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NOTE

From:	Presidency
To:	Permanent Representatives Committee
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

DOCUMENT PARTIALLY ACCESSIBLE TO THE PUBLIC (03.08.2023)

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: 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 European 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. Since then, two technical meetings and some informal contacts between the negotiating teams have taken place, in order to advance the discussions on some of the less controversial aspects of the proposal and to prepare the second political trilogue, which has been scheduled for 18 July 2023.

5. On 5 July 2023, the Presidency held an all-day meeting of the Working Party on Telecommunications and Information Society (hereinafter: WP TELECOM), during which delegations were invited to express their initial views on the topics that are going to be discussed during the second political trilogue on 18 July 2023.

II. STATE OF PLAY

6. During the technical meetings held so far, the following parts of the text have been discussed and prepared for confirmation at political level:

- **Obligations of providers and users/deployers of high-risk AI systems and other parties** (Articles 16-27, with the exception of Article 23a and Article 24)
  [rows 307-350c, 353-373b]
- **Notifying authorities and notified bodies** (Articles 30-39)
  [rows 389-442]
- **Standards, conformity assessment, certificates, registration** (Articles 40-50, with the exception of Article 47)
  [rows 443-484a, 492-508]

7. In Section I of the Annex, delegations will find the amendments made to the text by the EP and the Council with regard to the provisions mentioned above in the fourth column ("Draft Agreement"). As compared to the Commission's proposal, changes are marked as ***bold italics*** (additions) and ~~strikethrough~~ (deletions).

8. The rows marked as green have been provisionally agreed with the EP at the technical level. The rows marked as yellow have also been provisionally agreed, subject to final checks by the

EP, and are likely to be turned green before the second trilogue. Some elements in those rows have been placed in [square brackets] or are marked in red, which means that they will be adjusted at a later stage, subject to solutions on higher-level issues such as governance, foundation models/general purpose AI systems or exceptions for law enforcement authorities. During the meeting of WP TELECOM on 5 July 2023 delegations made several comments concering these proposals, which have been duly taken into account by the Presidency. The Presidency considers the compromise proposals in green and yellow to fall within the Council's Genral Approach from 6 December 2022 but it intends to ask the Permanent Representatives Committee for confirmation during its meeting on 14 July 2023.

III. POLITICAL ISSUES FOR POTENTIAL AGREEMENT DURING THE SECOND TRILOGUE

9. **DELETED**

10. **DELETED**

DELETED

11. **DELETED**

IV. CONCLUSION

12. In light of the above, and with a view to obtaining a revised mandate for trilogue negotiations on the AI Act, the Permanent Representatives Committee is invited to:

- **endorse the compromise proposals referred to in section III, point 9 of this note;**
- **indicate flexibility with regard to the topics and questions presented in section III, points 10 and 11 of this note.**

Section I – Articles for confirmation during the second trilogue on the AI Act

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	
	Chapter 3					
Y	306	Chapter 3 OBLIGATIONS OF PROVIDERS AND USERS OF HIGH-RISK AI SYSTEMS and other parties	Chapter 3 OBLIGATIONS OF PROVIDERS AND ~~*USERS*~~***DEPLOYERS*** OF HIGH-RISK AI SYSTEMS ~~*and other parties*~~***AND OTHER PARTIES***	Chapter 3 OBLIGATIONS OF PROVIDERS AND USERS OF HIGH-RISK AI SYSTEMS ~~*and other parties*~~***AND OTHER PARTIES***		Y
	Article 16					
G	307	Article 16 Obligations of providers of high-risk AI systems	Article 16 Obligations of providers ***and deployers*** of high-risk AI systems ***and other parties***	Article 16 Obligations of providers of high-risk AI systems	**DELETED FROM THIS POINT UNTIL THE END OF THE DOCUMENT (page 185)**	G
	Article 16, first paragraph					
G	308	Providers of high-risk AI systems shall:	Providers of high-risk AI systems shall:	Providers of high-risk AI systems shall:		G
	Article 16, first paragraph, point (a)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
309	(a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title;	(a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title ***before placing them on the market or putting them into service***;	(a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title;	
Article 16, first paragraph, point (aa)				
309a			***(aa) indicate their name, registered trade name or registered trade mark, the address at which they can be contacted on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as applicable;***	
Article 16, first paragraph, point (aa new)				
309b		***(aa) indicate their name, registered trade name or registered trade mark, and their address and contact information on the high-risk AI system or, where that is not possible, on its accompanying documentation, as appropriate;***		
Article 16, first paragraph, point (ab new)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Y	309c		***(ab) ensure that natural persons to whom human oversight of high-risk AI systems is assigned are specifically made aware of the risk of automation or confirmation bias;***		Y
	Article 16, first paragraph, point (ac new)				
Y	309d		***(ac) provide specifications for the input data, or any other relevant information in terms of the datasets used, including their limitation and assumptions, taking into account the intended purpose and the foreseeable and reasonably foreseeable misuses of the AI system;***		Y
	Article 16, first paragraph, point (b)				
G	310	(b) have a quality management system in place which complies with Article 17;	(b) have a quality management system in place which complies with Article 17;	(b) have a quality management system in place which complies with Article 17;	G

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

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

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

Article 16, first paragraph, point (ja new)						
G	318a		***(ja) ensure that the high-risk AI system complies with accessibility requirements.***			G
Article 17						
G	319	Article 17 Quality management system	Article 17 Quality management system	Article 17 Quality management system		G
Article 17(1)						
Y	320	1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:	1. Providers of high-risk AI systems shall ~~*put*~~***have*** a quality management system in place that ensures compliance with this Regulation. ~~*That system*~~***It*** shall be documented in a systematic and orderly manner in the form of written policies, procedures ~~*and*~~***or*** instructions, and ***can be incorporated into an existing quality management system under Union sectoral legislative acts. It*** shall include at least the following aspects:	1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:		Y
Article 17(1), point (a)						

Y	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;	*deleted*	*(a)* a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the high-risk AI system;		Y
	Article 17(1), point (b)					
G	322	(b) techniques, procedures and systematic actions to be used for the design, design control and design verification of the high-risk AI system;	(b) techniques, procedures and systematic actions to be used for the design, design control and design verification of the high-risk AI system;	(b) techniques, procedures and systematic actions to be used for the design, design control and design verification of the high-risk AI system;		G

	Article 17(1), point (c)				
G	323	(c) techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the high-risk AI system;	(c) techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the high-risk AI system;	(c) techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the high-risk AI system;	G
	Article 17(1), point (d)				
G	324	(d) examination, test and validation procedures to be carried out before, during and after the development of the high-risk AI system, and the frequency with which they have to be carried out;	(d) examination, test and validation procedures to be carried out before, during and after the development of the high-risk AI system, and the frequency with which they have to be carried out;	(d) examination, test and validation procedures to be carried out before, during and after the development of the high-risk AI system, and the frequency with which they have to be carried out;	G
	Article 17(1), point (e)				
G	325	(e) technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, the means to be used to ensure that the high-risk AI system complies with the requirements set out in Chapter 2 of this Title;	(e) technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, ***or do not cover all of the relevant requirements,*** the means to be used to ensure that the high-risk AI system complies with the requirements set out in Chapter 2 of this Title;	(e) technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, the means to be used to ensure that the high-risk AI system complies with the requirements set out in Chapter 2 of this Title;	G

Article 17(1), point (f)					
G	326	(f) systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market or putting into service of high-risk AI systems;	(f) systems and procedures for data management, including data ***acquisition, data*** collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market or putting into service of high-risk AI systems;	(f) systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market or putting into service of high-risk AI systems;	G
Article 17(1), point (g)					
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

	Article 17(1), point (h)				
G	328	(h) the setting-up, implementation and maintenance of a post-market monitoring system, in accordance with Article 61;	(h) the setting-up, implementation and maintenance of a post-market monitoring system, in accordance with Article 61;	(h) the setting-up, implementation and maintenance of a post-market monitoring system, in accordance with Article 61;	G
	Article 17(1), point (i)				
G	329	(i) procedures related to the reporting of serious incidents and of malfunctioning in accordance with Article 62;	(i) procedures related to the reporting of serious incidents and of malfunctioning in accordance with Article 62;	(i) procedures related to the reporting of ~~serious incidents and of malfunctioning~~***a serious incident*** in accordance with Article 62;	G
	Article 17(1), point (j)				
Y	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~~***relevant*** 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 authorities, including sectoral ones, providing or supporting the access to data, notified bodies, other operators, customers or other interested parties;	Y

Article 17(1), point (k)					
G	331	(k) systems and procedures for record keeping of all relevant documentation and information;	(k) systems and procedures for record keeping of all relevant documentation and information;	(k) systems and procedures for record keeping of all relevant documentation and information;	G
Article 17(1), point (l)					
G	332	(l) resource management, including security of supply related measures;	(l) resource management, including security of supply related measures;	(l) resource management, including security of supply related measures;	G
Article 17(1), point (m)					
G	333	(m) an accountability framework setting out the responsibilities of the management and other staff with regard to all aspects listed in this paragraph.	(m) an accountability framework setting out the responsibilities of the management and other staff with regard to all aspects listed in this paragraph.	(m) an accountability framework setting out the responsibilities of the management and other staff with regard to all aspects listed in this paragraph.	G

	Article 17(2)					
G	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. ***Providers shall in any event respect the degree of rigour and the level of protection required to ensure compliance of their AI systems with this Regulation.***	2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation.		G
	Article 17(2a)					
Y	334a			***2a. For providers of high-risk AI systems that are subject to obligations regarding quality management systems under relevant sectorial Union law, the aspects described in paragraph 1 may be part of the quality management systems pursuant to that law.***		Y
	Article 17(3)					
Y	335	3. For providers that are credit institutions regulated by Directive 2013/36/ EU, the obligation to put	3. For providers that are credit institutions regulated by Directive 2013/36/ EU, the obligation to put	3. For providers that are ~~credit~~***financial*** institutions ~~regulated by Directive 2013/36/~~		Y

		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.	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.	~~EU~~***subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation***, the obligation to put ***in place*** a quality management system ~~*in place*~~***with the exception of paragraph 1, points (g), (h) and (i)*** shall be deemed to be fulfilled by complying with the rules on internal governance arrangements~~,~~ ~~*processes and mechanisms*~~ ***or processes*** pursuant to ~~*Article 74 of that Directive*~~***the relevant Union financial services legislation***. In that context, any harmonised standards referred to in Article 40 of this Regulation shall be taken into account.	
Article 18					
Y	336	Article 18 Obligation to draw up technical documentation	*deleted*	Article 18 ~~*Obligation to draw up technical documentation*~~***Documentation keeping***	Y
Article 18(1)					
Y	337	1. Providers of high-risk AI systems shall draw up the technical	*deleted*	1. ~~*Providers of high-risk AI systems shall draw up the technical*~~	Y

		documen-tation referred to in Article 11 in accordance with Annex IV.		~~*documen-tation referred to in Article 11 in accordance with Annex IV.*~~ ***The provider shall, for a period ending 10 years after the AI system has been placed on the market or put into service, keep at the disposal of the national competent authorities:***	
Article 18(1), point (a)					
Y	337a			***(a) the technical documentation referred to in Article 11;***	Y
Article 18(1), point (b)					
Y	337b			***(b) the documentation concerning the quality management system referred to in Article 17;***	Y
Article 18(1), point (c)					
Y	337c			***(c) the documentation concerning the changes approved by notified bodies where applicable;***	Y

Article 18(1), point (d)					
Y	337d			***(d) the decisions and other documents issued by the notified bodies where applicable;***	Y
Article 18(1), point (e)					
Y	337e			***(e) the EU declaration of conformity referred to in Article 48.***	Y
Article 18(1), point (f)					
Y	337f			***1a. Each Member State shall determine conditions under which the documentation referred to in paragraph 1 remains at the disposal of the national competent authorities for the period indicated in that paragraph for the cases when a provider or its authorised representative established on its territory goes bankrupt or ceases its activity prior to the end of that period.***	Y
Article 18(2)					

Y	338	2. Providers that are credit institutions regulated by Directive 2013/36/EU shall maintain the technical documentation as part of the documentation concerning internal governance, arrangements, processes and mechanisms pursuant to Article 74 of that Directive.	*deleted*	2. Providers that are ~~credit~~***financial*** institutions ~~*regulated by Directive 2013/36/EU*~~***subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation*** shall maintain the technical documentation as part of the documentation ~~*concerning internal governance, arrangements, processes and mechanisms pursuant to Article 74 of that Directive*~~***kept under the relevant Union financial services legislation***.	Y
	Article 19				
G	339	Article 19 Conformity assessment	*deleted*	Article 19 Conformity assessment	G

Article 19(1)					
G	340	1. Providers of high-risk AI systems shall ensure that their systems undergo the relevant conformity assessment procedure in accordance with Article 43, prior to their placing on the market or putting into service. Where the compliance of the AI systems with the requirements set out in Chapter 2 of this Title has been demonstrated following that conformity assessment, the providers shall draw up an EU declaration of conformity in accordance with Article 48 and affix the CE marking of conformity in accordance with Article 49.	*deleted*	*1.* Providers of high-risk AI systems shall ensure that their systems undergo the relevant conformity assessment procedure in accordance with Article 43, prior to their placing on the market or putting into service. Where the compliance of the AI systems with the requirements set out in Chapter 2 of this Title has been demonstrated following that conformity assessment, the providers shall draw up an EU declaration of conformity in accordance with Article 48 and affix the CE marking of conformity in accordance with Article 49.	G
Article 19(2)					
G	341	2. For high-risk AI systems referred to in point 5(b) of Annex III that are placed on the market or put into service by providers that are credit institutions regulated by Directive 2013/36/EU, the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to101 of	*deleted*	*deleted*	G

		that Directive.				
Article 20						
G	342	Article 20 Automatically generated logs	Article 20 Automatically generated logs	Article 20 Automatically generated logs		G
Article 20(1)						
Y	343	1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. The logs shall be kept for a period that is appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under Union or national law.	1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control ~~by virtue of a contractual arrangement with the user or otherwise by law~~. ***Without prejudice to applicable Union or national law,*** the logs shall be kept for a period ~~that is appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under Union or national law~~***of at least 6 months. The retention period shall be in accordance with industry standards and appropriate to the intended purpose of high-risk AI system***.	1. Providers of high-risk AI systems shall keep the logs***, referred to in Article 12(1),*** automatically generated by their high-risk AI systems, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. ~~The logs~~***They*** shall ~~be kept~~***keep them*** for a period ~~that is appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under Union or national law~~***of at least six months, unless provided otherwise in applicable Union or national law, in particular in Union law on the protection of personal data***.		Y
Article 20(2)						

Y	344	2. Providers that are credit institutions regulated by Directive 2013/36/EU shall maintain the logs automatically generated by their high-risk AI systems as part of the documentation under Articles 74 of that Directive.	2. Providers that are credit institutions regulated by Directive 2013/36/EU shall maintain the logs automatically generated by their high-risk AI systems as part of the documentation under Articles 74 of that Directive.	2. Providers that are ~~credit~~***financial*** institutions ~~*regulated by Directive 2013/36/EU*~~***subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation*** shall maintain the logs automatically generated by their high-risk AI systems as part of the documentation ***kept*** under ~~*Articles 74 of that Directive*~~***the relevant financial service legislation***.		Y
	Article 21					
G	345	Article 21 Corrective actions	Article 21 Corrective actions	Article 21 Corrective actions		G

Article 21				
345a		*deleted*		
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***, to disable it*** or to recall it, as appropriate. ***In the cases referred to in the first paragraph, providers*** ~~*They*~~ shall ***immediately*** inform***:*** ***a.*** the distributors***;*** ***b. the importers;*** ***c. the national competent authorities*** of the ~~*high-risk*~~***Member States in which they made the*** AI system ~~*in question and,*~~***available or put it into service; and*** ***d.*** where ~~*applicable, the authorised representative and*~~	Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system which they have placed on the market or put into service is not in conformity with this Regulation shall immediately ***investigate, where applicable, the causes in collaboration with the reporting user and*** take the necessary corrective actions to bring that system into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the high-risk AI system in question and, where applicable, the authorised representative and importers accordingly.	

			~~*importers accordingly*~~***possible, the deployer***.		
Article 21, first paragraph 1a					
G	346a		***The providers shall also inform the authorised representative, if one was appointed in accordance with Article 25, and the notified body if the high-risk AI system had to undergo a third-party conformity assessment in accordance with Article 43. Where applicable, they shall also investigate the causes in collaboration with the deployer.***		G
Article 22					
G	347	Article 22 Duty of information	Article 22 Duty of information	Article 22 Duty of information	G
Article 22, first paragraph					
G	348	Where the high-risk AI system presents a risk within the meaning of Article 65(1) and that risk is known to the provider of the system, that provider shall immediately inform the national competent authorities of the	Where the high-risk AI system presents a risk within the meaning of Article 65(1) and ~~*that risk is known to the provider of the system*~~***the provider of the system becomes aware of that risk***, that provider shall immediately inform	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	G

		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.	the national ~~competent~~***supervisory*** authorities of the Member States in which it made the system available and, where applicable, the notified body that issued a certificate for the high-risk AI system, in particular ***the nature*** of the non-compliance and of any ***relevant*** corrective actions taken.	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.	
	Article 22, paragraph 1a (new)				
G	348a		***1a In the cases referred to inthe first paragraph, providers of the high-risk AI system shall immediately inform:*** ***a) the distributors;*** ***b) the importers;*** ***c) the national competent authorities of the Member States in which they made the AI system available or put it into service; and*** ***d) where possible, the deployers.***		G

Article 22, paragraph 1b (new)					
G	348b		***1b The providers shall also inform the authorised representative, if one was appointed in accordance with Article 25.***		G
	348c		*deleted*		
	348d		*deleted*		
	348e		*deleted*		
Article 23					
Y	*349*	Article 23 Cooperation with competent	Article 23 Cooperation with competent	Article 23 Cooperation with competent	Y

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

350a		*deleted*		
Article 23, paragraph 1a				
350b		***1a Upon a reasoned request by a national competent authority or, where applicable, by the Commission, providers and, where applicable, deployers shall also give the requesting national competent authority or the Commission, as applicable, access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control.***		
Article 23, paragraph 1b				
350c		***(1b) Any information obtained by a national competent authority or by the Commission pursuant to the provisions of this Article shall be considered a trade secret and be treated in compliance with the confidentiality obligations set out***		

			in Article 70.		
R	350d			***Article 23a*** ***Conditions for other persons to be subject to the obligations of a provider***	R
R	350e			***1. Any natural or legal person shall be considered a provider of a new high-risk AI system for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16, in any of the following circumstances:***	R
R	350f			***(a) they put their name or trademark on a high-risk AI system already placed on the market or put into service, without prejudice to contractual arrangements stipulating that the obligations are allocated otherwise;***	R

R	350g			***(b) they make a substantial modification to a high-risk AI system already placed on the market or put into service;***	R
R	350h			***(c) they modify the intended purpose of an AI system which is not high-risk and is already placed on the market or put ito service, in a way which makes the modified system a high-risk AI system;***	R
R	350i			***(d) they place on the market or put into service a general purpose AI system as a high-risk AI system or as a component of a high-risk AI system.***	R
R	350j			***2. Where the circumstances referred to in paragraph 1, point (a) or (c), occur, the provider that initially placed the high-risk AI***	R

				system on the market or put it into service shall no longer be considered a provider for the purposes of this Regulation.	
R	350k			***3. For high-risk AI systems that are safety components of products to which the legal acts listed in Annex II, section A apply, the manufacturer of those products shall be considered the provider of the high-risk AI system and shall be subject to the obligations under Article 16 under either of the following scenarios:***	R
R	350l			***(i) the high-risk AI system is placed on the market together with the product under the name or trademark of the product manufacturer;*** ***(ii) the high-risk AI system is put into service under the the name or trademark of the product manufacturer after the product has been placed on the market.***	R

	350m		*deleted*		
	Article 24				
Y	*351*	Article 24 Obligations of product manufacturers	Article 24 Obligations of product manufacturers	*deleted*	Y
	Article 24, first paragraph				
Y	*352*	Where a high-risk AI system related to products to which the legal acts listed in Annex II, section A, apply, is placed on the market or put into service together with the product manufactured in accordance with those legal acts and under the name of the product manufacturer, the manufacturer of the product shall take the responsibility of the compliance of the AI system with this Regulation and, as far as the AI system is concerned, have the same obligations imposed by the present Regulation on the provider.	Where a high-risk AI system related to products to which the legal acts listed in Annex II, section A, apply, is placed on the market or put into service together with the product manufactured in accordance with those legal acts and under the name of the product manufacturer, the manufacturer of the product shall take the responsibility of the compliance of the AI system with this Regulation and, as far as the AI system is concerned, have the same obligations imposed by the present Regulation on the provider.	*deleted*	Y

Article 25					
G	*353*	Article 25 Authorised representatives	Article 25 Authorised representatives	Article 25 Authorised representatives	G
Article 25(1)					
G	354	1. Prior to making their systems available on the Union market, where an importer cannot be identified, providers established 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.	G
Article 25(1a)					
G	354a		***1a. The authorised representative shall reside or be established in one of the Member States where the activities pursuant to Article 2, paragraphs 1(cb) are taking place.***		G

Article 25(1b)					
354b		***1b. The provider shall provide its authorised representative with the necessary powers and resources to comply with its tasks under this Regulation.***			
Article 25 second paragraph					
355	2. The authorised representative shall perform the tasks specified in the mandate received from the provider. The mandate shall empower the authorised representative to carry out the following tasks:	2. The authorised representative shall perform the tasks specified in the mandate received from the provider. ***It shall provide a copy of the mandate to the market surveillance authorities upon request, in one of the official languages of the institution of the Union determined by the national competent authority. For the purpose of this Regulation,*** 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. ***For the purpose of this Regulation,*** the mandate shall empower the authorised representative to carry out ***only*** the following tasks:		
Article 25(1c)(2), point (-a)					
355a			***(-a) verify that the EU declaration of conformity and the technical***		

				documentation have been drawn up and that an appropriate conformity assessment procedure has been carried out by the provider;	
Article 25, second paragraph, point (a)					
G	356	(a) keep a copy of the EU declaration of conformity and the technical documentation at the disposal of the national competent authorities and national authorities referred to in Article 63(7);	(a) ~~*keep a copy of*~~***ensure that*** the EU declaration of conformity and the technical documentation ~~*at the disposal of the national competent authorities and national authorities referred to in Article 63(7)*~~***have been drawn up and that an appropriate conformity assessment procedure has been carried out by the provider***;	(a) keep ~~*a copy*~~***at the disposal*** of the ~~*EU declaration of conformity and the technical documentation at the disposal*~~***national competent authorities and national authorities referred to in Article 63(7), for a period ending 10 years after the high-risk AI system has been placed on the market or put into service, the contact details*** of the ~~*national competent authorities and national authorities referred to in Article 63(7)*~~***provider by which the authorised representative has been appointed, a copy of the EU declaration of conformity, the technical documentation and, if applicable, the certificate issued by the notified body***;	G
Article 25, second paragraph, point (aa)					

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

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

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

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

	359	Article 26 Obligations of importers	Article 26 Obligations of importers	Article 26 Obligations of importers	
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 ***such a system is in conformity with this Regulation by ensuring that***:	1. Before placing a high-risk AI system on the market, importers of such system shall ensure that ***such a system is in conformity with this Regulation by verifying that***:	
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 ***referred to in Article 43*** has been carried out by the provider of that AI system***;***	(a) the ~~*appropriate*~~***relevant*** conformity assessment procedure ***referred to in Article 43*** has been carried out by the provider of that AI system***;***	
Article 26(1), point (b)					
	362	(b) the provider has drawn up the technical documentation in accordance with Annex IV;	(b) the provider has drawn up the technical documentation in accordance with ***Article 11 and*** Annex IV;	(b) the provider has drawn up the technical documentation in accordance with Annex IV;	

Article 26(1), point (c)					
G	363	(c) the system bears the required conformity marking and is accompanied by the required documentation and instructions of use.	(c) the system bears the required conformity marking and is accompanied by the required documentation and instructions of use.	(c) the system bears the required ***CE*** conformity marking and is accompanied by the ~~*required documentation*~~***EU declaration of conformity*** and instructions of use~~.~~**;**	G
G	363a			***(ca) the authorised representative referred to in Article 25 has been established by the provider.***	G
Article 26(1), point (ca)					
G	363b		***(ca) where applicable, the provider has appointed an authorised representative in accordance with Article 25(1).***		G
Article 26(2)					

G	364	2. Where an importer considers or has reason to consider that a high-risk AI system is not in conformity with this Regulation, it shall not place that system on the market until that AI system has been brought into conformity. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the importer shall inform the provider of the AI system and the market surveillance authorities to that effect.	2. Where an importer considers or has reason to consider that a high-risk AI system is not in conformity with this Regulation, ***or is counterfeit, or accompanied by falsified documentation*** it shall not place that system on the market until that AI system has been brought into conformity. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the importer shall inform the provider of the AI system and the market surveillance authorities to that effect.	2. Where an importer ~~considers or has reason~~***has sufficient reasons*** to consider that a high-risk AI system is not in conformity with this Regulation, ***or is falsified, or accompanied by falsified documentation,*** it shall not place that system on the market until that AI system has been brought into conformity. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the importer shall inform the provider of the AI system***, the authorised representatives*** and the market surveillance authorities to that effect.	G
Article 26(3)					
G	365	3. Importers shall indicate their name, registered trade name or registered trade mark, and the address at which they can be contacted on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as applicable.	3. Importers shall indicate their name, registered trade name or registered trade mark, and the address at which they can be contacted on the high-risk AI system ~~or, where that is not possible,~~***and*** on its packaging or its accompanying documentation, ~~as~~***where*** applicable.	3. Importers shall indicate their name, registered trade name or registered trade mark, and the address at which they can be contacted on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as applicable.	G

Article 26(4)					
G	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.	G
Article 26(4a)					
G	366a			***4a. Importers shall keep, for a period ending 10 years after the AI system has been placed on the market or put into service, a copy of the certificate issued by the notified body, where applicable, of the instructions for use and of the EU declaration of conformity.***	G
Article 26(5)					
G	367	5. Importers shall provide national competent authorities, upon a reasoned request, with all necessary information and documentation to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title in a language which can be easily	5. Importers shall provide national competent authorities, upon a reasoned request, with all ***the*** necessary information and documentation to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title in a language which can be easily	5. Importers shall provide national competent authorities, upon a reasoned request, with all necessary information and documentation***, including that kept in accordance with paragraph 5,*** to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2	G

		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.	understood by ~~that national competent authority~~***them***, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider ~~by virtue of a contractual arrangement with the user or otherwise by law. They shall also cooperate with those authorities on any action national competent authority takes in relation to that system~~***in accordance with Article 20.***	of this Title in a language which can be easily understood by that national competent authority~~, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law~~***. To this purpose*** they shall also ~~cooperate with those authorities on any action national competent authority takes in relation to that system~~***ensure that the technical documentation can be made available to those authorities***.	
Article 26(5a)					
G	367a			***5a. Importers shall cooperate with national competent authorities on any action those authorities take in relation to an AI system, of which they are the importer.***	G
Article 26(5b)					

G	367b		***5a. Importers shall cooperate with national competent authorities on any action those authorities take to reduce and mitigate the risks posed by the high-risk AI system.***			G
Article 27						
G	368	Article 27 Obligations of distributors	Article 27 Obligations of distributors	Article 27 Obligations of distributors		G
Article 27(1)						
G	369	1. Before making a high-risk AI system available on the market, distributors shall verify that the high-risk AI system bears the required CE conformity marking, that it is accompanied by the required documentation and instruction of use, and that the provider and the importer of the system, as applicable, have complied with the obligations set out in this Regulation.	1. Before making a high-risk AI system available on the market, distributors shall verify that the high-risk AI system bears the required CE conformity marking, that it is accompanied by the required documentation and instruction of use, and that the provider and the importer of the system, as applicable, have complied with ~~*the*~~***their*** obligations set out in this Regulation ***in Articles 16 and 26 respectively***.	1. Before making a high-risk AI system available on the market, distributors shall verify that the high-risk AI system bears the required CE conformity marking, that it is accompanied by ~~*the required documentation*~~***a copy of EU declaration of conformity*** and instruction of use, and that the provider and the importer of the system, as applicable, have complied with ~~*the*~~***their*** obligations set out ~~*in this Regulation*~~***Article 16, point (b) and 26(3) respectively***.		G

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

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

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

G	373b		***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.***			G
	Article 30					
G	390	Article 30 Notifying authorities	Article 30 Notifying authorities	Article 30 Notifying authorities		G
	Article 30(1)					
Y	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. ***Those procedures shall be developed in cooperation between the notifying authorities of all Member States.***	1. Each Member State shall designate or establish ~~a~~***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.		Y

	Article 30(2)					
Y	392	2. Member States may designate a national accreditation body referred to in Regulation (EC) No 765/2008 as a notifying authority.	2. Member States may designate a national accreditation body referred to in Regulation (EC) No 765/2008 as a notifying authority.	2. Member States may ~~designate~~***decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by*** a national accreditation body ~~*referred to in*~~ ***within the meaning of and in accordance with*** Regulation (EC) No 765/2008 ~~*as a notifying authority*~~.		Y
	Article 30(3)					
G	393	3. Notifying authorities shall be established, organised and operated in such a way that no conflict of interest arises with conformity assessment bodies and the objectivity and impartiality of their activities are safeguarded.	3. Notifying authorities shall be established, organised and operated in such a way that no conflict of interest arises with conformity assessment bodies and the objectivity and impartiality of their activities are safeguarded.	3. Notifying authorities shall be established, organised and operated in such a way that no conflict of interest arises with conformity assessment bodies and the objectivity and impartiality of their activities are safeguarded.		G

	Article 30(4)				
G	394	4. Notifying authorities shall be organised in such a way that decisions relating to the notification of conformity assessment bodies are taken by competent persons different from those who carried out the assessment of those bodies.	4. Notifying authorities shall be organised in such a way that decisions relating to the notification of conformity assessment bodies are taken by competent persons different from those who carried out the assessment of those bodies.	4. Notifying authorities shall be organised in such a way that decisions relating to the notification of conformity assessment bodies are taken by competent persons different from those who carried out the assessment of those bodies.		G
	Article 30(5)				
G	395	5. Notifying authorities shall not offer or provide any activities that conformity assessment bodies perform or any consultancy services on a commercial or competitive basis.	5. Notifying authorities shall not offer or provide any activities that conformity assessment bodies perform or any consultancy services on a commercial or competitive basis.	5. Notifying authorities shall not offer or provide any activities that conformity assessment bodies perform or any consultancy services on a commercial or competitive basis.		G
	Article 30(6)				
Y	396	6. Notifying authorities shall safeguard the confidentiality of the information they obtain.	6. Notifying authorities shall safeguard the confidentiality of the information they obtain.	6. Notifying authorities shall safeguard the confidentiality of the information they obtain ***in accordance with Article 70***.		Y

	Article 30(7)				
Y	397	7. Notifying authorities shall have a sufficient number of competent personnel at their disposal for the proper performance of their tasks.	7. Notifying authorities shall have a sufficient number of competent personnel at their disposal for the proper performance of their tasks. ***Where applicable, competent personnel shall have the necessary expertise, such as a degree in an appropriate legal field, in the supervision of fundamental rights enshrined in the Charter of Fundamental Rights of the European Union.***	7. Notifying authorities shall have ~~*a sufficient*~~***an adequate*** number of competent personnel at their disposal for the proper performance of their tasks.	Y
	Article 30(8)				
G	398	8. Notifying authorities shall make sure that conformity assessments are carried out in a proportionate manner, avoiding unnecessary burdens for providers and that notified bodies perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of the AI system in question.	8. Notifying authorities shall make sure that conformity assessments are carried out in a proportionate ***and timely*** manner, avoiding unnecessary burdens for providers, and that notified bodies perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of the AI system in question. ***Particular attention shall be paid to minimising administrative burdens and***	*deleted*	G

			compliance costs for micro and small enterprises as defined in the Annex to Commission Recommendation 2003/361/EC.			
	Article 31					
G	*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		G
	Article 31(1)					
G	400	1. Conformity assessment bodies shall submit an application for notification to the notifying authority of the Member State in which they are established.	1. Conformity assessment bodies shall submit an application for notification to the notifying authority of the Member State in which they are established.	1. Conformity assessment bodies shall submit an application for notification to the notifying authority of the Member State in which they are established.		G
	Article 31(2)					
Y	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,	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,	2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the ~~*artificial intelligence technologies*~~***AI systems*** for which the conformity assessment body claims to be competent, as well as by an		Y

		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.	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.	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)					
	402	3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 33. For notified bodies which are designated under any other Union harmonisation legislation, all documents and certificates linked to those designations may be used to support their designation procedure under this Regulation, as appropriate.	3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 33. For notified bodies which are designated under any other Union harmonisation legislation, all documents and certificates linked to those designations may be used to support their designation procedure under this Regulation, as appropriate.	3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with ***all*** the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 33. For notified bodies which are designated under any other Union harmonisation legislation, all documents and certificates linked to those designations may be used to support their designation procedure under this Regulation, as appropriate. ***The notified body shall update the documentation referred to in paragraph 2 and***	

				paragraph 3 whenever relevant changes occur, in order to enable the authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements laid down in Article 33.		
	Article 32					
G	403	Article 32 Notification procedure	Article 32 Notification procedure	Article 32 Notification procedure		G
	Article 32(1)					
Y	404	1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 33.	1. Notifying authorities ~~*may*~~***shall*** notify only conformity assessment bodies which have satisfied the requirements laid down in Article 33.	1. Notifying authorities may ***only*** notify ~~*only*~~ conformity assessment bodies which have satisfied the requirements laid down in Article 33.		Y

	Article 32(2)				
G	405	2. Notifying authorities shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.	2. Notifying authorities shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission ***of each conformity assessment body referred to in paragraph 1***.	2. Notifying authorities shall notify ***those bodies to*** the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.	G
	Article 32(3)				
Y	406	3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies concerned.	3. The notification ***referred to in paragraph 2*** shall include full details of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies concerned***, as well as the relevant attestation of competence***.	3. The notification ***referred to in paragraph 2*** shall include full details of the conformity assessment activities, the conformity assessment module or modules and the ~~*artificial intelligence technologies concerned*~~***AI systems concerned and the relevant attestation of competence. Where a notification is 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***	Y

				and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 33.	
Article 32(4)					
Y	407	4. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within one month of a notification.	4. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within ~~*one month of a*~~***two weeks of the validation of the*** notification ***where it includes an accreditation certificate referred to in Article 31(2), or within two months of the notification where it incudes documentary evidence referred to in Article 31(3***.	4. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within ~~*one month*~~***two weeks*** of a notification ***by a notifying authority where it includes an accreditation certificate referred to in Article 31(2), or within two months of a notification by the notifying authority where it includes documentary evidence referred to in Article 31(3)***.	Y
Article 32(4a)					
Y	407a		***4a. Where objections are raised, the Commission shall without delay enter into consultation with the relevant Member States and the conformity assessment body.***		Y

			In view thereof, the Commission shall decide whether the authorisation is justified or not. The Commission shall address its decision to the Member State concerned and the relevant conformity assessment body.		
Article 32(4b)					
G	407b		***4b. Member States shall notify the Commission and the other Member States of conformity assessment bodies.***		G
Article 32(5)					
Y	408	5. Notifying authorities shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.	5. Notifying authorities shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.	*deleted*	Y
Article 33					
G	*409*	Article 33 Notified bodies	Article 33 Notified bodies	Article 33 ***Requirements relating to notified bodies*** ~~*notified bodies*~~	G

	Article 33(1)					
Y	410	1. Notified bodies shall verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43.	1. Notified bodies shall verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43.	1. ***A*** notified ~~*bodies*~~***body*** shall ~~*verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43*~~***be established under national law and have legal personality***.		Y
	Article 33(2)					
G	411	2. Notified bodies shall satisfy the organisational, quality management, resources and process requirements that are necessary to fulfil their tasks.	2. Notified bodies shall satisfy the organisational, quality management, resources and process requirements that are necessary to fulfil their tasks ***as well as the minimum cybersecurity requirements set out for public administration entities identified as operators of essential services pursuant to Directive (EU 2022/2555***.	2. Notified bodies shall satisfy the organisational, quality management, resources and process requirements that are necessary to fulfil their tasks.		G

Article 33(3)					
G	412	3. The organisational structure, allocation of responsibilities, reporting lines and operation of notified bodies shall be such as to ensure that there is confidence in the performance by and in the results of the conformity assessment activities that the notified bodies conduct.	3. The organisational structure, allocation of responsibilities, reporting lines and operation of notified bodies shall be such as to ensure that there is confidence in the performance by and in the results of the conformity assessment activities that the notified bodies conduct.	3. The organisational structure, allocation of responsibilities, reporting lines and operation of notified bodies shall be such as to ensure that there is confidence in the performance by and in the results of the conformity assessment activities that the notified bodies conduct.	G
Article 33(4)					
G	413	4. Notified bodies shall be independent of the provider of a high-risk AI system in relation to which it performs conformity assessment activities. Notified bodies shall also be independent of any other operator having an economic interest in the high-risk AI system that is assessed, as well as of any competitors of the provider.	4. Notified bodies shall be independent of the provider of a high-risk AI system in relation to which it performs conformity assessment activities. Notified bodies shall also be independent of any other operator having an economic interest in the high-risk AI system that is assessed, as well as of any competitors of the provider. ***This shall not preclude the use of assessed AI systems that are necessary for the operations of the conformity assessment body or the use of such systems for personal purposes.***	4. Notified bodies shall be independent of the provider of a high-risk AI system in relation to which it performs conformity assessment activities. Notified bodies shall also be independent of any other operator having an economic interest in the high-risk AI system that is assessed, as well as of any competitors of the provider.	G

Article 33(4a)					
413a		***4a. A conformity assessment pursuant to paragraph 1 shall be performed by employees of notified bodies who have not provided any other other service related to the matter assessed than the conformity assessment to the provider of a high-risk AI system nor to any legal person connected to that provider in the 12 months' period before the assessment and have committed to not providing them with such services in the 12 month period following the completion of the assessment.***			
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 their organisation, personnel and assessment activities.	5. Notified bodies shall be organised and operated so as to safeguard the independence, objectivity and impartiality of their activities. Notified bodies shall document and implement a structure and procedures to safeguard impartiality and to promote and apply the principles of impartiality throughout their organisation, personnel and assessment activities.	5. Notified bodies shall be organised and operated so as to safeguard the independence, objectivity and impartiality of their activities. Notified bodies shall document and implement a structure and procedures to safeguard impartiality and to promote and apply the principles of impartiality throughout their organisation, personnel and assessment activities.	

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, except in relation to the notifying authorities of the Member State in which their activities are carried out.	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, except in relation to the notifying authorities of the Member State in which their activities are carried out. ***Any information and documentation obtained by notified bodies pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.***	6. Notified bodies shall have documented procedures in place ensuring that their personnel, committees, subsidiaries, subcontractors and any associated body or personnel of external bodies respect the confidentiality of the information ***in accordance with Article 70*** which comes into their possession during the performance of conformity assessment activities, except when disclosure is required by law. The staff of notified bodies shall be bound to observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the notifying authorities of the Member State in which their activities are carried out.	

Article 33(7)					
G	416	7. Notified bodies shall have procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the AI system in question.	7. Notified bodies shall have procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the AI system in question.	7. Notified bodies shall have procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the AI system in question.	G
Article 33(8)					
G	417	8. Notified bodies shall 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.	8. Notified bodies shall 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.	8. Notified bodies shall take out appropriate liability insurance for their conformity assessment activities, unless liability is assumed by the Member State ~~concerned~~***in which they are located*** in accordance with national law or that Member State is ***itself*** directly responsible for the conformity assessment.	G

Article 33(9)					
G	418	9. Notified bodies shall be capable of carrying out all the tasks falling to them under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by notified bodies themselves or on their behalf and under their responsibility.	9. Notified bodies shall be capable of carrying out all the tasks falling to them under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by notified bodies themselves or on their behalf and under their responsibility.	9. Notified bodies shall be capable of carrying out all the tasks falling to them under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by notified bodies themselves or on their behalf and under their responsibility.	G
Article 33(10)					
G	419	10. Notified bodies shall have sufficient internal competences to be able to effectively evaluate the tasks conducted by external parties on their behalf. To that end, at all times and for each conformity assessment procedure and each type of high-risk AI system in relation to which they have been designated, the notified 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	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	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, ***legal*** and scientific personnel who possess experience and knowledge relating to the relevant artificial intelligence technologies, data and	G

		data computing and to the requirements set out in Chapter 2 of this Title.	data computing and to the requirements set out in Chapter 2 of this Title.	data computing and to the requirements set out in Chapter 2 of this Title.	
	Article 33(11)				
G	420	11. Notified bodies shall participate in coordination activities as referred to in Article 38. They shall also take part directly or be represented in European standardisation organisations, or ensure that they are aware and up to date in respect of relevant standards.	11. Notified bodies shall participate in coordination activities as referred to in Article 38. They shall also take part directly or be represented in European standardisation organisations, or ensure that they are aware and up to date in respect of relevant standards.	11. Notified bodies shall participate in coordination activities as referred to in Article 38. They shall also take part directly or be represented in European standardisation organisations, or ensure that they are aware and up to date in respect of relevant standards.	G
	Article 33(12)				
Y	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 to facilitate the assessment outlined in this Chapter.	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 to facilitate the assessment outlined in this Chapter.	*deleted*	Y

	Article 33a				
Y	*421a*			***Article 33a*** ***Presumption of conformity with requirements relating to notified bodies***	Y
	Article 33a, first paragraph				
Y	421b			***Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union it shall be presumed to comply with the requirements set out in Article 33 in so far as the applicable harmonised standards cover those requirements.***	Y

Article 34					
G	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	G
Article 34(1)					
G	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.	G
Article 34(2)					
G	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.	G

Article 34(3)					
G	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. ***Notified bodies shall make a list of their subsidiaries publicly available.***	3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the provider.	G
Article 34(4)					
Y	426	4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.	4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the ~~*assessment*~~***verification*** of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.	4. ~~*Notified bodies shall keep at the disposal of the notifying authority*~~ The relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation ***shall be kept at the disposal of the notifying authority for a period of 5 years from the termination date of the subcontracting activity***.	Y
Article 34a					

Y	426a			***Article 34a*** ***Operational obligations of notified bodies***		Y
Article 34a(1)						
Y	426b			***1. Notified bodies shall verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43.***		Y
Article 34a(2)						
Y	426c			***2. Notified bodies shall perform their activities while avoiding unnecessary burdens for providers, and taking due account of the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of the high risk AI system in question. In so doing, the notified body shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the high risk AI system with the requirements of this Regulation.***		Y

	Article 34a(3)				
Y	426d			***3. Notified bodies shall make available and submit upon request all relevant documentation, including the providers' documentation, to the notifying authority referred to in Article 30 to allow that authority to conduct its assessment, designation, notification, monitoring activities and to facilitate the assessment outlined in this Chapter.***	Y
	Article 35				
Y	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	Y

Article 35(1)					
G	428	1. The Commission shall assign an identification number to notified bodies. It shall assign a single number, even where a body is notified under several Union acts.	1. The Commission shall assign an identification number to notified bodies. It shall assign a single number, even where a body is notified under several Union acts.	1. The Commission shall assign an identification number to notified bodies. It shall assign a single number, even where a body is notified under several Union acts.	G
Article 35(2)					
G	429	2. The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified. The Commission shall 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.	G
Article 36					
G	430	Article 36 Changes to notifications	Article 36 Changes to notifications	Article 36 Changes to notifications	G

	Article 36(-1)				
Y	430a			***-1. The notifying authority shall notify the Commission and the other Member States of any relevant changes to the notification of a notified body via the electronic notification tool referred to in Article 32(2).***	Y
	Article 36(-1a), first subparagraph				
Y	430b			***-1a. The procedures described in Article 31 and 32 shall apply to extensions of the scope of the notification. For changes to the notification other than extensions of its scope, the procedures laid down in the following paragraphs shall apply.***	Y
	Article 36(-1a), second subparagraph				

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

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

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

				request	
Article 36(2c)					
Y	432c			***2c. In the event of restriction, suspension or withdrawal of a designation, the notifying authority shall:***	Y
Article 36(2c), point (a)					
Y	432d			***(a) assess the impact on the certificates issued by the notified body;***	Y
Article 36(2c), point (b)					
Y	432e			***(b) submit a report on its findings to the Commission and the other Member States within three months of having notified the changes to the notification;***	Y
Article 36(2c), point (c)					

Y	432f			***(c) require the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued in order to ensure the conformity of AI systems on the market;***		Y
	Article 36(2c), point (d)					
Y	432g			***(d) inform the Commission and the Member States about certificates of which it has required their suspension or withdrawal;***		Y
	Article 36(2c), point (e)					
Y	432h			***(e) provide the national competent authorities of the Member State in which the provider has its registered place of business with all relevant information about the certificates for which it has required suspension or withdrawal. That competent authority shall take the appropriate measures, where***		Y

				necessary, to avoid a potential risk to health, safety or fundamental rights.	
	Article 36(2d)				
Y	432i			***2d. With the exception of certificates unduly issued, and where a notification has been suspended or restricted, the certificates shall remain valid in the following circumstances:***	Y
	Article 36(2d), point (a)				
Y	432j			***(a) the notifying authority has confirmed, within one month of the suspension or restriction, that there is no risk to health, safety or fundamental rights in relation to certificates affected by the suspension or restriction, and the notifying authority has outlined a timeline and actions anticipated to remedy the suspension or restriction; or***	Y

Article 36(2d), point (b)				
432k			***(b) the notifying authority has confirmed that no certificates relevant to the suspension will be issued, amended or re-issued during the course of the suspension or restriction, and states whether the notified body has the capability of continuing to monitor and remain responsible for existing certificates issued for the period of the suspension or restriction. In the event that the authority responsible for notified bodies determines that the notified body does not have the capability to support existing certificates issued, the provider shall provide to the national competent authorities of the 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.	
	Article 36(2e), first subparagraph				
Y	432l			***2e. With the exception of certificates unduly issued, and where a designation has been withdrawn, the certificates shall remain valid for a period of nine months in the following circumstances:***	Y
	Article 36(2e), first subparagraph, point (a)				
Y	432m			***(a) where the national competent authority of the Member State in which the provider of the AI system covered by the certificate has its registered place of business has confirmed that there is no risk to health, safety and fundamental rights associated with the systems in question; and***	Y

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

				affected by the change of notification shall immediately inform the Commission, the other Member States and the other notified bodies thereof.		
Article 37						
G	433	Article 37 Challenge to the competence of notified bodies	Article 37 Challenge to the competence of notified bodies	Article 37 Challenge to the competence of notified bodies		G
Article 37(1)						
Y	434	1. The Commission shall, where necessary, investigate all cases where there are reasons to doubt whether a notified body complies with the requirements laid down in Article 33.	1. The Commission shall, where necessary, investigate all cases where there are reasons to doubt ~~*whether*~~***the competence of*** a notified body ~~*complies with the requirements laid down in Article 33*~~***or the continued fulfilment by a notified body of the applicable requirements and responsibilities***.	1. The Commission shall, where necessary, investigate all cases where there are reasons to doubt whether a notified body complies with the requirements laid down in Article 33.		Y
Article 37(2)						

G	435	2. The Notifying authority shall provide the Commission, on request, with all relevant information relating to the notification of the notified body concerned.	2. The Notifying authority shall provide the Commission, on request, with all relevant information relating to the notification ***or the maintenance of the competence*** 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.	G
	Article 37(3)				
G	436	3. The Commission shall ensure that all confidential information obtained in the course of its investigations pursuant to this Article is treated confidentially.	3. The Commission shall ensure that all ~~*confidential*~~***sensitive*** information obtained in the course of its investigations pursuant to this Article is treated confidentially.	3. The Commission shall ensure that all confidential information obtained in the course of its investigations pursuant to this Article is treated confidentially ***in accordance with Article 70***.	G
	Article 37(4)				
G	437	4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements laid down in Article 33, it shall adopt a reasoned decision requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary. That implementing act	4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements ~~*laid down in Article 33*~~***for its notification***, it shall ~~*adopt a reasoned decision requesting*~~***inform*** the notifying Member State ***accordingly and request it*** to take the necessary corrective measures, including	4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements laid down in Article 33, it shall ~~*adopt a reasoned decision requesting the notifying Member State*~~***inform the notifying authority of the reasons of such an ascertainment and request it*** to take the necessary corrective	G

		shall be adopted in accordance with the examination procedure referred to in Article 74(2).	***suspension or*** withdrawal of ***the*** notification if necessary. ***Where the Member State fails to take the necessary corrective measures, the Commission may, by means of an implementing act, suspend, restrict or withdraw the designation***. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(2).	measures, including ***the suspension, restriction or*** withdrawal of ~~*notification*~~***the designation*** if necessary. ***Where the notifying authority fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the notification***. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(2).	
	Article 38				
G	438	Article 38 Coordination of notified bodies	Article 38 Coordination of notified bodies	Article 38 Coordination of notified bodies	G
	Article 38(1)				
Y	439	1. The Commission shall ensure that, with regard to the areas covered by this Regulation, appropriate coordination and cooperation between notified bodies active in the conformity assessment procedures of AI systems pursuant to this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.	1. The Commission shall ensure that, with regard to the areas covered by this Regulation, appropriate coordination and cooperation between notified bodies active in the conformity assessment procedures of AI systems pursuant to this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.	1. The Commission shall ensure that, with regard to ~~*the areas covered by this Regulation*~~***high-risk AI systems***, appropriate coordination and cooperation between notified bodies active in the conformity assessment procedures ~~*of AI systems*~~ pursuant to this Regulation are put in place and properly operated in the form of a sectoral group of notified	Y

				bodies.	
Article 38(2)					
G	440	2. Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.	2. Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.	2. ~~*Member States*~~***The notifying authority*** shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.	G
Article 38(2a)					
G	440a		***2a. The Commission shall provide for the exchange of knowledge and best practices between the Member States' national authorities responsible for notification policy.***		G
Article 39					
G	441	Article 39 Conformity assessment bodies of third countries	Article 39 Conformity assessment bodies of third countries	Article 39 Conformity assessment bodies of third countries	G

	Article 39, first paragraph					
Y	442	Conformity assessment bodies established under the law of a third country with which the Union has concluded an agreement may be authorised to carry out the activities of notified Bodies under this Regulation.	Conformity assessment bodies established under the law of a third country with which the Union has concluded an agreement may be authorised to carry out the activities of notified Bodies under this Regulation.	Conformity assessment bodies established under the law of a third country with which the Union has concluded an agreement may be authorised to carry out the activities of notified Bodies under this Regulation***, provided that they meet the requirements in Article 33***.		Y
	Chapter 5					
G	443	Chapter 5 STANDARDS, CONFORMITY ASSESSMENT, CERTIFICATES, REGISTRATION	Chapter 5 STANDARDS, CONFORMITY ASSESSMENT, CERTIFICATES, REGISTRATION	Chapter 5 STANDARDS, CONFORMITY ASSESSMENT, CERTIFICATES, REGISTRATION		G
	Article 40					

444	Article 40 Harmonised standards	Article 40 Harmonised standards	Article 40 Harmonised standards	
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 conformity with the requirements set out in Chapter 2 of this Title, to the extent those standards cover those requirements.	High-risk AI systems ***and foundation models*** which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union ***in accordance with Regulation (EU) 1025/2012*** shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title ***or Article 28b***, to the extent those standards cover those requirements.	High-risk AI systems ***or general purpose AI systems*** which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title ***or, as applicable, with requirements set out in Article 4a and Article 4b***, to the extent those standards cover those requirements.	
Article 40, first paragraph a				
445a			***2. 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:		
	Article 40, third paragraph					
G	445b			***(a) ensure that AI systems placed on the market or put into service in the Union are safe and respect Union values and strengthen the Union's open strategic autonomy;***		G

Article 40, third paragraph, point (a)					
G	445c			***(b) promote investment and innovation in AI, including through increasing legal certainty, as well as competitiveness and growth of the Union market;***	G
Article 40, third paragraph, point (b)					
G	445d			***(c) enhance multistakeholder governance, representative of all relevant European stakeholders (e.g. industry, SMEs, civil society, researchers);***	G
Article 40, third paragraph, point (c)					
G	445e			***(d) contribute to strengthening global cooperation on standardisation in the field of AI that is consistent with Union values and interests.***	G
Article 40, fourth paragraph					

G	445f			***The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the above objectives.***		G
	Article 40, (1a)					
G	445g		***1a. The Commission shall issue standardisation requests covering all requirements of this Regulation, in accordance with Article 10 of Regulation EU (No)1025/2012 by... [two months after the date of entry into force of this Regulation]. When preparing standardisation request, the Commission shall consult the AI Office and the Advisory Forum;***			G
	Article 40, (1c)					
G	445h		***1c The actors involved in the standardisation process shall take into account the general principles for trustworthy AI set out in Article 4(a), seek to promote investment and innovation in AI as well as***			G

			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, 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		
Article 40, (1b)					
G	445i		***1b When issuing a standardisation request to European standardisation organisations, the Commission shall specify that standards have to be consistent, including with the sectorial law listed in Annex II, and aimed at ensuring that AI systems or foundation models placed on the market or put into service in the Union meet the relevant requirements laid down in this Regulation;***		G

Article 41					
G	446	Article 41 Common specifications	Article 41 Common specifications	Article 41 Common specifications	G
Article 41(1)					
G	447	1. Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns, the Commission may, by means of implementing acts, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).	*deleted*	1. ~~*Where harmonised standards referred to in Article 40 do not exist or where*~~ The Commission ~~*considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns, the Commission may, by means of implementing acts, adopt*~~***is empowered to adopt, after consulting the AI Board referred to in Article 56, implementing acts in accordance with the examination procedure referred to in Article 74(2) establishing*** common ***technical*** specifications ~~*in respect of*~~***for*** the requirements set out in Chapter 2 of this Title~~. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2)~~***, or, as applicable, with requirements set out in***	G

				Article 4a and Article 4b, where the following conditions have been fulfilled:	
Article 41(1), point (a)					
G	447a			***(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;***	G
Article 41(1), point (b)					
G	447b			***(b) the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more European standardisation organisations to draft a harmonised standard for the requirements set out in Chapter 2 of this Title;***	G

Article 41(1), point (c)					
G	447c			***(c) the request referred to in point (b) has not been accepted by any of the European standardisation organisations or the harmonised standards addressing that request are not delivered within the deadline set in accordance with article 10(1) of Regulation 1025/2012 or those standards do not comply with the request.***	G
Article 41(1), point (d)					
G	447d			***1a. Before preparing a draft implementing act, the Commission shall inform the committee referred to in Article 22 of Regulation EU (No) 1025/2012 that it considers that the conditions in paragraph 1 are fulfilled.***	G

G	447e		***1a. The Commission may, by means of implementing act adopted in accordance with the examination procedure referred to in Article 74(2) and after consulting the AI Office and the AI Advisory Forum, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title or Article 28b wherein all of the following conditions are fulfilled:*** ***(a) there is no reference to harmonised standards already published in the Official Journal of the European Union related to the essential requirement(s), unless the harmonised standard in question is an existing standard that must be revised;*** ***(b) the Commission has requested one or more European standardisation organisations to draft a harmonised standard for the essential requirement(s) set out in Chapter 2;*** ***(c) the request referred to in point (b) has not been accepted by any of the European standardisation organisations; or***		G

			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.			
R	447f		***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.***			R
R	447g		***1c. Where the Commission considers there to be a need to address specific fundamental rights concerns, common specifications adopted by the Commission in accordance with paragraph 1a shall also address those specific fundamental rights concerns.***			R

Article 41(2)				
448	2. The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant bodies or expert groups established under relevant sectorial Union law.	2. The Commission ***shall, throughout the whole process of drafting*** ~~, when preparing~~ the common specifications referred to in ~~paragraph 1, shall gather the views of relevant~~***paragraphs 1a and 1b, regularly consult the AI Office and the Advisory Forum, the European standardisation organisations and*** bodies or expert groups established under relevant sectorial Union law ***as well as other relevant stakeholders. The Commission shall fulfil the objectives referred to in Article 40 (1c) and duly justify why it decided to resort to common specifications.*** ***Where the Commission intends to adopt common specifications pursuant to paragraph 1a of this Article, it shall also clearly identify the specific fundamental rights concern to be addressed.*** ***When adopting common specifications pursuant to paragraphs 1a and 1b of this Article, the Commission shall take into account the opinion issued by the AI Office referred to in Article***	2. ***In the early preparation of the draft implementing act establishing*** ~~The Commission, when preparing~~ the common ~~specifications~~***specification, the Commission shall fulfil the objectives*** referred to in ~~paragraph 1, shall~~***Article 40(2) and*** gather the views of relevant bodies or expert groups established under relevant sectorial Union law. ***Based on that consultation, the Commission shall prepare the draft implementing act.***	

			56e(b) of this Regulation. Where the Commission decides not to follow the opinion of the AI Office, it shall provide a reasoned explanation to the AI Office.		
Article 41(3)					
G	449	3. High-risk AI systems which are in conformity with the common specifications referred to in paragraph 1 shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title, to the extent those common specifications cover those requirements.	3. High-risk AI systems which are in conformity with the common specifications referred to in ~~*paragraph 1*~~***paragraphs 1a and 1b*** shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title, to the extent those common specifications cover those requirements~~.~~	3. High-risk AI systems ***or general purpose AI systems*** which are in conformity with the common specifications referred to in paragraph 1 shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title ***or, as applicable, with requirements set out in Article 4a and Article 4b***, to the extent those common specifications cover those requirements.	G

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

			Chapter II to a level at least equivalent thereto**.;**		
G	450a			***4a. When references of a harmonised standard are published in the Official Journal of the European Union, implementing acts referred to in paragraph 1, which cover the requirements set out in Chapter 2 of this Title or requirements set out in Article 4a and Article 4b, shall be repealed, as applicable.***	G
	Article 41(4a)				
G	450b			***4b. When a Member State considers that a common specification does not entirely satisfy the requirements set out in Chapter 2 of this Title or requirements set out in Article 4a and Article 4b, as applicable, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if appropriate, amend the implementing act establishing the common specification in question.***	G

Article 42					
G	451	Article 42 Presumption of conformity with certain requirements	Article 42 Presumption of conformity with certain requirements	Article 42 Presumption of conformity with certain requirements	G
Article 42(1)					
G	452	1. Taking into account their intended purpose, high-risk AI systems that have been trained and tested on data concerning the specific geographical, behavioural and functional setting within which they are intended to be used shall be presumed to be in compliance with the requirement set out in Article 10(4).	1. Taking into account their intended purpose, high-risk AI systems that have been trained and tested on data concerning the specific geographical, behavioural ***contextual*** and functional setting within which they are intended to be used shall be presumed to be in compliance with the ~~requirement~~***respective requirements*** set out in Article 10(4).	1. ~~*Taking into account their intended purpose,*~~ High-risk AI systems that have been trained and tested on data ~~*concerning*~~***reflecting*** the specific geographical, behavioural ~~*and*~~***or*** functional setting within which they are intended to be used shall be presumed to be in compliance with the ~~*requirement*~~***respective requirements*** set out in Article 10(4).	G
Article 42(2)					
G	453	2. High-risk AI systems that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 of the European Parliament and of the Council[1] and	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	2. High-risk AI systems ***or general purpose AI systems*** that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 of the European	G

		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. _____ 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).	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. _____ 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).	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. _____ 1. ***///*** Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 1).	
Article 43					
G	454	Article 43 Conformity assessment	Article 43 Conformity assessment	Article 43 Conformity assessment	G
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 referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall follow one of the following procedures:	1. For high-risk AI systems listed in point 1 of Annex III, where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider has applied harmonised standards referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall ~~*follow*~~***opt for*** one of the following procedures~~:~~**;**	1. For high-risk AI systems listed in point 1 of Annex III, where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider has applied harmonised standards referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall ~~*follow*~~***opt for*** one of the following procedures:	
Article 43(1), first subparagraph, point (a)					
456	(a) the conformity assessment procedure based on internal control referred to in Annex VI;	(a) the conformity assessment procedure based on internal control referred to in Annex VI; ***or***	(a) the conformity assessment procedure based on internal control referred to in Annex VI; ***or***		
Article 43(1), first subparagraph, point (b)					
457	(b) the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation, with the involvement of a notified body, referred to in Annex VII.	(b) the conformity assessment procedure based on assessment of the quality management system and ~~*assessment*~~ of the technical documentation, with the involvement of a notified body, referred to in Annex VII~~.~~**;**	(b) the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation, with the involvement of a notified body, referred to in Annex VII.		

Article 43(1), second subparagraph				
458	Where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider has not applied or has applied only in part harmonised standards referred to in Article 40, or where such harmonised standards do not exist and common specifications referred to in Article 41 are not available, the provider shall follow the conformity assessment procedure set out in Annex VII.	~~*Where,*~~ In demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider ~~*has not applied or has applied only in part*~~***shall follow the conformity assessment procedure set out in Annex VII in the following cases:*** ***(a) where*** harmonised standards referred to in Article 40, ~~*or where such harmonised standards*~~***the reference number of which has been published in the Official Journal of the European Union, covering all relevant safety requirements for the AI system,*** do not exist and common specifications referred to in Article 41 are not available~~.~~**;** ***(b) where the technical specifications referred to in point (a) exist but the provider has not applied them or has applied them only in part;*** ***(c) where one or more of the technical specifications referred to in point (a) has been published with a restriction and only on the part of the standard that was restricted;*** ***(d) when*** the provider ~~*shall*~~	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.	

			~~*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***.		
Article 43(1), third subparagraph					
G	459	For the purpose of the conformity assessment procedure referred to in Annex VII, the provider may choose any of the notified bodies. However, when the system is intended to be put into service by law enforcement, immigration or asylum authorities as well as EU institutions, bodies or agencies, the market surveillance authority referred to in Article 63(5) or (6), as applicable, shall act as a notified body.	***carrying out*** the conformity assessment procedure referred to in Annex VII, the provider may choose any of the notified bodies. However, when the system is intended to be put into service by law enforcement, immigration or asylum authorities as well as EU institutions, bodies or agencies, the market surveillance authority referred to in Article 63(5) or (6), as applicable, shall act as a notified body.	For the purpose of the conformity assessment procedure referred to in Annex VII, the provider may choose any of the notified bodies. However, when the system is intended to be put into service by law enforcement, immigration or asylum authorities as well as EU institutions, bodies or agencies, the market surveillance authority referred to in Article 63(5) or (6), as applicable, shall act as a notified body.	G
Article 43(2)					
G	460	2. For high-risk AI systems referred to in points 2 to 8 of Annex III, providers shall follow the conformity assessment procedure based on internal control as referred to in Annex VI, which	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	2. For high-risk AI systems referred to in points 2 to 8 of Annex III ***and for general purpose AI systems referred in Title 1a***, providers shall follow the conformity assessment procedure	G

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

Article 43(3), second subparagraph					
G	462	For the purpose of that assessment, notified bodies which have been notified under those legal acts shall be entitled to control the conformity of the high-risk AI systems with the requirements set out in Chapter 2 of this Title, provided that the compliance of those notified bodies with requirements laid down in Article 33(4), (9) and (10) has been assessed in the context of the notification procedure under those legal acts.	For the purpose of that assessment, notified bodies which have been notified under those legal acts shall be entitled to control the conformity of the high-risk AI systems with the requirements set out in Chapter 2 of this Title, provided that the compliance of those notified bodies with requirements laid down in Article 33(4), (9) and (10) has been assessed in the context of the notification procedure under those legal acts.	For the purpose of that assessment, notified bodies which have been notified under those legal acts shall be entitled to control the conformity of the high-risk AI systems with the requirements set out in Chapter 2 of this Title, provided that the compliance of those notified bodies with requirements laid down in Article 33(4), (9) and (10) has been assessed in the context of the notification procedure under those legal acts.	G
Article 43(3), third subparagraph					
G	463	Where the legal acts listed in Annex II, section A, enable the manufacturer of the product to opt out from a third-party conformity assessment, provided that that manufacturer has applied all harmonised standards covering all the relevant requirements, that manufacturer may make use of that option only if he has also applied harmonised standards or, where applicable, common specifications	Where the legal acts listed in Annex II, section A, enable the manufacturer of the product to opt out from a third-party conformity assessment, provided that that manufacturer has applied all harmonised standards covering all the relevant requirements, that manufacturer may make use of that option only if he has also applied harmonised standards or, where applicable, common specifications	Where the legal acts listed in Annex II, section A, enable the manufacturer of the product to opt out from a third-party conformity assessment, provided that that manufacturer has applied all harmonised standards covering all the relevant requirements, that manufacturer may make use of that option only if he has also applied harmonised standards or, where applicable, common specifications	G

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

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

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 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.	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 referred to in Annex VII or parts thereof. The Commission shall adopt such delegated acts taking into account the effectiveness of the conformity assessment procedure based on internal control referred to in Annex VI in preventing or minimizing the risks to health and safety and protection of fundamental rights posed by such systems as well as the availability of adequate capacities and resources among notified bodies. ***When preparing such delegated acts, the Commission shall consult the AI Office and the stakeholders affected.***	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 referred to in Annex VII or parts thereof. The Commission shall adopt such delegated acts taking into account the effectiveness of the conformity assessment procedure based on internal control referred to in Annex VI in preventing or minimizing the risks to health and safety and protection of fundamental rights posed by such systems as well as the availability of adequate capacities and resources among notified bodies.	

	Article 44				
G	468	Article 44 Certificates	Article 44 Certificates	Article 44 Certificates	G
	Article 44(1)				
G	469	1. Certificates issued by notified bodies in accordance with Annex VII shall be drawn-up in an official Union language determined by the 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~~***one or several*** official Union ~~language~~***languages*** determined by the Member State in which the notified body is established or in ~~an~~***one or several*** official Union ~~language~~***languages*** otherwise acceptable to the notified body.	1. Certificates issued by notified bodies in accordance with Annex VII shall be drawn-up in ~~an official Union~~***a a*** language ~~determined by the Member State in which the notified body is established or in an official Union language otherwise acceptable to~~***which can be easily understood by the relevant authorities in the Member State in which*** the notified body ***is established***.	G
	Article 44(2)				
Y	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	2. Certificates shall be valid for the period they indicate, which shall not exceed ~~five~~***four*** years. On application by the provider, the validity of a certificate may be extended for further periods, each not exceeding ~~five~~***four*** years, based	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	Y

		a re-assessment in accordance with the applicable conformity assessment procedures.	on a re-assessment in accordance with the applicable conformity assessment procedures.	a re-assessment in accordance with the applicable conformity assessment procedures. ***Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.***	
	Article 44(3)				
G	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 body. The notified body shall give reasons for its decision.	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 body. The notified body shall give reasons for its decision.	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 body. The notified body shall give reasons for its decision.	G

Article 45					
G	472	Article 45 Appeal against decisions of notified bodies	Article 45 Appeal against decisions of notified bodies	Article 45 Appeal against decisions of notified bodies	G
Article 45, first paragraph					
G	473	Member States shall ensure that an appeal procedure against decisions of the notified bodies is available to parties having a legitimate interest in that decision.	Member States shall ensure that an appeal procedure against decisions of the notified bodies***, including on issued conformity certificates*** is available to parties having a legitimate interest in that decision.	~~*Member States shall ensure that*~~ An appeal procedure against decisions of the notified bodies ~~*is available to parties having a legitimate interest in that decision*~~***shall be available***.	G
Article 46					
G	474	Article 46 Information obligations of notified bodies	Article 46 Information obligations of notified bodies	Article 46 Information obligations of notified bodies	G
Article 46(1)					
G	475	1. Notified bodies shall inform the notifying authority of the following:	1. Notified bodies shall inform the notifying authority of the following:	1. Notified bodies shall inform the notifying authority of the following:	G

Article 46(1), point (a)					
G	476	(a) any Union technical documentation assessment certificates, any supplements to those certificates, quality management system approvals issued in accordance with the requirements of Annex VII;	(a) any Union technical documentation assessment certificates, any supplements to those certificates, quality management system approvals issued in accordance with the requirements of Annex VII;	(a) any Union technical documentation assessment certificates, any supplements to those certificates, quality management system approvals issued in accordance with the requirements of Annex VII;	G
Article 46(1), point (b)					
G	477	(b) any refusal, restriction, suspension or withdrawal of a Union technical documentation assessment certificate or a quality management system approval issued in accordance with the requirements of Annex VII;	(b) any refusal, restriction, suspension or withdrawal of a Union technical documentation assessment certificate or a quality management system approval issued in accordance with the requirements of Annex VII;	(b) any refusal, restriction, suspension or withdrawal of a Union technical documentation assessment certificate or a quality management system approval issued in accordance with the requirements of Annex VII;	G
Article 46(1), point (c)					
G	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;	G

Article 46(1), point (d)					
G	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;	G
Article 46(1), point (e)					
G	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.	G
Article 46(2)					
G	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:	G
Article 46(2), point (a)					

G	482	(a) quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued;	(a) quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued;	(a) quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued;		G
Article 46(2), point (b)						
G	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.		G
Article 46(3)						
G	484	3. Each notified body shall provide the other notified bodies carrying out similar conformity assessment activities covering the same artificial intelligence technologies with relevant information on issues relating to negative and, on request, positive conformity assessment results.	3. Each notified body shall provide the other notified bodies carrying out similar conformity assessment activities ~~*covering the same artificial intelligence technologies*~~ with relevant information on issues relating to negative and, on request, positive conformity assessment results.	3. Each notified body shall provide the other notified bodies carrying out similar conformity assessment activities covering the same ~~*artificial intelligence technologies*~~***AI systems*** with relevant information on issues relating to negative and, on request, positive conformity assessment results.		G

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

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

Article 47(2)					
R	487	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 surveillance*~~***national supervisory authority and judicial*** authority ~~*concludes*~~***conclude*** that the high-risk AI system complies with the requirements of Chapter 2 of this Title. The ~~*market surveillance*~~***national supervisory*** authority shall inform the Commission***, the AI office,*** and the other Member States of any ***request made and any subsequent*** authorisation issued pursuant to paragraph 1.	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. ***This obligation shall not cover sensitive operational data in relation to the activities of law enforcement authorities.***		R
Article 47(3)					
R	488	3. Where, within 15 calendar days of receipt of the information referred to in paragraph 2, no objection has been raised by either a Member State or the Commission in respect of an authorisation issued by a market surveillance authority of a Member State in accordance with paragraph 1, that authorisation shall be deemed justified.	3. Where, within 15 calendar days of receipt of the information referred to in paragraph 2, no objection has been raised by either a Member State or the Commission in respect ***to the request of the national supervisory authority for*** ~~*of*~~ an authorisation issued by a ~~*market surveillance*~~***national supervisory*** authority of a Member State in accordance with paragraph 1, that authorisation shall be deemed justified.	*deleted*		R

Article 47(4)				
R *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 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.	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*~~***a request*** issued by a ~~*market surveillance*~~***national supervisory*** authority of another Member State, or where the Commission considers the authorisation to be contrary to Union law or the conclusion of the Member States regarding the compliance of the system as referred to in paragraph 2 to be unfounded, the Commission shall without delay enter into consultation with the relevant Member State ***and the AI Office***; the operator(s) concerned shall be consulted and have the possibility to present their views. In view thereof, the Commission shall decide whether the authorisation is justified or not. The Commission shall address its decision to the Member State concerned and the relevant operator ~~*or operators*~~***(s)***.	*deleted*	R
Article 47(5)				

R	*490*	*5.* If the authorisation is considered unjustified, this shall be withdrawn by the market surveillance authority of the Member State concerned.	5. If the authorisation is considered unjustified, this shall be withdrawn by the ~~*market surveillance*~~***national supervisory*** authority of the Member State concerned.	*deleted*	R
Article 47(6)					
R	*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,*~~***related to products*** covered by ~~*Regulation (EU) 2017/745 and Regulation (EU) 2017/746, Article 59 of Regulation (EU) 2017/745 and Article 54 of Regulation (EU) 2017/746 shall apply also with regard to the derogation from*~~***Union harmonisation legislation referred to in Annex II Section A, only*** the conformity assessment ~~*of the compliance with the requirements set out in Chapter 2 of this Title*~~***derogation procedures established in that legislation shall apply***.	R
Article 48					

G	492	Article 48 EU declaration of conformity	Article 48 EU declaration of conformity	Article 48 EU declaration of conformity		G
Article 48(1)						
G	493	1. The provider shall draw up a written EU declaration of conformity for each AI system and keep it at the disposal of the national competent authorities for 10 years after the AI 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 ***machine readable, physical or electronic*** EU declaration of conformity for each ***high-risk*** AI system and keep it at the disposal of the national ***supervisory authority and the national*** competent authorities for 10 years after the AI ***high-risk*** system has been placed on the market or put into service. ~~*The EU declaration of conformity shall identify the AI system for which it has been drawn up.*~~ A copy of the EU declaration of conformity shall be ~~*given to*~~***submitted to the national supervisory authority and*** the relevant national competent authorities upon request.	1. The provider shall draw up a written ***or electronically signed*** EU declaration of conformity for each AI system and keep it at the disposal of the national competent authorities for 10 years after the AI system has been placed on the market or put into service. The EU declaration of conformity shall identify the AI system for which it has been drawn up. A copy of the EU declaration of conformity shall be ~~*given*~~***submitted*** to the relevant national competent authorities upon request.		G

	Article 48(2)				
G	494	2. The EU declaration of conformity shall state that the high-risk AI system in question meets the requirements set out in Chapter 2 of this Title. The EU declaration of conformity shall contain the information set out in Annex V and shall be translated into an official Union language or languages required by the Member State(s) in which the high-risk AI system is made available.	2. The EU declaration of conformity shall state that the high-risk AI system in question meets the requirements set out in Chapter 2 of this Title. The EU declaration of conformity shall contain the information set out in Annex V and shall be translated into an official Union language or languages required by the Member State(s) in which the high-risk AI system is ***placed on the market or*** made available.	2. The EU declaration of conformity shall state that the high-risk AI system in question meets the requirements set out in Chapter 2 of this Title. The EU declaration of conformity shall contain the information set out in Annex V and shall be translated into ~~*an official Union language or languages required by*~~***a language that can be easily understood by the national competent authorities of*** the Member State(s) in which the high-risk AI system is made available.	G
	Article 48(3)				
Y	495	3. Where high-risk AI 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	3. Where high-risk AI systems are subject to other Union harmonisation legislation which also requires an EU declaration of conformity, a single EU declaration of conformity ~~*shall*~~***may*** be drawn up in respect of all Union legislations applicable to the high-risk AI system. The declaration shall contain all the information required for identification of the Union harmonisation legislation to	3. Where high-risk AI 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	Y

		which the declaration relates.	which the declaration relates.	which the declaration relates.	
Article 48(4)					
G	496	4. By drawing up the EU declaration of conformity, the provider shall assume responsibility for compliance with the requirements set out in Chapter 2 of this Title. The provider shall keep the EU declaration of conformity up-to-date as appropriate.	4. By drawing up the EU declaration of conformity, the provider shall assume responsibility for compliance with the requirements set out in Chapter 2 of this Title. The provider shall keep the EU declaration of conformity up-to-date as appropriate.	4. By drawing up the EU declaration of conformity, the provider shall assume responsibility for compliance with the requirements set out in Chapter 2 of this Title. The provider shall keep the EU declaration of conformity up-to-date as appropriate.	G
Article 48(5)					
G	497	5. The Commission shall be empowered to adopt delegated acts in accordance with Article 73 for the purpose of updating the content of the EU declaration of conformity set out in Annex V in order to introduce elements that become necessary in light of technical progress.	5. ***After consulting the AI Office,*** the Commission shall be empowered to adopt delegated acts in accordance with Article 73 for the purpose of updating the content of the EU declaration of conformity set 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.	G

Article 49					
G	498	Article 49 CE marking of conformity	Article 49 CE marking of conformity	Article 49 CE marking of conformity	G
Article 49(1)					
G	499	1. The CE marking shall be affixed visibly, legibly and indelibly for high-risk AI systems. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it shall be affixed to the packaging or to the accompanying documentation, as appropriate.	1. The ***physical*** CE marking shall be affixed visibly, legibly and indelibly for high-risk AI systems~~.~~ ***before the high-risk AI system is placed on the market*** Where that is not possible or not warranted on account of the nature of the high-risk AI system, it shall be affixed to the packaging or to the accompanying documentation, as appropriate. ***It may be followed by a pictogram or any other marking indicating a special risk of use.***	1. The CE marking ~~*shall be affixed visibly, legibly and indelibly for high-risk AI systems. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it*~~***of conformity*** shall be ~~*affixed*~~***subject*** to the ~~*packaging or to the accompanying documentation, as appropriate*~~***general principles set out in Article 30 of Regulation (EC) No 765/2008***.	G

Article 49(1a)					
G	499a		***1a. For digital only high-risk AI systems, a digital CE marking shall be used, only if it can be easily accessed via the interface from which the AI system is accessed or via an easily accessible machine-readable code or other electronic means.***		G
Article 49(2)					
G	500	2. The CE marking referred to in paragraph 1 of this Article shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.	2. The CE marking referred to in paragraph 1 of this Article shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.	2. The CE marking ~~*referred to in paragraph 1 of this Article*~~***shall be affixed visibly, legibly and indelibly for high-risk AI systems. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it*** shall be ~~*subject*~~***affixed*** to the ~~*general principles set out in Article 30 of Regulation (EC) No 765/2008*~~***packaging or to the accompanying documentation, as appropriate***.	G

Article 49(3)					
G	501	3. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 43. The identification number shall also be indicated in any promotional material which mentions that the high-risk AI system fulfils the requirements for CE marking.	3. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 43. The identification number ***of the notified body shall be affixed by the body itself or, under its instructions, by the provider's authorised representative. The identification number*** shall also be indicated in any promotional material which mentions that the high-risk AI system fulfils the requirements for CE marking.	3. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 43. The identification number shall also be indicated in any promotional material which mentions that the high-risk AI system fulfils the requirements for CE marking.	G
Article 49(3a)					
G	501a		***3a. Where high-risk AI systems are subject to other Union law which also provides for the affixing of the CE marking, the CE marking shall indicate that the high-risk AI system also fulfil the requirements of that other law.***		G

Article 50					
G	502	Article 50 Document retention	Article 50 Document retention	*deleted*	G
Article 50, first paragraph					
G	503	The provider shall, for a period ending 10 years after the AI system has been placed on the market or put into service, keep at the disposal of the national competent authorities:	The provider shall, for a period ending 10 years, after the AI system has been placed on the market or put into service, keep at the disposal of the national ***supervisory authority and the national*** competent authorities:	*deleted*	G
Article 50, first paragraph, point (a)					
G	*504*	*(a)* the technical documentation referred to in Article 11;	(a) the technical documentation referred to in Article 11;	*deleted*	G
Article 50, first paragraph, point (b)					
G	*505*	*(b)* the documentation concerning the quality management system referred to Article 17;	(b) the documentation concerning the quality management system referred to Article 17;	*deleted*	G
Article 50, first paragraph, point (c)					
G	*506*				G

		(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)					
G	*507*	*(d)* the decisions and other documents issued by the notified bodies where applicable;	(d) the decisions and other documents issued by the notified bodies where applicable;	*deleted*	G
Article 50, first paragraph, point (e)					
G	*508*	*(e)* the EU declaration of conformity referred to in Article 48.	(e) the EU declaration of conformity referred to in Article 48.	*deleted*	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
R	388d	***Article 29a*** ***Fundamental rights impact assessment for high-risk AI systems*** ***Prior to putting a high-risk AI system as defined in Article 6(2) into use, with the exception of AI systems intended to be used in area 2 of Annex III, deployers shall conduct an assessment of the systems' impact in the specific context of use. This assessment shall include, at a minimum, the following elements:*** ***(a) a clear outline of the intended purpose for which the system will be used;*** ***(b) a clear outline of the intended geographic and temporal scope of the system's use;*** ***(c) categories of natural persons and groups likely to be affected by the use of the system;*** ***(d) verification that the use of***		R

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		the system is compliant with relevant Union and national law on fundamental rights; ***(e) the reasonably foreseeable impact on fundamental rights of putting the high-risk AI system into use;*** ***(f) specific risks of harm likely to impact marginalised persons or vulnerable groups;*** ***(g) the reasonably foreseeable adverse impact of the use of the system on the environment;*** ***(h) a detailed plan as to how the harms and the negative impact on fundamental rights identified will be mitigated.*** ***(j) the governance system the deployer will put in place, including human oversight, complaint-handling and redress.*** ***2. If a detailed plan to mitigate the risks outlined in the course of the assessment outlined in paragraph 1 cannot be identified, the deployer shall refrain from putting the high-risk AI system into use and inform the provider and the National supervisory authority without undue delay. National supervisory authorities, pursuant to Articles 65 and 67, shall take this information into***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		account when investigating systems which present a risk at national level. ***3. The obligation outlined under paragraph 1 applies for the first use of the high-risk AI system. The deployer may, in similar cases, draw back on previously conducted fundamental rights impact assessment or existing assessment carried out by providers. If, during the use of the high-risk AI system, the deployer considers that the criteria listed in paragraph 1 are not longer met, it shall conduct a new fundamental rights impact assessment.*** ***4. In the course of the impact assessment, the deployer, with the exception of SMEs, shall shall notify national supervisory authority and relevant stakeholders and shall, to best extent possible, involve representatives of the persons or groups of persons that are likely to be affected by the high-risk AI system, as identified in paragraph 1, including but not limited to: equality bodies, consumer protection agencies, social partners and data protection agencies, with a view to receiving***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		input into the impact assessment. The deployer shall allow a period of six weeks for bodies to respond. SMEs may voluntarily apply the provisions laid down in this paragraph. ***In the case referred to in Article 47(1), public authorities may be exempted from this obligations.*** ***5. The deployer that is a public authority or an undertaking referred to in Article 51(1a) (b) shall publish a summary of the results of the impact assessment as part of the registration of use pursuant to their obligation under Article 51(2).*** ***6. Where the deployer is already required to carry out a data protection impact assessment under Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the fundamental rights impact assessment referred to in paragraph 1 shall be conducted in conjunction with the data protection impact assessment. The data protection impact assessment shall be published as an addendum.***		
Article 53				

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	
G	519	Article 53 AI regulatory sandboxes	Article 53 AI regulatory sandboxes	Article 53 AI regulatory sandboxes		G
R	519a			***-1. National competent authorities may establish AI regulatory sandboxes for the development, training, testing and validation of innovative AI systems under the direct supervision, guidance and support by the national competent authority, before those systems are placed on the market or put into service. Such regulatory sandboxes may include testing in real world conditions supervised by the national competent authorities.***		R
R	519b			***-1a. Where appropriate, national competent authorities shall cooperate with other relevant authorities and may allow for the involvement of other actors within the AI ecosystem.***		R

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
R 519c			***-1b. This Article shall not affect other regulatory sandboxes established under national or Union law, including in cases where the products or services that are tested in them are linked to the use of innovative AI systems. Member States shall ensure an appropriate level of cooperation between the authorities supervising those other sandboxes and the national competent authorities.***	R
Article 53(1)				
R 520	1. AI regulatory sandboxes established by one or more Member States competent authorities or the European Data Protection Supervisor shall provide a controlled environment that facilitates the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan. This shall take place under the direct supervision and guidance by the competent	1. ~~*AI regulatory sandboxes established by one or more Member States competent authorities or the European Data Protection Supervisor*~~***Member States shall establish at least one AI regulatory sandbox at national level, which*** shall ~~*provide a controlled environment that facilitates the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a*~~	*deleted*	R

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	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.	~~*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*~~.		
R	*520a*		***1a. The establishment of AI regulatory sandboxes under this Regulation shall aim to contribute to one or more of the following objectives:***	R
R	520b		***(a) foster innovation and competitiveness and facilitate the development of an AI ecosystem;***	R

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R	520c		***(b) facilitate and accelerate access to the Union market for AI systems, in particular when provided by small and medium enterprises (SMEs), including start-ups;***		R
R	520d		***(c) improve legal certainty and contribute to the sharing of best practices through cooperation with the authorities involved in the AI regulatory sandbox with a view to ensuring future compliance with this Regulation and, where appropriate, with other Union and Member States legislation;***		R
R	520e		***(d) contribute to evidence-based regulatory learning.***		R
R	520f	***1a. Additional AI regulatory sandboxes at regional or local***			R

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		levels or jointly with other Member States may also be established;		
R 520g		***1b. The Commission and the European Data Protection Supervisor, on their own, jointly or in collaboration with one or more Member States may also establish AI regulatory sandboxes at Union level;***		R
R 520h		***1c. Establishing authorities shall allocate sufficient resources to comply with this Article effectively and in a timely manner.***		R
R 520i		***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***		R

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		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.		
R 520j		***1e. Establishing authorities shall provide guidance and supervision within the sandbox with a view to identify risks, in particular to fundamental rights, democracy and rule of law, health and safety and the environment, test and demonstrate mitigation measures for identified risks, and their effectiveness and ensure compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation.***		R
R 520k		***1f. Establishing authorities shall provide sandbox prospective providers who develop high-risk AI systems with guidance and supervision on how to fulfil the***		R

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		requirements set out in this Regulation, so that the AI systems may exit the sandbox being in presumption of conformity with the specific requirements of this Regulation that were assessed within the sandbox. Insofar as the AI system complies with the requirements when exiting the sandbox, it shall be presumed to be in conformity with this regulation. In this regard, the exit reports created by the establishing authority shall be taken into account by market surveillance authorities or notified bodies, as applicable, in the context of conformity assessment procedures or market surveillance checks.		
R	520l	***1g. The establishment of AI regulatory sandboxes shall aim to contribute to the following objectives:*** ***a) for the competent authorities to provide guidance to AI systems prospective providers providers to achieve regulatory compliance with this Regulation or where relevant other applicable Union***		R

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		and Member States legislation; ***b) for the prospective providers to allow and facilitate the testing and development of innovative solutions related to AI systems;*** ***c) regulatory learning in a controlled environment.***		
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*~~***Establishing authorities*** shall ensure that**,** to the extent the innovative AI systems involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to ***personal*** data, the national data protection authorities**, *or in cases referred to in paragraph 1b the EDPS,*** and those other national authorities are associated to the operation of the AI regulatory sandbox ***and involved in the supervision of those aspects to the full extent of their respective tasks and powers***.	*deleted*	
521a				

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			2a. Access to the AI regulatory sandboxes shall be open to any 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.	
R	521b		***Participation in the AI regulatory sandbox shall be limited to a period that is appropriate to the complexity and scale of the project. This period may be extended by the national competent authority.***	R
R	521c		***Participation in the AI regulatory sandbox shall be based on a specific plan referred to in paragraph 6 of this Article that***	R

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			shall be agreed between the participant(s) and the national competent authoritie(s), as applicable.	
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***, including at regional or local level***. Any significant risks to ***fundamental rights, democracy and rule of law,*** health and safety ~~*and fundamental rights*~~***or the environment*** identified during the development and testing of such ***AI*** systems shall result in immediate ***and adequate*** mitigation***. Competent authorities shall have the power to temporarily or permanently suspend the testing process, or participation*** ~~*and, failing that,*~~ in the ~~*suspension of the development and testing process until such mitigation takes place*~~***sandbox if no effective mitigation is possible and inform the AI office of such decision***.	3. ***The participation in*** 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*~~***authorities supervising the sandbox. Those authorities shall exercise their supervisory powers in a flexible manner within the limits of the relevant legislation, using their discretionary powers when implementing legal provisions to a specific AI sandbox project, with the objective of supporting innovation in AI in the Union***.	

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R 522a			***Provided that the participant(s) respect the sandbox plan and the terms and conditions for their participation as referred to in paragraph 6(c) and follow in good 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.***	R
Article 53(4)				
R 523	4. Participants in the AI regulatory sandbox shall remain liable under applicable Union and Member States liability legislation for any harm inflicted on third parties as a result from the experimentation taking place in the sandbox.	4. ~~*Participants*~~***Prospective providers*** in the AI regulatory sandbox shall remain liable under applicable Union and Member States liability legislation for any harm inflicted on third parties as a result ~~*from*~~***of*** the experimentation taking place in the sandbox. ***However, provided that the prospective provider(s) respect the specific plan referred to in paragraph 1c and the terms and conditions for their participation and follow in good faith the***	4. ~~*Participants in the AI regulatory sandbox shall*~~***The participants*** remain liable under applicable Union and Member States liability legislation for any ~~*harm inflicted on third parties as a result from the experimentation taking place in the*~~***damage caused in the course of their participation in an AI regulatory*** sandbox.	R

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		guidance given by the establishing authorities, no administrative fines shall be imposed by the authorities for infringements of this Regulation.		
R 523a			***4a. Upon request of the provider or prospective provider of the AI system, the national competent authority shall provide, where applicable, a written proof of the activities successfully carried out in the sandbox. The national competent authority shall also provide an exit report detailing the activities carried out in the sandbox and the related results and learning outcomes. Such written proof and exit report could be taken into account by market surveillance authorities or notified bodies, as applicable, in the context of conformity assessment procedures or market surveillance checks.***	R
R 523b			***Subject to the confidentiality***	R

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			provisions 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).	
R	523c		***4b. The AI regulatory sandboxes shall be designed and implemented in such a way that, where relevant, they facilitate cross-border cooperation between the national competent authorities.***	R
	Article 53(5)			
R	524	5. Member States' competent authorities that have established AI regulatory sandboxes shall	5. ~~*Member States' competent*~~***Establishing*** authorities ~~*that have established AI regulatory*~~	5. ~~*Member States'*~~***National*** competent authorities ~~*that have established*~~***shall make publicly***	R

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

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			~~*where relevant, on the application of this Regulation and other Union legislation supervised within the sandbox*~~.	
R	524a		***5a. The Commission shall ensure that information about AI regulatory sandboxes, including about those established under this Article, is available through the single information platform referred to in Article 55(3)(b).***	R
R	524b	***5a. Establishing authorities shall inform the AI Office of the establishment of a sandbox and may ask for support and guidance. A list of planned and existing sandboxes shall be made publicly available by the AI office and kept up to date in order to encourage more interaction in the regulatory sandboxes and transnational cooperation.***		R

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R 524c		***5b. Establishing authorities shall submit to the AI office and, unless the Commission is the sole establishing authority, to the Commission, annual reports, starting one year after the establishment of the sandbox and then every year until its termination and a final report. Those reports shall provide information on the progress and results of the implementation of those sandboxes, including best practices, incidents, lessons learnt and recommendations on their setup 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.***		R
Article 53(6)				
R 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	6. The ~~*modalities and the conditions of the operation of the AI regulatory*~~***Commission shall develop a single and dedicated interface containing all relevant information related to*** sandboxes,	6. The modalities and the conditions ~~*of the*~~ ***for the establishment and*** operation of the AI regulatory sandboxes~~*, including the eligibility criteria and the procedure for the application,*~~	R

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	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).	~~*including the eligibility criteria and the procedure for the application, selection, participation and exiting from the sandbox, and the rights and obligations of the participants shall be set out in implementing acts. Those implementing acts*~~***together with a single contact point at Union level to interact with the regulatory sandboxes and to allow stakeholders to raise enquiries with competent authorities, and to seek non-binding guidance on the conformity of innovative products, services, business models embedding AI technologies; The Commission*** shall ~~*be adopted in accordance with the examination procedure referred to in Article 74(2)*~~***proactively coordinate with national, regional and also local authorities, where relevant***.	~~*selection, participation and exiting from the sandbox, and the rights and obligations of the participants*~~ ***under this Regulation*** shall be ~~*set out in*~~***adopted through*** implementing acts~~*. Those implementing acts shall be adopted*~~ in accordance with the examination procedure referred to in Article 74(2).	
R	525a		***The modalities and conditions shall to the best extent possible support flexibility for national competent authorities to establish and operate their AI regulatory***	R

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			sandboxes, foster innovation and regulatory learning and shall particularly take into account the special circumstances and capacities of participating SMEs, including start-ups.	
R	525b		***Those implementing acts shall include common main principles on the following issues:***	R
R	525c		***(a) eligibility and selection for participation in the AI regulatory sandbox;***	R
R	525d		***(b) procedure for the application, participation, monitoring, exiting from and termination of the AI regulatory sandbox, including the sandbox plan and the exit report;***	R
R	525e			R

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			(c) the terms and conditions applicable to the participants.	
R 525f		***6a. For the purpose of paragraph 1 and 1a, the Commission shall play a complementary role, enabling Member States to build on their expertise and, on the other hand, assisting and providing technical understanding and resources to those Member States that seek guidance on the set-up and running of these regulatory sandboxes.***		R
Article 53(a) new				
R 525g		***53 a Modalities and functioning of AI regulatory sandboxes*** ***1. In order to avoid fragmentation across the Union, the Commission, in consultation with the AI office, shall adopt a delegated act detailing the modalities for the establishment, development, implementation, functioning and supervision of the AI regulatory sandboxes, including the eligibility criteria***		R

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		and the procedure for the application, selection, participation and exiting from the sandbox, and the rights and obligations of the participants based on the provisions set out in this Article; ***2. The Commission is empowered to adopt delegated acts in accordance with the procedure referred to in Article 73, no later than 12 months following the entry into force of this Regulation and shall ensure that:*** ***a) regulatory sandboxes are open to any applying prospective provider of an AI system who fulfils eligibility and selection criteria. The criteria for accessing to the regulatory sandbox are transparent and fair and establishing authorities inform applicants of their decision within 3 months of the application;*** ***b) regulatory sandboxes allow broad and equal access and keep up with demand for participation;*** ***c) access to the AI regulatory sandboxes is free of charge for SMEs and start-ups without prejudice to exceptional costs that establishing authorities may recover in a fair and***	

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		proportionate manner; ***d) regulatory sandboxes facilitate the involvement of other relevant actors within the AI ecosystem, such as notified bodies and standardisation organisations (SMEs, start-ups, enterprises, innovators, testing and experimentation facilities, research and experimentation labs and digital innovation hubs, centers of excellence, individual researchers), in order to allow and facilitate cooperation with the public and private sector;*** ***e) they allow prospective providers to to fulfil, in a controlled environment, the conformity assessment obligations of this Regulation or the voluntary application of the codes of conduct referred to in Article 69;*** ***f) procedures, processes and administrative requirements for application, selection, participation and exiting the sandbox are simple, easily intelligible, clearly communicated in order to facilitate the participation of SMEs and start-ups with limited legal and administrative capacities and are streamlined across the Union, in***	

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		order to avoid fragmentation and that participation in a 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; ***g) participation in the AI regulatory sandbox is limited to a period that is appropriate to the complexity and scale of the project.*** ***h) the sandboxes shall facilitate the development of tools and infrastructure for testing, benchmarking, assessing and explaining dimensions of AI systems relevant to sandboxes, such as accuracy, robustness and cybersecurity as well as minimisation of risks to fundamental rights, environment and the society at large*** ***3. Prospective providers in the sandboxes, in particular SMEs and start-ups, shall be facilitated access to pre-deployment services such as guidance on the implementation of this Regulation, to other value-adding services such as help with standardisation documents and***	

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		certification and consultation, and to other Digital Single Market initiatives such as Testing & Experimentation Facilities, Digital Hubs, Centres of Excellence, and EU benchmarking capabilities.		
R 525h			***6b. When national competent authorities consider authorising testing in real world conditions supervised within the framework of an AI regulatory sandbox established under this Article, they shall specifically agree with the participants on the terms and conditions of such testing and in particular on the appropriate safeguards with the view to protect fundamental rights, health and safety. Where appropriate, they shall cooperate with other national competent authorities with a view to ensure consistent practices across the Union.***	R
Article 54				
R 526	Article 54	Article 54	Article 54	R

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	Further processing of personal data for developing certain AI systems in the public interest in the AI regulatory sandbox	Further processing of ~~*personal*~~ data for developing certain AI systems in the public interest in the AI regulatory sandbox	Further processing of personal data for developing certain AI systems in the public interest in the AI regulatory sandbox	
Article 54(1)				
R 527	1. In the AI regulatory sandbox personal data lawfully collected for other purposes shall be processed for the purposes of developing and testing certain innovative AI systems in the sandbox under the following conditions:	1. In the AI regulatory sandbox personal data lawfully collected for other purposes ~~*shall*~~***may*** be processed ***solely*** for the purposes of developing and testing certain ~~*innovative*~~ AI systems in the sandbox ~~*under*~~***when all of*** the following conditions ***are met***:	1. In the AI regulatory sandbox personal data lawfully collected for other purposes ~~*shall*~~***may*** be processed for the purposes of developing**,** ***testing and training of*** ~~*and testing certain*~~ innovative AI systems in the sandbox under the following ***cumulative*** conditions:	R
Article 54(1), point (a)				
R 528	(a) the innovative AI systems shall be developed for safeguarding substantial public interest in one or more of the following areas:	(a) ~~*the innovative*~~ AI systems shall be developed for safeguarding substantial public interest in one or more of the following areas:	(a) the innovative AI systems shall be developed for safeguarding substantial public interest ***by a public authority or another natural or legal person governed by public law or by private law and*** in one or more of the following areas:	R
Article 54(1), point (a)(i)				
G 529	(i) the prevention, investigation,			G

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	detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security, under the control and responsibility of the competent authorities. The processing shall be based on Member State or Union law;	*deleted*	*deleted*	
Article 54(1), point (a)(ii)				
R *530*	*(ii)* public safety and public health, including disease prevention, control and treatment;	(ii) ***public safety and public health, including disease detection, diagnosis prevention, control and treatment;*** ~~***public safety and public health, including disease prevention, control and treatment;***~~	(ii) public safety and ~~*public*~~ health, including ~~*disease*~~ prevention, control and treatment ***of disease and improvement of health care systems***;	R
Article 54(1), point (a)(iii)				
R 531	(iii) a high level of protection and improvement of the quality of the environment;	(iii) 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***;	(iii) ~~*a high level of*~~ protection and improvement of the quality of the environment***, including green transition, climate change mitigation and adaptation***;	R

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R	531a		***(iiia) energy sustainability, transport and mobility;***		R
R	531b	***(iiia) safety and resilience of transport systems, critical infrastructure and networks.***			R
R	531c		***(iiib) efficiency and quality of public administration and public services;***		R
R	531d		***(iiic) cybersecurity and resilience of critical infrastructure.***		R
Article 54(1), point (b)					
G	532	(b) the data processed are necessary for complying with one or more of the requirements referred to in Title III, Chapter 2 where those requirements cannot be effectively fulfilled by	(b) the data processed are necessary for complying with one or more of the requirements referred to in Title III, Chapter 2 where those requirements cannot be effectively fulfilled by	(b) the data processed are necessary for complying with one or more of the requirements referred to in Title III, Chapter 2 where those requirements cannot be effectively fulfilled by	G

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	processing anonymised, synthetic or other non-personal data;	processing anonymised, synthetic or other non-personal data;	processing anonymised, synthetic or other non-personal data;	
Article 54(1), point (c)				
R 533	(c) there are effective monitoring mechanisms to identify if any high risks to the fundamental rights of the data subjects may arise during the sandbox experimentation as well as response mechanism to promptly mitigate those risks and, where necessary, stop the processing;	(c) there are effective monitoring mechanisms to identify if any high risks to the ~~*fundamental rights*~~***rights and freedoms*** of the data subjects***, as referred to in Article 35 of Regulation (EU) 2016/679 and in Article 35 of Regulation (EU) 2018/1725*** may arise during the sandbox experimentation as well as response mechanism to promptly mitigate those risks and, where necessary, stop the processing;	(c) there are effective monitoring mechanisms to identify if any high risks to the ~~*fundamental rights*~~***rights and freedoms*** of the data subjects***, as referred to in Article 35 of Regulation (EU) 2016/679 and in Article 39 of Regulation (EU) 2018/1725,*** may arise during the sandbox experimentation as well as response mechanism to promptly mitigate those risks and, where necessary, stop the processing;	R
Article 54(1), point (d)				
R 534	(d) any personal data to be processed in the context of the sandbox are in a functionally separate, isolated and protected data processing environment under the control of the participants and only authorised persons have access to that data;	(d) any personal data to be processed in the context of the sandbox are in a functionally separate, isolated and protected data processing environment under the control of the ~~*participants*~~***prospective provider*** and only authorised persons have access to that ***those*** 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;	R

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Article 54(1), point (e)				
R	535	(e) any personal data processed are not be transmitted, transferred or otherwise accessed by other parties;	(e) any personal data processed are not ***to*** be transmitted, transferred or otherwise accessed by other parties ***that are not participants in the sandbox, unless such disclosure occurs in compliance with Regulation (EU) 2016/679 or, where applicable, Regulation 2018/725, and all participants have agreed to it***;	R
Article 54(1), point (f)				
R	536	(f) any processing of personal data in the context of the sandbox do not lead to measures or decisions affecting the data subjects;	(f) any processing of personal data in the context of the sandbox do not lead to measures or decisions affecting the data subjects ***nor affect the application of their rights laid down in Union law on the protection of personal data***;	(f) any processing of personal data in the context of the sandbox ~~*do not lead to measures or decisions affecting*~~***shall not affect the application of the rights of*** the data subjects ***as provided for under Union law on the protection of personal data, in particular in Article 22 of Regulation (EU) 2016/679 and Article 24 of Regulation (EU) 2018/1725***;	R
Article 54(1), point (g)				
G	537	(g) any personal data processed in the context of the sandbox are	(g) any personal data processed in the context of the sandbox are	(g) any personal data processed in the context of the sandbox are	G

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

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	technical documentation in Annex IV;	technical documentation in Annex IV;	technical documentation in Annex IV;	
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~~***system*** developed in the sandbox, its objectives, ***hypotheses,*** and expected results, published on the website of the competent authorities~~.~~***;***	(j) a short summary of the AI project developed in the sandbox, its objectives and expected results published on the website of the competent authorities. ***This obligation shall not cover sensitive operational data in relation to the activities of law enforcement, border control, immigration or asylum authorities.***	
540a			***1a. For the purpose of prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security, under the control and responsibility of law enforcement authorities, the processing of personal data in AI regulatory sandboxes shall be based on a specific Member State or Union***	

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			law and subject to the same cumulative conditions as referred to in paragraph 1.	
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 legislation.	2. Paragraph 1 is without prejudice to Union or Member States legislation excluding processing for other purposes than those explicitly mentioned in that legislation.	2. Paragraph 1 is without prejudice to Union or Member States ~~*legislation excluding*~~***laws laying down the basis for the*** processing ***of personal data which is necessary for the purpose of developing, testing and training of innovative AI systems or any other legal basis, in compliance with Union law on the protection of personal data***~~*for other purposes than those explicitly mentioned in that legislation*~~.	
Article 54a new				
541a		***54a Promotion of AI research and development in support of socially and environmentally beneficial outcomes*** ***1. Member States shall promote research and development of AI solutions which support socially and environmentally beneficial outcomes, including but not***		

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		limited to development of AI-based solutions to increase accessibility for persons with disabilities, tackle socio-economic inequalities, and meet sustainability and environmental targets, by: ***(a) providing relevant projects with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions;*** ***(b) earmarking public funding, including from relevant EU funds, for AI research and development in support of socially and environmentally beneficial outcomes;*** ***(c) organising specific awareness raising activities about the application of this Regulation, the availability of and application procedures for dedicated funding, tailored to the needs of those projects;*** ***(d) where appropriate, establishing accessible dedicated channels, including within the sandboxes, for communication with projects to provide guidance and respond to queries about the implementation of this Regulation.***		

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		Member States shall support civil society and social stakeholders to lead or participate in such projects.		
R 541b			***Article 54a*** ***Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes***	R
R 541c			***1. Testing of AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of high-risk AI systems listed in Annex III, in accordance with the provisions of this Article and the real-world testing plan referred to in this Article.***	R
R 541d			***The detailed elements of the real-world testing plan shall be specified in implementing acts***	R

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			adopted by the Commission in accordance with the examination procedure referred to in Article 74(2).	
R	541e		***This provision shall be without prejudice to Union or Member State legislation for the testing in real world conditions of high-risk AI systems related to products covered by legislation listed in Annex II.***	R
R	541f		***2. Providers or prospective providers may conduct testing of high-risk AI systems referred to in Annex III in real world conditions at any time before the placing on the market or putting into service of the AI system on their own or in partnership with one or more prospective users.***	R
R	541g		***3. The testing of high-risk AI***	R

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			systems in real world conditions under this Article shall be without prejudice to ethical review that may be required by national or Union law.	
R 541h			***4. Providers or prospective providers may conduct the testing in real world conditions only where all of the following conditions are met:***	R
R 541i			***(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;***	R
R 541j			***(b) the market surveillance authority in the Member State(s) where the testing in real world conditions is to be conducted have***	R

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			not objected to the testing within 30 days after its submission;	
R 541k			***(c) the provider or prospective provider with the exception of high-risk AI systems referred to in Annex III, points 1, 6 and 7 in the areas of law enforcement, migration, asylum and border control management, and high risk AI systems referred to in Annex III point 2, has registered the testing in real world conditions in the EU database referred to in Article 60(5a) with a Union-wide unique single identification number and the information specified in Annex VIIIa;***	R
R 541l			***(d) the provider or prospective provider conducting the testing in real world conditions is established in the Union or it has appointed a legal representative for the purpose of the testing in real world conditions who is***	R

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			established in the Union;	
R 541m			***(e) data collected and processed for the purpose of the testing in real world conditions shall not be transferred to countries outside the Union, unless the transfer and the processing provides equivalent safeguards to those provided under Union law;***	R
R 541n			***(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;***	R
R 541o			***(g) persons belonging to vulnerable groups due to their age, physical or mental disability are appropriately protected;***	R

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R 541p			***(h) where a provider or prospective provider organises the testing in real world conditions in cooperation with one or more prospective users, the latter have been informed of all aspects of the testing that are relevant to their decision to participate, and given the relevant instructions on how to use the AI system referred to in Article 13; the provider or prospective provider and the user(s) shall conclude an agreement specifying their roles and 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;***	R
R 541q			***(i) the subjects of the testing in real world conditions have given informed consent in accordance with Article 54b, or in the case of law enforcement, where the seeking of informed consent would prevent the AI system from being tested, the testing itself and***	R

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			the outcome of the testing in the real world conditions shall not have a negative effect on the subject;	
R	541r		***(j) the testing in real world conditions is effectively overseen by the provider or prospective provider and user(s) with persons who are suitably qualified in the relevant field and have the necessary capacity, training and authority to perform their tasks;***	R
R	541s		***(k) the predictions, recommendations or decisions of the AI system can be effectively reversed or disregarded.***	R
R	541t		***5. Any subject of the testing in real world conditions, or his or her legally designated representative, as appropriate, may, without any resulting***	R

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			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.	
R	541u		***6. Any serious incident identified in the course of the testing in real world conditions shall be reported to the national market surveillance authority in accordance with Article 62 of this Regulation. The provider or prospective provider shall adopt immediate mitigation measures or, failing that, suspend the testing in real world conditions until such mitigation takes place or otherwise terminate it. The provider or prospective provider shall establish a procedure for the prompt recall of the AI system upon such termination of the testing in real world conditions.***	R

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R	541v		***7. Providers or prospective providers shall notify the national market surveillance authority in the Member State(s) where the testing in real world conditions is to be conducted of the suspension or termination of the testing in real world conditions and the final outcomes.***		R
R	541w		***8. The provider and prospective provider shall be liable under applicable Union and Member States liability legislation for any damage caused in the course of their participation in the testing in real world conditions.***		R
R	541x		***Article 54b*** ***Informed consent to participate in testing in real world conditions outside AI regulatory sandboxes***		R

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
R	541y		***1. For the purpose of testing in real world conditions under Article 54a, informed consent shall be freely given by the subject of testing prior to his or her participation in such testing and after having been duly informed with concise, clear, relevant, and understandable information regarding:***	R
R	541z		***(i) the nature and objectives of the testing in real world conditions and the possible inconvenience that may be linked to his or her participation;*** ***(ii) the conditions under which the testing in real world conditions is to be conducted, including the expected duration of the subject's participation;*** ***(iii) the subject's rights and guarantees regarding participation, in particular his or her right to refuse to participate in and the right to withdraw from testing in real world conditions at any time without any resulting detriment and without having to***	R

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			provide any justification; ***(iv) the modalities for requesting the reversal or the disregard of the predictions, recommendations or decisions of the AI system;*** ***(v) the Union-wide unique single identification number of the testing in real world conditions in accordance with Article 54a(4c) and the contact details of the provider or its legal representative from whom further information can be obtained.***	
R	541aa		***2. The informed consent shall be dated and documented and a copy shall be given to the subject or his or her legal representative.***	
	Article 55			
Y	542	Article 55 Measures for small-scale providers and users	Article 55 Measures for ~~*small-scale providers*~~***SMEs, start-ups*** and users	Article 55 ***Support measures for operators, in particular SMEs, including start-ups*** ~~*measures for small-scale providers and users*~~	
	Article 55(1)			

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G	543	1. Member States shall undertake the following actions:	1. Member States shall undertake the following actions:	
	Article 55(1), point (a)			
Y	544	(a) provide small-scale providers and start-ups with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions;	(a) provide ~~small-scale providers~~**SMEs** and start-ups**, established in the Union,** with priority access to the AI regulatory sandboxes**,** to the extent that they fulfil the eligibility conditions;	(a) provide ~~small-scale providers and~~**SMEs, including** start-ups**,** with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility ~~conditions~~**and selection criteria**;
	Article 55(1), point (b)			
Y	545	(b) organise specific awareness raising activities about the application of this Regulation tailored to the needs of the small-scale providers and users;	(b) organise specific awareness raising **and enhanced digital skills development** activities ~~about~~**on** the application of this Regulation tailored to the needs of ~~the small-scale providers~~**SMEs, start-ups** and users;	(b) organise specific awareness raising **and training** activities about the application of this Regulation tailored to the needs of the ~~small-scale providers and users~~**SMEs, including start-ups, and, as appropriate, local public authorities**;
	Article 55(1), point (c)			
Y	546	(c) where appropriate, establish a dedicated channel for communication with small-scale providers and user and other	(c) **utilise existing dedicated channels and** where appropriate, establish ~~a~~**new** dedicated ~~channel~~**channels** for	(c) where appropriate, establish a dedicated channel for communication with ~~small-scale providers and user and other~~

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	innovators to provide guidance and respond to queries about the implementation of this Regulation.	communication with ~~small-scale providers and user~~***SMEs, start-ups, users*** and other innovators to provide guidance and respond to queries about the implementation of this Regulation~~.~~***;***	~~innovators~~***SMEs, including start-ups and, as appropriate, local public authorities*** to provide ~~guidance~~***advice*** and respond to queries about the implementation of this Regulation***, including as regards participation in AI regulatory sandboxes***.	
Y	546a	***(ca) foster the participation of SMEs and other relevant stakeholders in the standardisation development process.***		Y
Article 55(2)				
Y	547	2. The specific interests and needs of the small-scale providers shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size and market size.	2. The specific interests and needs of the ~~small-scale providers~~***SMEs, start-ups and users*** shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to ***development stage,*** their size***, market size*** and market ~~size~~***demand. The Commission shall regularly assess the certification and compliance costs for SMEs and start-ups,***	2. The specific interests and needs of the ~~small-scale~~***SME*** providers***, including start-ups,*** shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size***, market size and other relevant indicators*** ~~and market size~~.	Y

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		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).		
Y	547a		***2a. The Commission shall undertake the following actions:***	Y
Y	547b		***(a) upon request of the AI Board, provide standardised templates for the areas covered by this Regulation;***	Y
Y	547c		***(b) develop and maintain a single information platform providing easy to use information in relation to this Regulation for all operators***	Y

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			across the Union;		
Y	547d		***(c) organise appropriate communication campaigns to raise awareness about the obligations arising from this Regulation;***		Y
Y	547e		***(d) evaluate and promote the convergence of best practices in public procurement procedures in relation to AI systems.***		Y
R	547f		***Article 55a*** ***Derogations for specific operators***		R
R	547g		***1. The obligations laid down in Article 17 of this Regulation shall not apply to microenterprises as defined in Article 2(3) of the Annex to the Commission***		R

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			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.	
R	547h		***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.***	R
R	547i		***3. Requirements and obligations for general purpose AI systems laid down in Article 4b shall not apply to micro, small and medium-sized enterprises, provided those enterprises do not have partner enterprises or linked enterprises as defined in Article 3 of the the Annex to the Commission Recommendation***	R

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			2003/361/EC concerning the definition of micro, small and medium-sized enterprises.	