> <u><i>approach to ethical and</i></u> <u><i>trustworthy Artificial</i></u>			R <u><i>1. All operators falling</i></u> <u><i>under this Regulation</i></u> <u><i>shall make their best</i></u> <u><i>efforts to develop and use</i></u> <u><i>AI systems or foundation</i></u> <u><i>models in accordance with</i></u> <u><i>the following general</i></u> <u><i>principles establishing a</i></u> <u><i>high-level framework that</i></u> <u><i>promotes a coherent</i></u> <u><i>human-centric European</i></u> <u><i>approach to ethical and</i></u> <u><i>trustworthy Artificial</i></u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>Intelligence, which is fully in line with the Charter as well as the values on which the Union is founded:</u>			<u>Intelligence, which is fully in line with the Charter as well as the values on which the Union is founded:</u>
Article 4a, first paragraph, point (a new)					
177d		<u>(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;</u>			<u>(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;</u>
Article 4a, first paragraph, point (a new)					
177e		<u>(b) ‘technical robustness and safety’ means that AI systems shall be developed and used in a way to minimize unintended and unexpected harm as well as being robust in case of unintended problems and being resilient against</u>			<u>(b) ‘technical robustness and safety’ means that AI systems shall be developed and used in a way to minimize unintended and unexpected harm as well as being robust in case of unintended problems and being resilient against</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>attempts to alter the use or performance of the AI system so as to allow unlawful use by malicious third parties;</u>			<u>attempts to alter the use or performance of the AI system so as to allow unlawful use by malicious third parties;</u>
Article 4a, first paragraph, point (a new)					
177f		<u>(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;</u>			<u>(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;</u>
Article 4a, first paragraph, point (a new)					
177g		<u>(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</u>			<u>(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</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>users of the capabilities and limitations of that AI system and affected persons about their rights;</u>			<u>users of the capabilities and limitations of that AI system and affected persons about their rights;</u>
Article 4a, first paragraph, point (a new)					
177h		<u>(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;</u>			<u>(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;</u>
Article 4a, first paragraph, point (a new)					
177i		<u>(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</u>			<u>(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</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>way to benefit all human beings, while monitoring and assessing the long-term impacts on the individual, society and democracy.</u>			<u>way to benefit all human beings, while monitoring and assessing the long-term impacts on the individual, society and democracy.</u>
Article 4a, first paragraph new					
177j		<u>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 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</u>			<u>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 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</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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.</u>			<u>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.</u>
Article 4a, first paragraph new					
177k		<u>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</u>			<u>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</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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).</u>			<u>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).</u>
	Article 4b				
R 177q			<u>Article 4a</u> <u>Compliance of general purpose AI systems with this Regulation</u>		
	Article 4b(1)				
R 177r			<u>1. Without prejudice to Articles 5, 52, 53 and 69 of this Regulation, general purpose AI systems shall only comply with the requirements and obligations set out in Article 4b.</u>		
	Article 4b(2)				
R 177s			<u>2. Such requirements and</u>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>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.</u>		
Article 4c					
177t			<u>Article 4b</u> <u>Requirements for general purpose AI systems and obligations for providers of such systems</u>		
Article 4c(1)					
177u			<u>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</u>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>this Regulation as 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.</u>		
	Article 4c(2)				
R 177v					R

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>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.</u>		
Article 4c(3)					
177w			<u>3. For the purpose of complying with the obligations set out in Article 16e, providers shall follow the conformity assessment procedure based on internal control set out in Annex VI, points 3 and 4.</u>		
Article 4c(4)					
177x			<u>4. Providers of such systems shall also keep the technical documentation referred to in Article 11 at the disposal of the</u>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u><i>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.</i></u>		
Article 4c(5)					
177y			<u><i>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</i></u>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>Article 70. In 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).</u>		
Article 4c(6)					
177z			<u>6. In complying with the requirements and obligations referred to in paragraphs 1, 2 and 3:</u> <u>- 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;</u> <u>- any reference to the requirements for high-risk AI systems in Chapter II,</u>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>Title III shall be understood as referring only to the requirements set out in the present Article.</u>		
	Article 4d				
R 177aa			<u>Article 4c</u> <u>Exceptions to Article 4b</u>		Same as above.
	Article 4d(1)				
R 177ab			<u>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.</u>		
	Article 4d(2)				
R 177ac			<u>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</u>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>may be misused.</u>		
Article 4d(3)					
R 177ad			<u>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.</u>		
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 Proposal	
Article 5					
G 179	Article 5	Article 5	Article 5	Article 5	Article 5

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				Text Origin: Commission Proposal	
Article 5(1)					
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)					
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 <u>or purposefully manipulative or deceptive techniques, with the objective to or the effect of</u> materially distort <u>distorting</u> a person's <u>or a group of persons'</u> behaviour <u>by appreciably impairing the person's ability to make an informed decision,</u>	(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 <u>with the objective to or the effect of</u> materially distort <u>distorting</u> a person's behaviour in a manner that causes or is <u>reasonably</u> 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 <u>or purposefully manipulative or deceptive techniques, with the objective to or the effect of</u> materially distort <u>distorting</u> a person's <u>or a group of persons'</u> behaviour <u>by appreciably impairing the person's ability to make an informed decision,</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>thereby causing the person to take a decision that that person would not have otherwise taken</u> in a manner that causes or is likely to cause that person or₂ another person physical or psychological_{or group} <u>of persons significant</u> harm;		<u>thereby causing the person to take a decision that that person would not have otherwise taken</u> in a manner that causes or is likely to cause that person or₂ another person physical or psychological_{or group} <u>of persons significant</u> harm; Text Origin: EP Mandate	
Article 5(1), point (-a), second subparagraph					
181a		<u>The prohibition of AI system that deploys subliminal techniques referred to in the first subparagraph shall not apply to AI systems intended to be used for approved therapeutic purposes on the basis of specific informed consent of the individuals that are exposed to them or, where applicable, of their legal guardian;</u>		Text Origin: EP Mandate	
Article 5(1), point (b)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
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 physical or psychological harm;	(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a <u>person or a</u> specific group of persons, <u>including characteristics of such person's or a such group's known or predicted personality traits or social or economic situation</u> due to their age, physical or mental disability, in order to <u>ability with the objective or to the effect of</u> materially distort <u>distorting</u> the behaviour of <u>that person or</u> a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or <u>psychological</u> <u>significant</u> harm;	(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 <u>disability or a specific social or economic situation, with the objective to or the effect of</u> materially distort <u>distorting</u> the behaviour of a person pertaining to that group in a manner that causes or is <u>reasonably</u> likely to cause that person or another person physical or psychological harm;	(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a <u>person or a</u> specific group of persons due to their age, physical or mental disability, in order to <u>disability or a specific social or economic situation, with the objective to or the effect of</u> materially distort <u>distorting</u> the behaviour of <u>that person or</u> a person pertaining to that group in a manner that causes or is <u>reasonably</u> likely to cause that person or another person physical or psychological <u>harm; significant harm</u>	
Article 5(1), point (ba)					
182a		<u>(ba) the placing on the market, putting into</u>			<u>(ba) the placing on the market, putting into</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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 therapeutic purposes on the basis of specific informed consent of the individuals that are exposed to them or, where applicable, of their legal guardian.</u>			<u>service or use of categorisation systems that categorise natural persons according to their political opinions, trade union membership, religious or philosophical beliefs or sexual life or sexual orientation unless those characteristics have a link with a specific crime or threat. In this case, any processing of biometric data will be performed in accordance with Directive (EU) 2016/680. This prohibition shall not apply to AI systems intended to be used for approved therapeutic purposes on the basis of specific informed consent of the individuals that are exposed to them or, where applicable, of their legal guardian.</u>
Article 5(1), point (c)					
183	(c) the placing on the market, putting into service	(c) the placing on the market, putting into service	(c) the placing on the market, putting into service	(c) the placing on the market, putting into service	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	or use of AI systems by public authorities or on 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:	or use of AI systems by public authorities or on their behalf for the <u>for the social scoring</u> evaluation or classification of the trustworthiness of natural persons <u>natural persons or groups thereof</u> over a certain period of time based on their social behaviour or known, <u>inferred</u> or predicted personal or personality characteristics, with the social score leading to either or both of the following:	or use of AI systems by public authorities or on 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:	or use of AI systems by public authorities or on their behalf for the evaluation or classification of the trustworthiness of natural persons <u>natural persons or groups thereof</u> over a certain period of time based on their social behaviour or known, <u>inferred</u> 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)					
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 <u>that</u> 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 <u>that</u> are unrelated to the contexts in which the data was originally generated or collected; Text Origin: EP	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				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;
	Article 5(1), point (d)				
R	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 <u>by law enforcement authorities or on their behalf</u> 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)				
R	187	(i) the targeted search for	(i) the targeted search for		(i) the targeted search for

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	specific potential victims of crime, including missing children;	<i>deleted</i>	specific potential victims of crime, including missing children ;		specific potential victims of crime, including missing <u>abduction, trafficking in human beings and sexual exploitation of women and children</u> ;
Article 5(1), point (d)(ii)					
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;	<i>deleted</i>	(ii) the prevention of a specific, substantial and imminent <u>and substantial</u> threat to the <u>critical infrastructure, life, health</u> life or physical safety of natural persons or of a <u>the prevention of</u> terrorist attack <u>attacks</u> ;		(ii) the prevention of a specific, substantial and imminent threat to the life or physical safety of natural persons or <u>a specific and imminent threat</u> of a terrorist attack <u>or of an attack likely to cause serious disruption of critical infrastructure</u> ;
Article 5(1), point (d)(iii)					
189	(iii) the detection, localisation, identification or prosecution of a perpetrator or suspect of a criminal offence referred to in Article 2(2) of Council Framework Decision 2002/584/JHA ¹ and	<i>deleted</i>	(iii) the detection, localisation, identification or prosecution of a perpetrator or suspect of <u>or identification of a natural person for the purposes of conducting</u> a criminal		(iii) the detection, localisation, identification or prosecution of a perpetrator or suspect of <u>or identification of a natural person for the purposes of conducting</u> a criminal offence referred to

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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).		offence<u>investigation, prosecution or executing a criminal penalty for offences</u>, referred to in Article 2(2) of Council Framework Decision 2002/584/JHA¹ and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, <u>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</u>, as determined by the law of that Member State. 1. <u>[1]</u> 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).		in Article 2(2) of Council Framework Decision 2002/584/JHA¹<u>investigation, prosecution or executing a criminal penalty for offences, referred to in annex XXX</u> and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three<u>four</u> years. <u>Annex XXX (proposal of reduction of crimes from the JHA list).</u> <u>- terrorism,</u> <u>- trafficking in human beings,</u> <u>- sexual exploitation of children and child pornography,</u> <u>- illicit trafficking in narcotic drugs and psychotropic substances,</u> <u>- illicit trafficking in weapons, munitions and explosives,</u> <u>- murder, grievous bodily</u>

PUBLIC

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
					<u>injury,</u> <u>- illicit trade in human organs and tissue,</u> <u>- illicit trafficking in nuclear or radioactive materials,</u> <u>- kidnapping, illegal restraint and hostage-taking,</u> <u>- crimes within the jurisdiction of the International Criminal Court,</u> <u>- unlawful seizure of aircraft/ships</u> <u>- rape</u> <u>- participation in a criminal organisation involved in one or more crimes listed above</u> as <i>determined by the law of that Member State.</i> <i>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).</i>
	Article 5(1), point (d)(iia)				
R	189a	<u>(da)</u> <u>the placing on the</u>			<u>(iia)</u> <u>the use of an AI</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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 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;</u>			<u>system to predict a behaviour of a natural person that constitutes a criminal offence, based solely on the output of that system, infringing fundamental or civil rights.</u> In most cases predictive policing would remain high-risk, but in this narrow use case it could be considered as a prohibition.
Article 5(1), point (d)(iiib)					
189b		<u>(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</u>			<u>(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</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>facial images from the internet or CCTV footage;</u>			<u>facial images from the internet or CCTV footage;</u>
Article 5(1), point (d)(iiic)					
189c		<u>(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.</u>			<u>(iiic) the placing on the market, putting into service 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 safety reasons.</u>
Article 5(1), point (dd new)					
189d		<u>(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</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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.</u>			
Article 5(1a new)					
189e		<u>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;</u>			
Article 5(2), first subparagraph					
190	2. 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 paragraph 1 point d) shall	<i>deleted</i>	2. 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 paragraph 1 point d) shall		2. 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 paragraph 1 point d) shall

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	take into account the following elements:		take into account the following elements:		<u>only be deployed to confirm the specifically targeted individual's identity and it shall</u> take into account the following elements:
Article 5(2), first subparagraph, point (a)					
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;	<i>deleted</i>	(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;
Article 5(2), first subparagraph, point (b)					
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.	<i>deleted</i>	(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.
Article 5(2), second subparagraph					
193	In addition, the use of		In addition, the use of		In addition, the use of

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to 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.	<i>deleted</i>	‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to 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.		‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to 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. <u>The application must be limited to what is strictly necessary concerning the period of time as well as geographic and personal scope.</u> <u>The use of the 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</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
					<u>the non-public part of the database according to Article 51. However, in a duly justified situation of urgency, the use of the system may be commenced without a fundamental rights impact assessment and the registration, provided they are completed without undue delay</u>
Article 5(3), first subparagraph					
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 of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the	<i>deleted</i>	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 of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the		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 of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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.		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 <u>provided that, such</u> authorisation may <u>shall</u> be requested only <u>without undue delay</u> during or <u>after the use</u> <u>use of the AI system, and if such authorisation is rejected, its use shall be stopped with immediate effect.</u>		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 <u>provided that such authorisation shall be requested without undue delay, at the latest within 48 hours. If such</u> authorisation may be requested only during or after the use <u>is rejected, its use shall be stopped with immediate effect and all the results and outputs of this use shall be immediately discarded and deleted.</u>
Article 5(3), second subparagraph					
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-	<i>deleted</i>	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-		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-

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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 competent judicial or administrative authority shall take into account the elements referred to in paragraph 2.		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 competent judicial or administrative authority shall take into account the elements referred to in paragraph 2.		time' remote biometric identification system at issue is <u>strictly</u> 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 competent judicial or <u>independent</u> administrative authority shall take into account the elements referred to in paragraph 2. <u>3a. Without prejudice to paragraph 3, Member States shall set-up a national reporting system with comprehensive information about the use of 'real-time' remote biometric identification systems in publicly accessible spaces for law enforcement purpose, in accordance with the national rules referred to in paragraph 4. The reports shall as a minimum contain the information specified under paragraph 5 and</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
					<u>shall not include sensitive operational data.</u>
Article 5(4)					
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	<i>deleted</i>	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 <u>and reporting</u> 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		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<u>States</u> shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision <u>and reporting</u> 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

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.		criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.		criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement. <u>Member States shall notify those rules to the Commission at the latest 30 days following the adoption of such legislation.</u> <u>5. Pursuant to paragraph 4, Member States shall submit to the Commission an annual report on the use of remote biometric identification systems in publicly accessible spaces for law enforcement purposes pursuant to paragraph 4. These reports shall include information on the number of judicial decisions issued.</u> <u>6. The limits and conditions laid down in this Article only constitute minimum requirements and shall not preclude Member</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
					<u>States or the Union from maintaining or introducing laws, regulations or administrative provisions, which are more restrictive concerning those limits and conditions.</u> <u>7. The Commission shall send an annual report on the use of these systems to the national data protection agencies of each Member State.</u>
TITLE III					
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					
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		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
Article 6					
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)					
200	1. Irrespective of whether an AI 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:	1. Irrespective of whether an AI 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:	1. Irrespective of whether An AI system <u>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.</u> 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	1. Irrespective of whether an AI 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			fulfilled:		
Article 6(1), point (a)					
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 <u>the AI system</u> is itself a product, covered by the Union harmonisation legislation <u>law</u> listed in Annex II;	deleted	(a) the AI system is intended to be used as a safety component of a product, or <u>the AI system</u> is itself a product, covered by the Union harmonisation legislation listed in Annex II; Text Origin: EP Mandate	
Article 6(1), point (b)					
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 to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.	(b) the product whose safety component <u>pursuant to point (a)</u> is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment <u>related to risks for health and safety</u> , with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation	deleted	(b) the product whose safety component <u>pursuant to point (a)</u> is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment ₁ 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 ₁	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		legislation <u>law</u> listed in Annex II; ⁱ		Text Origin: EP Mandate	
Article 6(2)					
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.	21a. In addition to the high-risk AI systems referred to in paragraph 1, AI systems <u>falling under one or more of the critical areas and use cases</u> 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 <u>high-risk</u> .	2. In addition to the high-risk AI systems <u>An AI system intended to be used as a safety component of a product covered by the legislation</u> referred to in paragraph 1, AI systems referred to in Annex III shall be considered as <u>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.</u> <u>This provision</u> shall also be considered high-risk <u>apply irrespective of whether the AI system is placed on the market or put into service independently from the product.</u>	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.	
Article 6(2), second subparagraph					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
203a		<u>The Commission shall, six months prior to the entry into force of this Regulation, after consulting the AI Office and relevant stakeholders, 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.</u>			
Article 6(2a)					
203b			<u>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</u>	<u>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</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>fundamental rights.</u> <u>In order to ensure</u> <u>uniform conditions for the</u> <u>implementation of this</u> <u>Regulation, the</u> <u>Commission shall, no</u> <u>later than one year after</u> <u>the entry into force of this</u> <u>Regulation, adopt</u> <u>implementing acts to</u> <u>specify the circumstances</u> <u>where the output of AI</u> <u>systems referred to in</u> <u>Annex III would be purely</u> <u>accessory in respect of the</u> <u>relevant action or decision</u> <u>to be taken. Those</u> <u>implementing acts shall be</u> <u>adopted in accordance</u> <u>with the examination</u> <u>procedure referred to in</u> <u>Article 74, paragraph 2.</u>	<u>shall be the case if one or</u> <u>more of the following</u> <u>criteria are fulfilled:</u>	
	Article 6(2a), first subparagraph, point (a)				
203c				<u>(a) the AI system is</u> <u>intended to perform a</u> <u>narrow procedural task;</u>	
	Article 6(2a), first subparagraph, point (b)				
203d					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				<u>(b) the AI system is intended to improve the result of a previously completed human activity;</u>	
Article 6(2a), first subparagraph, point (c)					
G 203e				<u>(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</u>	G
Article 6(2a), first subparagraph, point (d)					
G 203f				<u>(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.</u>	G
Article 6(2a), second subparagraph					
G 203g					G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				<u>Notwithstanding first subparagraph of this paragraph, an AI system shall always be considered high-risk if the AI system performs profiling of natural persons.</u>	
Article 6(2a new)					
G 203h		<u>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</u>			G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>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.</u>			
	Article 6(2b new)				
203i		<u>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 authorities shall be subject to fines pursuant to Article 71.</u>			
	Article 6(2c new)				
203j		<u>2c. National supervisory authorities shall submit a yearly report to the AI Office detailing the number of notifications</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>received, the related high-risk areas at stake and the decisions taken concerning received notifications</u>			
Article 6(2b)					
203k				<u>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(2). Upon request of national competent authorities, the provider shall provide the documentation of the assessment.</u>	
Article 6(2c)					
203l				<u>2c. The Commission shall, no later than [...] before the date of</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				<u>application of this Regulation and after consulting the AI [Board/Office], 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.</u>	
Article 6(2d), first subparagraph					
G 203m				<u>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.</u>	G
Article 6(2d), second subparagraph					
G 203n				<u>The Commission may adopt delegated acts adding new criteria to those laid down in points a) to d) of the first</u>	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				<u>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.</u>	
	Article 6(2d), third subparagraph				
G 203o				<u>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.</u>	G
	Article 6(2d), fourth subparagraph				
G 203p					G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				<u>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.</u>	
Article 6(2d), fifth subparagraph					
203q				<u>When adopting the delegated acts, the Commission shall ensure consistency with the delegated as adopted pursuant to Article 7(1) and shall take account of market and technological developments.</u>	
Article 7					
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 Proposal	
Article 7(1)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
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 <u>amend</u> Annex III by adding <u>or modifying areas or use-cases of</u> high-risk AI systems where both of the following conditions are fulfilled: these pose a <u>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.</u>	1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update <u>amend</u> 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 <u>amend</u> Annex III by adding <u>or modifying use-cases of</u> 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	<i>deleted</i>	(a) the AI systems are intended to be used in any	(a) the AI systems are intended to be used in any	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	of the areas listed in points 1 to 8 of Annex III;		of the areas listed in points 1 to 8 of Annex III;	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 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.	<i>deleted</i>	(b) the AI systems pose a risk of 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.	(b) the AI systems pose a risk of 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, <u>to the environment, or to democracy and the rule of law,</u> 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)					
207a		<u>1a. The Commission is also empowered to adopt delegated acts in accordance with Article 73</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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;</u>			
Article 7(2)					
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; <u>for the purposes of paragraph 1 and 1a</u> 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	
Article 7(2), point (a)					
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;		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	Article 7(2), point (aa new)				
G	209a	<u>(aa) the general capabilities and functionalities of the AI system independent of its intended purpose;</u>		<u>(aa)</u> Text Origin: EP Mandate	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;	G
	Article 7(2), point (ba)				
R	210a	<u>(ba) the nature and amount of the data processed and used by the AI system;</u>			It has a link with FM/GPAI conversation, kept for later.
	Article 7(2), point (bb new)				
G	210b	<u>(bb) the extent to which the AI system acts autonomously;</u>		<u>(bb) the extent to which the AI system acts autonomously and the possibility for a human to override a decision or</u>	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				<u>recommendations that may lead to potential harm;</u> Text Origin: Presidency2	
Article 7(2), point (c)					
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, <u>has had an-or</u> adverse impact on the fundamental rights, <u>the environment, democracy and the rule of law</u> or has given rise to significant concerns in relation to the materialisation <u>likelihood</u> of such harm or adverse impact, as demonstrated <u>for example</u> by reports or documented allegations submitted to national competent <u>supervisory</u> authorities, <u>to the Commission, to the AI Office, to the EDPS, or to the European Union Agency for Fundamental Rights</u> ;	(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, <u>has had an-or</u> adverse impact on the fundamental rights or has given rise to significant concerns in relation to the materialisation <u>likelihood</u> of such harm or adverse impact, as demonstrated <u>for example</u> by reports or documented allegations submitted to national competent <u>supervisory</u> authorities; <u>or by other reports, as appropriate.</u> Text Origin: Presidency2	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 7(2), point (d)					
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 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 persons <u>or to disproportionately affect a particular group of persons</u> ;	(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 persons <u>or to disproportionately affect a particular group of persons</u> ; Text Origin: EP Mandate	
Article 7(2), point (e)					
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, <u>and that output is purely accessory in respect of the relevant action or decision to be taken</u> , 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	Article 7(2), point (ea new)				
213a		<u>(ea) the potential misuse and malicious use of the AI system and of the technology underpinning it;</u>			
	Article 7(2), point (f)				
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 age;	(f) the extent to which <u>there is an imbalance of power, or the</u> 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 <u>status, authority,</u> knowledge, economic or social circumstances, or age;	(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 age;	(f) the extent to which <u>there is an imbalance of power, or the</u> 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 <u>status, authority,</u> knowledge, economic or social circumstances, or age; Text Origin: Presidency2	
	Article 7(2), point (g)				
215	(g) the extent to which the	(g) the extent to which the	(g) the extent to which the	(g) the extent to which the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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;	outcome produced with <u>involving</u> an AI system is easily reversible <u>or remedied</u> , whereby outcomes having an <u>adverse</u> impact on <u>health, safety, fundamental rights of persons, the environment, or on democracy and rule of law</u> the health or safety of persons shall not be considered as easily reversible;	outcome produced with an AI system is <u>not</u> easily reversible, whereby outcomes having an impact on the health or safety of persons shall not be considered as easily reversible;	outcome produced with <u>involving</u> an AI system is easily <u>corrigible or</u> reversible, <u>taking into account the technical solutions available to correct or reverse</u> , whereby outcomes having an <u>and adverse</u> impact on the health or safety, <u>fundamental rights</u> , of persons shall not be considered as easily <u>corrigible or</u> reversible ; .	
Article 7(2), point (ga)					
215a		<u>(ga) the extent of the availability and use of effective technical solutions and mechanisms for the control, reliability and corrigibility of the AI system;</u>			<u>(ga) --deleted--</u>
Article 7(2), point (gb)					
215b		<u>(gb) the magnitude and likelihood of benefit of the deployment of the AI system for individuals,</u>		<u>(gb) the magnitude and likelihood of benefit of the deployment of the AI system for individuals,</u>	<u>(gb) this line covers line 218a from the Council.</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>groups, or society at large, including possible improvements in product safety;</u>		<u>groups, or society at large, including possible improvements in product safety;</u> Text Origin: Presidency2	
Article 7(2), point (gc new)					
215c		<u>(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;</u>			
Article 7(2), point (h)					
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	
Article 7(2), point (h)(i)					
217	(i) effective measures of	(i) effective measures of	(i) effective measures of	(i) effective measures of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	redress in relation to the risks posed by an AI system, with the exclusion of claims for damages;	redress in relation to the risks posed <u>damage caused</u> by an AI system, with the exclusion of claims for <u>direct or indirect</u> damages;	redress in relation to the risks posed by an AI system, with the exclusion of claims for damages;	redress in relation to the risks posed by an AI system, with the exclusion of claims for damages; Text Origin: Presidency2	
Article 7(2), point (h)(ii)					
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	
Article 7(2), point (h)(ia)					
218a			<u>(ha) the magnitude and likelihood of benefit of the AI use for individuals, groups, or society at large.</u>		<u>(ia) ---covered above---</u>
Article 7(2a new)					
218b		<u>2a. When assessing an AI system for the purposes of paragraphs 1 or 1a the Commission shall consult the AI Office and, where</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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;</u>			
Article 7(2a)					
g 218c			<u>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:</u>		g
Article 7(2a), point (a)					
g 218d			<u>(a) the high-risk AI</u>		g

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>system(s) concerned no longer pose any significant risks to fundamental rights, health or safety, taking into account the criteria listed in paragraph 2;</u>		
Article 7(2a), point (b)					
218e			<u>(b) the deletion does not decrease the overall level of protection of health, safety and fundamental rights under Union law.</u>		
Article 7(2b new)					
218f		<u>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 system in accordance with paragraphs 1 and 1a. The Commission shall give reasons for its decision and make them public.</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
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 <u>AI</u> systems	Chapter 2 Requirements for high-risk Ai <u>AI</u> 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, <u>taking into account the generally acknowledged state of the art.</u>	1. High-risk AI systems shall comply with the requirements established in this Chapter, <u>taking into account its intended purpose as well as the generally acknowledged state of the art.</u> <u>The risk management system referred to in</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				<u>Article 9 shall be taken into account when ensuring compliance with those requirements.</u> Text Origin: Council Mandate	
Article 8(1a new)					
221a		<u>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.</u>		<u>1a. --deleted</u> Text Origin: Presidency2	
Article 8(2)					
222	2. The intended purpose of the high-risk AI system and the risk management	2. The intended purpose of the high-risk AI system, <u>the reasonably foreseeable</u>	2. The intended purpose of the high-risk AI system and the risk management	2. The intended purpose of the high-risk AI system and the risk management	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.	<u>misuses</u> and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.	system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.	system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements. Text Origin: Auxiliary 1	
Article 8(2a new)					
G 222a		<u>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 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,</u>		<u>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 applicable requirements required under the Union harmonisation legislation.</u> <u>In ensuring the compliance of high-risk AI systems referred in paragraph 1 with the requirements set out in Chapter 2 of this Title,</u>	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>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.</u>		<u>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.</u> Text Origin: EP Mandate	
Article 9					
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)					
224					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.	1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems, <u>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.</u>	1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.	1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems. Text Origin: Commission Proposal	
Article 9(2)					
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 <u>review and</u> updating <u>of the risk management process, to ensure its continuing effectiveness, and documentation of any</u>	2. The risk management system shall consist of <u>be understood as</u> a continuous iterative process <u>planned and</u> 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 <u>be understood as</u> a continuous iterative process <u>planned and</u> run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic <u>review and</u> updating. It shall comprise the following steps: Text Origin: Auxiliary	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>significant decisions and actions taken subject to this Article</u> . It shall comprise the following steps:		¹	
Article 9(2), point (a)					
226	(a) identification and analysis of the known and foreseeable risks associated with each high-risk AI system;	(a) identification, <u>estimation and evaluation</u> and analysis of the known and <u>the reasonably</u> foreseeable risks associated with each <u>that the high-risk AI system can pose to the health or safety of natural persons, their fundamental rights including equal access and opportunities, democracy and rule of law or the environment when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse;</u>	(a) identification and analysis of the known and foreseeable risks associated with each <u>most likely to occur to health, safety and fundamental rights in view of the intended purpose of the</u> high-risk AI system;	(a) identification and analysis of the known and <u>the reasonably</u> foreseeable risks associated with each <u>that the high-risk AI system can pose to the [health, safety or fundamental rights] when the high-risk AI system is used in accordance with its intended purpose ;</u> Text Origin: Auxiliary ¹	
Article 9(2), point (b)					
227					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	(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;	<i>deleted</i>	<i>deleted</i>	(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;	
Article 9(2), point (c)					
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 <u>possibly arising emerging significant</u> risks <u>as described in point (a) and identified</u> 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	
Article 9(2), point (d)					
229	(d) adoption of suitable risk management measures in accordance with the provisions of the following paragraphs.	(d) adoption of suitable <u>appropriate and targeted</u> risk management measures <u>designed to address the risks identified pursuant to points a and b of this paragraph</u> in	(d) adoption of suitable risk management measures in accordance with the provisions of the following paragraphs.	(d) adoption of suitable <u>appropriate and targeted</u> risk management measures <u>designed to address the risks identified pursuant to point a of this paragraph</u> in accordance	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		accordance with the provisions of the following paragraphs.		with the provisions of the following paragraphs. Text Origin: Auxiliary 1	
Article 9(2a), first subparagraph					
229a			<u>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.</u>	<u>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.</u> Text Origin: Auxiliary 1	
Article 9(3)					
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	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	3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible interactions <u>interaction</u> resulting from the combined application of	3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible interactions <u>interaction</u> resulting from the combined application of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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.	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, <u>with a view to mitigate risks effectively while ensuring an appropriate and proportionate implementation of the requirements.</u>	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, <u>with a view to minimising risks more effectively while achieving an appropriate balance in implementing the measures to fulfil those requirements.</u>	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, <u>with a view to minimising risks more effectively while achieving an appropriate balance in implementing the measures to fulfil those requirements.</u> 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	4. The risk management measures referred to in paragraph 2, point (d) shall be such that any <u>relevant</u> residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is <u>reasonably</u> judged <u>to be</u> acceptable, provided that the high-risk AI system is used in accordance with its	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	4. The risk management measures referred to in paragraph 2, point (d) shall be such that any <u>relevant</u> residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable; <u>acceptable,</u> provided that the high-risk AI system is used in accordance with its	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user.	intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks <u>and the reasoned judgements made</u> shall be communicated to the user <u>deployer</u> .	intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user.	intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user <u>to be acceptable.</u> 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 as far as possible through adequate design and development;	(a) elimination or reduction of <u>identified</u> risks as far as possible <u>technically feasible</u> through adequate design and development <u>of the high-risk AI system, involving when relevant, experts and external stakeholders</u> ;	(a) elimination or reduction of risks <u>identified and evaluated pursuant to paragraph 2</u> as far as possible through adequate design and development <u>of the high risk AI system</u> ;	(a) elimination or reduction of <u>identified</u> risks <u>and evaluated pursuant to paragraph 2</u> as far as possible <u>technically feasible</u> through adequate design and development <u>of the high-risk AI system.</u> Text Origin: EP	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				Mandate	
Article 9(4), second subparagraph, point (b)					
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 <u>addressing significant</u> 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 <u>addressing</u> risks that cannot be eliminated; Text Origin: EP Mandate	
Article 9(4), second subparagraph, point (c)					
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 <u>the required</u> 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 <u>deployers</u> .	(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 <u>the required</u> 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 <u>deployers</u> . Text Origin: EP Mandate	
Article 9(4), third subparagraph					
236					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	In eliminating or reducing risks related to the use of the high-risk AI system, due 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.	In eliminating or reducing risks related to the use of the high-risk AI system, due consideration providers shall be given to <u>take into due consideration</u> the technical knowledge, experience, education, training to be expected by the user and the environment in which the system is intended to be used <u>and training the deployer may need, including in relation to the presumable context of use.</u>	In <u>With a view to</u> eliminating or reducing risks related to the use of the high-risk AI system, due 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.	In <u>With a view to</u> eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, training to be expected by the user <u>deployer</u> and the environment <u>presumable context</u> in which the system is intended to be used. Text Origin: Council Mandate	
Article 9(5)					
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 <u>and targeted</u> risk management measures <u>and weighing any such measures against the potential benefits and intended goals of the system.</u> Testing shall ensure that high-risk AI systems	5. High-risk AI systems shall be tested for the purposes of identifying the most appropriate risk management measures. <u>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</u> their	5. High-risk AI systems shall be tested for the purposes of identifying the most appropriate <u>and targeted</u> 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		perform consistently for their intended purpose and they are in compliance with the requirements set out in this Chapter.	intended purpose and they are in compliance with the requirements set out in this Chapter.	Chapter. Text Origin: EP Mandate	
Article 9(6)					
R 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 <u>may include testing in real world conditions in accordance with Article 54a.</u>	6. <u>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</u> <u>may include testing in real world conditions in accordance with Article 54a.</u> Text Origin: Council Mandate	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 <u>may include testing in real world conditions in accordance with Article 54a.</u>
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	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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.	the putting into service. Testing shall be made against preliminarily <u>prior</u> defined metrics, and probabilistic thresholds that are appropriate to the intended purpose <u>or reasonably foreseeable misuse</u> of the high-risk AI system.	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.	the putting into service. Testing shall be made against preliminarily <u>prior</u> 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)					
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 <u>providers shall give specific consideration</u> to whether the high-risk AI system is likely to be accessed by or have an impact on <u>adversely impact vulnerable groups of people or</u> children.	8. When implementing The risk management system described in paragraphs 1 to 7, specific consideration shall be given <u>shall give specific consideration</u> to whether the high-risk AI system is likely to be accessed by or have an impact on children <u>persons under the age of 18</u> .	8. When implementing the risk management system described in paragraphs 1 to 7 , specific <u>6, providers shall give</u> consideration shall be given to whether to <u>whether in view of its intended purpose</u> the high-risk AI system is likely to be accessed by or have an impact on <u>children</u> adversely impact <u>persons under the age of 18 and, as appropriate, other vulnerable groups of people</u> . Text Origin: Council Mandate	vulnerable groups of people needs last alignment with current legislation.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
Article 9(9)					
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 <u>providers and AI systems already covered by Union law that require them to establish a specific risk management, including</u> credit institutions regulated by Directive 2013/36/EU, the aspects described in paragraphs 1 to 8 shall be part of <u>or combined with</u> the risk management procedures established by those institutions pursuant to Article 74 of that Directive<u>that Union law.</u>	9. For credit institutions regulated by Directive 2013/36/EU<u>providers of high-risk AI systems that are subject to requirements regarding internal risk management processes under relevant sectorial Union law,</u> the aspects described in paragraphs 1 to 8 shall<u>may</u> be part of the risk management procedures established by those institutions pursuant to Article 74 of that Directive<u>that law.</u>	9. For credit institutions regulated by Directive 2013/36/EU<u>providers of high-risk AI systems that are subject to requirements regarding internal risk management processes under relevant sectorial Union law,</u> the aspects described in paragraphs 1 to 8 shall<u>may</u> be part of <u>or combined with</u> the risk management procedures established by those institutions pursuant to Article 74 of that Directive<u>that law.</u> Text Origin: Council Mandate	
Article 10					
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 10(1)					
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 <u>as far as this is technically feasible according to the specific market segment or scope of application.</u>	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 <u>whenever such datasets are used.</u> Text Origin: Commission Proposal	
Article 10(1), second subparagraph new					
243a		<u>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.</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
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 <u>practices appropriate for the context of use as well as the intended purpose of the AI system</u> . Those practices <u>measures</u> 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 <u>appropriate for the intended purpose of the AI system</u> . 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 new)					
245a		<u>(aa) transparency as regards the original purpose of data collection;</u>		<u>(aa) data collection processes and origin of data, and in the case of personal data, the original purpose of data collection;</u>	
Article 10(2), point (b)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
246	(b) data collection;	(b) data collection <u>processes</u> ;	(b) data collection <u>processes</u> ;	(b) data collection ; <u>[deleted]</u>	
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, <u>updating</u> , 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, <u>updating</u> , 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					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	(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; Text Origin: EP Mandate	
Article 10(2), point (f)					
250	(f) examination in view of possible biases;	(f) examination in view of possible biases <u>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;</u>	(f) examination in view of possible biases <u>that are likely to affect health and safety of natural persons or lead to discrimination prohibited by Union law;</u>	(f) examination in view of possible biases <u>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;</u> Text Origin: EP Mandate	
Article 10(2), point (fa new)					
250a		<u>(fa) appropriate measures to detect, prevent and mitigate possible biases;</u>		<u>(fa) appropriate measures to detect, prevent and mitigate possible biases identified according to</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				<u>point f:</u> 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 <u>relevant</u> data gaps or shortcomings <u>that prevent compliance with this Regulation</u> , 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 <u>relevant</u> data gaps or shortcomings <u>that prevent compliance with this Regulation</u> , and how those gaps and shortcomings can be addressed.	
				Text Origin: EP Mandate	
Article 10(3)					
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	3. Training <u>datasets, and where they are used</u> , validation and testing data sets <u>datasets, including the labels</u> , shall be relevant, <u>sufficiently</u> representative, free of <u>appropriately vetted for</u> errors and <u>be as complete as possible in view of the intended purpose</u> . They shall have	3. Training, validation and testing data sets shall be relevant, representative, <u>and to the best extent possible</u> , free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on	3. Training <u>datasets, and where they are used</u> , validation and testing data sets <u>datasets</u> shall be relevant, <u>sufficiently</u> representative, <u>and to the best extent possible</u> , free of errors and complete <u>in view of the intended purpose</u> . They shall have the appropriate statistical	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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.	the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on <u>which in relation to whom</u> the high-risk AI system is intended to be used. These characteristics of the data sets may <u>datasets shall</u> be met at the level of individual data sets <u>datasets</u> or a combination thereof.	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.	properties, including, where applicable, as regards the persons or groups of persons on <u>which in relation to whom</u> 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	
Article 10(4)					
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 <u>Datasets</u> shall take into account, to the extent required by the intended purpose <u>or reasonably foreseeable misuses of the AI system</u> , the characteristics or elements that are particular to the specific geographical, <u>contextual</u> , behavioural or functional setting within which the high-risk AI system is intended to be used.	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 <u>Datasets</u> shall take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, <u>contextual</u> , behavioural or functional setting within which the high-risk AI system is intended to be used. Text Origin: EP Mandate	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		used.			
Article 10(5)					
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	5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, <u>negative bias</u> detection and correction in relation to the high-risk AI systems, the providers of such systems may <u>exceptionally</u> 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. <u>In particular, all the following conditions shall apply in order for this</u>	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	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 <u>in accordance with the second subparagraph, point f/fa</u>, the providers of such systems may <u>exceptionally</u> 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	significantly affect the purpose pursued.	<u>processing to occur: measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.</u>	significantly affect the purpose pursued.	pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued. <u>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:</u>	
Article 10(5), first subparagraph, point (a new)					
254a		<u>(a) the bias detection and correction cannot be effectively fulfilled by processing synthetic or anonymised data;</u>		<u>(a) the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;</u>	
Article 10(5), first subparagraph, point (b new)					
254b		<u>(b) the data are pseudonymised;</u>		<u>(b) the special categories of personal data processed for the purpose of this paragraph are subject to technical limitations on</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				<u>the re-use of the personal data and state of the art security and privacy-preserving measures, including pseudonymisation;</u>	
Article 10(5), first subparagraph, point (c new)					
254c		<u>(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;</u>		<u>(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 for the purpose of this paragraph are secured, protected, subject to suitable safeguards strict controls, including documentation of the access, to avoid misuse and ensure only authorised persons have access to those personal data with appropriate confidentiality obligations;</u>	
Article 10(5), first subparagraph, point (d new)					
254d					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<i><u>(d) the data processed for the purpose of this paragraph are not to be transmitted, transferred or otherwise accessed by other parties;</u></i>		<i><u>(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;</u></i>	
Article 10(5), first subparagraph, point (e new)					
254e		<i><u>(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;</u></i>		<i><u>(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;</u></i>	
Article 10(5), first subparagraph, point (f new)					
254f		<i><u>(f) effective and appropriate measures are in place to ensure availability, security and resilience of processing systems and services against technical or</u></i>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>physical incidents;</u>			
Article 10(5), first subparagraph, point (g new)					
254g		<u>(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 governance and management, certification of processes and products;</u>			
Article 10(5), second subparagraph new					
254h		<u>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.</u>		<u>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</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				<u>processing other data.</u>	
Article 10(6)					
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 <u>not using</u> techniques involving the training of models, <u>paragraphs 2 to 5 shall apply only to the testing data sets</u> 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 <u>not using</u> techniques involving the training of models, <u>paragraphs 2 to 5 shall apply only to the testing data sets</u> in order to ensure that those high-risk AI systems comply with paragraph 2. Text Origin: Council Mandate	
Article 10(6a new)					
255a		<u>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</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u><i>the deployer, the deployer may, on the basis of a contract, be made responsible for any infringement of this Article.</i></u>			
Article 11					
256	Article 11 Technical documentation	Article 11 Technical documentation	Article 11 Technical documentation	Article 11 Technical documentation Text Origin: Commission Proposal	
Article 11(1), first subparagraph					
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	
Article 11(1), second subparagraph					
258					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI 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.	The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI 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 <u>or, in the case of SMEs and start-ups, any equivalent documentation meeting the same objectives, subject to approval of the competent national authority.</u>	The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information <u>in a clear and comprehensive form</u> to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV <u>or, in the case of SMEs, including start-ups, any equivalent documentation meeting the same objectives, unless deemed inappropriate by the competent authority.</u>	The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities^{supervisory authority} and notified bodies with all the necessary information <u>in a clear and comprehensive form</u> to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV. <u>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,</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				<u>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.</u> Text Origin: Auxiliary 1	
Article 11(2)					
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 documentation shall be drawn up containing all the information set out in Annex IV as well as the information required under those legal acts.	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 documentation shall be drawn up containing all the information set out in Annex IV<u>paragraph 1</u> as well as the information required under those legal acts.	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 documentation shall be drawn up containing all the information set out in Annex IV as well as the information required under those legal acts.	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 documentation shall be drawn up containing all the information set out in Annex IV<u>paragraph 1</u> as well as the information required under those legal acts. Text Origin: EP Mandate	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
Article 11(3)					
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.		
Article 11(3a new)					
260a		<u><i>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.</i></u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
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 <u>the state of the art and</u> recognised standards or common specifications.	1. High-risk AI systems shall be designed and developed with capabilities enabling <u>technically allow for</u> 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 <u>over the duration of the life cycle of the system.</u>	1. High-risk AI systems shall be designed and developed with capabilities enabling <u>technically allow for</u> 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 <u>over the duration of the lifetime of the system.</u> Text Origin: Council Mandate	
Article 12(2)					
263	2. The logging capabilities	2. The logging capabilities	2. The logging capabilities	2. The logging capabilities	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	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.	shall <u>In order to</u> ensure a level of traceability of the AI system's functioning throughout its lifecycle <u>entire lifetime</u> that is appropriate to the intended purpose of the system, <u>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 particular, they shall enable the recording of events relevant for the identification of situations that may:</u>	shall <u>In order to</u> ensure a level of traceability of the AI system's functioning throughout its lifecycle that is appropriate to the intended purpose of the system, <u>logging capabilities shall enable the recording of events relevant for:</u>	shall <u>In order to</u> ensure a level of traceability of the AI system's functioning throughout its lifecycle that is appropriate to the intended purpose of the system, <u>logging capabilities shall enable the recording of events relevant for:</u> Text Origin: Council Mandate	
Article 12(2), point (a new)					
263a		<u>(a) result in the AI system presenting a risk within the meaning of Article 65(1); or</u>			
Article 12(2), point (b new)					
263b		<u>(b) lead to a substantial</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>modification of the AI system.</u>			
Article 12(2a)					
R 263c		<u>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.</u>			<u>2a. Council position: not accepted</u>
Article 12(2a), first subparagraph					
G 263d			<u>2a. (i) identification of situations that may result in the AI system presenting a risk within the meaning of Article 65(1) or in a substantial modification;</u> <u>(ii) facilitation of the post-market monitoring referred to in Article 61;</u> <u>and</u>	<u>2a. (i) identification of situations that may result in the AI system presenting a risk within the meaning of Article 65(1) or in a substantial modification;</u> <u>(ii) facilitation of the post-market monitoring referred to in Article 61;</u> <u>and</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>(iii) monitoring of the operation of high-risk AI systems referred to in Article 29(4).</u>	<u>(iii) monitoring of the operation of high-risk AI systems referred to in Article 29(4).</u> Text Origin: Council Mandate	
Article 12(3)					
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.	<i>deleted</i>	<i>deleted</i>	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. <u>deleted</u>	
Article 12(4)					
265	4. For high-risk AI systems referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide,	4. For high-risk AI systems referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide,	4. For high-risk AI systems referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide,	4. For high-risk AI systems referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	at a minimum:	at a minimum:	at a minimum:	at a minimum: Text Origin: Commission Proposal	
Article 12(4), point (a)					
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)					
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)					
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				Text Origin: Commission Proposal	
Article 12(4), point (d)					
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					
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 <u>deployers</u> Text Origin: EP Mandate	
Article 13(-1)(1)					
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	1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable <u>providers and</u>	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	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 <u>deployers</u> to	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 <u>deployers</u> to

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	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.	users to interpret <u>reasonably understand</u> the system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured <u>functioning. Appropriate transparency shall be ensured in accordance with the intended purpose of the AI system</u> , with a view to achieving compliance with the relevant obligations of the user and of the provider <u>provider and user</u> set out in Chapter 3 of this Title.	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 <u>and enabling users to understand and use the system appropriately.</u>	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 <u>provider and deployer</u> set out in Chapter 3 of this Title.	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 <u>provider and deployer</u> set out in Chapter 3 of this Title. Green
Article 13(1), second subparagraph new					
271a		<u>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 acknowledged state of art are used to</u>		<u>Deletion</u> <u>most of the proposed text can go to the existing Recital 47.</u>	<u>-- deletion : it goes to recital 47 with reference to ISO.</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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).</u>			
Article 13(2)					
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 <u>intelligible</u> instructions for use in an appropriate digital format or <u>made available in a durable medium</u> that include concise, complete, correct and clear <u>correct, clear and to the extent possible complete</u> information that <u>helps operating and maintaining the AI system</u>	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 <u>and shall be</u> clear information that is relevant, accessible and comprehensible to users. <u>understandable and legible.</u> Text Origin: Commission Proposal	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. <u>It shall also serve the deployer as a support for performing the Fundamental Rights Impact Assessment, in</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>as well as supporting informed decision-making by users and is reasonably</u> is relevant, accessible and comprehensible to users.			<u>accordance with art 29a.</u> keep original COM version and add the following part to Recital 47 "helps operating and maintaining the AI system as well as supporting informed decision-making by deployers".
Article 13(3)					
273	3. The information referred to in paragraph 2 shall specify:	3. <u>To achieve the outcomes referred to in paragraph 1,</u> The information referred to in paragraph 2 shall specify:	3. The information referred to in paragraph 2 shall specify:	3. The information referred to in paragraph 2 shall specify <u>instructions for use shall contain at least the following information:</u>	3. The information referred to in paragraph 2 shall specify <u>instructions for use shall contain at least the following information:</u> To green
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 <u>representati</u> <u>ves</u> ;	(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	(a) the identity and the contact details of the provider and, where applicable, of its authorised representative; Green

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
Article 13(3), point (aa)					
274a		<u>(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;</u>		<u>(aa) Deletion</u>	<u>(aa) Deletion</u>
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, <u>where appropriate:</u>	(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	(b) the characteristics, capabilities and limitations of performance of the high-risk AI system, including:
Article 13(3), point (b)(i)					
276	(i) its intended purpose;	(i) its intended purpose;	(i) its intended purpose, <u>inclusive of the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used;</u>	(i) its intended purpose; Text Origin: EP Mandate	(i) its intended purpose;

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	Article 13(3), point (b)(ii)				
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 <u>clearly</u> known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;	(ii) the level of accuracy, <u>including its metrics</u> , 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, <u>including its metrics</u> , 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	(ii) the level of accuracy, <u>including its metrics</u> , 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;
	Article 13(3), point (b)(iii)				
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	(iii) any <u>clearly</u> 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	(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	(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	(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

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	health and safety or fundamental rights;	health and safety, <u>fundamental rights or the environment, including, where appropriate, illustrative examples of such limitations and of scenarios for which the system should not be used</u> or fundamental rights ;	health and safety or fundamental rights <u>referred to in Article 9(2)</u> ;	health and safety or fundamental rights <u>referred to in Article 9(2)</u> ; Text Origin: EP Mandate	health and safety or fundamental rights <u>referred to in Article 9(2)</u> . ; [including, where appropriate, illustrative examples of such limitations and of scenarios for which the system should not be used]; go to recital.
Article 13(3), point (b)(iia)					
278a		<u>(iia) the degree to which the AI system can provide an explanation for decisions it takes;</u>		<u>(iia) where applicable, the technical capabilities and characteristics of the AI system to provide information that is relevant to explain its output.</u>	<u>(iia) where applicable, the technical capabilities and characteristics of the AI system to provide information that is relevant to explain its output.</u>
Article 13(3), point (b)(iv)					
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) <u>when appropriate, its behaviour regarding specific</u> its performance as regards the persons or groups of persons on which the system is intended to be used;	(iv) <u>when appropriate,</u> its performance as regards the <u>regarding specific</u> persons or groups of persons on which the system is intended to be used;	(iv) <u>when appropriate,</u> its performance as regards the <u>regarding specific</u> persons or groups of persons on which the system is intended to be used;

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				Text Origin: Commission Proposal	
Article 13(3), point (b)(v)					
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 <u>the relevant information about user actions that may influence system performance, including type or quality of</u> 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. Text Origin: Commission Proposal	(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. relevant information about user actions that may influence system performance, including type or quality of input data: this goes to a recital.
Article 13(3), point (b)(va)					
280a			<u>(va) when appropriate, description of the expected output of the system.</u>	<u>(va) where applicable, information to enable deployers to interpret the system's output and use it appropriately.</u>	<u>(va) where applicable, information to enable deployers to interpret the system's output and use it appropriately.</u>
Article 13(3), point (c)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
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	(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;
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 <u>deployers</u> ; Text Origin: Commission Proposal	(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 <u>deployers</u> ;
Article 13(3), point (e)					
283	(e) the expected lifetime of the high-risk AI system and any necessary maintenance and care	(e) the expected lifetime of the high-risk AI system and any necessary maintenance and care measures to	(e) <u>the computational and hardware resources needed,</u> the expected lifetime of the high-risk AI	(e) <u>the computational and hardware resources needed,</u> the expected lifetime of the high-risk AI	(e) <u>the computational and hardware resources needed,</u> the expected lifetime of the high-risk AI

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	measures to ensure the proper functioning of that AI system, including as regards software updates.	ensure the proper functioning of that AI system, including as regards software updates, <u>through its expected lifetime</u> .	system and any necessary maintenance and care measures, <u>including their frequency</u> , to ensure the proper functioning of that AI system, including as regards software updates.	system and any necessary maintenance and care measures, <u>including their frequency</u> , to ensure the proper functioning of that AI system, including as regards software updates. Text Origin: Council Mandate	system and any necessary maintenance and care measures, <u>including their frequency</u> , to ensure the proper functioning of that AI system, including as regards software updates.
Article 13(3), point (ea)					
283a			<u>(ea) a description of the mechanism included within the AI system that allows users to properly collect, store and interpret the logs, where relevant.</u>	<u>(ea) Deletion</u>	<u>(ea) Deletion</u>
Article 13(3), point (eb)					
283b		<u>(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).</u>		<u>(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.</u> Text Origin: EP	<u>(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.</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				Mandate	
	Article 13(3), point (ec)				
G	283c	<u>(eb) The information shall be provided at least in the language of the country where the AI system is used.</u>		<u>(ec) parked, possible Deletion</u>	<u>(ec) Deletion</u>
	Article 13(3a)				
Y	283d	<u>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.</u>		<u>3a. parked</u> linked to AI literacy	<u>3a. --deleted--</u>
	Article 14				
G	284	Article 14 Human oversight	Article 14 Human oversight	Article 14 Human oversight Text Origin: Commission Proposal	Article 14 Human oversight
	Article 14(1)				
G	285				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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 <u>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,</u> during the period in which the AI system is in use <u>and to allow for thorough investigation after an incident.</u>	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.	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. To a recital: relevant information about user actions that may influence system performance, including type or quality of input data
Article 14(2)					
286	2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when a high-	2. Human oversight shall aim at preventing or minimising the risks to health, safety or ₁ fundamental rights <u>or environment</u> that may	2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when a high-	2. Human oversight shall aim at preventing or minimising the risks to health, safety or ₁ fundamental rights, <u>{democracy and rule of</u>	2. Human oversight shall aim at preventing or minimising the risks to health, safety or ₁ fundamental rights, <u>{democracy and rule of</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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.	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 <u>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.</u>	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.	<u>law and environment</u>) 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	<u>law and environment</u>) 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.
Article 14(3)					
287	3. Human oversight shall be ensured through either one or all of the following measures:	3. Human oversight shall <u>take into account the specific risks, the level of automation, and context of the AI system and shall</u> be ensured through either one or all of the following <u>types of</u> measures:	3. Human oversight shall be ensured through either one or all of the following <u>types of</u> measures:	3. Human <u>The</u> oversight <u>measures shall be commensurate to the risks, level of autonomy and context of use of the AI system and</u> shall be ensured through either one or all of the following <u>types of</u> measures:	3. Human <u>The</u> oversight <u>measures shall be commensurate to the risks, level of autonomy and context of use of the AI system and</u> shall be ensured through either one or all of the following <u>types of</u> measures:

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 14(3), point (a)					
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) <u>measures</u> 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) <u>measures</u> 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; Text Origin: Council Mandate	(a) <u>measures</u> 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;
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) <u>measures</u> 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) <u>measures</u> 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	(b) <u>measures</u> 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.
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	4. <u>For the purpose of implementing paragraphs 1 to 3, the high-risk AI system</u> <i>The measures referred to in paragraph 3</i>	4. <u>For the purpose of implementing paragraphs 1 to 3, the high-risk AI system</u> <i>The measures referred to in paragraph 3</i>	4. <u>For the purpose of implementing paragraphs 1 to 3, the high-risk AI system</u> <i>The measures referred to in paragraph 3</i>	4. <u>For the purpose of implementing paragraphs 1 to 3, the high-risk AI system</u> <i>The measures referred to in paragraph 3</i>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	following, as appropriate to the circumstances:	shall enable the individuals <u>be provided to the user in such a way that natural persons</u> to whom human oversight is assigned to do the following <u>are enabled</u> , as appropriate <u>and proportionate</u> to the circumstances:	shall enable the individuals <u>be provided to the user in such a way that natural persons</u> to whom human oversight is assigned to do the following <u>are enabled</u> , as appropriate <u>and proportionate</u> to the circumstances:	shall enable the individuals <u>be provided to the user in such a way that natural persons</u> to whom human oversight is assigned to do the following <u>are enabled</u> , as appropriate <u>and proportionate</u> to the circumstances: Text Origin: Council Mandate	shall enable the individuals <u>be provided to the user in such a way that natural persons</u> to whom human oversight is assigned to do the following <u>are enabled</u> , as appropriate <u>and proportionate</u> to the circumstances:
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 unexpected performance can be detected and addressed as soon as possible;	(a) fully <u>be aware of and sufficiently</u> understand the <u>relevant</u> capacities and limitations of the high-risk AI system and be able to duly monitor its operation, so that signs of anomalies, dysfunctions and unexpected performance can be detected and addressed as soon as possible;	(a) fully <u>to</u> 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 unexpected performance can be detected and addressed as soon as possible ;	(a) fully <u>to properly</u> understand the <u>relevant</u> capacities and limitations of the high-risk AI system and be able to duly monitor its operation, so that signs of anomalies, dysfunctions and unexpected performance can be detected and addressed as soon as possible ; Text Origin: Council Mandate	(a) fully <u>to properly</u> understand the <u>relevant</u> capacities and limitations of the high-risk AI system and be able to duly monitor its operation, so that signs of anomalies, dysfunctions and unexpected performance can be detected and addressed as soon as possible ;

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 14(4), point (b)					
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) <u>to</u> 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) <u>to</u> 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	(b) <u>to</u> 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;
Article 14(4), point (c)					
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 <u>for example</u> 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 <u>for example</u> the interpretation tools and methods available; Text Origin: Council Mandate	(c) be able to correctly interpret the high-risk AI system's output, taking into account in particular the characteristics of the system and <u>for example</u> the interpretation tools and methods available;
Article 14(4), point (d)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
G 294	(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	(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;
Article 14(4), point (e)					
G 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 <u>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.</u>	(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” <u>“stop”</u> button or a similar procedure <u>that allows the system to come to a halt in a safe state.</u>	(e) be able to intervene on the operation of the high-risk AI system or interrupt the system through a “stop” <u>“stop”</u> button or a similar procedure <u>that allows the system to come to a halt in a safe state.</u> "human interference should not increase the risks or negatively impact the performance in consideration of generally acknowledged state-of-the-art."
Article 14(5)					
R 296					R

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
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 <u>with the necessary competence, training and authority</u>.	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 <u>separately</u> verified and confirmed by at least two natural persons. <u>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.</u>	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<u>deployer</u> on the basis of the identification resulting from the system unless this has been <u>separately</u> verified and confirmed by at least two natural persons <u>with the necessary competence, training and authority</u>. <u>[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].</u>	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<u>deployer</u> on the basis of the identification resulting from the system unless this has been <u>separately</u> verified and confirmed by at least two natural persons <u>with the necessary competence, training and authority</u>. <u>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.</u> Link

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
Article 15					
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)					
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, <u>following the principle of security by design and by default.</u> In the light of their intended purpose, <u>they should achieve</u> an appropriate level of accuracy, robustness, <u>safety,</u> and cybersecurity, and perform consistently in those respects throughout their lifecycle. <u>Compliance with these requirements shall include implementation of state-of-the-art measures, according to the specific market segment or scope</u>	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. <u>[Compliance with these requirements shall include implementation of state-of-the-art measures.]</u> Pending article 8 agreement from EP, but alligned with Council	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>of application.</u>		Text Origin: EP Mandate	
Article 15(1a new)					
298a		<u>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).</u>		<u>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 AI Office shall bring together national and international metrology and benchmarking authorities and other relevant actors to provide guidance on the matter as set out in Article 56, paragraph 2, point (a).</u> This element stays in the Regulation, to check if legally/technically it should be in art. 58. Text Origin: EP Mandate	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 15(1b new)					
298b		<u>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).</u>			
Article 15(2)					
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. <u>The language used shall be clear, free of misunderstandings or misleading statements.</u>	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	
Article 15(3), first subparagraph					
300	3. High-risk AI systems shall be resilient as regards	3. <u>Technical and organisational measures</u>	3. High-risk AI systems shall be resilient as regards	3. High-risk AI systems shall be <u>as</u> resilient as	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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.	<u>shall be taken to ensure that</u> high-risk AI systems shall be <u>as</u> resilient as regards <u>possible regarding</u> 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.	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.	regards <u>possible regarding</u> 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. <u>Technical and organisational measures shall be taken towards this regard.</u> Text Origin: Commission Proposal	
Article 15(3), second subparagraph					
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 <u>by the appropriate provider with input from the user, where necessary,</u> 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.	The robustness of high-risk AI systems may be achieved through technical redundancy solutions, which may include backup or fail-safe plans. Text Origin: EP Mandate	
Article 15(3), third subparagraph					
302					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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 <u>influencing</u> input for future operations ('feedback loops') <u>and malicious manipulation of inputs used in learning during operation</u> 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 <u>eliminate or reduce as far as possible the risk of possibly biased outputs influencing</u> 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 <u>eliminate or reduce as far as possible the risk of possibly biased outputs influencing</u> input for future operations ('feedback loops') are duly addressed with appropriate mitigation measures. Text Origin: Council Mandate	
Article 15(4), first subparagraph					
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 <u>to</u> attempts by unauthorised third parties to alter their use, <u>behaviour, outputs</u> 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 <u>to</u> attempts by unauthorised third parties to alter their use, <u>outputs</u> or performance by exploiting the system vulnerabilities. Text Origin: EP Mandate	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 15(4), second subparagraph					
304	The technical solutions aimed at ensuring the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks.	The technical solutions aimed at ensuring the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks.	The technical solutions aimed at ensuring the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks.	The technical solutions aimed at ensuring the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks. Text Origin: Commission Proposal	
Article 15(4), third subparagraph					
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, <u>detect, respond to, resolve</u> and control for attacks trying to manipulate the training dataset ('data poisoning'), <u>or pre-trained components used in training ('model poisoning')</u> , inputs designed to cause the model to make a mistake ('adversarial examples' <u>or 'model evasion'</u>), <u>confidentiality attacks</u> or	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, <u>detect, respond to, resolve</u> and control for attacks trying to manipulate the training dataset ('data poisoning'), <u>or pre-trained components used in training ('model poisoning')</u> , inputs designed to cause the model to make a mistake ('adversarial examples' <u>or 'model evasion'</u>), <u>confidentiality attacks</u> or	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		model flaws, <u>which could lead to harmful decision-making</u> .		model flaws. Text Origin: EP Mandate	
Chapter 3					
306	Chapter 3 OBLIGATIONS OF PROVIDERS AND USERS OF HIGH-RISK AI SYSTEMS and other parties	Chapter 3 OBLIGATIONS OF PROVIDERS AND USERS <u>DEPLOYERS</u> OF HIGH-RISK AI SYSTEMS and other parties <u>AND OTHER PARTIES</u>	Chapter 3 OBLIGATIONS OF PROVIDERS AND USERS OF HIGH-RISK AI SYSTEMS and other parties <u>AND OTHER PARTIES</u>	Chapter 3 OBLIGATIONS OF PROVIDERS AND USERS <u>USERS/DEPLOYERS</u> OF HIGH-RISK AI SYSTEMS and other parties <u>AND OTHER PARTIES</u> Text Origin: EP Mandate	
Article 16					
307	Article 16 Obligations of providers of high-risk AI systems	Article 16 Obligations of providers <u>and deployers</u> of high-risk AI systems <u>and other parties</u>	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					
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:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				Text Origin: Commission Proposal	
Article 16, first paragraph, point (a)					
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 <u>before placing them on the market or putting them into service;</u>	(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)					
309a			<u>(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;</u>	<u>(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;</u> Text Origin: Council Mandate	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	Article 16, first paragraph, point (aa new)				
309b		<u>(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;</u>		<u>(ab) [Covered in line 309a]</u>	
	Article 16, first paragraph, point (ab new)				
309c		<u>(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;</u>			
	Article 16, first paragraph, point (ac new)				
309d		<u>(ac) provide specifications for the input data, or any other relevant information in terms of the datasets used, including their limitation and</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>assumptions, taking into account the intended purpose and the foreseeable and reasonably foreseeable misuses of the AI system;</u>			
Article 16, first paragraph, point (b)					
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)					
311	(c) draw-up the technical documentation of the high-risk AI system;	(c) draw-up <u>and keep</u> the technical documentation of the high-risk AI system <u>referred to in Article 11</u> ;	(c) draw-up the technical <u>keep the</u> documentation of the high-risk AI system <u>referred to in Article 18</u> ;	(c) draw-up the technical <u>keep the</u> documentation of the high-risk AI system <u>referred to in Article 18</u> ;	
Article 16, first paragraph, point (d)					
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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<i><u>that are required for ensuring and demonstrating compliance with this Regulation, in accordance with Article 20;</u></i>	<i><u>as referred to in Article 20;</u></i>	<i><u>as referred to in Article 20;</u></i> Text Origin: Council Mandate	
Article 16, first paragraph, point (e)					
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, <i><u>in accordance with Article 43;</u></i>	(e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure <i><u>as referred to in Article 43,</u></i> 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 <i><u>as referred to in Article 43,</u></i> prior to its placing on the market or putting into service; Text Origin: Council Mandate	
Article 16, first paragraph, point (ea new)					
313a		<i><u>(ea) draw up an EU declaration of conformity in accordance with Article 48;</u></i>		<i><u>(ea) draw up an EU declaration of conformity in accordance with Article 48;</u></i> Text Origin: EP Mandate	
Article 16, first paragraph, point (eb new)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
313b		<u>(eb) affix the CE marking to the high-risk AI system to indicate conformity with this Regulation, in accordance with Article 49;</u>		<u>(eb) affix the CE marking to the high-risk AI system to indicate conformity with this Regulation, in accordance with Article 49;</u> 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 <u>(1)</u> ;	(f) comply with the registration obligations referred to in Article 51 <u>(1)</u> ; 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 <u>as referred to in Article 21 and provide information in that regard;</u>	(g) take the necessary corrective actions <u>as referred to in Article 21</u> , 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 <u>and provide information as required in Article 21;</u> Text Origin: EP	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				Mandate	
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;	<i>deleted</i>	(h) inform the <u>relevant</u> national competent authorities <u>authority</u> 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;	<i>deleted</i>	(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; <u>Moved above in line 313b</u>	
Article 16, first paragraph, point (j)					
318	(j) upon request of a national competent	(j) upon <u>a reasoned</u> request of a national	(j) upon request of a national competent	(j) upon <u>a reasoned</u> request of a national	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title.	competent ^{supervisory} authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title.	authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title.	competent ^{/supervisory/} 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) new)					
318a		<u>(ja) ensure that the high-risk AI system complies with accessibility requirements.</u>		<u>(ja) ensure that the high-risk AI system complies with accessibility 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.</u>	
Article 17					
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 17(1)					
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 <u>have</u> a quality management system in place that ensures compliance with this Regulation. That system <u>It</u> shall be documented in a systematic and orderly manner in the form of written policies, procedures and <u>and</u> instructions, and <u>can be incorporated into an existing quality management system under Union sectoral legislative acts. It</u> 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)					
321	(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;	<i>deleted</i>	(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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
Article 17(1), point (b)					
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	
Article 17(1), point (c)					
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	
Article 17(1), point (d)					
324	(d) examination, test and validation procedures to be carried out before, during	(d) examination, test and validation procedures to be carried out before, during	(d) examination, test and validation procedures to be carried out before, during	(d) examination, test and validation procedures to be carried out before, during	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	and after the development of the high-risk AI system, and the frequency with which they have to be carried out;	and after the development of the high-risk AI system, and the frequency with which they have to be carried out;	and after the development of the high-risk AI system, and the frequency with which they have to be carried out;	and after the development of the high-risk AI system, and the frequency with which they have to be carried out; Text Origin: Commission Proposal	
Article 17(1), point (e)					
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, <u>or do not cover all of the relevant requirements</u> , 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, <u>or do not cover all of the relevant requirements set out in Chapter II of this Title</u> , the means to be used to ensure that the high-risk AI system complies with the <u>those</u> requirements set out in Chapter 2 of this Title ; Text Origin: EP Mandate	
Article 17(1), point (f)					
326					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	(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 <u>acquisition</u> , <u>data</u> 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 <u>acquisition</u> , <u>data</u> 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	
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	(h) the setting-up, implementation and	(h) the setting-up, implementation and	(h) the setting-up, implementation and	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	maintenance of a post-market monitoring system, in accordance with Article 61;	maintenance of a post-market monitoring system, in accordance with Article 61;	maintenance of a post-market monitoring system, in accordance with Article 61;	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 <u>a serious incident</u> in accordance with Article 62;	(i) procedures related to the reporting of serious incidents and of malfunctioning <u>a serious incident</u> 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 supporting the access to data, notified bodies, other operators, customers or other interested parties;	(j) the handling of communication with national <u>relevant</u> competent authorities, competent authorities, including sectoral ones; providing or supporting the access to data, notified bodies, other operators, customers or other	(j) the handling of communication with national competent authorities, competent authorities, including sectoral ones, providing or supporting the access to data, notified bodies, other operators, customers or other interested parties;	(j) the handling of communication with national competent authorities, competent <u>other relevant</u> authorities, including sectoral ones, <u>those</u> providing or supporting the access to data, notified bodies, other operators, customers or	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<i>interested parties;</i>		other interested parties;	
Article 17(1), point (k)					
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)					
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)					
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				Text Origin: Commission Proposal	
Article 17(2)					
334	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. <u>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.</u>	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. <u>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.</u> Text Origin: EP Mandate	
Article 17(2a)					
334a			<u>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</u>	<u>2a. For providers of high-risk AI systems that are subject to obligations regarding quality management systems or their equivalent under relevant sectorial Union law, the aspects described</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>may be part of the quality management systems pursuant to that law.</u>	<u>in paragraph 1 may be part of the quality management systems pursuant to that law.</u> Text Origin: Council Mandate	
Article 17(3)					
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 74 of that Directive. In that context, any harmonised standards referred to in Article 40 of this Regulation shall be taken into account.	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 74 of that Directive. In that context, any harmonised standards referred to in Article 40 of this Regulation shall be taken into account.	3. For providers that are credit <u>financial</u> institutions regulated by Directive 2013/36/ EU <u>subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation</u> , the obligation to put <u>in place</u> a quality management system in place <u>with the exception of paragraph 1, points (g), (h) and (i)</u> shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms <u>or processes</u> pursuant to Article 74 of that Directive <u>the relevant Union financial services</u>	3. For providers that are credit <u>financial</u> institutions regulated by Directive 2013/36/ EU <u>subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation</u> , the obligation to put <u>in place</u> a quality management system in place <u>with the exception of paragraph 1, points (g), (h) and (i)</u> shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms <u>or processes</u> pursuant to Article 74 of that Directive <u>the relevant Union financial services</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>legislation</u> . In that context, any harmonised standards referred to in Article 40 of this Regulation shall be taken into account.	<u>legislation</u> . In that context, any harmonised standards referred to in Article 40 of this Regulation shall be taken into account.	
Article 18					
336	Article 18 Obligation to draw up technical documentation	<i>deleted</i>	Article 18 Obligation to draw up technical documentation <u>Documentation keeping</u>	Article 18 Obligation to draw up technical documentation <u>Documentation keeping</u> Text Origin: Council Mandate	
Article 18(1)					
337	1. Providers of high-risk AI systems shall draw up the technical documentation referred to in Article 11 in accordance with Annex IV.	<i>deleted</i>	1. Providers of high-risk AI systems shall draw up the technical documentation referred to in Article 11 in accordance with Annex IV. <u>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:</u>	1. Providers of high-risk AI systems shall draw up the technical documentation referred to in Article 11 in accordance with Annex IV. <u>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:</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				Text Origin: Council Mandate	
	Article 18(1), point (a)				
337a			<u>(a) the technical documentation referred to in Article 11;</u>	<u>(a) the technical documentation referred to in Article 11;</u> Text Origin: Council Mandate	
	Article 18(1), point (b)				
337b			<u>(b) the documentation concerning the quality management system referred to in Article 17;</u>	<u>(b) the documentation concerning the quality management system referred to in Article 17;</u> Text Origin: Council Mandate	
	Article 18(1), point (c)				
337c			<u>(c) the documentation concerning the changes approved by notified bodies where applicable;</u>	<u>(c) the documentation concerning the changes approved by notified bodies where applicable;</u> Text Origin: Council Mandate	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	Article 18(1), point (d)				
G 337d			<u>(d) the decisions and other documents issued by the notified bodies where applicable;</u>	<u>(d) the decisions and other documents issued by the notified bodies where applicable;</u> Text Origin: Council Mandate	G
	Article 18(1), point (e)				
G 337e			<u>(e) the EU declaration of conformity referred to in Article 48.</u>	<u>(e) the EU declaration of conformity referred to in Article 48.</u> Text Origin: Council Mandate	G
	Article 18(1a)				
G 337f			<u>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</u>	<u>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</u>	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>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.</u>	<u>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.</u> Text Origin: Council Mandate	
Article 18(2)					
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.	<i>deleted</i>	2. Providers that are credit <u>financial</u> institutions regulated by Directive 2013/36/EU <u>subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation</u> shall maintain the technical documentation as part of the documentation concerning internal governance, arrangements, processes and mechanisms pursuant to Article 74 of that Directive <u>kept under the relevant Union financial services legislation.</u>	2. Providers that are credit <u>financial</u> institutions regulated by Directive 2013/36/EU <u>subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation</u> shall maintain the technical documentation as part of the documentation concerning internal governance, arrangements, processes and mechanisms pursuant to Article 74 of that Directive <u>kept under the relevant Union financial services legislation.</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				Text Origin: Council Mandate	
Article 19					
339	Article 19 Conformity assessment	<i>deleted</i>	Article 19 Conformity assessment	Article 19 Conformity assessment <u>deleted</u>	
Article 19(1)					
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	<i>deleted</i>	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	marking of conformity in accordance with Article 49.		marking of conformity in accordance with Article 49.	marking of conformity in accordance with Article 49. <u>deleted</u>	
Article 19(2)					
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 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 to 101 of that Directive.	<i>deleted</i>	<i>deleted</i>	2. For high-risk AI systems referred to in point 5(b) of Annex III that are placed on the market or put into 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 to 101 of that Directive. <u>deleted</u>	
Article 20					
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)					
343					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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. <u>Without prejudice to applicable Union or national law,</u> 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 <u>of at least 6 months. The retention period shall be in accordance with industry standards and appropriate to the intended purpose of high-risk AI system.</u>	1. Providers of high-risk AI systems shall keep the logs, <u>referred to in Article 12(1),</u> 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 <u>They</u> shall be kept <u>keep them</u> 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 <u>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.</u>	1. Providers of high-risk AI systems shall keep the logs, <u>referred to in Article 12(1),</u> automatically generated by their high-risk AI systems, to the extent such logs are under their control <u>by virtue of a contractual arrangement with the user or otherwise by law</u> . <u>Without prejudice to applicable Union or national law,</u> the logs shall be kept for a period that is appropriate in the light of 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, <u>in particular in Union law on the protection of personal data.</u>	
Article 20(2)					
344	2. Providers that are credit institutions regulated by Directive 2013/36/EU shall	2. Providers that are credit institutions regulated by Directive 2013/36/EU shall	2. Providers that are credit <u>financial</u> institutions regulated by Directive	2. Providers that are credit <u>financial</u> institutions regulated by Directive	

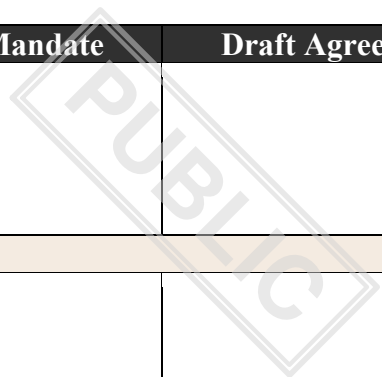
	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	maintain the logs automatically generated by their high-risk AI systems as part of the documentation under Articles 74 of that Directive.	maintain the logs automatically generated by their high-risk AI systems as part of the documentation under Articles 74 of that Directive.	2013/36/EU <u>subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation</u> shall maintain the logs automatically generated by their high-risk AI systems as part of the documentation <u>kept</u> under Articles 74 of that Directive <u>the relevant financial service legislation</u> .	2013/36/EU <u>subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation</u> shall maintain the logs automatically generated by their high-risk AI systems as part of the documentation <u>kept</u> under Articles 74 of that Directive <u>the relevant financial service legislation</u> . Text Origin: Council Mandate	
Article 21					
345	Article 21 Corrective actions	Article 21 Corrective actions	Article 21 Corrective actions	Article 21 Corrective actions <u>and duty of information</u> Text Origin: Commission Proposal	
Article 21					
345a		<i>deleted</i>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 21, first paragraph					
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, <u>to disable it</u> or to recall it, as appropriate. <u>In the cases referred to in the first paragraph, providers</u> They shall <u>immediately</u> inform: <u>a. the distributors;</u> <u>b. the importers;</u> <u>c. the national competent authorities</u> of the high-risk <u>Member States in which they made the</u> AI system in question and, <u>available or put it into service; and</u> <u>d. where applicable, the authorised representative</u>	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 <u>investigate, where applicable, the causes in collaboration with the reporting user and</u> 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, <u>to disable it</u>, or to recall it, as appropriate. They shall inform the distributors of the high-risk AI system in question and, where applicable, the <u>deployers, the</u> authorised representative and importers accordingly.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		and importers accordingly <u>possible, the</u> <u>deployer</u> .			
Article 21, first paragraph 1a					
346a		<u>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 Article 43. Where applicable, they shall also investigate the causes in collaboration with the deployer.</u>		<u>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 [user/deployer], where applicable, and inform the [competent 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.</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				Text Origin: EP Mandate	
Article 22					
347	Article 22 Duty of information	Article 22 Duty of information	Article 22 Duty of information	Article 22 Duty of information Text Origin: Commission Proposal	
Article 22, first paragraph					
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 actions taken.	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 <u>the provider of the system becomes aware of that risk</u> , that provider shall immediately inform the national competent <u>supervisory</u> 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 <u>the nature</u> of the non-	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 actions taken.	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 actions taken. Text Origin: EP	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		compliance and of any <u>relevant</u> corrective actions taken.		Mandate	
Article 22, paragraph 1a (new)					
348a		<u>1a In the cases referred to in the first paragraph, providers of the high-risk AI system shall immediately inform:</u> <u>a) the distributors;</u> <u>b) the importers;</u> <u>c) the national competent authorities of the Member States in which they made the AI system available or put it into service; and</u> <u>d) where possible, the deployers.</u>			
Article 22, paragraph 1b (new)					
348b		<u>1b The providers shall also inform the authorised representative, if one was appointed in accordance with Article 25.</u>			
Article 22, fourth paragraph					



	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
348c		<i>deleted</i>			
Article 22, fifth paragraph					
348d		<i>deleted</i>			
Article 22, sixth paragraph					
348e		<i>deleted</i>			
Article 23					
349	Article 23 Cooperation with competent authorities	Article 23 Cooperation with competent authorities, <u>the Office and the Commission</u>	Article 23 Cooperation with competent authorities	Article 23 Cooperation with competent authorities <u>and the AI Office</u>	
Article 23, first paragraph					
350	Providers of high-risk AI systems shall, upon request by a national competent authority, provide that authority with all the	Providers <u>and where applicable, deployers</u> of high-risk AI systems shall, upon <u>a reasoned</u> request by a national competent	Providers of high-risk AI systems shall, upon request by a national competent authority, provide that authority with all the	Providers of high-risk AI systems shall, upon <u>a reasoned</u> request by a national competent authority <u>or where</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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 of a contractual arrangement with the user or otherwise by law.	authority <u>or where applicable, by the AI Office or the Commission, provide them</u>, 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 of a contractual arrangement with the user or otherwise by law.	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 <u>a language which can be easily understood</u> by the <u>authority of the</u> Member State concerned. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs, <u>referred to in Article 12(1)</u>, 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.	<u>applicable, by the [AI Office], provide them</u>, 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 <u>a language which can be easily understood</u> 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 <u>authority in an official Union language determined by the Member State concerned.</u>	
Article 23, first paragraph a					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
350a		<i>deleted</i>			
Article 23, paragraph 1a					
350b		<u>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.</u>		<u>1a Upon a reasoned request by a national competent authority or, where applicable, by the [AI Office], 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.</u> Text Origin: EP Mandate	
Article 23, paragraph 1b					
350c		<u>(1b) Any information obtained by a national competent authority or by the Commission pursuant to the provisions of this</u>		<u>(1b) Any information obtained by a national competent authority pursuant to the provisions of this Article shall be</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>Article shall be considered a trade secret and be treated in compliance with the confidentiality obligations set out in Article 70.</u>		<u>treated in compliance with the confidentiality obligations set out in Article 70.</u> Text Origin: EP Mandate	
Article 23a					
350d			<u>Article 23a</u> <u>Conditions for other persons to be subject to the obligations of a provider</u>	Deleted from here, included in article 28	
Article 23a(1)					
350e			<u>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:</u>		
Article 23a(1), point (a)					
350f					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>(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;</u>		
	Article 23a(1), point (b)				
G 350g			<u>(b) they make a substantial modification to a high-risk AI system already placed on the market or put into service;</u>		G
	Article 23a(1), point (c)				
G 350h			<u>(c) they modify 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 which makes the modified system a high-risk AI system;</u>		G
	Article 23a(1), point (d)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
350i			<u>(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.</u>		
Article 23a(2)					
350j			<u>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.</u>		
Article 23a(3), first subparagraph					
350k			<u>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</u>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>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:</u>		
Article 23a(3), second subparagraph					
350l			<u>(i) the high-risk AI system is placed on the market together with the product under the name or trademark of the product manufacturer;</u> <u>(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.</u>		
Article 23a					
350m		<i>deleted</i>			
Article 24					
35l					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	Article 24 Obligations of product manufacturers	Article 24 Obligations of product manufacturers	<i>deleted</i>		
<i>Article 24, first paragraph</i>					
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.	<i>deleted</i>		
<i>Article 25</i>					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
353	Article 25 Authorised representatives	Article 25 Authorised representatives	Article 25 Authorised representatives	Article 25 Authorised representatives Text Origin: Commission Proposal	
Article 25(1)					
354	1. Prior to making their systems available on the Union market, where an importer cannot be identified, providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.	1. Prior to making their systems available on the Union market, where an importer cannot be identified , providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.	1. Prior to making their systems available on the Union market, where an importer cannot be identified , providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.	1. Prior to making their systems available on the Union market, where an importer cannot be identified , providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union. Text Origin: Council Mandate	
Article 25(1a)					
354a		<u>1a. The authorised representative shall reside or be established in one of the Member States where the activities pursuant to Article 2, paragraphs</u>		Text Origin: EP Mandate	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u><i>1(cb) are taking place.</i></u>			
Article 25(1b)					
354b		<u><i>1b. The provider shall provide its authorised representative with the necessary powers and resources to comply with its tasks under this Regulation.</i></u>		<u><i>1b. The provider shall enable its authorised representative to perform its tasks under this Regulation.</i></u> Text Origin: EP Mandate	
Article 25(2)					
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. <u><i>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 competent authority. For the purpose of this Regulation,</i></u> the mandate shall empower the authorised representative	2. The authorised representative shall perform the tasks specified in the mandate received from the provider. <u><i>For the purpose of this Regulation,</i></u> the mandate shall empower the authorised representative to carry out <u><i>only</i></u> the following tasks:	2. The authorised representative shall perform the tasks specified in the mandate received from the provider. <u><i>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 competent authority. For the purpose of this Regulation,</i></u> the mandate shall empower the authorised representative	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		to carry out the following tasks:		to carry out the following tasks: Text Origin: EP Mandate	
Article 25(2), point (-a)					
355a			<u>(-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;</u>	<u>(-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;</u> Text Origin: Council Mandate	
Article 25(2), point (a)					
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 <u>ensure that</u> 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) <u>have been drawn up</u>	(a) keep a copy at the disposal of the EU declaration of conformity and the technical documentation at the disposal <u>national competent authorities and national authorities referred to in Article</u>	(a) keep a copy at the disposal of the EU declaration of conformity and the technical documentation at the disposal <u>national competent authorities and national authorities referred to in Article</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>and that an appropriate conformity assessment procedure has been carried out by the provider;</u>	<u>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</u> of the national competent authorities and national authorities referred to in Article 63(7) <u>provider by which the authorised representative has been appointed, a copy of the EU declaration of conformity, the technical documentation and, if applicable, the certificate issued by the notified body;</u>	<u>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</u> of the national competent authorities and national authorities referred to in Article 63(7) <u>provider by which the authorised representative has been appointed, a copy of the EU declaration of conformity, the technical documentation and, if applicable, the certificate issued by the notified body;</u> Text Origin: Council Mandate	
Article 25, second paragraph, point (aa)					
356a		<u>(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</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>applicable, the certificate issued by the notified body;</u>			
Article 25(2), point (b)					
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, <u>including that kept according to point (b),</u> 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, <u>referred to in Article 12(1),</u> 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, <u>including that kept according to point (a),</u> 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, <u>as referred to in Article 12(1),</u> automatically generated by the high-risk AI system to the extent such logs are under the control of the provider <u>[by virtue of a contractual arrangement with the user or otherwise by law]</u> ; Text Origin: Council Mandate	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 25(2), point (c)					
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 <u>supervisory</u> authorities, upon a reasoned request, on any action the latter <u>authority</u> takes in relation to <u>to reduce and mitigate the risks posed by</u> the high-risk AI system.	(c) cooperate with competent national <u>competent</u> authorities, upon a reasoned request, on any action the latter takes in relation to the high-risk AI system.	(c) cooperate with <u>national</u> competent national <u>[supervisory]</u> authorities, upon a reasoned request, on any action the latter takes in relation to the high-risk AI system, <u>in particular to reduce and mitigate the risks posed by the high-risk AI system;</u> Text Origin: Council Mandate	
Article 25(2), point (ca)					
358a			<u>(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.</u>		
Article 25, second paragraph, point (ca)					
358b		<u>(ca) where applicable,</u>		<u>(ca) where applicable,</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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.</u>		<u>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.</u> Text Origin: EP Mandate	
Article 25, paragraph 2a					
358c		<u>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.</u>		<u>2a The mandate shall empower the authorised representative to be addressed, in addition to or instead of the provider, by [the national supervisory authority] or the national competent authorities, on all issues related to ensuring compliance with this Regulation.</u> Text Origin: EP Mandate	
Article 25, paragraph 2b					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
358d		<u>(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.</u>		<u>(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.</u> Text Origin: EP Mandate	
Article 25(2a)					
358e			<u>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</u>		covered in line above.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>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.</u>		
Article 25(2a), second subparagraph					
358f			<u>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.</u>	Applies anyway. Text Origin: Council Mandate	
Article 26					
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	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				Commission Proposal	
Article 26(1)					
360	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 <u>such a system is in conformity with this Regulation by ensuring that:</u>	1. Before placing a high-risk AI system on the market, importers of such system shall ensure that <u>such a system is in conformity with this Regulation by verifying that:</u>	1. Before placing a high-risk AI system on the market, importers of such system shall ensure that <u>such a system is in conformity with this Regulation by verifying that:</u> Text Origin: Council Mandate	
Article 26(1), point (a)					
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 <u>referred to in Article 43</u> has been carried out by the provider of that AI system;	(a) the appropriate relevant conformity assessment procedure <u>referred to in Article 43</u> has been carried out by the provider of that AI system;	(a) the appropriate relevant conformity assessment procedure <u>referred to in Article 43</u> has been carried out by the provider of that AI system; Text Origin: Council Mandate	
Article 26(1), point (b)					
362					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	(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 <u>and</u> 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 <u>and</u> Annex IV; Text Origin: EP Mandate	
Article 26(1), point (c)					
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.;	
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)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
363b		<u>(ca) where applicable, the provider has appointed an authorised representative in accordance with Article 25(1).</u>		<u>(ca) the provider has appointed an authorised representative in accordance with Article 25(1).</u> 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, <u>or is counterfeit, or accompanied by falsified documentation</u> 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 <u>has sufficient reasons</u> to consider that a high-risk AI system is not in conformity with this Regulation, <u>or is falsified, or accompanied by falsified documentation,</u> 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, <u>the authorised representatives</u> and the market surveillance	2. Where an importer considers or has <u>has sufficient</u> reason to consider that a high-risk AI system is not in conformity with this Regulation, <u>or is falsified, or accompanied by falsified documentation,</u> 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, <u>the authorised representatives</u> -and the market surveillance	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			authorities to that effect.	authorities to that effect.	
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, <u>and</u> on its packaging or its accompanying documentation, as <u>where</u> 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, <u>and</u> on its packaging or its accompanying documentation, as <u>where</u> 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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				Text Origin: Council Mandate	
Article 26(4a)					
366a			<u>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 declaration of conformity.</u>	<u>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 declaration of conformity.</u> 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	5. Importers shall provide national competent authorities, upon a reasoned request, with all <u>the</u> necessary information and documentation to demonstrate the conformity of a high-risk AI system with the	5. Importers shall provide national competent authorities, upon a reasoned request, with all necessary information and documentation, <u>including that kept in accordance with paragraph 5</u> , to demonstrate the	5. <u>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</u> to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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.	requirements set out in Chapter 2 of this Title in a language which can be easily understood by that national competent authority <u>them</u> , 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. <u>in accordance with Article 20.</u>	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. <u>To this purpose</u> they shall also cooperate with those authorities on any action national competent authority takes in relation to that system <u>ensure that the technical documentation can be made available to those authorities.</u>	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. <u>them.</u> <u>To this purpose</u> they shall also cooperate with those authorities on any action national competent authority takes in relation to that system <u>ensure that the technical documentation can be made available to those authorities.</u>	
Article 26(5a)					
367a			<u>5a. Importers shall cooperate with national</u>	Text Origin: Council Mandate	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>competent authorities on any action those authorities take in relation to an AI system, of which they are the importer.</u>		
Article 26(5a)					
367b		<u>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.</u>		<u>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.</u> 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-	1. Before making a high-	1. Before making a high-	1. Before making a high-	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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 system, as applicable, have complied with the obligations set out in this Regulation.	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 system, as applicable, have complied with the <u>their</u> obligations set out in this Regulation <u>in Articles 16 and 26 respectively</u> .	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 <u>required documentation a copy of EU declaration of conformity</u> and instruction of use, and that the provider and the importer of the system, as applicable, have complied with the <u>their</u> obligations set out in this Regulation <u>Article 16, point (b) and 26(3) respectively</u> .	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 <u>required documentation a copy of EU declaration of conformity</u> and instruction of use, and that the provider and the importer of the system, as applicable, have complied with the <u>their</u> obligations set out in this Regulation <u>Article 16, point (aa) and (b) and 26(3) respectively</u> .	
Article 27(2)					
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	2. Where a distributor considers or has reason to consider, <u>on the basis of the information in its possession</u> 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-	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	2. Where a distributor considers or has reason to consider, <u>on the basis of the information in its possession</u> , 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-	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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.	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, <u>the relevant national competent authority</u> , as applicable, to that effect.	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.	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.	
Article 27(3)					
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 this Title.	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 this Title.	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 this Title.	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 this Title. Text Origin: Council Mandate	
Article 27(4)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
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, <u>on the basis of the information in its possession</u>, 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 <u>provider or importer of the system and the</u> national competent authorities of the Member States in which it has made the product available to that	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, <u>on the basis of the information in its possession</u>, 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 <u>provider or importer of the system and the</u> national competent authorities of the Member States in which it has made the product available to that	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		effect, giving details, in particular, of the non-compliance and of any corrective actions taken.		effect, giving details, in particular, of the non-compliance and of any corrective actions taken. Text Origin: EP Mandate	
Article 27(5)					
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 <u>system</u> shall provide that authority with all the information and documentation <u>in their possession or available to them, in accordance with the obligations of distributors as outlined in paragraph 1, that are</u> 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 <u>regarding its activities as described in paragraph 1 to 4.</u>	5. Upon a reasoned request from a national competent authority, distributors of high-risk AI systems <u>the high-risk AI system</u> shall provide that authority with all the information and documentation <u>regarding its activities as described in paragraph 1 to 4</u> 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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	Article 27(5a)				
G 373a			<u>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.</u>	<u>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.</u> Text Origin: Council Mandate	
	Article 27(5a)				
G 373b		<u>5a. Distributors 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.</u>			
	Article 28				
G 374	Article 28	Article 28		Article 28	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	Obligations of distributors, importers, users or any other third-party	Obligations of <u>Responsibilities along the AI value chain of providers</u> , distributors, importers, users or any deployers or other third party <u>third parties</u>	deleted	Obligations of <u>Responsibilities along the AI value chain of providers</u> , distributors, importers, users or any deployers or other third party <u>third parties</u> This article will need some tuning in order to avoid duplicities with any provision regarding GPAIS 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 <u>deployer</u> or other third-party shall be considered a provider <u>of a high-risk AI system</u> 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 <u>deployer</u> or other third-party shall be considered a provider <u>of a high-risk AI system</u> 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
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 <u>put their name or trademark on</u> a high-risk AI system under their name or trademark <u>already placed on the market or put into service</u> ;	deleted	(a) they place <u>put their name or trademark on a high-risk AI system already placed</u> on the market or put into service, <u>[without prejudice to contractual arrangements stipulating that the obligations are allocated otherwise.]</u> a high-risk AI system under their name or trademark ;	(a) they place on the market or put into service <u>put their name or trademark on</u> a high-risk AI system under their name or trademark <u>already placed on the market or put into service</u> .
Article 28(1), point (b)					
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 <u>make a substantial modification to</u> a high-risk AI system <u>that has</u> already <u>been</u> placed on the market or <u>has already been</u> put into service <u>and in a way that it remains a high-risk AI system in accordance with Article 6</u> ;	deleted	(b) they modify the intended purpose of <u>make a substantial modification to</u> a high-risk AI system <u>that has</u> already <u>been</u> placed on the market or <u>has already been</u> put into service <u>and in a way that it remains a high-risk AI system in accordance with Article 6</u> ; Text Origin: EP Mandate	
Article 28(1), point (ba)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
377a		<u>(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</u>	<u>(ba) they modify 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 which makes the modified system a high-risk AI system;</u>	<u>(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</u> Waiting output of GPAIS. Text Origin: EP Mandate	
Article 28(1), point (c)					
378	(c) they make a substantial modification to the high-risk AI system.	(c) they make a substantial modification to the high-risk AI system.	deleted	(c) they make a substantial modification to the high-risk AI system. <u>deleted</u>	
Article 28(2)					
379	2. Where the circumstances referred to in paragraph 1, point (b) or (c), occur, the provider that	2. Where the circumstances referred to in paragraph 1, point (b) or (c) , <u>(a) to (ba)</u> occur, the	deleted	2. Where the circumstances referred to in paragraph 1, point (b) or (c) , <u>(a) to (ba)</u> occur, the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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.	provider that initially placed the high-risk AI system on the market or put it into service shall no longer be considered a provider <u>of that specific AI system</u> for the purposes of this Regulation. <u>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.</u> <u>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.</u>		provider that initially placed the high-risk AI system on the market or put it into service shall no longer be considered a provider <u>of that specific AI system</u> for the purposes of this Regulation. <u>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.</u> <u>[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.].</u> <u>This paragraph shall not apply in the cases where the former provider has</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				<u>expressely excluded the change of its system into a high-risk sytem and therefore the obligation to hand over the documentation.</u> Text Origin: EP Mandate	
Article 28(2a)					
379a		<u>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.</u>	<u>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:</u> <u>(i) the high-risk AI system is placed on the market together with the product under the name or trademark of the product manufacturer;</u> <u>(ii) the high-risk AI</u>	<u>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:</u> <u>(i) the high-risk AI system is placed on the market together with the product under the name or trademark of the product manufacturer;</u> <u>(ii) the high-risk AI</u>	<u>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:</u> <u>(i) the high-risk AI system is placed on the market together with the product under the name or trademark of the product manufacturer;</u> <u>(ii) the high-risk AI</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>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 electronic format on the AI Office's website.</u>	<u>system is put into service under the the name or trademark of the product manufacturer after the product has been placed on the market.</u>	<u>system is put into service under the the name or trademark of the product manufacturer after the product has been placed on the market.</u> <u>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.</u> <u>[The Commission shall develop and recommend non-binding model contractual terms between providers of high-risk AI</u>	<u>system is put into service under the the name or trademark of the product manufacturer after the product has been placed on the market.</u> <u>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.</u> Final wording linked to final agreement on FM GPAI

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				<u>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 electronic format on the AI Office's website.]</u> Row still to final checks after agreements on FM and GPAI. Text Origin: EP Mandate	
Article 28(2b)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
G 379b		<u>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 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.</u>		<u>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 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.</u> Text Origin: EP Mandate	
Article 28a					
R 379c		<u>Article 28a</u> <u>Unfair contractual terms unilaterally imposed on an SME or startup</u> <u>1. A contractual term concerning the supply of tools, services,</u>			<u>Article 28a</u> <u>Position of Council: Deletion</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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.</u> <u>2. A contractual term is not to be considered unfair where it arises from applicable Union law.</u> <u>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 commercial practice in the supply of tools, services, components or processes that are used or integrated in a high-risk AI system,</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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).</u> <u>4. A contractual term is unfair for the purposes of this Article if its object or effect is to:</u> <u>(a) exclude or limit the liability of the party that unilaterally imposed the term for intentional acts or gross negligence;</u> <u>(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</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>obligations;</u> <u>(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.</u> <u>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.</u> <u>6. Where the unfair contractual term is severable from the remaining terms of the contract, those remaining</u>			



	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>terms shall remain binding. The party that supplied the contested term shall not argue that the term is an unfair term.</u> <u>7. This Article shall apply to all new contracts entered into force after ... [date of entry into force of this Regulation].</u> <u>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].</u> <u>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.</u>			
Article 28b					
R 379d		<u>Article 28b</u> <u>Obligations of the provider of a foundation</u>		Subject to FM dicussions	<u>Article 28b</u> <u>See note on FM and GPAI</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>model</u> <u>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.</u> <u>2. For the purpose of paragraph 1, the provider of a foundation model shall:</u> <u>(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</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>appropriate methods such as with the involvement of independent experts, as well as the documentation of remaining non-mitigable risks after development</u> <u>(b) process and incorporate only datasets that are subject to appropriate data governance measures for foundation models, in particular measures to examine the suitability of the data sources and possible biases and appropriate mitigation</u> <u>(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,</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>documented analysis, and extensive testing during conceptualisation, design, and development;</u> <u>(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, without 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;</u> <u>(e) draw up extensive technical documentation</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>and intelligible instructions for use, in order to enable the downstream providers to comply with their obligations pursuant to Articles 16 and 28(1);</u> <u>(f) establish a quality management system to ensure and document compliance with this Article, with the possibility to experiment in fulfilling this requirement,</u> <u>(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.</u> <u>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</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>benchmarking guidance and capabilities referred to in Article 58a;</u> <u>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</u> <u>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</u> <u>a) comply with the transparency obligations outlined in Article 52 (1),</u> <u>b) train, and where applicable, design and</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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,</u> <u>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.</u>			
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 <u>deployers</u> of high-risk AI systems Text Origin: Commission Proposal	
Article 29(1)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
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 <u>Deployers</u> of high-risk AI systems shall <u>take appropriate technical and organisational measures to ensure they</u> use such systems in accordance with the instructions of use accompanying the systems, pursuant to paragraphs 2 and 5 <u>of this Article</u> .	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 <u>of this Article</u> .	1. Users <u>Deployers</u> of high-risk AI systems shall <u>take appropriate technical and organisational measures to ensure they</u> use such systems in accordance with the instructions of use accompanying the systems, pursuant to paragraphs 2 and 5 <u>of this Article</u> . Text Origin: EP Mandate	
Article 29(1a)					
381a			<u>1a. Users shall assign human oversight to natural persons who have the necessary competence, training and authority.</u>	<u>1a. Deployers shall assign human oversight to natural persons who have the necessary competence, training and authority, as well as the necessary support.</u>	
Article 29(1a)					
381b		<u>1a. To the extent deployers exercise control over the high-risk AI system, they</u>		Text Origin: EP Mandate	As agreed with MS, this row is deleted. Better addressed as in the row above.



	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>shall</u> <u>i) implement human oversight according to the requirements laid down in this Regulation</u> <u>(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</u> <u>(iii) ensure that relevant and appropriate robustness and cybersecurity measures are regularly monitored for effectiveness and are regularly adjusted or updated.</u>			
Article 29(2)					
G 382	2. The obligations in	2. The obligations in	2. The obligations in	2. The obligations in	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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.	paragraph 1 <u>and 1a</u> , are without prejudice to other user <u>deployer</u> obligations under Union or national law and to the user <u>deployer</u> 's discretion in organising its own resources and activities for the purpose of implementing the human oversight measures indicated by the provider.	paragraph 1 <u>and 1a</u> 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.	paragraph 1 <u>and 1a</u> , are without prejudice to other user <u>deployer</u> obligations under Union or national law and to the user <u>deployer</u> '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)					
383	3. Without prejudice to paragraph 1, to the extent the user exercises 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.	3. Without prejudice to paragraph 1 <u>and 1a</u> , to the extent the user <u>deployer</u> exercises control over the input data, that user <u>deployer</u> shall ensure that input data is relevant <u>and sufficiently representative</u> in view of the intended purpose of the high-risk AI system.	3. Without prejudice to paragraph 1, to the extent the user exercises 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.	3. Without prejudice to paragraph 1 <u>and 1a</u> , to the extent the user <u>deployer</u> exercises control over the input data, that user <u>deployer</u> shall ensure that input data is relevant <u>and sufficiently representative</u> in view of the intended purpose of the high-risk AI system. Text Origin: EP Mandate	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	Article 29(4), first subparagraph				
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<u>Deployers</u> shall monitor the operation of the high-risk AI system on the basis of the instructions of use <u>and when relevant, inform providers in accordance with Article 61</u>. 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, <u>without undue delay</u>, inform the provider or distributor and <u>relevant national supervisory authorities and</u> suspend the use of the system. They shall also <u>immediately</u> inform <u>first</u> the provider, <u>and then the importer or distributor and relevant national supervisory authorities</u> when they have identified any serious incident or any malfunctioning within the meaning of Article 62 and interrupt the use of the AI	4. Users shall <u>implement human oversight and</u> 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. <u>This obligation shall not cover sensitive operational data of users of AI systems which are law</u>	4. Users<u>Deployers</u> shall monitor the operation of the high-risk AI system on the basis of the instructions of use <u>and when relevant, inform providers in accordance with Article 61</u>. 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, <u>without undue delay</u>, inform the provider or distributor <u>and relevant national supervisory authorities</u> and suspend the use of the system. They shall also <u>immediately</u> inform <u>first</u> the provider, <u>and then the importer or distributor and relevant national supervisory authorities</u> when they have identified any serious incident 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	4. Users<u>Deployers</u> shall monitor the operation of the high-risk AI system on the basis of the instructions of use <u>and when relevant, inform providers in accordance with Article 61</u>. 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, <u>without undue delay</u>, inform the provider or distributor and <u>relevant market surveillance authority and</u> suspend the use of the system. They shall also <u>immediately</u> inform <u>first</u> the provider, <u>and then the importer or distributor and relevant market surveillance authorities</u> when they have identified any serious incident or any malfunctioning within the meaning of Article 62 and interrupt the use of the AI

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		system. In case the user <u>If the deployer</u> is not able to reach the provider, Article 62 shall apply mutatis mutandis.	<u>enforcement authorities.</u>	meaning of Article 62 and interrupt the use of the AI system. In case the user <u>If the deployer</u> is not able to reach the provider, Article 62 shall apply mutatis mutandis. <u>[This obligation shall not cover sensitive operational data of users of AI systems which are law enforcement authorities.]</u> to align once LEAS package and national governance. Text Origin: EP Mandate	system. In case the user <u>If the deployer</u> is not able to reach the provider, Article 62 shall apply mutatis mutandis. <u>This obligation shall not cover sensitive operational data of users of AI systems which are law enforcement authorities.</u>
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	For users <u>deployers</u> 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	For users that are credit <u>financial</u> institutions regulated by Directive 2013/36/EU <u>subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation</u> , the monitoring obligation set out in the first subparagraph shall be	For users <u>deployers</u> that are credit <u>financial</u> institutions regulated by Directive 2013/36/EU <u>subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation</u> , the monitoring obligation set out in the first subparagraph shall be	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	Directive.	Directive.	deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to Article 74 of that Directive <u>the relevant financial service legislation.</u>	deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to Article 74 of that Directive <u>the relevant financial service legislation.</u> Text Origin: Council Mandate	
Article 29(5), first subparagraph					
386	5. Users of high-risk AI systems shall keep the logs 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 the intended purpose of the high-risk AI system and applicable legal obligations under Union or national law.	5. Users <u>Deployers</u> of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system, to the extent <u>that</u> such logs are under their control <u>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.</u>	5. Users of high-risk AI systems shall keep the logs, <u>referred to in Article 12(1)</u> , automatically generated by that high-risk AI system, to the extent such logs are under their control. The logs <u>They</u> shall be kept <u>keep them</u> 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 <u>of at least six months, unless provided otherwise in applicable Union or</u>	5. Users <u>Deployers</u> of high-risk AI systems shall keep the logs 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 <u>to</u> the intended purpose of the high-risk AI system, <u>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</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>Without prejudice to applicable Union or national law,</u> –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 <u>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.</u>	<u>national law, in particular in Union law on the protection of personal data.</u>	<u>personal data.</u>	
Article 29(5), second subparagraph					
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 <u>Deployers</u> 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 <u>financial</u> institutions regulated by Directive 2013/36/EU <u>subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation</u> shall maintain the logs as part of the documentation concerning internal	Users <u>Deployers</u> that are credit <u>financial</u> institutions regulated by Directive 2013/36/EU <u>subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation</u> shall maintain the logs as part of the documentation concerning internal	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			governance arrangements, processes and mechanisms<u>kept</u> pursuant to Article 74 of that Directive<u>the relevant Union financial service legislation.</u>	governance arrangements, processes and mechanisms<u>kept</u> pursuant to Article 74 of that Directive<u>the relevant Union financial service legislation.</u> Text Origin: Council Mandate	
Article 29(5), second subparagraph, point (a)					
387a		<u>(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.</u>		<u>(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.</u> Text Origin: EP	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				Mandate	
Article 29(5), second subparagraph, point (a)					
387b		<u>(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.</u>		<u>(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. 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.</u> Text Origin: EP Mandate	<u>(a) [Article 51 has been modified to provide for a non-public part of the database]</u>
Article 29(5a)					
387c			<u>5a. Users of high-risk AI systems that are public authorities, agencies or</u>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>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.</u>		
Article 29(6)					
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 <u>Where applicable, deployers</u> 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 <u>applicable a summary of</u>	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 <u>Where applicable, deployers</u> 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 <u>applicable.</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>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.</u>		Text Origin: EP Mandate	
	Article 29(6a)				
388a			<u>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.</u>		
	Article 29(6a)				
388b		<u>6a. Without prejudice to Article 52, deployers of high-risk AI systems referred to in Annex III, which make decisions or</u>		Text Origin: EP Mandate	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>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.</u>			
	Article 29(6b)				
G	388c	<u>6b. 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.</u>		<u>6b. 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.</u> Text Origin: EP Mandate	G
	Article 29(6a)				
R	388d				R

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
					<u>6a. Deployers using AI systems for ‘post’ remote biometric identification of natural persons shall notify the market surveillance authority and their national data protection authorities about the deployment of such systems. Member States may introduce more restrictive laws on the use of these systems.</u>
Article 29a					
388e		<u>Article 29a</u> <u>Fundamental rights impact assessment for high-risk AI systems</u> <u>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,</u>		<u>Article 29a</u> <u>Fundamental rights impact assessment for high-risk AI systems</u> <u>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 that are public authorities or private actors providing services of general interest shall perform an assessment on the impact</u>	<u>Article 29a</u> <u>Fundamental rights impact assessment for high-risk AI systems</u> <u>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 that are bodies governed by public law or private actors providing services of general interest shall perform an assessment on</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>the following elements:</u> <u>(a) a clear outline of the intended purpose for which the system will be used;</u> <u>(b) a clear outline of the intended geographic and temporal scope of the system's use;</u> <u>(c) categories of natural persons and groups likely to be affected by the use of the system;</u> <u>(d) verification that the use of the system is compliant with relevant Union and national law on fundamental rights;</u> <u>(e) the reasonably foreseeable impact on fundamental rights of putting the high-risk AI system into use;</u> <u>(f) specific risks of harm likely to impact marginalised persons or vulnerable groups;</u> <u>(g) the reasonably foreseeable adverse impact of the use of the system on the environment;</u> <u>(h) a detailed plan as to</u>		<u>on fundamental rights that the use of the system may produce. For that purpose, deployers will perform an analysis consisting of:</u> <u>a) a description of the concrete use, including as appropriate its specific temporal and geographic scope;</u> <u>b) the categories of natural persons and groups likely to be affected by its use in the specific context;</u> <u>[(d) verification that the use of the system is compliant with relevant Union and national law on fundamental rights;]</u> <u>[c) the specific risks of harm likely to impact vulnerable persons or group of persons, taking into account the information given by the provider;]</u> <u>ALTERNATIVE:</u> <u>[c) Possible adverse impact on vulnerable persons or group of persons (to be defined or</u>	<u>the impact on fundamental rights that the use of the system may produce. For that purpose, deployers will perform an analysis consisting of:</u> <u>a) a description of the situations and internal procedures in which each high-risk AI system is intended to be used with a view to confirm that such situations and internal procedures are in line with the intended purpose of the relevant high-risk AI system, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used;</u> <u>b) a description of the period of time and frequency in which each high-risk AI system is intended to be used</u> <u>c) the specific risks of harm likely to impact vulnerable persons or group of persons, taking into account the</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>how the harms and the negative impact on fundamental rights identified will be mitigated.</u> <u>(j) the governance system the deployer will put in place, including human oversight, complaint-handling and redress.</u> <u>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.</u> <u>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.</u> <u>3. The obligation outlined under paragraph</u>		<u>reference to Art. 5 (1) b), taking into account the relevant information given by the provider pursuant to Art. 13]</u> <u>d) a description of the implementation of the human oversight, according to the instructions of use;</u> <u>e) the measures to be taken in case of the materialization of these risks.</u> <u>[For the purpose of conducting this assessment, deployers shall fill the template provided in annex XXX only for the purposes of identifying new elements or risks that are not contained in the instructions of use.]</u> <u>2. 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</u>	<u>information given by the provider;</u> <u>d) a description of the implementation of the human oversight, according to the instructions of use;</u> <u>e) the measures to be taken in case of the materialization of these risks.</u> <u>2. The obligation outlined under paragraph 1 applies to 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 assessments carried out by providers. If, during the use of the high-risk AI system, the deployer considers that the criteria listed in paragraph 1 are not longer met, the deployer will take the necessary steps to be in line with such obligations.</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>1 applies for the first use of the high-risk AI system.</u> <u>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 criteria listed in paragraph 1 are not longer met, it shall conduct a new fundamental rights impact assessment.</u> <u>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</u>		<u>fundamental rights impact assessment or existing assessments carried out by providers. If, during the use of the high-risk AI system, the deployer considers that the criteria listed in paragraph 1 are not longer met, the deployer will take the necessary steps to be in line with such obligations.</u> <u>3. Once the impact assessment has been performed, the deployer shall notify national supervisory of the results of the assessment, submitting the filled template as a part of the notification. In the case referred to in Article 47(1), deployers may be exempted from these obligations.</u> <u>4. If any of the obligations established in this article are already met through the data protection impact assessment under Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680,</u>	<u>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 as a part of the notification. In the case referred to in Article 47(1), deployers may be exempted from these obligations.</u> <u>4. If any of the obligations established in this article are already met through the 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.</u> <u>5. The Commission shall develop a template for a questionnaire, including</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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.</u> <u>In the case referred to in Article 47(1), public authorities may be exempted from this obligations.</u> <u>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).</u> <u>6. Where the deployer is already required to carry out a data protection impact assessment under</u>		<u>the fundamental rights impact assessment referred to in paragraph 1 shall be conducted in conjunction with the data protection impact assessment.</u> Text Origin: EP Mandate	<u>through an automated tool, to enable users to implement the obligations of this Article in a simplified manner.</u> (xx) “private actor providing services of general interest” means any private operator providing services that public authorities of the Member States classify as being of general interest and, therefore, subject to specific public service obligations.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>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.</u>			
Chapter 4					
389	Chapter 4 NOTIFYING AUTHORITIES AND NOTIFIED BODIES	Chapter 4 NOTIFYING AUTHORITIES AND NOTIFIED BODIES	Chapter 4 NOTIFYING AUTHORITIES AND NOTIFIED BODIES	Chapter 4 NOTIFYING AUTHORITIES AND NOTIFIED BODIES Text Origin: Commission Proposal	
Article 30					
390	Article 30 Notifying authorities	Article 30 Notifying authorities	Article 30 Notifying authorities	Article 30 Notifying authorities Text Origin: Commission Proposal	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 30(1)					
391	1. Each Member State shall designate or establish a notifying 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.	1. Each Member State shall designate or establish a notifying 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. <u>Those procedures shall be developed in cooperation between the notifying authorities of all Member States.</u>	1. Each Member State shall designate or establish at least one notifying 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.	1. Each Member State shall designate or establish at least one notifying 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. <u>These procedures shall be developed in cooperation between the notifying authorities of all Member States.</u>	
Article 30(2)					
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 <u>decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by</u> a national accreditation body referred to in <u>within the meaning of and in accordance with</u>	2. Member States may designate <u>decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by</u> a national accreditation body referred to in <u>within the meaning of and in accordance with</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			Regulation (EC) No 765/2008 as a notifying authority.	Regulation (EC) No 765/2008 as a notifying authority.	
Article 30(3)					
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	
Article 30(4)					
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				Text Origin: Commission Proposal	
Article 30(5)					
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)					
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 <u>in accordance with Article 70.</u>	6. Notifying authorities shall safeguard the confidentiality of the information they obtain <u>in accordance with Article 70.</u>	
Article 30(7)					
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 <u>an adequate</u> number of	7. Notifying authorities shall have a sufficient <u>an adequate</u> number of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	personnel at their disposal for the proper performance of their tasks.	personnel at their disposal for the proper performance of their tasks. <u>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.</u>	competent personnel at their disposal for the proper performance of their tasks.	competent personnel at their disposal for the proper performance of their tasks. <u>[Where applicable,] competent personnel shall have the necessary expertise in fields such as information technologies, artificial intelligence and law, including the supervision of fundamental rights.</u>	
Article 30(8)					
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 <u>and timely</u> 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.	<i>deleted</i>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>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.</u>			
Article 31					
399	Article 31 Application of a conformity assessment body for notification	Article 31 Application of a conformity assessment body for notification	Article 31 Application of a conformity assessment body for notification	Article 31 Application of a conformity assessment body for notification Text Origin: Commission Proposal	
Article 31(1)					
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 31(2)					
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 legislation shall be added.	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 legislation shall be added.	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 <u>AI systems</u> 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 legislation shall be added.	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 <u>types of AI systems</u> 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 legislation shall be added.	
Article 31(3)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
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 <u>all</u> 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. <u>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</u>	3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with <u>all</u> 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. <u>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</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>compliance with all the requirements laid down in Article 33.</u>	<u>compliance with all the requirements laid down in Article 33.</u>	
Article 32					
403	Article 32 Notification procedure	Article 32 Notification procedure	Article 32 Notification procedure	Article 32 Notification procedure 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 <u>shall</u> notify only conformity assessment bodies which have satisfied the requirements laid down in Article 33.	1. Notifying authorities may <u>only</u> notify only conformity assessment bodies which have satisfied the requirements laid down in Article 33.	1. Notifying authorities may notify only <u>notify</u> 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 <u>of each conformity assessment</u>	2. Notifying authorities shall notify <u>those bodies to</u> 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 <u>of each conformity assessment</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>body referred to in paragraph 1.</u>		<u>body referred to in paragraph 1.</u> 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 <u>referred to in paragraph 2</u> shall include full details of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies concerned, <u>as well as the relevant attestation of competence.</u>	3. The notification <u>referred to in paragraph 2</u> shall include full details of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies concerned <u>AI systems concerned and the relevant attestation of competence. Where a notification is 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</u>	3. The notification <u>referred to in paragraph 2</u> shall include full details of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies <u>types of AI systems concerned and the relevant attestation of competence. Where a notification is 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</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>be monitored regularly and will continue to satisfy the requirements laid down in Article 33.</u>	<u>be monitored regularly and will continue to satisfy the requirements laid down in Article 33.</u>	
Article 32(4)					
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 <u>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 includes documentary evidence referred to in Article 31(3).</u>	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 <u>two weeks</u> of a notification <u>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).</u>	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 <u>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).</u>	
Article 32(4a)					
407a		<u>4a. Where objections are</u>		<u>4a. Where objections are</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>raised, the Commission shall without delay enter into consultation with the 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.</u>		<u>raised, the Commission shall without delay enter into consultation with the 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.</u>	
Article 32(4b)					
G 407b		<u>4b. Member States shall notify the Commission and the other Member States of conformity assessment bodies.</u>		<u>4b. Deleted [covered by par.2]</u>	G
Article 32(5)					
G 408	5. Notifying authorities shall notify the Commission and the other Member States of any subsequent relevant	5. Notifying authorities shall notify the Commission and the other Member States of any subsequent relevant	deleted		G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	changes to the notification.	changes to the notification.			
Article 33					
409	Article 33 Notified bodies	Article 33 Notified bodies	Article 33 <u>Requirements relating to notified bodies</u> notified bodies	Article 33 <u>Requirements relating to notified bodies</u> notified bodies Text Origin: Council Mandate	
Article 33(1)					
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. <u>A</u> notified bodies <u>body</u> shall verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43 <u>be established under national law and have legal personality.</u>	1. <u>A</u> notified bodies <u>body</u> shall verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43 <u>be established under national law of a Member State and have legal personality.</u>	
Article 33(2)					
411	2. Notified bodies shall satisfy the organisational, quality management, resources and process	2. Notified bodies shall satisfy the organisational, quality management, resources and process	2. Notified bodies shall satisfy the organisational, quality management, resources and process	2. Notified bodies shall satisfy the organisational, quality management, resources and process	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	requirements that are necessary to fulfil their tasks.	requirements that are necessary to fulfil their tasks <u>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).</u>	requirements that are necessary to fulfil their tasks.	requirements that are necessary to fulfil their tasks, <u>as well as suitable cybersecurity requirements.</u>	
Article 33(3)					
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	
Article 33(4)					
413	4. Notified bodies shall be	4. Notified bodies shall be	4. Notified bodies shall be	4. Notified bodies shall be	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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.	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. <u><i>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.</i></u>	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.	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. <u><i>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.</i></u> Text Origin: EP Mandate	
Article 33(4a)					
G 413a		<u><i>4a. A conformity assessment pursuant to paragraph 1 shall be performed by employees of notified bodies who have not provided any other</i></u>		<u><i>4a. A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment</i></u>	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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 not providing them with such services in the 12 month period following the completion of the assessment.</u>		<u>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 judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.</u>	
Article 33(5)					
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	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	their organisation, personnel and assessment activities.	their organisation, personnel and assessment activities.	their organisation, personnel and assessment activities.	their organisation, personnel and assessment activities. Text Origin: Commission Proposal	
Article 33(6)					
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, 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,	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, 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,	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 <u>in accordance with Article 70</u> which comes into their possession during the performance 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	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 <u>in accordance with Article 70</u> which comes into their possession during the performance 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	except in relation to the notifying authorities of the Member State in which their activities are carried out.	except in relation to the notifying authorities of the Member State in which their activities are carried out. <u>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.</u>	under this Regulation, except in relation to the notifying authorities of the Member State in which their activities are carried out.	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)					
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)					
417	8. Notified bodies shall	8. Notified bodies shall	8. Notified bodies shall	8. Notified bodies shall	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	take out appropriate liability insurance for their conformity assessment activities, unless liability is assumed by the Member State concerned in accordance with national law or that Member State is directly responsible for the conformity assessment.	take out appropriate liability insurance for their conformity assessment activities, unless liability is assumed by the Member State concerned in accordance with national law or that Member State is directly responsible for the conformity assessment.	take out appropriate liability insurance for their conformity assessment activities, unless liability is assumed by the Member State concerned <u>in which they are located</u> in accordance with national law or that Member State is <u>itself</u> directly responsible for the conformity assessment.	take out appropriate liability insurance for their conformity assessment activities, unless liability is assumed by the Member State concerned <u>in which they are established</u> in accordance with national law or that Member State is <u>itself</u> directly responsible for the conformity assessment. Text Origin: Council Mandate	
Article 33(9)					
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	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				Commission Proposal	
Article 33(10)					
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 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.	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 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.	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 body shall have permanent availability of sufficient administrative, technical, <u>legal</u> 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.	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 body shall have permanent availability of sufficient administrative, technical, <u>legal</u> and scientific personnel who possess experience and knowledge relating to the relevant <u>types of</u> artificial intelligence technologies<u>systems</u>, data and data computing and to the requirements set out in Chapter 2 of this Title. Text Origin: Council Mandate	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 33(11)					
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)					
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, designation, notification, monitoring and surveillance activities and	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, designation, notification, monitoring and surveillance activities and	<i>deleted</i>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	to facilitate the assessment outlined in this Chapter.	to facilitate the assessment outlined in this Chapter.			
Article 33a					
421a			<u>Article 33a</u> <u>Presumption of</u> <u>conformity with</u> <u>requirements relating to</u> <u>notified bodies</u>	<u>Article 33a</u> <u>Presumption of</u> <u>conformity with</u> <u>requirements relating to</u> <u>notified bodies</u> Text Origin: Council Mandate	
Article 33a, first paragraph					
421b			<u>Where a conformity</u> <u>assessment body</u> <u>demonstrates its</u> <u>conformity with the</u> <u>criteria laid down in the</u> <u>relevant harmonised</u> <u>standards or parts thereof</u> <u>the references of which</u> <u>have been published in the</u> <u>Official Journal of the</u> <u>European Union it shall</u> <u>be presumed to comply</u> <u>with the requirements set</u> <u>out in Article 33 in so far</u> <u>as the applicable</u> <u>harmonised standards</u>	<u>Where a conformity</u> <u>assessment body</u> <u>demonstrates its</u> <u>conformity with the</u> <u>criteria laid down in the</u> <u>relevant harmonised</u> <u>standards or parts thereof</u> <u>the references of which</u> <u>have been published in the</u> <u>Official Journal of the</u> <u>European Union it shall</u> <u>be presumed to comply</u> <u>with the requirements set</u> <u>out in Article 33 in so far</u> <u>as the applicable</u> <u>harmonised standards</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>cover those requirements.</u>	<u>cover those requirements.</u> Text Origin: Council Mandate	
Article 34					
422	Article 34 Subsidiaries of and subcontracting by notified bodies	Article 34 Subsidiaries of and subcontracting by notified bodies	Article 34 Subsidiaries of and subcontracting by notified bodies	Article 34 Subsidiaries of and subcontracting 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
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. <u>Notified bodies shall make a list of their subsidiaries publicly available.</u>	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. <u>Notified bodies shall make a list of their subsidiaries publicly available.</u> Text Origin: EP Mandate	
Article 34(4)					
426	4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents	4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents	4. Notified bodies shall keep at the disposal of the notifying authority The relevant documents	4. Notified bodies shall keep at the disposal of the notifying authority The relevant documents	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.	concerning the assessment <u>verification</u> of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.	concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation <u>shall be kept at the disposal of the notifying authority for a period of 5 years from the termination date of the subcontracting activity.</u>	concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation <u>shall be kept at the disposal of the notifying authority for a period of 5 years from the termination date of the subcontracting activity.</u>	
Article 34a					
G 426a			<u>Article 34a</u> <u>Operational obligations of notified bodies</u>	<u>Article 34a</u> <u>Operational obligations of notified bodies</u> Text Origin: Council Mandate	G
Article 34a(1)					
G 426b			<u>1. Notified bodies shall verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43.</u>	<u>1. Notified bodies shall verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43.</u> Text Origin: Council	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				Mandate	
Article 34a(2)					
G 426c			<u>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.</u>	<u>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.</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	Article 34a(3)				
426d			<u>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, notification, monitoring activities and to facilitate the assessment outlined in this Chapter.</u>	<u>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, notification, monitoring activities and to facilitate the assessment outlined in this Chapter.</u>	
	Article 35				
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)				
428					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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)					
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 ensure that the list is kept up to date.	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 ensure that the list is kept up to date.	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 ensure that the list is kept up to date.	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 ensure that the list is kept up to date. Text Origin: Commission Proposal	
Article 36					
430	Article 36	Article 36	Article 36	Article 36	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	Changes to notifications	Changes to notifications	Changes to notifications	Changes to notifications Text Origin: Commission Proposal	
Article 36(-1)					
430a			<u>-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).</u>	<u>-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).</u> Text Origin: Council Mandate	
Article 36(-1a), first subparagraph					
430b			<u>-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.</u>	<u>-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.</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				Text Origin: Council Mandate	
	Article 36(-1a), second subparagraph				
G 430c			<u>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</u>	<u>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</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>systems. Where the notified body has ceased its activity, the notifying authority shall withdraw the designation.</u>	<u>systems. Where the notified body has ceased its activity, the notifying authority shall withdraw the designation.</u> Text Origin: Council Mandate	
Article 36(1)					
431	1. Where a notifying authority has suspicions or has been informed 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 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	1. Where a notifying authority has suspicions or has been informed 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 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	1. Where a notifying authority has suspicions or has been informed <u>sufficient reasons to consider</u> 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 <u>the notifying authority shall, provided that the</u> the notified body concerned about the objections raised and give it the possibility <u>had the opportunity</u> to make its views known. If the	1. Where a notifying authority has suspicions or has been informed <u>sufficient reasons to consider</u> 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 <u>notifying</u> 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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.	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.	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 <u>to meet those requirements or fulfil those obligations</u> . It shall also immediately inform the Commission and the other Member States accordingly.	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 <u>to meet those requirements or fulfil those obligations</u> . 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 appropriate steps to ensure that the files of that notified body are either taken over by another	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 appropriate steps to ensure that the files of that notified body are either taken over by another	deleted		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	notified body or kept available for the responsible notifying authorities at their request.	notified body or kept available for the responsible notifying authorities, <u>and market surveillance authority</u> at their request.			
Article 36(2a)					
G 432a			<u>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.</u>	<u>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.</u>	
Article 36(2b)					
G 432b			<u>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</u>	<u>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</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>Member States and to market surveillance authorities at their request.</u>	<u>Member States and to market surveillance authorities at their request.</u>	
Article 36(2c)					
432c			<u>2c. In the event of restriction, suspension or withdrawal of a designation, the notifying authority shall:</u>	<u>2c. In the event of restriction, suspension or withdrawal of a designation, the notifying authority shall:</u>	
Article 36(2c), point (a)					
432d			<u>(a) assess the impact on the certificates issued by the notified body;</u>	<u>(a) assess the impact on the certificates issued by the notified body;</u> Text Origin: Council Mandate	
Article 36(2c), point (b)					
432e			<u>(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;</u>	<u>(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;</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				Text Origin: Council Mandate	
Article 36(2c), point (c)					
432f			<u>(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;</u>	<u>(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;</u> Text Origin: Council Mandate	
Article 36(2c), point (d)					
432g			<u>(d) inform the Commission and the Member States about certificates of which it has required their suspension or withdrawal;</u>	<u>(d) inform the Commission and the Member States about certificates of which it has required their suspension or withdrawal;</u> Text Origin: Council Mandate	
Article 36(2c), point (e)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
G 432h			<u>(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.</u>	<u>(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.</u> Text Origin: Council Mandate	
Article 36(2d)					
G 432i			<u>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:</u>	<u>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:</u> Text Origin: Council	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				Mandate	
Article 36(2d), point (a)					
432j			<u>(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</u>	<u>(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</u> Text Origin: Council Mandate	
Article 36(2d), point (b)					
432k			<u>(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</u>	<u>(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</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>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 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.</u>	<u>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 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.</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				Text Origin: Council Mandate	
Article 36(2e), first subparagraph					
432l			<u>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:</u>	<u>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:</u> Text Origin: Council Mandate	
Article 36(2e), first subparagraph, point (a)					
432m			<u>(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 rights associated with the systems in question; and</u>	<u>(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 rights [democracy, rule of law] associated with the</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				<u>systems in question; and</u>	
Article 36(2e), first subparagraph, point (b)					
G 432n			<u>(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.</u>	<u>(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.</u> Text Origin: Council Mandate	
Article 36(2e), second subparagraph					
G 432o			<u>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</u>	<u>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</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>periods of three months, which altogether shall not exceed twelve months.</u>	<u>periods of three months, which altogether shall not exceed twelve months.</u> Text Origin: Council Mandate	
Article 36(2e), third subparagraph					
432p			<u>The national competent authority or the notified body assuming the functions of the notified body affected by the change of notification shall immediately inform the Commission, the other Member States and the other notified bodies thereof.</u>	<u>2f. The national competent authority or the notified body assuming the functions of the notified body affected by the change of notification shall immediately inform the Commission, the other Member States and the other notified bodies thereof.</u> Text Origin: Council Mandate	
Article 37					
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 37(1)					
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 <u>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.</u>	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 <u>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.</u>	
Article 37(2)					
435	2. The Notifying authority shall provide the Commission, on request, with all relevant information relating to the notification of the notified body concerned.	2. The Notifying authority shall provide the Commission, on request, with all relevant information relating to the notification <u>or the maintenance of the competence</u> of the notified body concerned.	2. The notifying authority shall provide the Commission, on request, with all relevant information relating to the notification of the notified body concerned.	2. The Notifying authority shall provide the Commission, on request, with all relevant information relating to the notification <u>or the maintenance of the competence</u> of the notified body concerned. Text Origin: EP Mandate	
Article 37(3)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
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 <u>sensitive</u> 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 <u>in accordance with Article 70.</u>	3. The Commission shall ensure that all confidential <u>sensitive</u> information obtained in the course of its investigations pursuant to this Article is treated confidentially <u>in accordance with Article 70.</u> Text Origin: EP Mandate	
Article 37(4)					
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 <u>for its notification</u> , it shall adopt a reasoned decision requesting <u>inform</u> the notifying Member State <u>accordingly and request it</u> to take the necessary corrective measures, including <u>suspension or withdrawal of the notification if necessary.</u> <u>Where the Member State</u>	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 <u>inform the notifying authority of the reasons of such an ascertainment and request it</u> to take the necessary corrective measures, including <u>the suspension, restriction or</u> withdrawal of notification <u>the</u>	4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements laid down in Article 33 <u>for its notification</u> , it shall adopt a reasoned decision requesting <u>inform</u> -the notifying Member State <u>accordingly and request it</u> to take the necessary corrective measures, including <u>suspension or withdrawal of the notification if necessary.</u> <u>Where the Member State</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>fails to take the necessary corrective measures, the Commission may, by means of an implementing act, suspend, restrict or withdraw the designation.</u> That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(2).	<u>designation</u> if necessary. <u>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.</u> That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(2).	<u>fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the designation.</u> That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(2).	
Article 38					
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)					
439	1. The Commission shall ensure that, with regard to the areas covered by this Regulation, appropriate coordination and cooperation between	1. The Commission shall ensure that, with regard to the areas covered by this Regulation, appropriate coordination and cooperation between	1. The Commission shall ensure that, with regard to the areas covered by this Regulation <u>high-risk AI systems</u> , appropriate coordination and	1. The Commission shall ensure that, with regard to the areas covered by this Regulation <u>high-risk AI systems</u> , appropriate coordination and	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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.	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.	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.	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)					
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 <u>The notifying authority</u> 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 <u>The notifying authority</u> shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives. Text Origin: Council Mandate	
Article 38(2a)					
440a		<u>2a. The Commission shall provide for the exchange of knowledge and best practices between the Member States' national authorities responsible for</u>		<u>2a. The Commission shall provide for the exchange of knowledge and best practices between the Member States' notifying authorities.</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>notification policy.</u>		Text Origin: EP Mandate	
Article 39					
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					
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, <u>provided that they meet the requirements in Article 33.</u>	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, <u>provided that they meet the requirements in Article 33 or they ensure an equivalent level of compliance.</u>	
Chapter 5					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
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					
444	Article 40 Harmonised standards	Article 40 Harmonised standards	Article 40 Harmonised standards	Article 40 Harmonised standards <u>and</u> <u>standardisation</u> <u>deliverables</u> Text Origin: Commission Proposal	
Article 40, first paragraph					
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	High-risk AI systems <u>and foundation models</u> 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 <u>in accordance with</u>	High-risk AI systems <u>or general purpose AI systems</u> which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European	High-risk AI systems <u>for general purpose AI/and foundation models</u> which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	conformity with the requirements set out in Chapter 2 of this Title, to the extent those standards cover those requirements.	<u>Regulation (EU) 1025/2012</u> shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title <u>or Article 28b</u> , to the extent those standards cover those requirements.	Union shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title <u>or, as applicable, with requirements set out in Article 4a and Article 4b</u> , to the extent those standards cover those requirements.	Union <u>in accordance with Regulation (EU) 1025/2012</u> shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title <u>or, as applicable, with the requirements set out in [Article 4b/28b]</u> , to the extent those standards cover those requirements.	
Article 40(-1), first subparagraph					
445a			<u>-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:</u>	<u>2. 2. The Commission shall issue standardisation requests covering all requirements of Title II Chapter III and [...] of this Regulation, in accordance with Article 10 of Regulation EU (No) 1025/2012 by... [six months after the date of entry into force of this Regulation]. The standardisation request, shall also ask for deliverables on reporting and documentation processes to improve AI</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				<u>systems resource performance, such as reduction of energy and other resources consumption of the high-risk AI system during its lifecycle. When preparing standardisation request, the Commission shall consult the [AI Office] and [the Advisory Forum].</u> Office and forum to be cleared after governance Text Origin: Council Mandate	
Article 40(-1), first subparagraph, point (a)					
445b			<u>(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;</u>	<u>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 by the existing Union safety legislation listed in Annex</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				<u><i>It, clear 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.</i></u>	
Article 40(-1), first subparagraph, point (b)					
G 445c			<u><i>(b) promote investment and innovation in AI, including through increasing legal certainty, as well as competitiveness and growth of the Union market;</i></u>	Text Origin: Council Mandate	G
Article 40(-1), first subparagraph, point (c)					
G 445d			<u><i>(c) enhance multistakeholder governance, representative of all relevant European stakeholders (e.g. industry, SMEs, civil society, researchers);</i></u>	Text Origin: Council Mandate	G
Article 40(-1), first subparagraph, point (d)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
G 445e			<u>(d) contribute to strengthening global cooperation on standardisation in the field of AI that is consistent with Union values and interests.</u>	Text Origin: Council Mandate	G
Article 40(-1), second subparagraph					
G 445f			<u>The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the above objectives.</u>	<u>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.</u> Text Origin: Council Mandate	G
Article 40, (1a)					
G 445g		<u>1a. The Commission shall issue standardisation requests covering all requirements of this Regulation, in accordance with Article 10 of</u>			G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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;</u>			
Article 40, (1c)					
G 445h		<u>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 on standardisation and taking into account existing international standards in the field of AI that are consistent with Union values,</u>		<u>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, 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 account existing international standards in the field of AI that are consistent with</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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</u>		<u>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</u> Text Origin: EP Mandate	
Article 40, (1b)					
445i		<u>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</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>this Regulation;</u>			
Article 41					
446	Article 41 Common specifications	Article 41 Common specifications	Article 41 Common specifications	Article 41 Common specifications Text Origin: Commission Proposal	
Article 41(1)					
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).	<i>deleted</i>	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 <u>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</u> common	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 <u>The Commission is empowered to adopt, after consulting the AI [Board] referred to in Article 56 [and the AI Forum referred to in Article 58], implementing acts in accordance with</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>technical</u> specifications in respect of <u>for</u> 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). <u>or, as applicable, with requirements set out in Article 4a and Article 4b, where the following conditions have been fulfilled:</u>	<u>the examination procedure referred to in Article 74(2) establishing</u> common specifications in respect of <u>for</u> 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). <u>or, as applicable, with requirements set out in Article [28b], where the following conditions have been fulfilled:</u>	
Article 41(1), point (a)					
447a			<u>(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;</u>	<u>(a) (a) 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</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				<u>reasonable period;</u> <u>aa) that there is a need to address specific safety or fundamental right concerns.</u>	
Article 41(1), point (b)					
G 447b			<u>(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;</u>	<u>(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;</u> Text Origin: Council Mandate	G
Article 41(1), point (c)					
G 447c			<u>(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</u>	<u>(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</u>	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>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.</u>	<u>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.</u> Text Origin: Council Mandate	
Article 41(1a)					
447d			<u>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.</u>	<u>1a. Before preparing a draft implementing act, the Commission shall inform the committee referred to in Article 22 of Regulation EU (No) 1025/2012 [and the AI Office] that it considers that the conditions in paragraph 1 are fulfilled.</u> Text Origin: Council Mandate	
Article 41(1a)					
447e		<u>1a. The Commission may, by means of implementing act adopted</u>		Included in row 477	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>in accordance with the examination procedure referred to in Article 74(2) and after consulting the AI Office and the AI Advisory Forum, 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:</u> <u>(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;</u> <u>(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;</u> <u>(c) the request referred</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>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.</u>			
Article 41(1a)					
R 447f		<u>1b. The Commission shall develop common specifications for the methodology to fulfil the reporting and documentation requirement on the consumption of energy and resources during development, training and deployment of the high risk AI system.</u>		Dropped, to be substituted by a standardization deliverable (see art. 40)	<u>1a. Proposal to be deleted, as art. 40, line 445a would be acting as part of the compromise.</u>
Article 41(1b)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
R 447g		<u>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.</u>			<u>1b. To be dropped, with introduction in 447 as a compromise.</u>
Article 41(2)					
R 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 <u>shall, throughout the whole process of drafting,</u> when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant paragraphs 1a and 1b, <u>regularly consult the AI Office and the Advisory Forum, the European standardisation organisations and</u> bodies or expert groups established under relevant	2. <u>In the early preparation of the draft implementing act establishing</u> The Commission, when preparing the common specifications <u>specification,</u> the Commission shall fulfil the objectives referred to in paragraph 1, shall <u>Article 40(2) and</u> gather the views of relevant bodies or expert groups established under relevant sectorial Union		2. <u>2. In the early preparation of the draft implementing act establishing</u> The Commission, when preparing the common specifications <u>specification,</u> the Commission shall fulfil the objectives referred to in paragraph 1, shall <u>Article 40(2) and</u> gather the views of relevant bodies or expert groups established under relevant <u>Union law. Based</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		sectorial Union law <u>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 specifications.</u> <u>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.</u> <u>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.</u> <u>Where the Commission decides not to follow the opinion of the AI Office, it shall provide a reasoned explanation to the AI Office.</u>	law. <u>Based on that consultation, the Commission shall prepare the draft implementing act.</u>		<u>on that consultation, the Commission shall prepare the draft implementing act</u> sectorial Union law. to add a recital explaining more about these bodies.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 41(3)					
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 <u>paragraphs 1a and 1b</u> 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 <u>or general purpose AI systems</u> 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 <u>or, as applicable, with requirements set out in Article 4a and Article 4b,</u> to the extent those common specifications cover those requirements.	3. High-risk AI systems <u>or [foundation models]</u> which are in conformity with the common specifications referred to in paragraph 1 <u>[and 1a], or parts thereof,</u> shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title <u>or, as applicable, with requirements set out in [Article 28b],</u> to the extent those common specifications cover those requirements.	
Article 41(3a)					
449a		<u>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</u>		<u>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</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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.</u>		<u>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.</u> Text Origin: EP Mandate	
Article 41(4)					
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 <u>of high-risk AI systems</u> do not comply with the common specifications referred to in paragraph 1, they shall duly justify that they have adopted technical solutions that are <u>meet the requirements referred to in Chapter II to a level</u> at least equivalent thereto.	<i>deleted</i>	4. Where providers <u>of high-risk AI systems</u> do not comply with the common specifications referred to in paragraph 1, they shall duly justify that they have adopted technical solutions that are <u>meet the requirements referred to in Chapter II to a level</u> at least equivalent thereto.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				Text Origin: EP Mandate	
Article 41(4a)					
G 450a			<u>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.</u>		G
Article 41(4b)					
G 450b			<u>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</u>	<u>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</u>	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>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.</u>	<u>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.</u> Text Origin: Council Mandate	
Article 42					
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 Text Origin: Commission Proposal	
Article 42(1)					
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	1. Taking into account their intended purpose, high-risk AI systems that have been trained and tested on data concerning the specific geographical, behavioural <u>contextual</u> and functional setting within which they are intended to	1. Taking into account their intended purpose, High-risk AI systems that have been trained and tested on data concerning <u>reflecting</u> the specific geographical, behavioural and <u>or</u> functional setting within	1. Taking into account their intended purpose, High-risk AI systems that have been trained and tested on data concerning <u>reflecting</u> the specific geographical, behavioural, <u>contextual or</u> and functional setting	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	shall be presumed to be in compliance with the requirement set out in Article 10(4).	be used shall be presumed to be in compliance with the requirement <u>respective requirements</u> set out in Article 10(4).	which they are intended to be used shall be presumed to be in compliance with the requirement <u>respective requirements</u> set out in Article 10(4).	within which they are intended to be used shall be presumed to be in compliance with the requirement <u>respective requirements</u> set out in Article 10(4).	
Article 42(2)					
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 certificate or statement of conformity or parts thereof cover those requirements.	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 certificate or statement of conformity or parts thereof cover those requirements.	2. High-risk AI systems <u>or [general purpose AI systems]</u> 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 certificate or statement of conformity or	2. High-risk AI systems <u>or [general purpose AI systems]</u> 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 certificate or statement of conformity or	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	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).	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).	parts thereof cover those requirements. 1. <u>III</u> 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).	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					
454	Article 43 Conformity assessment	Article 43 Conformity assessment	Article 43 Conformity assessment		
Article 43(1), first subparagraph					
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	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall follow one of the following procedures:	referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall follow ^{opt} <u>for</u> one of the following procedures ² :	referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall follow ^{opt} <u>for</u> one of the following procedures:	referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall follow ^{opt} <u>for</u> one of the following procedures:	
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; <u>or</u>	(a) the conformity assessment procedure based on internal control referred to in Annex VI; <u>or</u>	(a) the conformity assessment procedure based on internal control referred to in Annex VI; <u>or</u> 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 ² :	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				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 <u>shall follow the conformity assessment procedure set out in Annex VII in the following cases:</u> <u>(a) where</u> harmonised standards referred to in Article 40, or where such harmonised standards <u>the reference number of which has been published in the Official Journal of the European Union, covering all relevant safety requirements for the AI system,</u> do not exist and common specifications referred to in Article 41 are not available; <u>(b) where the technical specifications referred to in point (a) exist but the</u>	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, <u>shall follow the conformity assessment procedure set out in Annex VII in the following cases:</u> <u>(a) where</u> 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; <u>(aa) the provider shall follow the conformity assessment procedure set out in Annex VII.</u> has not applied or has applied only in part the <u>harmonised standard;</u> <u>(b) where the common specifications referred to</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>provider has not applied them or has applied them only in part;</u> <u>(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;</u> <u>(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.</u>		<u>in point (a) exist but the provider has not applied them;</u> <u>(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;</u>	
Article 43(1), third subparagraph					
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	For the purpose of <u>carrying out</u> 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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	enforcement, immigration or asylum authorities as well as EU institutions, bodies or agencies, the market surveillance authority referred to in Article 63(5) or (6), as applicable, shall act as a notified body.	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) or (6), as applicable, shall act as a notified body.	enforcement, immigration or asylum authorities as well as EU institutions, bodies or agencies, the market surveillance authority referred to in Article 63(5) or (6), as applicable, shall act as a notified body.	enforcement, immigration or asylum authorities as well as EU institutions, bodies or agencies, the market surveillance authority referred to in Article 63(5) or (6), as applicable, shall act as a notified body. Text Origin: Council Mandate	
Article 43(2)					
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	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	2. For high-risk AI systems referred to in points 2 to 8 of Annex III <u>and for general purpose AI systems referred in Title 1a</u> , 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	2. For high-risk AI systems referred to in points 2 to 8 of Annex III <u>and for [general purpose AI systems referred in Title 1a]</u> , 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	shall be carried out as part of the procedure referred to in Articles 97 to 101 of that Directive.	shall be carried out as part of the procedure referred to in Articles 97 to 101 of that Directive.	<i>Directive 2013/36/EU, the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to 101 of that Directive.</i>	<i>Directive 2013/36/EU, the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to 101 of that Directive.</i> Text Origin: Council Mandate	
Article 43(3), first subparagraph					
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 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.	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 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.	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 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.	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 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					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
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					
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	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	standards covering all the relevant requirements, that manufacturer may make use of that 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.	standards covering all the relevant requirements, that manufacturer may make use of that 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.	standards covering all the relevant requirements, that manufacturer may make use of that 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.	standards covering all the relevant requirements, that manufacturer may make use of that 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					
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 <u>that have already been subject to a conformity assessment procedure</u> 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 <u>deployer</u> ;	deleted	4. High-risk AI systems <u>that have already been subject to a conformity assessment procedure</u> 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 <u>[user/deployer]</u> user .	
Article 43(4), second subparagraph					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
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 constitute a substantial modification.	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 constitute a substantial modification.	<i>deleted</i>	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 constitute a substantial modification. Text Origin: EP Mandate	
Article 43(4a)					
G 465a		<u><i>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;</i></u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 43(5)					
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. <u>When preparing such delegated acts, the Commission shall consult the AI Office and the stakeholders affected.</u>	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. <u>light of technical progress.</u> <u>When preparing such delegated acts, the Commission shall consult the [AI Office].</u>	
Article 43(6)					
467	6. The Commission is empowered to adopt delegated acts to amend paragraphs 1 and 2 in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure	6. The Commission is empowered to adopt delegated acts to amend paragraphs 1 and 2 in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure	6. The Commission is empowered to adopt delegated acts to amend paragraphs 1 and 2 in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure	6. The Commission is empowered to adopt delegated acts to amend paragraphs 1 and 2 in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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.	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. <u><i>When preparing such delegated acts, the Commission shall consult the AI Office and the stakeholders affected.</i></u>	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.	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. <u><i>When preparing such delegated acts, the Commission shall consult the [AI Office].</i></u>	
	Article 44				
G 468	Article 44 Certificates	Article 44 Certificates	Article 44 Certificates		
	Article 44(1)				
G 469					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	1. Certificates issued by notified bodies in accordance with Annex VII shall be drawn-up in an official Union language determined by the Member State in which the notified body is established or in an official Union language otherwise acceptable to the notified body.	1. Certificates issued by notified bodies in accordance with Annex VII shall be drawn-up in an <u>one or several</u> official Union language <u>languages</u> determined by the Member State in which the notified body is established or in an <u>one or several</u> official Union language <u>languages</u> otherwise acceptable to the notified body.	1. Certificates issued by notified bodies in accordance with Annex VII shall be drawn-up in an official Union <u>a</u> language determined by the Member State in which the notified body is established or in an official Union language otherwise acceptable to <u>which can be easily understood by the relevant authorities in the Member State in which the notified body is established.</u>	1. Certificates issued by notified bodies in accordance with Annex VII shall be drawn-up in an official Union language determined <u>a language which can be easily understood</u> by the <u>relevant authorities in the</u> 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 <u>four</u> years. On application by the provider, the validity of a certificate may be extended for further periods, each not exceeding five <u>four</u> years, based on a re-assessment in accordance with the applicable conformity assessment	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 years <u>for AI systems covered by Annex II and four years for AI systems covered by Annex III</u> . On application by the provider, the validity of a certificate may be extended for further periods, each not exceeding five years <u>for AI systems covered by</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		procedures.	<u>Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.</u>	<u>Annex II and four years for AI systems covered by Annex III</u> , based on a re-assessment in accordance with the applicable conformity assessment procedures. <u>Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.</u>	
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 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	3. Where a notified body finds that an AI system no longer meets the requirements set out in Chapter 2 of 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	3. Where a notified body finds that an AI system no longer meets the requirements set out in Chapter 2 of 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	3. Where a notified body finds that an AI system no longer meets the requirements set out in Chapter 2 of 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	body. The notified body shall give reasons for its decision.	body. The notified body shall give reasons for its decision.	body. The notified body shall give reasons for its decision.	body. The notified body shall give reasons for its decision. Text Origin: Council Mandate	
Article 45					
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		
Article 45, first paragraph					
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, <u>including on issued conformity certificates</u> 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 <u>shall be available.</u>	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. <u>including on issued conformity certificates, shall be available.</u>	
Article 46					
474	Article 46 Information obligations of notified bodies	Article 46 Information obligations of notified bodies	Article 46 Information obligations of notified bodies	Article 46 Information obligations of notified bodies	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				Text Origin: Council Mandate	
Article 46(1)					
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)					
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)					
477	(b) any refusal, restriction,	(b) any refusal, restriction,	(b) any refusal, restriction,	(b) any refusal, restriction,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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;	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;	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;	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	
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
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	
Article 46(2), point (a)					
482	(a) quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system	(a) quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system	(a) quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system	(a) quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	approvals which it has issued;	approvals which it has issued;	approvals which it has issued;	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	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	3. Each notified body shall provide the other notified bodies carrying out similar conformity assessment activities covering the same artificial intelligence technologies <u>AI systems</u> with relevant information	3. Each notified body shall provide the other notified bodies carrying out similar conformity assessment activities covering the same artificial intelligence technologies <u>types of AI systems</u> with relevant	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	relating to negative and, on request, positive conformity assessment results.	relating to negative and, on request, positive conformity assessment results.	on issues relating to negative and, on request, positive conformity assessment results.	information on issues relating to negative and, on request, positive conformity assessment results.	
Article 46(3a)					
G 484a			<u>3a. The obligations referred to in paragraphs 1 to 3 shall be complied with in accordance with Article 70.</u>	<u>3a. The obligations referred to in paragraphs 1 to 3 shall be complied with in accordance with Article 70.</u> Text Origin: Council Mandate	
Article 47					
G 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)					
R 486	1. By way of derogation from Article 43, any	1. By way of derogation from Article 43, any	1. By way of derogation from Article 43 <u>and upon</u>		1. By way of derogation from Article 43 <u>and upon</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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 are being carried out, and shall terminate once those procedures have been completed. The completion of those procedures shall be undertaken without undue delay.	market surveillance <u>national supervisory request a judicial authority to</u> 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 <u>critical infrastructure</u>. That authorisation 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.	<u>a duly justified request</u>, 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 are being carried out, and shall terminate once those procedures have been completed <u>taking into account the exceptional reasons justifying the derogation</u>. The completion of those procedures shall be undertaken without undue delay.		<u>a duly justified request</u>, 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 are being carried out, and shall terminate once those procedures have been completed <u>taking into account the exceptional reasons justifying the derogation</u>. The completion of those procedures shall be undertaken without undue delay.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
Article 47(1a)					
R 486a			<u>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.</u>		<u>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.</u> LEAS exemptions
Article 47(2)					
R 487					R

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	2. The authorisation referred to in paragraph 1 shall be issued only if 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.	2. The authorisation referred to in paragraph 1 shall be issued only if the market <u>surveillance national supervisory authority and judicial</u> authority concludes <u>conclude</u> that the high-risk AI system complies with the requirements of Chapter 2 of this Title. The market <u>surveillance national supervisory</u> authority shall inform the Commission, <u>the AI office</u> , and the other Member States of any <u>request made and any subsequent</u> authorisation issued pursuant to paragraph 1.	2. The authorisation referred to in paragraph 1 shall be issued only if 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. <u>This obligation shall not cover sensitive operational data in relation to the activities of law enforcement authorities.</u>		2. The authorisation referred to in paragraph 1 shall be issued only if 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. <u>This obligation shall not cover sensitive operational data in relation to the activities of law enforcement authorities.</u> Politica, linked to governance (MS level) and LEAs exemptions.
Article 47(3)					
488	3. Where, within 15 calendar days of receipt of the information referred to in paragraph 2, no objection has been raised	3. Where, within 15 calendar days of receipt of the information referred to in paragraph 2, no objection has been raised	<i>deleted</i>		3. Where, within 15 calendar days of receipt of the information referred to in paragraph 2, no objection has been raised

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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.	by either a Member State or the Commission in respect <u>to the request of the national supervisory authority for</u> of an authorisation issued by a market surveillance <u>national supervisory</u> authority of a Member State in accordance with paragraph 1, that authorisation shall be deemed justified.			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.
Article 47(4)					
489	4. Where, within 15 calendar days of receipt of the notification referred to in paragraph 2, objections are 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	4. Where, within 15 calendar days of receipt of the notification referred to in paragraph 2, objections are raised by a Member State against an <u>authorisation a request</u> issued by a market surveillance <u>national supervisory</u> 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	<i>deleted</i>		4. Where, within 15 calendar days of receipt of the notification referred to in paragraph 2, objections are 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

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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.	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 <u>and the AI Office</u> ; 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 <u>operators(s)</u> .			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)					
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 <u>national supervisory</u> authority of the Member State concerned.	<i>deleted</i>		5. If the authorisation is considered unjustified, this shall be withdrawn by the market surveillance authority of the Member State concerned.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
Article 47(6)					
491	6. By way of derogation from 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.	6. By way of derogation from 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.	6. By way of derogation from paragraphs 1 to 5, For high-risk AI systems intended to be used as safety components of devices, or which are themselves devices,<u>related to products</u> 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<u>Union harmonisation legislation referred to in Annex II Section A, only</u> the conformity assessment of the compliance with the requirements set out in Chapter 2 of this Title<u>derogation procedures established in that legislation shall apply.</u>		6. By way of derogation from paragraphs 1 to 5, For high-risk AI systems intended to be used as safety components of devices, or which are themselves devices,<u>related to products</u> 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<u>Union harmonisation legislation referred to in Annex II Section A, only</u> the conformity assessment of the compliance with the requirements set out in Chapter 2 of this Title<u>derogation procedures established in that legislation shall apply.</u>
Article 48					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
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)					
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 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.	1. The provider shall draw up a written <u>machine readable, physical or electronic</u> EU declaration of conformity for each <u>high-risk</u> AI system and keep it at the disposal of the national <u>supervisory authority and the national</u> competent authorities for 10 years after the AI <u>high-risk</u> 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 <u>given</u> to <u>submitted to the national supervisory authority and</u> the relevant national	1. The provider shall draw up a written <u>or electronically signed</u> 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 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 <u>given</u> submitted to the relevant national competent authorities upon request.	1. The provider shall draw up a written <u>machine readable, physical or electronically signed</u> EU declaration of conformity for each <u>high-risk</u> AI system and keep it at the disposal of the national <u>[supervisory authority] and the national</u> competent authorities for 10 years after the AI <u>high-risk</u> system has been placed on the market or put into service. The EU declaration of conformity shall identify the <u>high-risk</u> AI system for which it has been drawn up. <u>up.</u> A copy of the EU declaration of conformity shall be <u>given</u> to <u>submitted to the</u> <u>[national supervisory</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		competent authorities upon request.		<u>authority]</u> and the relevant national competent authorities upon request.	
Article 48(2)					
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 <u>placed on the market or</u> 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 <u>language that can be easily understood by the national competent authorities of</u> 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 a <u>language that can be easily understood by the [national competent authorities] of the</u> Member State(s) in which the high-risk AI system is <u>placed on the market or</u> made available.	
Article 48(3)					
495	3. Where high-risk AI	3. Where high-risk AI	3. Where high-risk AI	3. Where high-risk AI	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	systems are 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.	systems are subject to other Union harmonisation legislation which also requires an EU declaration of conformity, a single EU declaration of conformity shall <u>may</u> 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.	systems are 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.	systems are 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)					
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				Text Origin: Commission Proposal	
Article 48(5)					
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 elements that become necessary in light of technical progress.	5. <u>After consulting the AI Office</u> , 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 elements that become necessary in light of technical progress.	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 elements that become necessary in light of technical progress.	5. <u>[After consulting the AI Office]</u> , 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 elements that become necessary in light of technical progress. Text Origin: EP Mandate	
Article 49					
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)					
499					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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 <u>physical</u> 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. <u>It may be followed by a pictogram or any other marking indicating a special risk of use.</u>	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 <u>of conformity</u> shall be affixed <u>subject</u> to the packaging or to the accompanying documentation, as appropriate <u>general principles set out in Article 30 of Regulation (EC) No 765/2008.</u>	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 <u>of conformity</u> shall be affixed <u>subject</u> to the packaging or to the accompanying documentation, as appropriate <u>general principles set out in Article 30 of Regulation (EC) No 765/2008.</u> Text Origin: Council Mandate	
Article 49(1a)					
499a		<u>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 which the AI system is accessed or via an easily accessible machine-readable code or other electronic means.</u>		<u>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 from which the AI system is accessed or via an easily accessible machine-readable code or other electronic means.</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				Text Origin: EP Mandate	
Article 49(2)					
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 <u>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</u> shall be subject <u>affixed</u> to the general principles set out in Article 30 of Regulation (EC) No 765/2008 <u>packaging or to the accompanying documentation, as appropriate.</u>	2. The CE marking referred to in paragraph 1 of this Article shall be <u>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</u> shall be subject <u>affixed</u> to the general principles set out in Article 30 of Regulation (EC) No 765/2008 <u>packaging or to the accompanying documentation, as appropriate.</u> Text Origin: Council Mandate	
Article 49(3)					
501	3. Where applicable, the CE marking shall be followed by the identification number of	3. Where applicable, the CE marking shall be followed by the identification number of	3. Where applicable, the CE marking shall be followed by the identification number of	3. Where applicable, the CE marking shall be followed by the identification number of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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 system fulfils the requirements for CE marking.	the notified body responsible for the conformity assessment procedures set out in Article 43. The identification number <i><u>of the notified body shall be affixed by the body itself or, under its instructions, by the provider's authorised representative.</u></i> 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.	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 system fulfils the requirements for CE marking.	the notified body responsible for the conformity assessment procedures set out in Article 43. The identification number <i><u>of the notified body shall be affixed by the body itself or, under its instructions, by the provider or by its authorised representative.</u></i> 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)					
501a		<i><u>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.</u></i>		<i><u>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.</u></i>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 50					
502	Article 50 Document retention	Article 50 Document retention	<i>deleted</i>	Article 50 Document retention <u>Moved to Article 18</u>	
Article 50, first paragraph					
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 <u>supervisory authority and the national</u> competent authorities:	<i>deleted</i>		
Article 50, first paragraph, point (a)					
504	(a) the technical documentation referred to in Article 11;	(a) the technical documentation referred to in Article 11;	<i>deleted</i>		
Article 50, first paragraph, point (b)					
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;	<i>deleted</i>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	Article 50, first paragraph, point (c)				
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		
	Article 50, first paragraph, point (d)				
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		
	Article 50, first paragraph, point (e)				
508	(e) the EU declaration of conformity referred to in Article 48.	(e) the EU declaration of conformity referred to in Article 48.	deleted		
	Article 51				
509	Article 51 Registration	Article 51 Registration	Article 51 <u>Registration of relevant operators and of high-risk AI systems listed in Annex III</u> <u>Registration</u>	Article 51 Registration Text Origin: Commission Proposal	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 51, first paragraph					
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. <u>in accordance with Article 60(2);</u>	Before placing on the market or putting into service a high-risk AI system <u>listed in Annex III with the exception of high-risk AI systems</u> referred to in Article 6(2) <u>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</u>, the provider or <u>and</u> where applicable, the authorised representative shall register that system <u>themselves</u> in the EU database referred to in Article 60. <u>The provider or, where applicable the authorised representative, shall also register their systems in that database.</u>	Before placing on the market or putting into service a high-risk AI system <u>listed in Annex III [with the exception of high-risk AI systems]</u> referred to in Article 6(2) <u>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]</u>, 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 <u>listed in Annex III the provider or, where applicable, the authorised representative shall register themselves and their system in the EU database</u> referred to in Article 6(2) <u>60</u>. <u>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(3), the provider or, where applicable, the authorised representative shall register themselves and that system in the EU database referred to in Article 60.</u> <u>1b. Before putting into service or using a high-risk AI system listed in Annex III deployers who</u>



	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
					<u>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.</u> <u>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, and AI systems referred to in Annex III point 2, the registration obligations laid down 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:</u> <u>- points 1 to 9 of Annex VIII, section A with the exception of points 5a, 7 and 8</u> <u>- points 1 to 3 of Annex VIII, section B</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
					<u>- points 1 to 9 of Annex VIII, section X with the exception of points 6 and 7</u> <u>- points 1 to 5 of Annex VIIIa with the exception of point 4</u>
Article 51(-1), first subparagraph					
510a			<u>-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.</u>	<u>Before putting into service or using a high-risk AI system in accordance with Article 6(2), deployers who are public authorities, agencies or bodies, Union institutions or deployers acting on their behalf, shall register the use of that AI system in the EU database referred to in Article 60.</u>	
Article 51(-1), second subparagraph					
510b			<u>The obligations laid down in the previous subparagraph shall not apply to law enforcement, border control,</u>	<u>[The obligations laid down in the previous subparagraph shall not apply to law enforcement, border control,</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>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.</u>	<u>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.]</u> Text Origin: Council Mandate	
Article 51, (1a)					
G 510c		<u>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:</u> <u>a) deployers who are public authorities or Union institutions, bodies, offices or agencies or deployers acting on their behalf;</u> <u>b) deployers who are undertakings designated</u>			G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<i>as a gatekeeper under Regulation (EU) 2022/1925.</i>			
Article 51, first paragraph a					
510d					
Article 51, third paragraph					
510e					
Article 51, fourth paragraph					
510f					
Article 51, (1b)					
510g		<i>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.</i>		<i>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.</i>	
Article 51, (1c)					
510h		<i>1c An updated registration entry must be</i>		<i>An updated registration entry must be completed</i>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>completed immediately following each substantial modification.</u>		<u>immediately following each substantial modification.</u>	
TITLE IV					
Y	511	TITLE IV TRANSPARENCY OBLIGATIONS FOR CERTAIN AI SYSTEMS	TITLE IV TRANSPARENCY OBLIGATIONS FOR CERTAIN AI SYSTEMS	TITLE IV TRANSPARENCY OBLIGATIONS FOR <u>PROVIDERS AND</u> <u>USERS OF</u> CERTAIN AI SYSTEMS	
Article 52(2)					
R	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 <u>which is not prohibited pursuant to Article 5</u> shall inform <u>in a timely, clear and intelligible manner</u> of the operation of the system the natural persons exposed thereto <u>and obtain their consent prior to the processing of their biometric and other personal data in accordance with</u>	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, <u>subject to appropriate safeguards for the rights and freedoms of third parties.</u>	2. Users <u>Deployers</u> of an emotion recognition system or a biometric categorisation system shall inform of the operation of the system the natural persons exposed thereto <u>and process the personal data in accordance with Regulation (EU) 2016/679, Regulation (EU) 2016/1725 and Directive (EU) 2016/280, as applicable.</u> This obligation shall not apply to AI systems used for

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>Regulation (EU) 2016/679, Regulation (EU) 2016/1725 and Directive (EU) 2016/280, as applicable.</u> This obligation shall not apply to AI systems used for biometric categorisation, which are permitted by law to detect, prevent and investigate criminal offences.		biometric eategorisation <u>categorizati</u> <u>on [and emotion recognition]</u> , which are permitted by law to detect, prevent and investigate criminal offences, <u>subject to appropriate safeguards for the rights and freedoms of third parties.</u>	
TITLE V					
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					
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)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
519a			<u>-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.</u>		
Article 53(-1a)					
519b			<u>-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.</u>		
Article 53(-1b)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
519c			<u>-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 between the authorities supervising those other sandboxes and the national competent authorities.</u>		
Article 53(1)					
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	1. AI regulatory sandboxes established by one or more Member States competent authorities or the European Data Protection Supervisor <u>Member States shall establish at least one AI regulatory sandbox at national level, which</u> shall provide a controlled	deleted	1. AI regulatory sandboxes established by one or more Member States competent authorities or the European Data Protection Supervisor <u>Member States shall ensure that their [national competent authorities] establish at least one AI regulatory</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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.	<i>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.</i>		<u>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 on the day of the entry into application of this Regulation]. 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 establishment and</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				<u>operation of AI regulatory sandboxes.</u> <u>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.</u>	
	Article 53(1a)				
G	520a		<u>1a. The establishment of AI regulatory sandboxes under this Regulation shall aim to contribute to one or more of the following objectives:</u>		G
	Article 53(1a), point (a)				
G	520b		<u>(a) foster innovation and competitiveness and facilitate the development of an AI ecosystem;</u>		G
	Article 53(1a), point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
G 520c			<u>(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;</u>		
Article 53(1a), point (c)					
G 520d			<u>(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;</u>		
Article 53(1a), point (d)					
G 520e			<u>(d) contribute to evidence-based regulatory learning.</u>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	Article 53(1a)				
G 520f		<u><i>1a. Additional AI regulatory sandboxes at regional or local levels or jointly with other Member States may also be established;</i></u>		<u><i>1a. Additional AI regulatory sandboxes at regional or local levels or jointly with other Member States' competent authorities may also be established;</i></u> Text Origin: EP Mandate	
	Article 53(1b)				
G 520g		<u><i>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 level;</i></u>		<u><i>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 accordance with this chapter.</i></u> Text Origin: EP Mandate	
	Article 53(1c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
G 520h		<u>1c. Establishing authorities shall allocate sufficient resources to comply with this Article effectively and in a timely manner.</u>		<u>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.</u> <u>Where appropriate, national competent authorities shall cooperate with other relevant authorities and may allow for the involvement of other actors within the AI ecosystem.</u> <u>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.</u> Text Origin: EP Mandate	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 53(1d)					
520i		<u>1d. AI regulatory sandboxes shall, in accordance with criteria set out in Article 53a, provide for a 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.</u>		<u>1d. AI regulatory sandboxes established under Article 53(1) of this Regulation shall, in accordance 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.]</u>	
Article 53(1e)					
520j					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u><i>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.</i></u>		<u><i>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, [democracy and rule of law], health and safety and [the environment], 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.</i></u>	
Article 53(1f)					
520k		<u><i>1f. Establishing authorities shall provide sandbox prospective providers who develop high-risk AI systems with guidance and supervision on how to fulfil the requirements set out in</i></u>		<u><i>1f. Competent authorities shall provide providers and prospective providers with guidance on regulatory expectations and how to fulfil the requirements and obligations set out in this</i></u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<i><u>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.</u></i>		<i><u>Regulation.</u></i> <i><u>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 national 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</u></i>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				<u>accelerate conformity assessment procedures to a reasonable extent.</u> <u>Ifa Subject to the confidentiality provisions in Article 70 and with the agreement of the sandbox provider/prospective provider, [the European Commission] and the [AI Office/ 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/ 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.</u>	
Article 53(1g)					
520l		<u>Ig. The establishment of AI regulatory sandboxes</u>		<u>Ig. The establishment of AI regulatory sandboxes</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>shall aim to contribute to the following objectives:</u> <u>a) for the competent authorities to provide guidance to AI systems prospective providers to achieve regulatory compliance with this Regulation or where relevant other applicable Union and Member States legislation;</u> <u>b) for the prospective providers to allow and facilitate the testing and development of innovative solutions related to AI systems;</u> <u>c) regulatory learning in a controlled environment.</u>		<u>shall aim to contribute to the following objectives:</u> <u>a) improve legal certainty to achieve regulatory compliance with this Regulation or, where relevant, other applicable Union and Member States legislation;</u> <u>b) support the sharing of best practices through cooperation with the authorities involved in the AI regulatory sandbox;</u> <u>c) foster innovation and competitiveness and facilitate the development of an AI ecosystem;</u> <u>d) contribute to evidence-based regulatory learning;</u> <u>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.</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 53(2)					
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 <u>Establishing authorities</u> 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 <u>personal</u> data, the national data protection authorities, <u>or in cases referred to in paragraph 1b the EDPS,</u> and those other national authorities are associated to the operation of the AI regulatory sandbox <u>and involved in the supervision of those aspects to the full extent of their respective tasks and powers.</u>	deleted	2. Member States <u>National competent authorities</u> 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 <u>and involved in the supervision of those aspects to the extent of their respective tasks and powers, as applicable.</u> Text Origin: EP Mandate	
Article 53(2a), first subparagraph					
521a			<u>2a. Access to the AI regulatory sandboxes shall be open to any</u>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>provider or prospective provider of an AI system who fulfils the 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.</u>		
Article 53(2a), second subparagraph					
521b			<u>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.</u>		
Article 53(2a), third subparagraph					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
521c			<u>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 authority(ies), as applicable.</u>		
Article 53(3)					
522	3. The AI regulatory sandboxes shall not affect 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.	3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities, <u>including at regional or local level</u> . Any significant risks to <u>fundamental rights, democracy and rule of law</u> , health and safety and fundamental rights <u>or the environment</u> identified during the development and testing of such <u>AI</u> systems shall result in immediate <u>and adequate</u> mitigation. <u>Competent authorities</u>	3. <u>The participation in</u> the AI regulatory sandboxes shall not affect 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 <u>authorities</u>	3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities <u>supervising the sandboxes, including at regional or local level</u> . Any significant risks to health and safety and fundamental rights identified during the development and testing of such <u>AI</u> systems shall result in immediate <u>an adequate</u> mitigation. <u>National competent authorities shall have the power to temporarily or</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>shall have the power to temporarily or permanently suspend the testing process, or participation</u> and, failing that, in the suspension of the development and testing process until such mitigation takes place <u>sandbox if no effective mitigation is possible and inform the AI office of such decision.</u>	<u>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.</u>	<u>permanently suspend the testing process</u> and, failing that, or participation <u>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</u> <u>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.</u>	
	Article 53(3a), first subparagraph				
G 522a			<u>3a. Provided that the participant(s) respect the sandbox plan and the terms and conditions for their participation as</u>		G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>referred to in paragraph 6(c) and follow in good 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.</u>		
Article 53(4)					
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 <u>Prospective providers</u> 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. <u>However, provided that the prospective provider(s) respect the specific plan referred to in paragraph</u>	4. Participants in the AI regulatory sandbox shall <u>The participants</u> 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 <u>damage caused in the course of their participation in an AI regulatory</u> sandbox.	4. Participants <u>Providers and prospective providers</u> in the AI regulatory sandbox shall remain liable under applicable Union and Member States liability legislation for any harm <u>damage</u> inflicted on third parties as a result from of the experimentation taking place in the sandbox. <u>However, provided that the prospective provider(s) respect the specific plan</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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.</u>		<u>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, no administrative fines shall be imposed regarding that legislation.</u> <u>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.</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
Article 53(4a), first subparagraph					
523a			<u>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.</u>		
Article 53(4a), second subparagraph					
523b			<u>Subject to the confidentiality provisions</u>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>in Article 70 and with 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).</u>		
Article 53(4b)					
523c			<u>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.</u>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
Article 53(5)					
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 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.	5. Member States' competent<u>Establishing</u> 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 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<u>AI office</u>.	5. Member States' National competent authorities that have established<u>shall make publicly available annual reports on the implementation of the</u> AI regulatory sandboxes, <u>including good practices, lessons learnt and recommendations on</u> shall coordinate their activities and cooperate within the framework of the European Artificial Intelligence Board. They shall submit <u>setup and, where relevant, on the application of this Regulation and other Union legislation supervised within the sandbox. Those</u> annual reports to the Board and the Commission on the results from the implementation of those scheme, including<u>shall be submitted to the AI Board which shall make publicly available a summary of all</u>	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 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<u>[AI Office]</u>. Text Origin: EP Mandate	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			good practices, lessons learnt and recommendations. <u><i>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</i></u> <i>on their setup and, where relevant, on the application of this Regulation and other Union legislation supervised within the sandbox.</i>		
Article 53(5a)					
G 524a			<u><i>5a. The Commission shall ensure that information about AI regulatory sandboxes, including about those established</i></u>		G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>under this Article, is available through the single information platform referred to in Article 55(3)(b).</u>		
Article 53(5a)					
524b		<u>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.</u>		<u>5a. National competent authorities shall inform the [AI Office/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.</u>	
Article 53(5b)					
524c		<u>5b. Establishing authorities shall submit to the AI office and, unless the Commission is the sole establishing authority, to</u>		<u>5b. National competent authorities shall submit to [the AI Office] and to the Commission, annual</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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 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.</u>		<u>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 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.</u> <u>The Commission and [the AI Office] shall, where appropriate, take the annual reports into account when exercising their tasks under this</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				<u>Regulation.</u> Text Origin: EP Mandate	
Article 53(6)					
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 <u>regulatory Commission shall develop a single and dedicated interface containing all relevant information related to</u> 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 <u>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</u>	6. The modalities and the conditions of the <u>for the establishment and</u> 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 <u>under this Regulation</u> shall be set out <u>in adopted through</u> 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 <u>regulatory Commission shall develop a single and dedicated interface containing all relevant information related to</u> sandboxes, including the eligibility criteria and the procedure for the application, selection to <u>allow stakeholders to interact with regulatory sandboxes and to raise enquiries with competent authorities,</u> participation and exiting from the sandbox, and the rights and obligations of the participants shall be set out in implementing acts. Those implementing acts and to seek non-binding guidance on the conformity of innovative	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>guidance on the conformity of innovative products, services, business models embedding AI technologies;</u> <u>The Commission</u> shall be adopted in accordance with the examination procedure referred to in Article 74(2)<u>proactively coordinate with national, regional and also local authorities, where relevant.</u>		<u>products, services, business models embedding AI technologies, in accordance with Article 55(1)(c).</u> <u>The Commission</u> shall be adopted in accordance with the examination procedure referred to in Article 74(2)<u>proactively coordinate with national, regional and also local competent authorities, where relevant.</u> Text Origin: EP Mandate	
Article 53(6a), first subparagraph					
525a			<u>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</u>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>capacities of participating SMEs, including start-ups.</u>		
Article 53(6a), second subparagraph					
525b			<u>Those implementing acts shall include common main principles on the following issues:</u>		
Article 53(6a), second subparagraph, point (a)					
525c			<u>(a) eligibility and selection for participation in the AI regulatory sandbox;</u>		
Article 53(6a), second subparagraph, point (b)					
525d			<u>(b) procedure for the application, participation, monitoring, exiting from and termination of the AI regulatory sandbox, including the sandbox plan and the exit report;</u>		
Article 53(6a), second subparagraph, point (c)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
525e			<u>(c) the terms and conditions applicable to the participants.</u>		
Article 53(6a)					
525f		<u>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.</u>		<u>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 those Member States that seek guidance on the set-up and running of these regulatory sandboxes.</u> Text Origin: EP Mandate	
Article 53(a) new					
525g		<u>53 a Modalities and functioning of AI regulatory sandboxes</u> <u>1. In order to avoid fragmentation across the Union, the Commission, in consultation with the</u>		<u>6b. In order to avoid fragmentation across the Union, the Commission, in consultation with [the AI Office], shall adopt a [delegated act/implementing act]</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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;</u> <u>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:</u> <u>a) regulatory sandboxes are open to any applying prospective provider of an AI system who fulfils</u>		<u>detailing the modalities for the establishment, development, implementation, operation and supervision of the AI regulatory sandboxes. The [implementing act/delegated act] shall include common principles on the following issues:</u> <u>a) eligibility and selection for participation in the AI regulatory sandbox;</u> <u>b) procedure for the application, participation, monitoring, exiting from and termination of the AI regulatory sandbox, including the sandbox plan and the exit report;</u> <u>c) the terms and conditions applicable to the participants.</u> <u>The [implementing/delegated acts] shall ensure that:</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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;</u> <u>b) regulatory sandboxes allow broad and equal access and keep up with demand for participation;</u> <u>c) access to the AI regulatory sandboxes is free of charge for SMEs and start-ups without prejudice to exceptional costs that establishing authorities may recover in a fair and proportionate manner;</u> <u>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</u>		<u>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;</u> <u>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;</u> <u>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;</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>experimentation labs and digital innovation hubs, centers of excellence, individual researchers), in order to allow and facilitate cooperation with the public and private sector;</u> <u>e) they allow prospective providers 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;</u> <u>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</u>		<u>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;</u> <u>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;</u> <u>f) 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,</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>regulatory 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;</u> <u>g) participation in the AI regulatory sandbox is limited to a period that is appropriate to the complexity and scale of the project.</u> <u>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</u> <u>3. Prospective providers in the sandboxes, in particular SMEs and start-ups, shall be facilitated access to pre-</u>		<u>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;</u> <u>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;</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>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.</u>		<u>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;</u> <u>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.</u> <u>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</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				<u>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].</u>	
Article 53(6a)					
525h			<u>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 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.</u>		<u>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 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.</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<i>Where appropriate, they shall cooperate with other national competent authorities with a view to ensure consistent practices across the Union.</i>		<i>Where appropriate, they shall cooperate with other national competent authorities with a view to ensure consistent practices across the Union.</i>
Article 54					
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)					
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	1. In the AI regulatory sandbox personal data lawfully collected for other purposes shall <u>may</u> be processed <u>solely</u> for the purposes of developing and testing certain innovative AI systems in the sandbox under <u>when all of</u> the	1. In the AI regulatory sandbox personal data lawfully collected for other purposes shall <u>may</u> be processed for the purposes of developing, <u>testing and training of</u> and testing certain innovative AI systems in the sandbox	1. In the AI regulatory sandbox personal data lawfully collected for other purposes shall <u>may</u> be processed <u>solely</u> for the purposes of developing, <u>training</u> and testing certain innovative AI systems in the sandbox under <u>when all</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	conditions:	following conditions <u>are met</u> :	under the following <u>cumulative</u> conditions:	<u>of</u> the following conditions <u>are met</u> :	
Article 54(1), point (a)					
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 <u>by a public authority or another natural or legal person governed by public law or by private law and</u> in one or more of the following areas:	(a) the innovative AI systems shall be developed for safeguarding substantial public interest <u>by a public authority or another natural or legal person governed by public law or by private law and</u> 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	<i>deleted</i>	<i>deleted</i>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	law;				
Article 54(1), point (a)(ii)					
530	(ii) public safety and public health, including disease prevention, control and treatment;	(ii) <u>public safety and public health, including disease detection, diagnosis prevention, control and treatment;</u> public safety and public health, including disease prevention, control and treatment;	(ii) public safety and public health, including disease prevention, control and treatment <u>of disease and improvement of health care systems;</u>	(ii) public safety and public health, including disease <u>detection, diagnosis prevention, control and treatment and improvement of health care systems;</u>	
Article 54(1), point (a)(iii)					
531	(iii) a high level of protection and improvement of the quality of the environment;	(iii) <u>a high level of protection and improvement of the quality of the environment, protection of biodiversity, pollution as well as climate change mitigation and adaptation;</u>	(iii) a high level of protection and improvement of the quality of the environment, <u>including green transition, climate change mitigation and adaptation;</u>	(iii) a high level of protection and improvement of the quality of the environment, <u>protection of biodiversity, pollution as well as green transition, climate change mitigation and adaptation;</u>	
Article 54(1), point (a)(iia)					
531a			<u>(iia) energy sustainability, transport</u>	<u>(iia) energy sustainability</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>and mobility;</u>		
Article 54(1), point (a)(iiia)					
G 531b		<u>(iiia) safety and resilience of transport systems, critical infrastructure and networks.</u>		<u>(iiib) safety and resilience of transport systems and mobility, critical infrastructure and networks;</u>	G
Article 54(1), point (a)(iiib)					
G 531c			<u>(iiib) efficiency and quality of public administration and public services;</u>	<u>(iiic) efficiency and quality of public administration and public services [in the benefit of citizens];</u>	G
Article 54(1), point (a)(iiic)					
G 531d			<u>(iiic) cybersecurity and resilience of critical infrastructure.</u>		G
Article 54(1), point (b)					
G 532	(b) the data processed are necessary for complying with one or more of the	(b) the data processed are necessary for complying with one or more of the	(b) the data processed are necessary for complying with one or more of the	(b) the data processed are necessary for complying with one or more of the	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	requirements referred to in Title III, Chapter 2 where those requirements cannot be effectively fulfilled by processing anonymised, synthetic or other non-personal data;	requirements referred to in Title III, Chapter 2 where those requirements cannot be effectively fulfilled by processing anonymised, synthetic or other non-personal data;	requirements referred to in Title III, Chapter 2 where those requirements cannot be effectively fulfilled by processing anonymised, synthetic or other non-personal data;	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)					
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 <u>rights and freedoms</u> of the data subjects, <u>as referred to in Article 35 of Regulation (EU) 2016/679 and in Article 35 of Regulation (EU) 2018/1725</u> 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 <u>rights and freedoms</u> of the data subjects, <u>as referred to in Article 35 of Regulation (EU) 2016/679 and in Article 39 of Regulation (EU) 2018/1725</u> , 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 <u>rights and freedoms</u> of the data subjects, <u>as referred to in Article 35 of Regulation (EU) 2016/679 and in Article 39 of Regulation (EU) 2018/1725</u> , 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	Article 54(1), point (d)				
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 <u>prospective provider</u> and only authorised persons have access to that <u>those</u> 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 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 <u>prospective provider</u> and only authorised persons have access to that <u>those</u> data; Text Origin: EP Mandate	
	Article 54(1), point (e)				
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 <u>to</u> be transmitted, transferred or otherwise accessed by other parties <u>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</u>	(e) <u>Providers can only further share the originally collected data in compliance with EU data protection law.</u> Any personal data processed are not be transmitted, transferred or otherwise accessed by other parties; <u>crated in the sandbox cannot be shared outside the sandbox</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>all participants have agreed to it</u> ;	Text Origin: Council Mandate	
Article 54(1), point (f)					
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 <u>nor affect the application of their rights laid down in Union law on the protection of personal data</u> ;	(f) any processing of personal data in the context of the sandbox do not lead to measures or decisions affecting <u>shall not affect the application of the rights of</u> the data subjects <u>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</u> ;	(f) any processing of personal data in the context of the sandbox do not lead to measures or decisions affecting the data subjects <u>nor affect the application of their rights laid down in Union law on the protection of personal data</u> ; Text Origin: EP Mandate	
Article 54(1), point (g)					
537	(g) any personal data processed in 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;	(g) any personal data processed in the context of the sandbox are <u>protected by means of appropriate technical and organisational measures and</u> deleted once the participation in the	(g) any personal data processed in the context of the sandbox are <u>protected by means of appropriate technical and organisational measures and</u> deleted once the participation in the	(g) <u>(g)</u> any personal data processed in the context of the sandbox are <u>protected by means of appropriate technical and organisational measures and</u> deleted once the participation in the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		sandbox has terminated or the personal data has reached the end of its retention period;	sandbox has terminated or the personal data has reached the end of its retention period;	sandbox has terminated or the personal data has reached the end of its retention period;	
Article 54(1), point (h)					
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 <u>national law</u> ;	(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 <u>national law</u> ; Text Origin: Council Mandate	
Article 54(1), point (i)					
539	(i) complete and detailed	(i) complete and detailed	(i) complete and detailed	(i) complete and detailed	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	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;	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;	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;	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; Text Origin: Council Mandate	
Article 54(1), point (j)					
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 <u>system</u> developed in the sandbox, its objectives, <u>hypotheses</u> , 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. <u>This obligation shall not cover sensitive operational data in relation to the activities of law enforcement, border control, immigration or asylum authorities.</u>	(j) a short summary of the AI project <u>system</u> developed in the sandbox, its objectives and expected results published on the website of the competent authorities. <u>[This obligation shall not cover sensitive operational data in relation to the activities of law enforcement, border control, immigration or asylum authorities.]</u> Text Origin: Council Mandate	(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. <u>This obligation shall not cover sensitive operational data in relation to the activities of law enforcement, border control, immigration or asylum authorities.</u>
Article 54(1), point (ja)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
540a			<u>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.</u>	<u>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.</u> Text Origin: Council Mandate	<u>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.</u>
Article 54(2)					
541	2. Paragraph 1 is without prejudice to Union or Member States legislation excluding processing for other purposes than those explicitly mentioned in that	2. Paragraph 1 is without prejudice to Union or Member States legislation excluding processing for other purposes than those explicitly mentioned in that	2. Paragraph 1 is without prejudice to Union or Member States legislation excluding laws laying down <u>the basis for the processing of personal</u>	2. Paragraph 1 is without prejudice to Union or Member States legislation excluding processing for other purposes than those explicitly mentioned in that	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	legislation.	legislation.	<u>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</u> for other purposes than those explicitly mentioned in that legislation.	legislation, <u>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.</u> Text Origin: Council Mandate	
Article 54a new					
541a		<u>54a Promotion of AI research and development in support of socially and environmentally beneficial outcomes</u> <u>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</u>			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		<u>increase accessibility for persons with disabilities, tackle socio-economic inequalities, and meet sustainability and environmental targets, by:</u> <u>(a) providing relevant projects with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions;</u> <u>(b) earmarking public funding, including from relevant EU funds, for AI research and development in support of socially and environmentally beneficial outcomes;</u> <u>(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;</u> <u>(d) where appropriate, establishing accessible dedicated channels, including within the</u>			

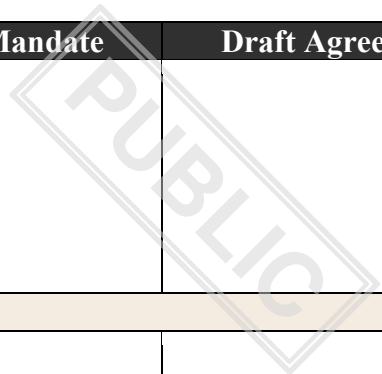
	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		<u>sandboxes, for communication with projects to provide guidance and respond to queries about the implementation of this Regulation.</u> <u>Member States shall support civil society and social stakeholders to lead or participate in such projects.</u>			
	Article 54(2a)				
R	541b		<u>Article 54a</u> <u>Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes</u>		<u>Article 54a</u> <u>Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes</u>
	Article 54(2b), first subparagraph				
R	541c		<u>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</u>		<u>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</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>accordance with the provisions of this Article and the real-world testing plan referred to in this Article.</u>		<u>accordance with the provisions of this Article and the real-world testing plan referred to in this Article.</u>
Article 54(2b), second subparagraph					
541d			<u>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).</u>		<u>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).</u>
Article 54(2c)					
541e			<u>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.</u>		<u>2c. 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.</u>
Article 54(2d)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
R 541f			<u>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.</u>		<u>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.</u>
Article 54(2e)					
R 541g			<u>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.</u>		<u>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.</u>
Article 54(2f)					
R 541h			<u>4. Providers or prospective providers may conduct the testing in real world conditions only where all of the following</u>		<u>4. Providers or prospective providers may conduct the testing in real world conditions only where all of the following</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>conditions are met:</u>		<u>conditions are met:</u>
Article 54(2f), point (a)					
541i			<u>(a) the provider or prospective 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;</u>		<u>(a) the provider or prospective 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;</u>
Article 54(2f), point (b)					
541j			<u>(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;</u>		<u>(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</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
					<u>conditions and the real-world testing plan shall be understood as approved;</u>
Article 54(2f), point (c)					
541k			<u>(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, 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 VIIa;</u>		<u>(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, 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 VIIa. In the cases 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, the</u>



	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
					<u>registration will take place in a non-publicly available area of the EU database, as referred to in Article 60 (xx);</u>
Article 54(2f), point (d)					
R 5411			<u>(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;</u>		<u>(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;</u>
Article 54(2f), point (e)					
R 541m			<u>(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</u>		<u>(e) data collected and processed for the purpose of the testing in real world conditions shall not be transferred to third countries outside the Union, unless the transfer and the processing provides equivalent</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>those provided under Union law;</u>		<u>safeguards to those provided under Union law;</u>
Article 54(2f), point (f)					
541n			<u>(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;</u>		<u>(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;</u>
Article 54(2f), point (g)					
541o			<u>(g) persons belonging to vulnerable groups due to their age, physical or mental disability are appropriately protected;</u>		<u>(g) persons belonging to vulnerable groups due to their age, physical or mental disability are appropriately protected;</u>
Article 54(2f), point (h)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
541p			<u>(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 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;</u>		<u>(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 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;</u>
Article 54(2f), point (i)					
541q			<u>(i) the subjects of the</u>		<u>(i) the subjects of the</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>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;</u>		<u>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 related data shall be deleted after the test is performed.</u>
Article 54(2f), point (j)					
541r			<u>(i) 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;</u>		<u>(i) 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;</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	Article 54(2f), point (k)				
R 541s			<u>(k) the predictions, recommendations or decisions of the AI system can be effectively reversed or disregarded.</u>		<u>(k) the predictions, recommendations or decisions of the AI system can be effectively reversed and disregarded.</u>
	Article 54(2g)				
R 541t			<u>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.</u>		<u>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.</u>



	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
					<u>5a. 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 tests.</u>
Article 54(2h)					
541u			<u>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</u>		<u>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</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>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.</u>		<u>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.</u>
	Article 54(2i)				
541v			<u>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.</u>		<u>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.</u>
	Article 54(2j)				
541w					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>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.</u>		<u>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.</u>
Article 54b					
541x			<u>Article 54b</u> <u>Informed consent to participate in testing in real world conditions outside AI regulatory sandboxes</u>		<u>Article 54b</u> <u>Informed consent to participate in testing in real world conditions outside AI regulatory sandboxes</u>
Article 54b(1), first subparagraph					
541y			<u>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,</u>		<u>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,</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>clear, relevant, and understandable information regarding:</u>		<u>clear, relevant, and understandable information regarding:</u>
Article 54b(1), second subparagraph					
541z			<u>(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;</u> <u>(ii) the conditions under which the testing in real world conditions is to be conducted, including the expected duration of the subject's participation;</u> <u>(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;</u> <u>(iv) the modalities for requesting the reversal or</u>		<u>(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;</u> <u>(ii) the conditions under which the testing in real world conditions is to be conducted, including the expected duration of the subject's participation;</u> <u>(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, as well as his or her right to ask for the permanent deletion of his</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>the disregard of the predictions,</u> <u>recommendations or decisions of the AI system;</u> (v) <u>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.</u>		<u>or her personal data used during the test;</u> (iv) <u>the modalities for requesting the reversal and the disregard of the predictions,</u> <u>recommendations or decisions of the AI system;</u> (v) <u>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.</u>
	Article 54b(2)				
R 541aa			<u>2. The informed consent shall be dated and documented and a copy shall be given to the subject or his or her legal representative.</u>		<u>2. The informed consent shall be dated and documented and a copy shall be given to the subject or his or her legal representative.</u>
	Article 55				
G 542					G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	Article 55 Measures for small-scale providers and users	Article 55 Measures for small-scale providers <u>SMEs, start-ups</u> and users	Article 55 <u>Support measures for operators, in particular SMEs, including start-ups</u> measures for small-scale providers and users	Article 55 Measures for small-scale providers and users <u>deployers, in particular SMEs, including start-ups</u>	
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 <u>SMEs</u> and start-ups, <u>established in the Union</u> , with priority access to the AI regulatory sandboxes, to the extent that they fulfil the eligibility conditions;	(a) provide small-scale providers and <u>SMEs</u> , <u>including</u> start-ups, with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions <u>and selection criteria</u> ;	(a) provide small-scale providers and <u>SMEs</u> , <u>including</u> start-ups, <u>having a registered office or a branch in the Union</u> , with priority access to the AI regulatory sandboxes, to the extent that they fulfil the eligibility conditions <u>and selection criteria</u> . <u>The priority access shall not preclude other SMEs including start-ups other than those referred to in</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				<u>the first subparagraph to access to the AI regulatory sandbox, provided that they fulfil the eligibility conditions and selection criteria;</u>	
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 <u>and enhanced digital skills development</u> activities about <u>on</u> the application of this Regulation tailored to the needs of the small-scale providers <u>SMEs, start-ups</u> and users;	(b) organise specific awareness raising <u>and training</u> activities about the application of this Regulation tailored to the needs of the small-scale providers and users <u>SMEs, including start-ups, and, as appropriate, local public authorities;</u>	(b) organise specific awareness raising <u>and training</u> activities about <u>on</u> the application of this Regulation tailored to the needs of the small-scale providers and users <u>SMEs including start-ups, users and, as appropriate, local public authorities;</u>	
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	(c) <u>utilise existing dedicated channels and</u> where appropriate, establish a new <u>dedicated channels</u> for communication with small-scale providers and user <u>SMEs, start-ups, users</u> and other innovators to	(c) where appropriate, establish a dedicated channel for communication with small-scale providers and user and other innovators <u>SMEs, including start-ups and, as appropriate, local public authorities</u> to provide	(c) <u>utilise existing dedicated channels and</u> where appropriate, establish a dedicated channel <u>new ones</u> for communication with small-scale providers and user and other innovators <u>SMEs including start-ups, users,</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
	Regulation.	provide guidance and respond to queries about the implementation of this Regulation.;	guidance <u>advice</u> and respond to queries about the implementation of this Regulation, <u>including as regards participation in AI regulatory sandboxes.</u>	<u>other innovators and, as appropriate, local public authorities</u> to provide guidance <u>advice</u> and respond to queries about the implementation of this Regulation, <u>including as regards participation in AI regulatory sandboxes.</u> ;	
Article 55(1), point (ca)					
546a		<u>(ca) foster the participation of SMEs and other relevant stakeholders in the standardisation development process.</u>		<u>(ca) facilitate the participation of SMEs and other relevant stakeholders in the standardisation development process.</u>	
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 <u>SMEs, start-ups and users</u> shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to <u>development stage</u> , their	2. The specific interests and needs of the small-scale <u>SME</u> providers, <u>including start-ups</u> , shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size, <u>market size</u>	2. The specific interests and needs of the small-scale <u>SME</u> providers, <u>including start-ups</u> , shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size, <u>market size</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		size, <u>market size</u> and market size <u>demand</u> . <u>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).</u>	<u>and other relevant indicators</u> and market size .	<u>and other relevant indicators</u> and market size .	
	Article 55(2a)				
G	547a		<u>2a. The Commission shall undertake the following actions:</u>	<u>2a. The Commission shall undertake the following actions:</u>	G
	Article 55(2a), point (a)				
G	547b		<u>(a) upon request of the AI</u>	<u>(a) upon request of the</u>	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			<u>Board, provide standardised templates for the areas covered by this Regulation;</u>	<u>[AI Board], provide standardised templates for the areas covered by this Regulation;</u>	
Article 55(2a), point (b)					
547c			<u>(b) develop and maintain a single information platform providing easy to use information in relation to this Regulation for all operators across the Union;</u>	<u>(b) develop and maintain a single information platform providing easy to use information in relation to this Regulation for all operators across the Union;</u>	
Article 55(2a), point (c)					
547d			<u>(c) organise appropriate communication campaigns to raise awareness about the obligations arising from this Regulation;</u>	<u>(c) organise appropriate communication campaigns to raise awareness about the obligations arising from this Regulation;</u>	
Article 55(2a), point (d)					
547e			<u>(d) evaluate and promote the convergence of best practices in public procurement procedures</u>	<u>(d) evaluate and promote the convergence of best practices in public procurement procedures</u>	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>in relation to AI systems.</u>	<u>in relation to AI systems.</u>	
Article 55a					
R	547f		<u>Article 55a</u> <u>Derogations for specific operators</u>		R
Article 55a(1)					
G	547g		<u>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.</u>	<u>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</u>	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
				<u>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.</u>	
	Article 55a(2)				
G	547h		<u>2. Paragraph 1 shall not be interpreted as exempting those operators from fulfilling any other requirements and obligations laid down in this Regulation, including those established in Articles 9, 61 and 62.</u>	<u>2c. 2. Paragraph 1 shall not be interpreted as exempting those operators from fulfilling any other requirements and obligations laid down in this Regulation, including those established in Articles 9, 10, 11, 12, 13, 14, 15, 61 and 62.</u>	G
	Article 55(2a)				
R	547i		<u>3. Requirements and obligations for general</u>		<u>3. [Requirements and obligations for general</u>

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
			<u>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.</u>		<u>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.</u>

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
	Article 61(2)					
	590	2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources on the performance of high-risk	2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users <u>deployers</u> or collected through other sources on the	2. <u>In order to allow the provider to evaluate the compliance of AI systems with the requirements set out in Title III, Chapter 2 throughout their life cycle,</u> the post-market monitoring system shall	2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data <u>which may be</u> provided by users of <u>deployers or which may be</u> collected through	2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data <u>which may be</u> provided by users of <u>deployers or which may be</u> collected through

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
		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.	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. <u>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.</u>	actively and systematically collect, document and analyse relevant data, <u>which may be</u> provided by users or <u>which may be</u> collected through other sources on the performance of high-risk AI systems. <u>This obligation shall not cover sensitive operational data of users throughout their lifetime, and allow the provider to evaluate the continuous compliance</u> of AI systems with the requirements set out in Title III, Chapter 2 <u>which are law enforcement authorities.</u>	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. <u>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 users which are law enforcement authorities.]</u>	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. <u>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 users which are law enforcement authorities.</u>
	Article 63(5)					
R	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	5. For AI systems listed in point 1(a) in so far as the systems <u>that</u> are used for law enforcement purposes, points 6 and 7 of Annex III , Member	5. For <u>high-risk</u> AI systems listed in point 1(a) in so far as the systems are used for law enforcement purposes, points 6, <u>7 and 8</u> and 7 of	5. For <u>high-risk</u> AI systems listed in point 1(a) in so far as the systems are used for law enforcement purposes, points 6, <u>7 and 8</u> and 7 of	5. For <u>high-risk</u> AI systems listed in point 1(a) in so far as the systems are used for law enforcement purposes, points 6, <u>7 and 8</u> and 7 of

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
		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.	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.	Annex III, Member States shall designate as market surveillance authorities for the purposes of this Regulation either the <u>national authorities supervising the activities of the law enforcement, border control, immigration, asylum or judicial authorities, or the</u> competent data protection supervisory authorities under Directive (EU) 2016/680, or Regulation 2016/679. <u>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</u> or the national competent authorities supervising the activities of the law enforcement, immigration or asylum authorities putting into service or using those systems.	Annex III, Member States shall designate as market surveillance authorities for the purposes of this Regulation either <u>the (national authorities supervising the activities of the law enforcement, border control, immigration, asylum or judicial authorities), or the</u> competent data protection supervisory authorities under Directive (EU) 2016/680, or Regulation 2016/679. <u>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</u> or the national competent authorities supervising the activities of the law enforcement, immigration or asylum authorities putting into service or using those systems. Text Origin: Council	Annex III, Member States shall designate as market surveillance authorities for the purposes of this Regulation either the <u>national authorities supervising the activities of the law enforcement, border control, immigration, asylum or judicial authorities, or the</u> competent data protection supervisory authorities under Directive (EU) 2016/680, or Regulation 2016/679. <u>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</u> or the national competent authorities supervising the activities of the law enforcement, immigration or asylum authorities putting into service or using those systems.

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
					Mandate	
	Article 70(2), first subparagraph					
	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 security interests.	2. Without prejudice to paragraph 1 <u>paragraphs 1 and 1a</u> , 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 <u>deployer</u> 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 <u>or</u> national security interests .	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, <u>border control</u> , immigration or asylum authorities, when such disclosure would jeopardise public and national security interests. <u>This obligation to exchange information shall not cover sensitive operational data in relation to the activities</u>	2. Without prejudice to paragraph 1 <u>[and 1a]</u> , 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 <u>deployer</u> when high-risk AI systems referred to in points 1, 6 and 7 of Annex III are used by law enforcement, <u>border control</u> , immigration or asylum authorities, when such disclosure would jeopardise public and national security interests. <u>[This obligation to exchange information shall not cover sensitive</u>	2. Without prejudice to paragraph 1 <u>[and 1a]</u> , 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 <u>deployer</u> when high-risk AI systems referred to in points 1, 6 and 7 of Annex III are used by law enforcement, <u>border control</u> , immigration or asylum authorities, when such disclosure would jeopardise public and national security interests. <u>This obligation to exchange information shall not cover sensitive operational data in</u>

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency3
				<u>of law enforcement, border control, immigration or asylum authorities.</u>	<u>operational data in relation to the activities of law enforcement, border control, immigration or asylum authorities.</u> Text Origin: Auxiliary 1	<u>relation to the activities of law enforcement, border control, immigration or asylum authorities.</u>
Article 83(1), first subparagraph						
	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 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.	1. This Regulation shall not apply to <u>Operators of</u> 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 <u>prior to ...</u> <u>[the date of application]</u> <u>entry into force</u> of this Regulation <u>shall take the necessary steps to comply with the requirements laid down in this Regulation by ...</u> <u>[four years after the date of entry into force of this Regulation]</u> referred to	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 <u>[12 months after the date of application of this Regulation referred to in Article 85(2)]</u> 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		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 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

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Presidency ³
			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.	change in the design or intended purpose of the AI system or AI systems concerned.		<u>brought into compliance with this Regulation by end of 2030.</u>
Annex III, first paragraph, point (aa)						
	810a		<u>(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;</u> <u>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.</u>		<u>(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;</u> <u>ab) AI systems intended to be used for emotion recognition;</u>	

PUBLIC