Deutscher Bundestag
Ausschuss für Digitales

Ausschussdrucksache
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Deadline for comments: ***6 January 2022***

Presidency compromise text for Artificial Intelligence Act (doc. 14278/21)

Comments and drafting suggestions requested on Articles 30-85, Annexes V-IX)

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
1.	**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**		Germany aims to regulate AI systems and supports the European AI Act. We note that this shall include the swift and simultaneous regulation of AI systems used in public administrations, including public security, migration and asylum authorities as well as customs and tax administrations (including the Financial Intelligence Unit (FIU)). We would like to point out that it will be difficult to meet the specific needs of these public authorities as well as fundamental rights requirements for sovereign actions within the framework of the current provisions of the proposal, which are primarily aimed at private sector businesses and the internal market.

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	(Text with EEA relevance)		Necessary various individual amendments to or exemptions from the current provisions will lead to legal uncertainty among the addressees of the AI Act. In principle, a separate stand-alone legal act to regulate AI systems used by such authorities would be possible. This act would then have to be developed and negotiated quickly and at the same time as the draft AI Act. But in any case, a separate chapter in the draft AI Act should be aimed for to regulate AI systems used by public administrations, including public security, migration and asylum authorities as well as customs and tax administration (including the Financial Intelligence Unit (FIU)), in order to adequately meet the specific needs of these public authorities and fundamental rights requirements for sovereign actions.

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			For these reasons, Germany is currently refraining from commenting comprehensively on the individual provisions of the draft AI Act with regard to the aforementioned authorities and reserves the right to make further comments at a later stage. The German proposals regarding AI systems developed or used for purposes of the defence sector or the armed forces are without prejudice to our proposal to amend Article 2(3) of the draft by way of substituting '[German version: wenn und soweit] they are developed or used for purposes of the defence sector or the armed forces' for 'developed or used exclusively for military purposes'. Please note that these views are preliminary as we are still examining the proposal.

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2.			We would approve a clarification (either in a recital or in a seperate new article) - firstly, with regards to possible legal bases for processing of personal data in the AIA and - secondly, that the GDPR and other EU or national data protection law remains fully applicable, whenever personal data is processed under the AIA. As a starting point we propose the following formulation: This Regulation is without prejudice to the relevant EU data protection legislation, in particular Regulation (EU) 2016/679, Regulation (EU) 2018/1725, Directive 2002/58/EC and Directive (EU) 2016/680, including the corresponding provisions of national law. The Union's legislation for the protection of personal data shall apply to any processing of personal data falling within the scope of this Regulation.

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			In general it seems no OpenSource products can be used for AI application / can be conform with AIA because licenses included disclaimer of warranty and liability. For example EUPL (https://joinup.ec.europa.eu/collection/eupl/eupl-text-eupl-12) article 7 and 8 contains it. Other are GPL, LGPL, Apache, MIT and BSD.
3.	**CHAPTER 4**		
4.			
5.	**NOTIFIYING AUTHORITIES AND NOTIFIED BODIES**		How should notifiying authorities and notified bodies responsible for high-risk AI systems, to which legal acts listetd in Annex II, section A, provide the documentary evidence of its compliance with requirements laid down in Article 33(4), (9) and (10)? For clarification it might be useful to add a rectical.
6.			
7.			

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8.			
9.			
10.	*Article 30* *Notifying authorities*		
11.			
12.	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.	Each Member State shall designate or establish a notifying authority responsible for setting up and carrying out the necessary procedures for the assessment, designation, notification and for their monitoring, of conformity assessment bodies including their compliance with the provisions of Article 34.	
13.			
14.	2. Member States may designate a national accreditation body referred	2. Member States may ~~designate that the a national accreditation body referred to in Regulation (EC) No 765/2008 as a notifying authority.~~ decide that the	The exact wording of R14(2) Decision 768/2008/EC should be used.

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	to in Regulation (EC) No 765/2008 as a notifying authority.	assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.	
15.		(new). The Commission shall provide for the organisation of exchange of experience between national notifying or designating authorities responsible for notification policy.	To improve exchange of experience betweend national notifying or designating authorities responsible for notification policy. Based on R29 Decision 768/2008/EC
16.	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.		
17.			
18.	4. Notifying authorities shall be organised in such a		

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	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.		
19.			
20.	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.		
21.			

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22.	6. Notifying authorities shall safeguard the confidentiality of the information they obtain.		There are different interpretations, if this provision is also applicable to the cross-border exchange of information between notifying or competent authorities and the COM. Therefor we suggest to add the following sentence: "However, notifying authorities shall exchange information on conformity assessment bodies, the Commission and, when required, with other regulatory authorities of other Member States."
23.			
24.	7. Notifying authorities shall have a sufficient number of competent personnel at their disposal for the proper performance of their tasks.		

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25.			
26.	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.		
27.			
28.	*Article 31* *Application of a conformity*		

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	assessment body for notification		
29.			
30.	1. Conformity assessment bodies shall submit an application for notification to the notifying authority of the Member State in which they are established.		
31.			
32.	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	The application for notification shall be accompanied by a description ~~of~~ the conformity assessment activities~~,~~ and the conformity assessment module or modules ~~and the artificial intelligence technologies~~ for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements	No distinction should be made on artificial intelligence (unclear criteria).

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	for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 33. Any valid document related to existing designations of the applicant notified body under any other Union harmonisation legislation shall be added.	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.	
33.			
34.	3. Where the conformity assessment	Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall	The exact wording of R22(3) Decision 768/2008/EC should be used.

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	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	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.	

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	under this Regulation, as appropriate.		
35.			How to deal with changes to the notification? It should be further examined – also within the upcoming Council Working Parties - whether to add a new paragraph based on Article 38(3) Regulation 2017/745: "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."
36.			
37.			
38.	*Article 32* *Notification procedure*		
39.			

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40.	1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 33.		
41.			
42.	2. Notifying authorities shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.	Notifying authorities shall notify the Commission and the other Member States using the electronic notification tool within the database of notified bodies developed and managed by the Commission (NANDO).	For clarification, it is propose to modify the reference provision of R23 Decision 768/2008/EC and to add a reference to the database of notified bodies (NANDO).
43.			
44.	3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or	The notification shall include full details of the conformity assessment activities~~,~~ and the conformity assessment module or modules ~~and the artificial intelligence technologies concerned.~~ which the	For clarification, it is propose to modify the reference provision of R23 Decision 768/2008/EC. It is noted that notified bodies responsible for measuring instruments should not assess AI systems for educational or

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	modules and the artificial intelligence technologies concerned.	notified body is authorised to assess and any conditions associated with the notification.	vocational training. Therefore, it seems useful to differentiate between different product sectors.
45.			
46.			
47.	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.		
48.			
49.	5. Notifying authorities shall notify the Commission and the other Member States of any		We would welcome a clear definition of 'relevant changes'.

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	subsequent relevant changes to the notification.		
50.		(new) The Commission shall immediately publish the amended notification in NANDO.	For clarification, it is propose to modify the reference provision of R23 Decision 768/2008/EC and to add this new paragraph.
51.	*Article 33* *Notified bodies*		
52.			
53.	1. Notified bodies shall verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43.		
54.			
55.	2. Notified bodies shall satisfy the organisational, quality management, resources and process		Maybe specify the requirements by adding a new annex.

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	requirements that are necessary to fulfil their tasks.		
56.			
57.	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.		
58.			
59.	4. Notified bodies shall be independent of the provider of a high-risk AI system in relation to which		

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	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.		
60.			
61.	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		

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	impartiality and to promote and apply the principles of impartiality throughout their organisation, personnel and assessment activities.		
62.			
63.	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		

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	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.		
64.			
65.	7. Notified bodies shall have procedures for the performance of activities which take due account of		

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	the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the AI system in question.		
66.			
67.	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.		
68.			
69.	9. Notified bodies shall be capable of carrying out		

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	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.		
70.			
71.	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		

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	assessment procedure and each type of high-risk AI system in relation to which they have been designated, the notified body shall have permanent availability of sufficient administrative, technical and scientific personnel who possess experience and knowledge relating to the relevant artificial intelligence technologies, data and data computing and to the requirements set out in Chapter 2 of this Title.		
72.			
73.	11. Notified bodies shall participate in coordination activities as referred to in		

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	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.		
74.			
75.	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		

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	surveillance activities and to facilitate the assessment outlined in this Chapter.		
76.			
77.	*Article 34* *Subsidiaries of and subcontracting by notified bodies*		
78.			
79.	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		

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	the notifying authority accordingly.		
80.			
81.	2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.		
82.			
83.	3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the provider.		
84.			
85.	4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents		

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	concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.		
86.			
87.	*Article 35* *Identification numbers and lists of notified bodies designated under this Regulation*		
88.			
89.	1. The Commission shall assign an identification number to notified bodies. It shall assign a single number, even where a body is		Does a notified body receive a new identification number that has already been notified under a legal act listed in Annex II, section A?

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	notified under several Union acts.		
90.			
91.	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.	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 accessible to the public in NANDO. The Commission shall ensure that the list is kept up to date.	
92.			
93.	*Article 36* *Changes to notifications*		
94.			
95.			

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96.			
97.			
98.	1. Where a notifying authority has suspicions or has been informed that a notified body no longer meets the requirements laid down in Article 33, or that it is failing to fulfil its obligations, that authority shall without delay investigate the matter with the utmost diligence. In that context, it shall inform the notified body concerned about the objections raised and give it the possibility to make its views known. If the notifying authority comes		In several sectors the issues of notified bodies ceasing their activities or where a notification has been withdrawn require special provisions to prevent a scenario in which AI systems would lose the marketability during the phase where the provider has to apply for a new qualified notified body. To address this issue this paragraph has been modified from reference provision of R25 Decision 768/2008/EC and further modifications are needed. There are several procedures missing in the event of insufficient implementation of corrective measures or information of providers in the event of notification changes. It is suggested to consider to add relevant paragraphs from Regulation 2017/745 to clarify these procedures.

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	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.		
99.			
100.			
101.	2. In the event of restriction, suspension or withdrawal of notification,		There is no provision/procedure in the event of notified bodies ceasing the conformity assessment activities and in the event of

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	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.		restriction, suspension or withdrawal of a notification as well as exception of certificates unduly issued, and where a notification has been suspended or restricted. It is propose to add paragraphs based on Regulation 2017/745 to clarify these procedures.
102.			
103.			
104.			
105.			
106.	*Article 37* *Challenge to the competence of notified bodies*		
107.			

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108.	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.		
109.			
110.	2. The Notifying authority shall provide the Commission, on request, with all relevant information relating to the notification of the notified body concerned.		This paragraph has been modified from reference provision of R26 Decision 768/2008/EC and there is a further modification needed that the notifying authority shall monitor the notified bodies.
111.			
112.	3. The Commission shall ensure that all confidential information		

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	obtained in the course of its investigations pursuant to this Article is treated confidentially.		
113.			
114.	4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements laid down in Article 33, it shall adopt a reasoned decision requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary. That implementing act shall be adopted in accordance with	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~~ inform the notifying ~~Member State~~ authority to take the necessary corrective measures, including withdrawal of notification 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). It shall notify the notifying authority concerned of its decision and update NANDO.	Clarification. COM responsibilities in event of insufficient corrective measures. increase transparency.

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	the examination procedure referred to in Article 74(2).		
115.			
116.	*Article 38* *Coordination of notified bodies*		
117.			
118.	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	The Commission shall ensure that, with regard to the ~~areas covered by this Regulation~~ high-risk AI systems covered by Annex III, 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**.**	Exception for Annex II products.

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	form of a sectoral group of notified bodies**.**		
119.			
120.	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.	The notifying authority ~~Member States~~ shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.	Clarification
121.		(new) The Commission may establish the specific arrangements for the functioning of the coordination group of notified bodies.	To increase functioning of coordination group of notified bodies, it is propose to modify the reference provision of R30 Decision 768/2008/EC and to add this new paragraph.
122.			
123.	*Article 39* *Conformity assessment bodies of third countries*		
124.			
125.	Conformity assessment bodies established under	~~an~~ a respective agreement	To increase precision.

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	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.		
126.			
127.			
128.			
129.	**CHAPTER 5**		
130.			
131.	**STANDARDS, CONFORMITY ASSESSMENT, CERTIFICATES, REGISTRATION**		
132.			

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133.	*Article 40* *Harmonised standards*		
134.			
135.	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 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~~ in this Regulation, to the extent those standards cover those requirements. This proposal will be reconsidered in light of any alterations of the exemption clause contained in Article 2(3) of the draft	Taking into account other requirements, e. g. quality management system, post-market-surveilliance system, etc.. The initial draft shall become paragraph 1 and a second paragraph addressing conformity requirements specific to high-risk AI systems developed or used for purposes of the defence sector or the armed forces. In as much as such AI systems are not exempt from the application of the Regulation by virtue of Article 2(3) of the draft they will nevertheless be developed or used in accordance with relevant military standards. Compliance with these military standards, some of which may be classified or

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		(2) High-risk AI systems developed or used for purposes of the defence sector or the armed forces or national security purposes, which are in conformity with relevant military standards, including military standards adopted in the framework of the North Atlantic Treaty Organization, shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title for the purposes of this Regulation.	otherwise outside the public domain, shall be deemed equivalent to compliance with standards the references of which have been published in the Official Journal of the European Union.
136.			
137.	*Article 41* *Common specifications*		We welcome that the COM announced on 10th December 2021 in the Committee on Standards to provide an explanatory document on the subject of implementing acts/common specifications. There are still considerable reservations about authorising the COM to lay down specifications without the participation of the member states

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			and on an unspecific basis ('insufficient standards') and we reserve the right to further examine the relevant paragraphs for a horizontal comparison of the proposals currently under discussion in the various texts of the regulations submitted. We therefore ask the COM to present the announced paper quickly so that the corresponding regulatory projects are not delayed too much.
138.			
139.	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	1. Where harmonised standards referred to in Article 40 paragraph 1 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, environmental ~~or~~ fundamental right or environmental concerns, the Commission may, by means of implementing acts,	The application of high-risk AI systems might result in environmental outcomes that are unintended or difficult to estimate and address as of today, such as novel risks to the environment stemming from use cases not yet conceived. The explicit mention of environmental concerns as an impetus to adopt common specifications would strengthen the

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	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).	adopt common specifications in respect of the requirements set out in Chapter 2 of this Title.	Unions commitment to align the application of AI with the European Green Deal.
140.			
141.	2. The Commission, when preparing the common specifications referred to in paragraph 1,		

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	shall gather the views of relevant bodies or expert groups established under relevant sectorial Union law.		
142.			
143.	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.		
144.			

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145.	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.		
146.			
147.	*Article 42* *Presumption of conformity with certain requirements*		
148.			
149.	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		

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	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).		
150.		1a. High-risk AI systems that have been trained or tested on data provided or approved for purposes of the defence sector or the armed forces shall be presumed to be in compliance with the requirement set out in Article 10(4).	Inasmuch as high-risk AI systems developed or used for purposes of the defence sector or the armed forces are not exempt from the application of the Regulation by virtue of Article 2(3) of the draft they should be presumed to be in compliance with the requirement set out in Article 10(4) if they are trained on data provided or approved for these purposes.
151.	2. High-risk AI systems that have been certified or for which a statement of conformity has been issued under a cybersecurity		

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	scheme pursuant to Regulation (EU) 2019/881 of the European Parliament and of the Council[1] and the references of which have been published in the Official Journal of the European Union shall be presumed to be in compliance with the cybersecurity requirements set out in Article 15 of this Regulation in so far as the cybersecurity certificate or statement of conformity or parts thereof cover those requirements.		
152.			

[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).

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153.	*Article 43* *Conformity assessment*	3. For high-risk AI systems where the provider is a credit institutions regulated by Directive 2013/36/EU or an entity regulated by Directive 2009/138/EC, Directive (EU) 2016/2341, Directive 2014/65/EU resp. Directive (EU) 2015/2366, Directive 2009/65/EG and Directive 2011/61/EU, conformity is assumed when these entities fulfill the requirements following Directive 2013/36/EU, Directive 2009/138/EC, Directive (EU) 2016/2341, Directive 2014/65/EU, Directive (EU) 2015/2366, Directive 2009/65/EG resp. Directive 2011/61/EU to the extent those Directives cover the requirements set out in this Regulation.	As the entities regulated by Directive 2013/36/EU, Directive 2009/138/EC, Directive (EU) 2016/2341, Directive 2014/65/EU, Directive (EU) 2015/2366, Directive 2009/65/EG resp. Directive 2011/61/EU already follow highest standards, conformity of high-risk AI systems provided by them should be assumed when they fulfill the respective requirements to the extent that those requirements cover the requirements set out in this Directive. In view of the following statements from recital 64 as well as from the explanation to chapter 4, we ask for clarification to what extent this is only intended as a transitional arrangement to restrict conformity assessment by third parties and what conditions must be met for it to be extended.

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			Recital 64: Given the more extensive experience of professional pre-market certifiers in the field of product safety and the different nature of risks involved, it is appropriate to limit, at least in an initial phase of application of this Regulation, the scope of application of third-party conformity assessment for high-risk AI systems other than those related to products. Therefore, the conformity assessment of such systems should be carried out as a general rule by the provider under its own responsibility, with the only exception of AI systems intended to be used for the remote biometric identification of persons, for which the involvement of a notified body in the conformity assessment should be foreseen, to the extent they are not prohibited. AIA, page 14:

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			Chapter 4 sets the framework for notified bodies to be involved as independent third parties in conformity assessment procedures, while Chapter 5 explains in detail the conformity assessment procedures to be followed for each type of high-risk AI system. The conformity assessment approach aims to minimise the burden for economic operators as well as for notified bodies, whose capacity needs to be progressively ramped up over time.
154.			
155.	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	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~~this Regulation, the provider has applied harmonised standards referred to in Article 40, or, where applicable, common	Taking into account other requirements, e. g. quality management system, post-market-surveilliance system, etc..

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	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:	specifications referred to in Article 41, the provider shall follow one of the following procedures: 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 paragraph (1), or	This addition reflects the addition of Article 40(2).
156.			
157.	(a) the conformity assessment procedure based on internal control referred to in Annex VI;		
158.			
159.	(b) the conformity assessment procedure based on assessment of the quality management system and assessment of		

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	the technical documentation, with the involvement of a notified body, referred to in Annex VII.		
160.			
161.	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	Where, in demonstrating the compliance of a high-risk AI system listed in point 1 of Annex III with the requirements set out in ~~Chapter 2 of this Title~~this Regulation, 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.	Clarification and taking into account other requirements, e. g. quality management system, post-market-surveilliance system, etc..

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	shall follow the conformity assessment procedure set out in Annex VII.		
162.			
163.	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		It might be helpful to clarify whether providers may choose any notified body across the EU.

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	applicable, shall act as a notified body.		
164.			
165.	2. For high-risk AI systems referred to in points 2 to 8 of Annex III, providers shall follow the conformity assessment procedure based on internal control as referred to in Annex VI, which does not provide for the involvement of a notified body. For high-risk AI systems referred to in point 5(b) of Annex III, placed on the market or put into service by credit institutions regulated by Directive 2013/36/EU, the	~~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~~to 101 of that Directive.~~	As the procedure referred to in Art. 97 to 101 in the Directive 2013/36/EU concerns supervisory and evaluation processes conducted by the supervisory authority, we do not see how the product-oriented, internal conformity assessment of high-risk AI systems could be part of it. Please specify how the internal product-oriented conformity assessment is meant to be included in the procedure referred to in Art. 97 to 101 in the Directive 2013/36/EU and why this would seemingly include the involvement of a supervisory authority, whereas for all other AI systems in point 2 to 8 of Annex III, an assessment based on internal control is sufficient.

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	conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to 101 of that Directive.		It remains unclear whether the AI Act poses additional requirements for entities already regulated by comprehensive financial sector regulation. Please specify how the AI Act does avoid double regulation for the highly regulated financial sector.
166.			
167.	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.,	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~~ this Regulation 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.	Taking into account other requirements, e. g. quality management system, post-market-surveilliance system, etc..

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	4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII shall also apply.		
168.			
169.	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		

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	procedure under those legal acts.		
170.			
171.	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 referred to in Article 41, covering the	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 referred to in Article 41, covering the requirements set out in ~~Chapter 2 of this Title~~ this Regulation.	Taking into account other requirements, e. g. quality management system, post-market-surveilliance system, etc..

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	requirements set out in Chapter 2 of this Title.		
172.			
173.	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.		The different sectors listed in Annex II section A consider substantial modifications of the products concerns differently. There might be cases that non-substantial changes (according to the AI regulation) of the AI-part are considered as substantial changes under the specific sector legislation. In these cases. the concerned High-risk AI systems shall also undergo a new conformity procedure whenever the modification are considered as being substantially under legal acts listed in Annex II, section A. For clarification, it is proposed to add the following sentence: “High-risk AI systems, to which legal acts listed in Annex II, section A, apply, shall undergo a

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
			new conformity procedure whenever they are substantially modified under those legal acts."
174.			
175.	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 optimisation, except changes regarding the intended purpose and use, 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.	Allow changes to performance optimisation and minior software changes. Changes to the intended purpose and use must be excluded.

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
176.			
177.	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.		
178.			
179.	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	The Commission is empowered to adopt delegated acts in accordance with Article 73 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.	Consequential amendments of Article 73

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	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.	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, the ~~and~~ protection of fundamental rights and the environment posed by such systems as well as the availability of adequate capacities and resources among notified bodies.	When deciding on the necessity 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, the Commission should also consider the effectiveness of the conformity assessment procedure based on internal control in preventing or miniziming risks to the environment. A strong and consistent recognition of the importance of environmental protection would demonstrate a holistic and value-based understanding of the risks and potentials of AI. It would distinguish the Union from other global actors and sharpen the profile of the European approach to AI.

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180.			
181.	*Article 44* *Certificates*	*Article 44* *Certificates of conformity*	Clarification
182.			
183.	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.		
184.			
185.	2. Certificates shall be valid for the period they indicate, which shall not exceed five years. On		In event of certain changes to the product portfolio or to the existing quality management system, the Notified Body usually issues supplements to the existing certificates. These supplements are generally only valid together

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	application by the provider, the validity of a certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures.		with the underlying certificate and therefore cannot be valid longer than the certificate they supplement. It should be further examined – also within the upcoming Council Working Parties - whether to add the following sentence "Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid."
186.			
187.	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,	Where a notified body finds that an AI system no longer meets the requirements set out in ~~Chapter 2 of this Title~~ this Regulation, 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.	Taking into account other requirements, e. g. quality management system, post-market-surveilliance system, etc..

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	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.		
188.			
189.	*Article 45* *Appeal against decisions of notified bodies*	~~*Article 45*~~ ~~*Appeal against decisions of notified bodies*~~	
190.			
191.	Member States shall ensure that an appeal procedure against decisions of the notified bodies is available to parties having a	~~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.~~	The term "parties having a legitimate interest" is too broad. It also allows appeal in event of positive notifications of products. Furthermore the rule is inconsistent to Article 43(6) and the empowerment of the EU COM.

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	legitimate interest in that decision.		
192.			
193.	*Article 46* *Information obligations of notified bodies*		
194.			
195.	1. Notified bodies shall inform the notifying authority of the following:		
196.			
197.	(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;		

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198.			
199.	(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;		
200.			
201.	(c) any circumstances affecting the scope of or conditions for notification;		
202.			
203.	(d) any request for information which they have received from market surveillance authorities		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	regarding conformity assessment activities;		
204.			
205.	(e) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.		
206.			
207.	2. Each notified body shall inform the other notified bodies of:		
208.			
209.	(a) quality management system approvals which it has refused, suspended or		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	withdrawn, and, upon request, of quality system approvals which it has issued;		
210.			
211.	(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.		
212.			
213.	3. Each notified body shall provide the other notified bodies carrying out similar conformity		

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	assessment activities covering the same artificial intelligence technologies with relevant information on issues relating to negative and, on request, positive conformity assessment results.		
214.			
215.	*Article 47* *Derogation from conformity assessment procedure*		May be add a paragraph to empower the EU COM by means of implementing acts extend for a limited period of time the validity of an authorisation to the territory of the Union
216.			
217.	1. By way of derogation from Article 43, any market surveillance authority may authorise the placing on the market or putting into service of	By way of derogation from Article 43, ~~any market surveillance~~ a competent authority may authorise, on a duly justified request, 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~~ for which the applicable	Only one competent authority shall authorise, on a duly justified request.

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	specific high-risk AI systems within the territory of the Member State concerned, for exceptional reasons of public security or the protection of life and health of persons, environmental protection and the protection of key industrial and infrastructural assets. That authorisation shall be for a limited period of time, while the necessary conformity assessment procedures are being carried out, and shall terminate once those procedures have been completed. The completion	requirements referred to in this Regulation have not been carried out but use which is in interest of public security or the protection of life and health of persons, environmental protection and the protection of key industrial and infrastructural assets. That authorisation shall be for a limited period of time, while the necessary conformity assessment procedures are being carried out, and shall terminate once those procedures have been completed. The completion of those procedures shall be undertaken without undue delay.	Specify exceptional reasons.

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	of those procedures shall be undertaken without undue delay.		
218.			
219.	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.	The authorisation referred to in paragraph 1 shall be issued only if the ~~market surveillance~~ competent authority concludes that the high-risk AI system complies with the requirements of ~~Chapter 2 of this Title~~ this Regulation. The ~~market surveillance~~ competent authority shall inform the Commission and the other Member States of any authorisation issued pursuant to paragraph 1.	Consequential amendments and taking into account other requirements, e. g. quality management system, post-market-surveilliance system, etc..
220.			

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221.	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.	~~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.~~	These are national decisions that are only be valid at national level. Any objection of a Member State or the COM is an intervention in the sovereignty of a state.
222.			
223.	4. Where, within 15 calendar days of receipt of the notification referred to in paragraph 2, objections are raised by a Member	~~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~~	These are national decisions that are only be valid at national level. Any objection of a Member State or the COM is an intervention in the sovereignty of a state.

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	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	~~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.~~	

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	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.		
224.			
225.	5. If the authorisation is considered unjustified, this shall be withdrawn by the market surveillance authority of the Member State concerned.	~~If the authorisation is considered unjustified, this shall be withdrawn by the market surveillance authority of the Member State concerned.~~	Consequential amendments
226.			
227.	6. By way of derogation from paragraphs 1 to 5, for high-risk AI systems	By way of derogation from paragraphs 1 to ~~5~~2, for high-risk AI systems intended to be used as safety components of devices, or which are themselves	Consequential amendments and taking into account other requirements, e. g. quality

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	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.	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~~ this Regulation.	management system, post-market-surveilliance system, etc..
228.		7. Member States' military authorities may authorise the putting into service of high-risk AI systems developed for purposes of the defence sector or the	This addition reflects the addition of Article 40(2).

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
		armed forces, or national security purposes. The authorisation shall be issued only if the high-risk AI system complies with the requirements specified in Article 40 paragraph (2).	
229.			
230.	*Article 48* *EU declaration of conformity*		
231.			
232.	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		Does the provider shall draw up a written declaration of conformity before each single AI system is placed on the market or only before the first AI system or a new version of an AI System? Our understanding is that the written declaration of conformity covers several AI system of the same version which are placed on the market or put into service.

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	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.		
233.			
234.	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	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~~ this Regulation. 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.	Taking into account other requirements, e. g. quality management system, post-market-surveilliance system, etc..

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	languages required by the Member State(s) in which the high-risk AI system is made available.		
235.			
236.	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		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	legislation to which the declaration relates.		
237.			
238.	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 **laid down in this regulation**~~set out in Chapter 2 of this Title.~~ The provider shall keep the EU declaration of conformity up-to-date as appropriate.	The reference to title 2, chapter 2 is not correct.
239.			
240.	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		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	declaration of conformity set out in Annex V in order to introduce elements that become necessary in light of technical progress.		
241.		(new) Where high-risk AI systems are subject to other Union legislation which also provides for the EU declaration of conformity, the EU declaration of conformity shall indicate that the high-risk AI systems also fulfil the requirements of that other legislation.	Avoid additional EU declaration
242.			
243.	*Article 49* *CE marking of conformity*		
244.			
245.		(new) High-risk AI systems that do not have an authorisation referred to Article 47 and that are in conformity with the requirements of this Regulation shall bear the CE marking of conformity.	Consequential amendments of Article 47.

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
246.		(new) 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.	Moved from paragraph 2 (old)
247.	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.		
248.			
249.	2. The CE marking referred to in paragraph 1 of this Article shall be	The CE marking shall be affixed before the high-risk AI system is placed on the market. It may be	In healthcare, there are some standardised pictogram or any other mark indicating a special risk or use.

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	subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.	followed by a pictogram or any other mark indicating a special risk or use.	
250.			
251.	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		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	requirements for CE marking.		
252.		(new) Where high-risk AI systems are subject to other Union legislation which also provides for the affixing of the CE marking, the CE marking shall indicate that the high-risk AI systems also fulfil the requirements of that other legislation.	Avoid additional CE marking
253.			
254.	*Article 50* *Document retention*		
255.			
256.	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:		
257.			

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258.	(a) the technical documentation referred to in Article 11;		
259.			
260.	(b) the documentation concerning the quality management system referred to Article 17;		
261.			
262.	(c) the documentation concerning the changes approved by notified bodies where applicable;		
263.			
264.	(d) the decisions and other documents issued by the notified bodies where applicable;		
265.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
266.	(e) the EU declaration of conformity referred to in Article 48.		
267.			
268.	*Article 51* *Registration*		
269.			
270.	Before placing on the market or putting into service a high-risk AI system referred to in Article 6(2), the provider or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60.		Depends from the definition of putting into service. Only high-risk AI systems which are not placed on the market but put into service (because the AI-System was programmed produced at the facility of the user/operator) shall be registered. High-risk AI systems placed on the market will be registered.
271.		2. Before using an AI system, public authorities shall register the use of that system in the EU database referred to in Article 60a.	Due to the unique role and responsibility public authorities bear, the sensitive personal data they have access to, the consequential effects their

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			decisions have on individuals, and thus their primary obligation to respect, protect and fulfil fundamental rights, public authorities should be subject to more stringent transparency requirements when using AI systems. Hence, any deployments of AI systems – regardless of their level of risk – by or on behalf of public authorities should be registered within a separate EU database if applicable in addition to the registration as High Risk AI in the database referred to in Article 60.
272.			
273.	**TITLE IV**		
274.			
275.	**TRANSPARENCY OBLIGATIONS FOR CERTAIN AI SYSTEMS**	**TRANSPARENCY ~~OBLIGATIONS~~ REQUIREMENTS FOR CERTAIN AI SYSTEMS**	
276.			

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277.	*Article 52* *Transparency obligations for certain AI systems*	*Article 52* *Transparency ~~obligations~~requirements for certain AI systems*	In order to accommodate the AI-specific environmental and sustainability aspects, appropriate changes should be made. For example, DE strongly considers laying down horizontal transparency rules in Art. 52 in order to enable providers and users to lower the energy and resource consumption caused by the development and the application of AI systems and to contribute to reach the goal of carbon neutrality.
278.			
279.	1. Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in	~~1.~~ Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that natural persons are informed that they are interacting with an AI system, unless this is obvious from the	To increase transparency for all users. In this context, we want to emphasize the particular importance of AI in the area of media as well as in democratic processes.

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	such a way that natural persons are informed that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences, unless those systems are available for the public to report a criminal offence.	circumstances and the context of use. This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences, unless those systems are available for the public to report a criminal offence.	By the use of these applications, public discourse can be manipulated and thus significantly influenced. It is therefore important that this regulation does not preclude further regulation in this area. Furthermore, the information of the user should be as uniform and simple as possible.
280.		Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that natural persons are informed that they are interacting with an AI system,	Obviousness is no objective criteria. To guarantee that the interaction with an AI is recognizable for persons with different kinds of disabilities we suggest to delete this addition.

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		~~unless this is obvious from the circumstances and the context of use~~.	
281.			
282.		**TITLE IVA**	
283.		**INFORMATION TO BE PROVIDED TO NATURAL PERSONS**	Regarding supervision, it would still be necessary to discuss further which authorities should be responsible for enforcing the respective obligations under this Title. Contradictions with the supervisory responsibilities under the GDPR as well as supervisory structures under other Union legislation should be avoided.
284.			
285.		***Art. 52a*** ***Information to be provided for emotion recognition and biometric categorisation systems***	
286.			
287.		1. Users of an emotion recognition system or a biometric categorisation system shall inform of the	

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		operation of the system the natural persons exposed thereto. This obligation shall not apply to AI systems used for biometric categorisation, which are permitted by law to detect, prevent and investigate criminal offences.	
288.			
289.		2. Users of an AI system that generates or manipulates image, audio or video content that appreciably resembles existing persons, objects, places or other entities or events and would falsely appear to a person to be authentic or truthful ('deep fake'), shall disclose that the content has been artificially generated or manipulated.	
290.			
291.		However, the first subparagraph shall not apply where the use is authorised by law to detect, prevent, investigate and prosecute criminal offences or it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental	

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		Rights of the EU, and subject to appropriate safeguards for the rights and freedoms of third parties.	
292.			
293.		***Art. 52b*** ***Information to be provided for high-risk AI systems***	
294.			
295.		1. Users of High Risk-AI systems shall provide the person affected by a decision at least partially determined by the output of the AI system ("Affected Person") with standardized information about	One of the primary reasons why AI is being regulated at all is to protect individuals from the risks generated by AI systems to fundamental rights and to create trust. In this context, the need for transparency is one of the main factors explicitly addressed by the AIA. The GDPR already grants certain rights to information to natural persons/data subjects. However, the GDPR does not sufficiently cover constellations where AI systems are involved. For example, Articles 22, 13 (2) (f), 14 (2) (g) and 15 (1) (h)

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			address automated processing, but these provisions only cover cases where natural persons are directly exposed to automated decision making. This would – at least according to the wording of the GDPR - not cover the constellation that AI is used to prepare a decision ultimately made by a human (for example, an AI might provide a credit rating score that a bank employee uses to decide on the granting of a loan to a natural person).This constellation may have consequences for the natural person that can be just as serious as where the natural person is direclty exposed to automated processing, and gives therefore rise to a similar need for protection. It is necessary for an affected natural person to understand the risks which they are being subjected to in order to be able to seek redress. Therefore, we consider it necessary to include an obligation of the user to provide the affected

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			natural person with standardized information on the use and general function of the AI system and to include a substantive right for affected persons to request further information on the input data and the relevant data categories, in constellations, where an AI system is used to prepare a human decision. We also consider it necessary to supplement the existing information requirements in the GDPR with some further information that seem necessary specifically in the context of AI systems in order to provide natural persons with all relevant knowledge to understand their situation.. With the suggested Article 52b, we aim to avoid any duplication or overlapping with existing rights under the GDPR, but merely to supplement them only to the extent necessary, as it is important to avoid legal uncertainty

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			regarding the relation of this Regulation to the GDPR. In addition to the implementation of Art. 52b new, the following sentence should be added to Recital 43: „Natural persons affected by decisions at least partially determined by high-risk AI systems (this includes decisions that were made after a high-risk AI system provided a recommendation for the decision) placed on the EU market or otherwise put into service should be informed in an appropriate, easily accessible and comprehensible manner about the use of the AI system, the role and purpose of the AI system in the decision-making process, the logic involved and the main parameters of decision making. Such information could be provided in electronic form, for example, when addressed to the public, through a user‘s website while providing the link to this website at the

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			time the decision is communicated to the affected person. For this purpose, with regard to the standardized information to be provided under para. 1 and 2, the user should be able utilise the information received from the provider according to article 13 paragraph 3 letters b and d. With regard to the individual explanation according to para. 3, the affected natural person must be provided with the individual input data relating to the affected natural person and the relevant data categories that serve as the main parameters on the basis of which the output was given." Furthermore, the term "affected natural person" should be defined in Art. 3 AIA. The rights of the persons affected are limited by the wording to individual persons. This does not include the protection or representation of

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			collective interests. This means that particularly vulnerable groups or groups at risk of discrimination can exercise their rights less effectively. Possibilities for collective enforcement still need to be examined within the federal government. Generally, it has to be made sure that Union or Member State law containing prohibitions of disclosure or relevant restrictions on the affected person's right of access to the information covered by Art. 52a (new) remains unaffected, especially in the area of law enforcement. For example: In case of suspicion of money laundering, the competent authority (Financial Intelligence Unit, "FIU") is prohibited to reveal information to the affected person (based on Art. 41 para. 4 EU-act). Therefore, we suggest to add para. 4 or a similar provision inspired by Art. 23 GDPR saying that the obligations or

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			rights granted under Art. 52 a (new) can be restricted by Union or Member State law that e.g. prohibits or restricts the user of the AI system to reveal the information, provided that such a prohibition or restriction respects the essence of the fundamental rights and freedoms and is a necessary and proportionate measure in a democratic society.
296.			
297.		(a) the fact that an AI system has been used within the context of the decision-making process;	
298.			
299.		(b) a reference to the EU-data base as referred to in Art 51, 60 and Annex VIII;	
300.			
301.		(c) the general role and purpose of the AI system in the decision-making-process;	
302.			
303.		(d) the relevant data categories of the input data;	

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304.			
305.		(e) information provided to the user pursuant to Article 13 paragraph 3 letters b and d; and	
306.			
307.		(f) the right to receive an explanation upon request according to paragraph 3.	
308.			
309.		The information shall be provided at the time the decision is communicated to the affected natural person.	
310.			
311.		2. Where a high-risk AI system is used for automated individual decision-making, including profiling, within the meaning of Article 22 of Regulation (EU) 2016/679, information according to Articles 13 (2) (f), 14 (2) (f) and 15 (1) (h) of Regulation (EU) 2016/679 shall also comprise	Paragraph 2 only covers situations that are already covered by automated processing in accordance with Article 22 of the GDPR (i.e., constellations where a natural person is exposed directly to an AI system). In these constellations, information obligations under the

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		information according to paragraph (1) (b), (d), (e) and (f).	GDPR are extented to certain further, AI specific information accordingt to paragraph 1.
312.			
313.		3. Users of high-risk AI systems shall provide the affected natural person upon his or her request in addition to the standardized information provided according to paragraph 1 with concise, complete, correct and clear explanation of the individual input data relating to the affected natural person and the relevant data categories on the basis of which the decision was made.	
314.			
315.		4. Paragraph 1 (e),2 insofar as it refers to paragraph 1 lit. (e) and paragraph 3 shall not apply to the use of AI systems that are authorised by law to detect, prevent, investigate and prosecute criminal offences.	
316.			
317.		5. Paragraph 1 to 3 shall not apply to the use of AI systems	

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318.			
319.		(a) for which exceptions from, or restrictions to, the obligations under this Article follow from Union or Member State law (such as a prohibition or restriction to disclose information covered by paragraph 1 and 2 to the affected person), which lays down appropriate other safeguards for the affected person's rights and freedoms and legitimate interests when such an exception or restriction respects the essence of the fundamental rights and freedoms and is a necessary and proportionate measure in a democratic society; or	
320.			
321.		(b) that have only minor influence within the decision-making process.	
322.			
323.		6. Information according to paragraph 1 to 3 shall be given in a concise, transparent, intelligible and	

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		easily accessible form appropriate to different kinds of disabilities, using clear and plain language.	
324.			
325.		***Article 52c*** ***Relation to Title III***	
326.			
327.		Obligations under this Title shall not affect the requirements and obligations set out in Title III of this Regulation.	This corresponds to the current Article 52(4) and should apply to the entire title.
328.			
329.	**TITLE IVA**		
330.			
331.	**GENERAL PURPOSE AI SYSTEMS**	**GENERAL PURPOSE AI SYSTEMS**	
332.			

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333.	*Article 52a*		**We ask for an explanation of general purpose AI systems and the exact intention behind the presidency proposal.** We understand the goal to foster the development of innovative AI systems. However, we are concerned that Article 52a might have adverse effects. How can the persons mentioned in para 2 and 3 fulfil the requirements of the AIA, if the providers of the general purpose AI systems do not cooperate and provide the necessary information, e.g. with reference to trade secrets? This could make it impossible to place AI systems with an intended purpose on the markets. Furthermore, from a data protection point of view, it does not seem to be justified to exclude general purpose AI systems from the scope of the AIA. How can risks like automation bias,

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			deep fakes and transparency concerns be tackled if the development of general AI systems for image/speech recognition, audio/video generation are not subject to the requirements set out title 3? If a general AI system inherits automation bias, the persons mentioned in para 2 and 3 can hardly fix it. .
334.			
335.	***General purpose AI systems***	***General purpose AI systems:***	***The newly introduced concept of general purpose AI systems has not yet been sufficiently examined within the German Government. Futher explanation and discussion is needed. In any case we encourage to add a definition of general purpose AI systems. This should be done within the scope of the definitions and not within the framework of Art. 52 a.***
336.			

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337.	**1. The placing on the market, putting into service or use of general purpose AI systems shall not, by themselves only, make those systems subject to the provisions of this Regulation.**	1. The placing on the market, putting into service or use of general purpose AI systems shall not, by themselves only, make those systems subject to the provisions of this Regulation.	General purpose AI systems, the requirements for them and the scope of the Article are unclear. There is no definition of general purpose AI system.
338.			
339.	**2. Any person who places on the market or puts into service under its own name or trademark or uses a general purpose AI system made available on the market or put into service for an intended purpose that makes it subject to the provisions of this Regulation shall be**	2. Any person who places on the market or puts into service under its own name or trademark or uses a general purpose AI system made available on the market or put into service for an intended purpose that makes it subject to the provisions of this Regulation shall be considered the provider of the AI system subject to the provisions of this Regulation.	**The transition from a "user" to a "provider" with regard to the new definition of "general purpose AI" is not sufficiently clear. Since the role of the "provider" is linked to essential obligations, the transition from "user" to "provider should be clarified in the respective definitions.** **That discussion should take place in the context of the announced changes to the definitions of "provider" and "user" and not in the context of Article 52a.**

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	considered the provider of the AI system subject to the provisions of this Regulation.		
340.			
341.	**3. Paragraph 2 shall apply, mutatis mutandis, to any person who integrates a general purpose AI system made available on the market, with or without modifying it, into an AI system whose intended purpose makes it subject to the provisions of this Regulation.**	3. Paragraph 2 shall apply, mutatis mutandis, to any person who integrates a general purpose AI system made available on the market, with or without modifying it, into an AI system whose intended purpose makes it subject to the provisions of this Regulation.	
342.			
343.	**4. The provisions of this Article shall apply**		

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	irrespective of whether the general purpose AI system is open source software or not.		
344.			
345.		**TITLE IV B**	
346.		***Article 52c***	
347.	**4. The provisions of this Article shall apply irrespective of whether the general purpose AI system is open source software or not.**	**~~4. The provisions of this Article shall apply irrespective of whether the general purpose AI system is open source software or not.~~** **If a general purpose AI system or an AI system specified for an intended purpose is misappropriated for purposes falling under the provisions of Article 5, Article 6 or Annex III, it shall be subject to the regulations covering the purpose it is used for and not only the "intended purpose"**	**The wording "intended purpose" and the newly provided Article 52a, paragraphs 1-4 leaves the door wide open for misappropriation of systems specified for purposes not falling under this regulation. Somewhere this needs to reflected.**
348.			

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349.	**TITLE V**		
350.			
351.	**MEASURES IN SUPPORT OF INNOVATION**		
352.			
353.	*Article 53* *AI regulatory sandboxes*		We ask for further clarification with regards to the concrete setting of the AI sandboxes. How would a "controlled environment" be guaranteed? How do the competent authorities and the EDPS ensure "supervision and guidance"? Do they provide and/or control the technological infrastructure of the sandboxes? From a data protection point it is of utmost importance, that the AI regulatory sandboxes are understood as "safe spaces" that are established and run by the aforementioned authorities which allows an effective public control and supervision. This is a mandatory requirement to justify the privileges that are granted under Art. 53 et seqq. AIA, especially with regards to the processing of special categories of personal data.

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			The regulatory sandboxes enable the development of AI systems - under supervision and guidance -according to a specific plan. The establishment and definition of the basic conditions for the management, supervision and liability of the regulatory sandboxes is governed by the competent authorities referred to in Article 59 of the AI Regulation. It is necessary for the regulation to be designed in such a way that the development of AI systems through a regulatory lab will be possible for FIUs.
354.			
355.	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	1. AI regulatory sandboxes established by one or more Member States competent authorities or the European Data Protection Supervisor in accordance with the provisions of Title V of this Regulation shall provide a controlled environment that facilitates the development, testing, training, and validation of innovative AI systems for a limited time before their placement on the market or putting	Add *"in accordance with the provisions of Title V of this Regulation"*: Since there are also regulatory sandboxes related to AI in other regulatory areas in some Member States, it should be clarified that AI regulatory sandboxes as defined in this regulation are meant here. Add term *"training"*. Training of the AI algorithm or model is the most important part in the design and development process of an AI system. Clarification that the term training and validation in this article is to be used based on

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	the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan. This shall take place under the direct supervision and guidance by the competent authorities with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.	into service pursuant to a specific plan. This shall take place under the direct supervision, support and guidance by the competent authorities with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.	the definitions of “training data” and "validation data". Add *“support”*: Especially for start-ups it is very important that competent authorities – within their legal possibilities – act as supporters in ensuring compliance, e.g. through mentoring, personal exchange or customized guidance. The impressive examples of data regulatory sandboxes by the French CNIL and the British ICO also explicitly “support” the projects. The term “support” is also used in EU Commission’s Better Regulation Toolbox Tool #69 on regulatory sandboxes (page 597). The relationship between the latest amendments of the SVN-Prs. regarding Art. 2 and title V is unclear. One the one hand, according to Art. 2 para. 6 and Recital 12a, the AIA shall not apply to AI Systems including their output, specifically developed and put into service for the sole purpose of scientific research and development. One the other hand Articles 53 and 54 are laying down the legal framework for the development of certain AI-systems within regulatory sandboxes. Does the AIA still apply to the development of AI systems? If not, do Articles 53 and 54 still have a scope?

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356.			
357.	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.		
358.			
359.	3. The AI regulatory sandboxes shall not affect	[..] Any significant risks to health and safety, the environment, and fundamental rights identified	Add *"the environment"*: It is possible that climate and environmental risks and hazards

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	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.	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.	will also be identified during the development and testing of the systems. These must also be covered by the immediate risk mitigation mechanism.
360.			
361.	4. Participants in the AI regulatory sandbox shall remain liable under applicable Union and Member States liability		To avoid legal uncertainties, it is necessary to regulate which stakeholder/participant is the data controller. If it is correct that the technical infrastructure is established and run by Member States competent authorities or the European

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	legislation for any harm inflicted on third parties as a result from the experimentation taking place in the sandbox.		Data Protection Supervisor, it should be considered to amend para. 4 correspondingly.
362.			
363.	5. Member States' competent authorities that have established AI regulatory sandboxes shall coordinate their activities and cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results from the implementation of those scheme, including good		

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	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.		
364.			
365.	6. The modalities and the conditions of the operation of the AI regulatory sandboxes, including the eligibility criteria and the procedure for the application, selection, participation and exiting from the sandbox, and the rights and obligations of the	6. The modalities and the conditions of the operation of the AI regulatory sandboxes, including the eligibility criteria and the procedure for the application, selection, participation and exiting from the sandbox, ~~and~~ the rights and obligations of the participants, the evaluation and the transfer of results intothe legislative process, and provisions for a possible subsequent introduction into permenant operation shall be set out in implementing acts.These modalities and conditions shall foster innovation and shall take into account particularly	Add *"the evaluation and the transfer of results into legislative process"*: As emphasized in recital 72, one objectives of the regulatory sandboxes is to enhance the competent authorities' oversight and understanding. EU Commission's Better Regulation Toolkit (page 595 and 597) and the Council Conclusions on Reg. Sandboxes (para 10) also stress the objective of advancing regulation through regulatory learning. To achieve this overarchingly, clear rules shall be set up. Add *"and provisions for a possible subsequent introduction into permanent operation":* In order to provide innovators with transparent and reliable investment conditions, perspectives for

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	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).	the special circumstances of participating small and medium-sized enterprises. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).	scaling the AI systems outside the regulatory sandbox should be set up. Add *"These modalities and conditions shall foster innovation and shall take into account particularly the special circumstances of participating small and medium-sized enterprises"*: The objectives of the regulatory sandboxes should be to foster AI innovation (recital 71). In order to promote innovation, it is important that the interests of small-scale providers are taken into particular account (recital 73. Both must be reflected in the regulatory sandboxes' modalities and conditions. Prevention of discrimination, e.g. gender discrimination, shall be explicitly part of the eligibility criteria.
366.		(new) The AI regulatory sandboxes do not modify the competencies and regulations regarding the fulfilment of requirements on the clinical evaluation, performance evaluation and clinical evidence for high-risk AI systems which are safety components of devices, or are devices themselves, covered by	Data collected for medical device AI-systems and used for the demonstration of compliance or of the clinical evidence should fulfill the regulatory requirements of Regulation 2017/745 and 2017/746.

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		Regulation (EU) 2017/745 or Regulation (EU) 2017/746. Without prejudice to the requirements on clinical evaluation, performance evaluation and clinical evidence of Regulation 2017/745 and 2017/746, data collected for those devices within regulatory sandboxes may be used with regard to clinical evaluation or performance evaluation and for demonstration of compliance with those regulatory requirements.	
367.		(new) By derogation from paragraphs 1 through 6, only Member States' military authorities may establish, operate, and supervise AI regulatory sandboxes for purposes of the defence sector or the armed forces. Member States' military authorities shall establish the necessary conditions for such developing and testing.	Given their innovative nature and the resulting effects on the development of advanced military capabilities, AI regulatory sandboxes for purposes of the defence sector or the armed forces should be fully outside the public domain. They also should be controled by Member States' military authorities only since Member States are the sole owners of military capabilities in accordance with Union law (cf. Article 42(3) TEU).
368.			

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369.	*Article 54* *Further processing of personal data for developing certain AI systems in the public interest in the AI regulatory sandbox*		
370.			
371.	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:	In the AI regulatory sandbox established by the Member States or the European Data Protection Supervisor personal data lawfully collected for other purposes shall be processed by participants of the sandbox for the purposes of developing and testing certain innovative AI systems in the sandbox under the following conditions:	Amendment to clarify the scope of the legal basis. The privilege to process personal data collected for other purposes is only justified when the data are processed in the sandboxes under the supervision of public authorities, in particular if special categories of personal data (Art. 9, 10 GDPR) are processed. It is still unclear, who are the participants of the sandboxes (other public authorities e.g. the Federal Criminal Office Germany/private actors?). Hence, it is unclear who the data controller is.
372.			

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373.	(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~~ realizing substantial public interest in one or more of the following areas:	Replace *"safeguarding"* by *"realizing"*: Innovative AI systems shall not only serve to conserve but to pursue and realize substantial public interest through new and innovative means.
374.			
375.	(i) the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security, under the control and responsibility of the competent authorities. The processing shall be based		

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	on Member State or Union law;		
376.			
377.	(ii) public safety and public health, including disease prevention, control and treatment;	public safety and ~~public~~ health~~care~~, including disease prevention, control and treatment;	There is a need for reliable and innovative AI in health. However, the word "public" is misleading and should be deleted, since "disease prevention, control and treatment" is mainly done outside public health. There is a "substantial public interest" in improving AI in health in general. The entire population benefits from new and innovative tools for diagnoses and treatment. Thus, regulatory sandboxes should enable the processing of personal data within the secure environment with the required safeguards for training AI in healthcare. In the current draft, AI in the field of care cannot be trained and supported in regulatory sandboxes. Germany is still currently considering whether an addition in Art. 54 (1) lit a is necessary.
378.			

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379.	(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~~;~~, including climate change mitigation and adaptation;	This addition hightlights the potential of AI to address pressing issues posed by climate change, that go beyond the term environmental protection in its narrow interpretation. For example, AI-assisted climate change adaptation measures such as AI-based extreme heat risk maps for urban planning may exceed the scope of environmental protection. Civil society stakeholders have called for a stronger recognition of AIs positive and negative effects on climate change, which are largly absent in the regulation. This admentment would demonstrate a recognition of the large positive impacts that may result from AI systems in the area of climate change related technologies and is much in line with the promotion of innovative approaches.
380.		Add: (iv) sustainable mobility (v) e-government	The draft regulation itself mentions the “high impact sectors” mobility and public sector as sectors in which the Commission sees a particular need for the use of AI (p. 1). Those sectors should be explicitly included as they are

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			important current and future areas where AI can be of substantial benefit to society and the environment and may provide competitive advantages to companies and the European economy.
381.	(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 processing anonymised, synthetic or other non-personal data;	(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 processing anonymised, synthetic or other non-personal data or at least pseudonymized personal data;	In line with the GDPR, it should be clarified, that pseudonymized personal data must be the first choice before processing other personal data.
382.			
383.	(c) there are effective monitoring mechanisms to identify if any high risks to		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	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;		
384.			
385.	(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;		
386.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
387.	(e) any personal data processed are not be transmitted, transferred or otherwise accessed by other parties;		
388.			
389.	(f) any processing of personal data in the context of the sandbox do not lead to measures or decisions affecting the data subjects;		
390.			
391.	(g) any personal data processed in the context of the sandbox are deleted once the participation in the sandbox has terminated or the personal data has reached the end of its retention period;		We ask for further clarification with regard to the retention period.

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392.			
393.	(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;		
394.			
395.	(i) complete and detailed description of the process and rationale behind the		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	training, testing and validation of the AI system is kept together with the testing results as part of the technical documentation in Annex IV;		
396.			
397.	(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.		
398.			
399.			
400.			
401.	2. Paragraph 1 is without prejudice to Union or Member States legislation excluding	[Add in Recital 72] „Article 54 is an Union law which constitutes a necessary and proportionate measure in a democratic society to safeguard the objectives referred to in Article 23 (1) of Regulation	Recital 72: „This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI

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	processing for other purposes than those explicitly mentioned in that legislation.	(EU) 2016/679 and Article 25 (1) of Regulation (EU) 2018/1725.	regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680.“ Recital 72 does not make it clear what „in line with Article 6 (4)“ means (Is Article 54 meant to be an Union law which constitutes a necessary and proportionate measure in a democratic society to safeguard the objectives referred to in Article 23(1) GDPR?). We would approve a clarification in Recital 72.
402.			
403.			
404.			
405.	*Article 55* *Measures for* ***SME*** ~~*small-scale*~~ *providers and users*		
406.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
407.	1. Member States shall undertake the following actions:		
408.			
409.	(a) provide ~~small-scale~~ SME providers**, including** ~~and~~ start-ups with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions;		
410.			
411.	(b) organise specific awareness raising activities about the application of this Regulation tailored to the needs of the ~~small-scale~~ **SME** providers and users;		
412.			

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413.	(c) where appropriate, establish a dedicated channel for communication with ~~small-scale~~ **SME** providers and user and other innovators to provide guidance and respond to queries about the implementation of this Regulation.	(c) ~~where appropriate,~~ establish a dedicated channel for communication with ~~small-scale~~ **SME** providers and user and other innovators to provide guidance, ~~and~~ respond to queries about the implementation of this Regulation, and provide assistance for participation in AI regulatory sandboxes.	Delete *"where appropriate"* and add *"and provide assistance for participation in AI regulatory sandboxes"*: Numerous companies, especially startups, have told us about the need for a contact point. Especially for the access to the novel instrument of the regulatory sandbox, low-threshold and practice-oriented information offers are necessary.
414.			
415.	2. The specific interests and needs of the ~~small-scale~~ **SME** providers shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	to their size and market size.		
416.			
417.			
418.	**TITLE VI**		
419.			
420.	**GOVERNANCE**		
421.			
422.	**CHAPTER 1**		
423.			
424.	**EUROPEAN ARTIFICIAL INTELLIGENCE BOARD**		
425.			**WE SUGGEST AN ORIENTATIONAL DEBATE REGARDING THE AI BOARD. THIS DEBATE SHOULD INCLUDE THE GENERAL ALIGNEMENT OF THE BOARD**

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			AND THE SCOPE, ITS MEMEBERS AND POSSIBLE RULES OF PROCEDURE. WE WOULD LIKE TO RESERVE THE OPPORTUNITY TO MAKE FURTHER COMMENTS AFTER THAT PROPOSED DEBATE.
426.	*Article 56* *Establishment of the European Artificial Intelligence Board*		
427.			
428.	1. A 'European Artificial Intelligence Board' (the 'Board') is established.		
429.			
430.	2. The Board shall provide advice and		

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	assistance to the Commission in order to:		
431.			
432.	(a) contribute to the effective cooperation of the national supervisory authorities and the Commission with regard to matters covered by this Regulation;		
433.			
434.	(b) coordinate and contribute to guidance and analysis by the Commission and the national supervisory authorities and other competent authorities on emerging issues across the internal market with regard		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	to matters covered by this Regulation;		
435.			
436.	(c) assist the national supervisory authorities and the Commission in ensuring the consistent application of this Regulation.		
437.			
438.			
439.	*Article 57* *Structure of the Board*		
440.			
441.	1. The Board shall be composed of the national supervisory authorities, who shall be represented by the head or equivalent high-level official of that		

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	authority, and the European Data Protection Supervisor. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.		
442.			
443.	2. The Board shall adopt its rules of procedure by a simple majority of its members, following the consent of the Commission. The rules of procedure shall also contain the operational aspects related to the execution of the Board's tasks as listed in Article 58. The Board may establish		

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	sub-groups as appropriate for the purpose of examining specific questions.		
444.			
445.			
446.			
447.	3. The Board shall be chaired by the Commission. The Commission shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. The Commission shall provide administrative and analytical support for the		

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	activities of the Board pursuant to this Regulation.		
448.			
449.			
450.	4. The Board may invite external experts and observers to attend its meetings and may hold exchanges with interested third parties to inform its activities to an appropriate extent. To that end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups.		
451.			
452.	*Article 58* *Tasks of the Board*		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
453.			
454.	When providing advice and assistance to the Commission in the context of Article 56(2), the Board shall in particular:		
455.			
456.	(a) collect and share expertise and best practices among Member States;		
457.			
458.	(b) contribute to uniform administrative practices in the Member States, including for the functioning of regulatory sandboxes referred to in Article 53;		
459.			

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460.	(c) issue opinions, recommendations or written contributions on matters related to the implementation of this Regulation, in particular		
461.			
462.	(i) on technical specifications or existing standards regarding the requirements set out in Title III, Chapter 2,		
463.			
464.	(ii) on the use of harmonised standards or common specifications referred to in Articles 40 and 41,		
465.			

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466.	(iii) on the preparation of guidance documents, including the guidelines concerning the setting of administrative fines referred to in Article 71.**;**		
467.			
468.	**(d) issue an advisory opinion on the need for amendment of Annex I and Annex III, including in light of available evidence.**		
469.			
470.			
471.			
472.			
473.			
474.	**CHAPTER 2**		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
475.			
476.	**NATIONAL COMPETENT AUTHORITIES**		
477.			
478.	*Article 59* *Designation of national competent authorities*		
479.			
480.	1. National competent authorities shall be established or designated by each Member State for the purpose of ensuring the application and implementation of this Regulation. National competent authorities shall be organised so as to safeguard the objectivity		

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	and impartiality of their activities and tasks.		
481.			
482.	2. Each Member State shall designate a national supervisory authority among the national competent authorities. The national supervisory authority shall act as notifying authority and market surveillance authority unless a Member State has organisational and administrative reasons to designate more than one authority.	2. Each Member State shall establish~~designate~~ a national AI board~~supervisory authority among the national competent authorities.~~ The national AI board~~supervisory authority~~ shall consist of ~~act as~~ a national competent authorities, a notifying authority~~y~~ies and a market surveillance authorities~~y~~ ~~unless a Member State has organisational and administrative reasons to designate more than one authority.~~	If the "national supervisory authority" would act as notifying authority and market surveillance authority **at the same time**, the independency is not guaranteed because they are part of the same authority. To prevent conflicting interests we propose to establish a "national AI board" instead of a "national supervisory authority". The "national AI board" would consists of the national competent authority, notifying authority, market surveillance authority, which are all independent from each other. **This change is necessary to ensure the independency of the different authorities in each Member State.**
483.			

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484.	3. Member States shall inform the Commission of their designation or designations and, where applicable, the reasons for designating more than one authority.		
485.			
486.	4. Member States shall ensure that national competent authorities are provided with adequate financial and human resources to fulfil their tasks under this Regulation. In particular, national competent authorities shall have a sufficient number of personnel permanently available whose		

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	competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements.		
487.			
488.	5. Member States shall report to the Commission on an annual basis on the status of the financial and human resources of the national competent authorities with an assessment of their adequacy. The Commission		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	shall transmit that information to the Board for discussion and possible recommendations.		
489.			
490.	6. The Commission shall facilitate the exchange of experience between national competent authorities.		
491.			
492.	7. National competent authorities may provide guidance and advice on the implementation of this Regulation, including **tailored** to ~~small-scale~~ **SME** providers. Whenever national competent authorities intend to	7. National ~~competent authorities~~ AI board may provide guidance and advice on the implementation of this Regulation, including **tailored** to ~~small-scale~~ **SME** providers. Whenever national competent authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the competent national authorities under that Union legislation shall be consulted, as appropriate. Member States may also	Editorial adjustment necessary due to the proposed change of Art. 59 (2).

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the competent national authorities under that Union legislation shall be consulted, as appropriate. Member States may also establish one central contact point for communication with operators.	establish one central contact point for communication with operators.	
493.			
494.	8. When Union institutions, agencies and bodies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as the		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	competent authority for their supervision.		
495.			
496.	**TITLE VII**		
497.			
498.	**EU DATABASE FOR STAND-ALONE HIGH-RISK AI SYSTEMS**		
499.			
500.	*Article 60* *EU database for stand-alone high-risk AI systems*		*(1) Reference to arguments on art. 51.* *(2) see article 69-comment* *(3) It is suggested to provide general exceptions for an access to sensitive data when included in the database. In particular, there should be exceptions to the public access to sensitive data of VS-NfD or higher-classified (secret) AI systems contained in the database.*

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
501.			
502.	1. The Commission shall, in collaboration with the Member States, set up and maintain a EU database containing information referred to in paragraph 2 concerning high-risk AI systems referred to in Article 6(2) which are registered in accordance with Article 51.	The Commission shall, in collaboration with the Member States, set up, ~~and~~ maintain and manage a EU database to enable the public to be adequately informed about high-risk AI systems placed on the market and containing information referred to in paragraph 2 concerning high-risk AI systems referred to in Article 6(2) which are registered in accordance with Article 51.	Clarification and addition of the scope of the database.
503.		(new) The Commission, in collaboration with the Member States, shall set up the functional and non-functional requirements of the EU database.	Clarification of the development process.
504.		(new) The Commission, in collaboration with the Member States, shall draw up annual acitivity plans and allocate a sufficient number of material and competent human resources in order to carry	Determining needed material and human resources. Given their nature as advanced military capabilities, AI systems developed or used for

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		activities taking into account the requirements set out in this Article.	purposes of the defence sector or the armed forces should be fully outside the public domain. They also should be controled by Member States military authorities only since Member States are the sole owners of military capabilities in accordance with Union law (cf. Article 42(3) TEU).
505.			
506.	2. The data listed in Annex VIII shall be entered into the EU database by the providers. The Commission shall provide them with technical and administrative support.		Amendment to clarify, that the list of data mentioned in Annex VIII is exhaustive. Furthermore, we examine whether obligation to register should also be upon users of AI systems, rather than just on providers. Can Commission clarify the reasons why it has chosen to address only the provider and not the user?

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		The data listed in Annex VIII points 1 to 5 and 8 to 12 shall be entered into the EU database by the providers. The data listed in Annex VIII point 6 and 7 shall be entered into the EU database by the notified body. The Commission shall provide them with technical and administrative support. The data listed in Annex VIII shall be entered into the EU database by the providers. **The EU database shall contain personal data only insofar as necessary for collecting and processing information in accordance with this Regulation.** The Commission shall provide them with technical and administrative support.	Data referred to notified bodies shall be entered by the notified body.
507.			
508.	3. Information contained in the EU database shall be accessible to the public.		
509.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
510.	4. The EU database shall contain personal data only insofar as necessary for collecting and processing information in accordance with this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider.	Deletion	See amendment in para 2.
511.			
512.	5. The Commission shall be the controller of the EU database. It shall also ensure to providers	The Commission shall be the controller and the operator of the EU database. It shall also ensure to providers and users adequate technical and administrative support.	Clarification.

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	adequate technical and administrative support.		
513.			
514.		*Article 60a* *EU database for stand-alone AI systems used by public authorities*	
515.			
516.		1. The Commission shall, in collaboration with the Member States, set up, maintain and manage a EU database to enable the public to be adequately informed about AI systems placed on the market and containing information referred to in paragraph 2 concerning any AI systems used by public authorities registered in accordance with Article 51(2).	Due to the unique role and responsibility public authorities bear, the sensitive personal data they have access to, the consequential effects their decisions have on individuals, and thus their primary obligation to respect, protect and fulfil fundamental rights, public authorities should be subject to more stringent transparency requirements when using AI systems. Hence, any deployments of AI systems – regardless of their level of risk – by or on behalf of public authorities should be registered within a separate EU database.

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517.		2. The data listed in Annex VIIIa shall be entered into the EU database by the public authorities. The Commission shall provide them with technical and administrative support.	We refrain from drafting up an Annex VIIIa for this comment. However, the data base should include the name of the AI system and a short description of its intended purpose as well as the name, address and contact details of the public authority by whom or on whose behalf it is used.
518.		3. Art. 60 par. 3-5 shall apply accordingly.	
519.			
520.	**TITLE VIII**		
521.			
522.	**POST-MARKET MONITORING, INFORMATION SHARING, MARKET SURVEILLANCE**		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
523.			
524.	**CHAPTER 1**		
525.			
526.	**POST-MARKET MONITORING**		
527.			
528.	*Article 61* *Post-market monitoring by providers and post-market monitoring plan for high-risk AI systems*		
529.			
530.	1. Providers shall establish and document a post-market monitoring system in a manner that is proportionate to the nature of the artificial intelligence	Providers shall plan, establish ~~and~~, document, implement, maintain and update a post-market monitoring system in a manner that is proportionate to the ~~nature of the artificial intelligence technologies and~~ the risks of the high-risk AI system. That system shall be an integral part of the	Clarification.

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	technologies and the risks of the high-risk AI system.	provider's quality management system referred to in Article 17(1).	
531.			
532.	2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.	The post-market monitoring system shall be suited to actively and systematically collect, document and analyse relevant data on the quality, performance, safety and security provided by users or collected through ~~other sources on the performance of high-risk AI systems~~ throughout their entire lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in ~~Title III, Chapter 2~~ this Regulation.	Clarification
533.			

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534.	3. The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt an implementing act laying down detailed provisions establishing a template for the post-market monitoring plan and the list of elements to be included in the plan.		
535.			
536.	4. For high-risk AI systems covered by the legal acts referred to in		

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	Annex II, where a post-market monitoring system and plan is already established under that legislation, the elements described in paragraphs 1, 2 and 3 shall be integrated into that system and plan as appropriate.		
537.			
538.	The first subparagraph shall also apply to high-risk AI systems referred to in point 5(b) of Annex III placed on the market or put into service by credit institutions regulated by Directive 2013/36/EU.		Please specify in which specific existing plan credit institutions should include the elements described in paragraph 1 to 3. Moreover, similar procedures exist for entities regulated by Directive 2009/138/EC, Directive (EU) 2016/2341, Directive 2014/65/EU resp. Directive (EU) 2015/2366, Directive 2009/65/EG and Directive 2011/61/EU which should be referenced here.

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			It remains unclear whether the AI Act poses additional requirements for entities already regulated by comprehensive financial sector regulation. Please specify how the AI Act does avoid double regulation for the highly regulated financial sector.
539.			
540.	**CHAPTER 2**		
541.			
542.	**SHARING OF INFORMATION ON SERIOUS INCIDENTS ~~AND MALFUNCTIONING~~**		
~~**543.**~~			
544.	*Article 62* *Reporting of serious incidents ~~and of malfunctioning~~*		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
~~*545.*~~			
546.	1. Providers of high-risk AI systems placed on the Union market shall report any serious incident ~~or any malfunctioning of those systems which constitutes a breach of obligations under Union law intended to protect fundamental rights~~ to the market surveillance authorities of the Member States where that incident ~~or breach~~ occurred.		: If a serious incident according to Art. 3 para 44 AIA entails a personal data breach, providers of high-risk AI systems are obliged to report the incident to both the market surveillance authorities as well as to data protection supervisory authorities. To prevent legal uncertainties, a clarification should be added e.g. in Art. 2 para 8: This Directive is without prejudice to Union law on the protection of personal data, in particular Regulation (EU) 2016/679 and Directive 2002/58/EC. Corresponding Recital XY: This Directive is without prejudice to Regulation (EU) 2016/679 and Directive 2002/58/EC of the European Parliament and of the Council and therefore

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			should in particular not affect the tasks and powers of the independent supervisory authorities competent to monitor compliance with the respective Union data protection law.
547.			
548.	Such notification shall be made immediately after the provider has established a causal link between the AI system and the **serious** incident ~~or malfunctioning~~ or the reasonable likelihood of such a link, and, in any event, not later than 15 days after the providers becomes aware of the serious incident ~~or of the malfunctioning~~.		
549.			

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550.	2. Upon receiving a notification related to a **serious incident referred to in Article 3(44)(c)** ~~a breach of obligations under Union law intended to protect fundamental rights~~, the **relevant** market surveillance authority shall inform the national public authorities or bodies referred to in Article 64(3). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1. That guidance shall be issued 12 months after the entry into		

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	force of this Regulation, at the latest.		
551.			
552.	3. For high-risk AI systems referred to in point 5(b) of Annex III which are placed on the market or put into service by providers that are credit institutions regulated by Directive 2013/36/EU and for high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746, the notification of serious incidents ~~or malfunctioning~~ shall be	For high-risk AI systems referred to in point 5(b) and 5 (d) of Annex III which are placed on the market or put into service by providers that are credit institutions regulated by Directive 2013/36/EU and entities regulated by Directive 2009/138/EC, Directive (EU) 2016/2341, Directive 2014/65/EU, Directive (EU) 2015/2366, Directive 2009/65/EG resp. Directive 2011/61/EU and for high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746, the notification of serious incidents shall be limited to those referred to in Article 3(44)(c).	Moved exception of medical devices to a new paragraph . As entities regulated by Directive 2009/138/EC, Directive (EU) 2016/2341, Directive 2014/65/EU, Directive (EU) 2015/2366, Directive 2009/65/EG resp. Directive 2011/61/EU fulfil similarly strict requirements compared to credit institutions regulated by Directive 2013/36/EU, their obligation should also be limited to serious incidents referred to in Article 3(44)(c). It remains unclear whether the AI Act poses additional requirements for entities already

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	limited to those **referred to in Article 3(44)(c)**~~that that constitute a breach of obligations under Union law intended to protect fundamental rights~~.		regulated by comprehensive financial sector regulation. Please specify how the AI Act does avoid double regulation for the highly regulated financial sector.
553.		(new) For high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746 the notification of serious incidents, field safety corrective actions or other non-compliance shall be apply under those legal acts.	Dealing with serious incidents and other incidents (field safety corrective action, other non compliance) are more specifically regulated in the Regulations 2017/745 and 2017/746 (e. g. vigilance system).
554.			
555.	**CHAPTER 3**		
556.			
557.	**ENFORCEMENT**		
558.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
559.	*Article 63* *Market surveillance and control of AI systems in the Union market*		
560.			
561.	1. Regulation (EU) 2019/1020 shall apply to AI systems covered by this Regulation. However, for the purpose of the effective enforcement of this Regulation:		Our understanding is that the Regulation 2017/745 and 2017/746 are lex specialis and provide more specific provisions for market surveillance and control of AI systems so that the Regulation 2019/1020 are not apply to AI systems, covered by Regulation 2017/745 and 2017/746.
562.			
563.	(a) any reference to an economic operator under Regulation (EU) 2019/1020 shall be understood as including all operators identified in ~~Title~~		

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	~~III, Chapter 3~~ **Article 2** of this Regulation;		
564.			
565.	(b) any reference to a product under Regulation (EU) 2019/1020 shall be understood as including all AI systems falling within the scope of this Regulation.		
566.			
567.	2. The national supervisory authority shall report to the Commission on a regular basis the outcomes of relevant market surveillance activities. The national supervisory authority shall report, without delay, to the	2. The national AI board~~supervisory authority~~ shall report to the Commission on a regular basis the outcomes of relevant market surveillance activities. The national ~~supervisory~~ authority~~authority~~AI board shall report, without delay, to the Commission and relevant national competition authorities any information identified in the course of market surveillance activities that may be of potential	Clarification. Legal acts listed in Annex II already established reports to the COM. Editorial adjustment necessary due to the proposed change of Art. 59 (2).

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	Commission and relevant national competition authorities any information identified in the course of market surveillance activities that may be of potential interest for the application of Union law on competition rules.	interest for the application of Union law on competition rules.	
568.			
569.	3. For high-risk AI systems, related to products to which legal acts listed in Annex II, section A apply, the market surveillance authority for the purposes of this Regulation shall be the authority responsible for market surveillance		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	activities designated under those legal acts.		
570.			
571.	4. For AI systems placed on the market, put into service or used by financial institutions regulated by Union legislation on financial services, the market surveillance authority for the purposes of this Regulation shall be the relevant authority responsible for the financial supervision of those institutions under that legislation.		
572.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
573.	5. For AI systems listed in point 1(a) in so far as the systems are used for law enforcement purposes, points 6 and 7 of Annex III, Member States shall designate as market surveillance authorities for the purposes of this Regulation either the competent data protection supervisory authorities under Directive (EU) 2016/680, or Regulation 2016/679 or the national competent authorities supervising the activities of the law enforcement, immigration or asylum authorities putting into		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	service or using those systems.		
574.			
575.		5a. For AI systems developed or used for purposes of the defence sector or the armed forces Member States shall designate a military authority to perform the functions assigned to market surveillance authorities under this Regulation.	
576.			
577.	6. Where Union institutions, agencies and bodies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as their market surveillance authority.		
578.			
579.		6a. Paragraph 6 shall not apply to the European Union Military Committee, the European Union	The military uses of AI systems as well as related activities of the institutions, agencies

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
		Military Staff, the Military Planning and Conduct Capability within the European External Action Service, the European Defence Agency, and any missions or operations established in the framework of the Common Security and Defence Policy.	and bodies is not suited for surveillance by the European Data Protection Supervisor.
580.			
581.	7. Member States shall facilitate the coordination between market surveillance authorities designated under this Regulation and other relevant national authorities or bodies which supervise the application of Union harmonisation legislation listed in Annex II or other Union legislation that might be relevant for the high-risk		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	AI systems referred to in Annex III.		
582.			
583.	*Article 64* *Access to data and documentation*		
584.			
585.	1. Access to data and documentation in the context of their activities, the market surveillance authorities shall be granted full access to the training, validation and testing datasets used by the provider, including through application programming interfaces ('API') or other appropriate technical	Access to data and documentation in the context of their activities, the market surveillance authorities shall be granted full access to the training, validation and testing datasets used by the provider, including through application programming interfaces ('API') or other appropriate technical means and tools enabling remote access, as well as all relevant information referred in Article 10.	Information referred in Article 10 are needed to understand the design of the AI system.

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	means and tools enabling remote access.		
586.		Art 64 1a – 1d new 1a Upon a reasoned request from the market surveillance authorities, providers shall within a reasonable period, as specified in the request, provide access to training, validation and testing datasets used by the provider to vetted researchers who meet the requirements in paragraph 1b of this article for the sole purpose of conducting research that contributes to the development, training, validation and testing of AI systems within the existing legal framework, in particular with regards to bias monitoring, detection and correction of such systems and that is related to a public interest. Access to personal data shall be provided in anonymised or at least pseudonymised form as long as this is possible without jeopardizing the research purpose.	Acces to data for research is key for understanding and raising the knowledge on AI. The role of research as a central actor is acknowledged inter alia by recital 45 of this regulation. It is stated there that also "researchers should be able to access and use high quality datasets within their respective fields of activities which are related to this Regulation". However, this acces to data for research is not yet enshrined in the text of the Regulation itself. Therefore we provide the enclosed text proposal for a new paragraph 1a. This proposal is taking into account and making reference to the acces to data provision in the Digital Services Act (Art. 31). Both legislative proposals share the aim to establish rules for a safe, predictable and trusted online environment.

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
		1b Upon a duly substantiated application from researchers, the responsible market surveillance authority shall award them the status of vetted researchers and issue data access requests pursuant to paragraph 1a, where the researchers demonstrate that they meet all of the following conditions: (a) researchers shall be affiliated to a research organisation as defined in Article 2 (1) of Directive (EU) 2019/790 of the European Parliament and of the Council (b) be independent from commercial interests, (c) have proven records of expertise in the fields related to the risks investigated or related research methodologies, (d) the application submitted by the researchers justifies the necessity and proportionality for the purpose of their research of the data requested and the timeframes within which they request access to	

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		the data, and they demonstrate the contribution of the expected research results to the purposes laid down in paragraph 1a, (e) the planned research activities will be carried out only for the purposes laid down in paragraph 1a, (f) shall commit and be in a capacity to preserve the specific data security and confidentiality requirements corresponding to each request. In particular, a protection concept shall be provided with the request, containing a description of the research purpose, the intended use of the information, measures taken to protect the interests of the data subject and technical and organisational measures taken to protect personal data. 1c The provider may refuse the requested information, if trade secrets are affected and the public interest in the research does not outweigh the interest in confidentiality. The provider may refuse access to personal data, if the legitimate interests of	

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		the data subject outweigh the public interest in the research. Access shall be granted free of charge. If this poses an undue hardship on the provider, the provider may require reasonable compensation, which shall not be so high that it creates a significant obstacle to the research. 1d The market surveillance authority that awarded the status of vetted researcher and issued the access request in favour of a vetted researcher shall issue a decision terminating the access if it determines, following an investigation either on its own initiative or on the basis information received from third parties, that the vetted researcher no longer meets the conditions set out in paragraph 1b. Before terminating the access, the market surveillance authority shall allow the vetted researcher to react to the findings of its investigation and its intention to terminate the access. As soon as the vetted researcher no longer meets the conditions set out in	

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		paragraph 1b, the vetted researcher shall report this circumstance to the market surveillance authority.	
587.	2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the market surveillance authorities shall be granted access to the source code of the AI system.	Where necessary to assess the conformity of the high-risk AI system with the requirements set out in ~~Title III, Chapter 2~~ this Regulation and upon ~~a reasoned~~ request, the market surveillance authorities shall be granted access to the source code of the AI system.	Taking into account other requirements, e. g. quality management system, post-market-surveilliance system, etc.. The obligation to grant access to the source code of the AI system might necessitate an exception or limitation to the copyright protection under Directive 2009/24/EC on the legal protection of computer programs. Granting access to the source code will probably imply a reproduction within the meaning of Article 4 (1) (a) of Directive 2009/24/EC on the legal protection of computer programs. Unlike Directive 2001/29/EC (InfoSoc-Directive) and Directive 96/9/EC on the legal protection of databases, Directive 2009/24/EC on the legal protection of computer programs does not contain an exception or limitation for

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			the purposes of public security or for the purposes of an administrative or judicial procedure.
588.			
589.	3. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights in relation to the use of high-risk AI systems referred to in Annex III shall have the power to request and access any documentation created or maintained under this Regulation when access to that documentation is necessary for the fulfilment of the	3. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights in relation to the use of high-risk AI systems referred to in Annex III, including the right to non-discrimination, shall have the power to request and access any documentation created or maintained under this Regulation when access to that documentation is necessary for the fulfilment of the competences under their mandate within the limits of their jurisdiction. The relevant public authority or body shall inform the market surveillance authority of the Member State concerned of any such request	A corresponding recital should clarify that national equality bodies are the relevant bodies in cases of discrimination (see drafting suggestion for Art. 59 (1a)).should recommend that national equality bodies be given the necessary competences to allow them to access the documentation.

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	competences under their mandate within the limits of their jurisdiction. The relevant public authority or body shall inform the market surveillance authority of the Member State concerned of any such request.		
590.			
591.	4. By 3 months after the entering into force of this Regulation, each Member State shall identify the public authorities or bodies referred to in paragraph 3 and make a list publicly available on the website of the national supervisory authority. Member States	4. By 3 months after the entering into force of this Regulation, each Member State shall identify the public authorities or bodies referred to in paragraph 3 and make a list publicly available on the website of the national ~~supervisory authority~~AI board. Member States shall notify the list to the Commission and all other Member States and keep the list up to date.	Editorial adjustment necessary due to the proposed change of Art. 59 (2).

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	shall notify the list to the Commission and all other Member States and keep the list up to date.		
592.			
593.	5. Where the documentation referred to in paragraph 3 is insufficient to ascertain whether a breach of obligations under Union law intended to protect fundamental rights has occurred, the public authority or body referred to paragraph 3 may make a reasoned request to the market surveillance authority to organise testing of the high-risk AI	5. Where the documentation referred to in paragraph 3 is insufficient to ascertain whether a breach of obligations under Union law intended to protect fundamental rights, including the right to non-discrimination, has occurred, the public authority or body referred to paragraph 3 may make a reasoned request to the market surveillance authority to organise testing of the high-risk AI system through technical means. The market surveillance authority shall organise the testing with the close involvement of the requesting public authority or body within reasonable time following the request.	

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	system through technical means. The market surveillance authority shall organise the testing with the close involvement of the requesting public authority or body within reasonable time following the request.		
594.			
595.	6. Any information and documentation obtained by the national public authorities or bodies referred to in paragraph 3 pursuant to the provisions of this Article shall be treated in compliance with the confidentiality		

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	obligations set out in Article 70.		
596.			
597.	*Article 65* *Procedure for dealing with AI systems presenting a risk at national level*		
598.			
599.		(new) For high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746, shall apply procedures for dealing with risks under those legal acts.	Dealing with serious incidents and other incidents (field safety corrective action, other non compliance) are more specifically regulated in the Regulations 2017/745 and 2017/746 (e. g. vigilance system).
600.	1. AI systems presenting a risk shall be understood as a product presenting a risk defined in Article 3, point 19 of Regulation (EU) 2019/1020 insofar as risks	AI systems presenting a risk shall be understood as a product presenting a risk defined in Article 3, point 19 of Regulation (EU) 2019/1020 insofar as risks to the health or safety or to the protection of fundamental rights of persons or to environmental protection are concerned.	Following the definition in Article 3, point 19 of Regulation (EU) 2019/1020 we propose not to exclude environmental aspects of product-related risks. This would benefit a strong "Sustainable AI – Made in Europe" brand as previously endorsed by DEU.

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	to the health or safety or to the protection of fundamental rights of persons are concerned.		
601.			
602.	2. Where the market surveillance authority of a Member State has sufficient reasons to consider that an AI system presents a risk as referred to in paragraph 1, they shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. When risks to the protection of		

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	fundamental rights are present, the market surveillance authority shall also inform the relevant national public authorities or bodies referred to in Article 64(3). The relevant operators shall cooperate as necessary with the market surveillance authorities and the other national public authorities or bodies referred to in Article 64(3).		
603.			
604.	Where, in the course of that evaluation, the market surveillance authority finds that the AI system does not comply with the requirements and		

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	obligations laid down in this Regulation, it shall without delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.		
605.			
606.	The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to		

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	the measures referred to in the second subparagraph.		
607.			
608.	3. Where the market surveillance authority considers that non-compliance is not restricted to its national territory, it shall inform the Commission and the other Member States of the results of the evaluation and of the actions which it has required the operator to take.		
609.			
610.	4. The operator shall ensure that all appropriate corrective action is taken in respect of all the AI		

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	systems concerned that it has made available on the market throughout the Union.		
611.			
612.	5. Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market, to withdraw the product from that market or to recall it. That authority shall inform		

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	the Commission and the other Member States, without delay, of those measures.		
613.			
614.	6. The information referred to in paragraph 5 shall include all available details, in particular the data necessary for the identification of the non-compliant AI system, the origin of the AI system, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant operator. In		

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	particular, the market surveillance authorities shall indicate whether the non-compliance is due to one or more of the following:		
615.			
616.	(a) a failure of the AI system to meet requirements set out in Title III, Chapter 2;	a failure of the AI system to meet requirements set out in ~~Title III, Chapter 2~~ this Regulation;	Taking into account other requirements, e. g. quality management system, post-market-surveilliance system, etc..
617.			
618.	(b) shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 conferring a presumption of conformity.		
619.			

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620.	7. The market surveillance authorities of the Member States other than the market surveillance authority of the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the AI system concerned, and, in the event of disagreement with the notified national measure, of their objections.		
621.			

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622.	8. Where, within three months of receipt of the information referred to in paragraph 5, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified. This is without prejudice to the procedural rights of the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020.		
623.			
624.	9. The market surveillance authorities of all Member States shall		

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	ensure that appropriate restrictive measures are taken in respect of the product concerned, such as withdrawal of the product from their market, without delay.		
625.			
626.	*Article 66* *Union safeguard procedure*		
627.			
628.	1. Where, within three months of receipt of the notification referred to in Article 65(5), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the		

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	measure to be contrary to Union law, the Commission shall without delay enter into consultation with the relevant Member State and operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not within 9 months from the notification referred to in Article 65(5) and notify such decision to the Member State concerned.		
629.			

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630.	2. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant AI system is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.		
631.			
632.	3. Where the national measure is considered justified and the non-compliance of the AI system is attributed to		

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	shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.		
633.			
634.	*Article 67* *Compliant AI systems which present a risk*		
635.			
636.	1. Where, having performed an evaluation under Article 65, the market surveillance authority of a Member State finds that although an	Where, having performed an evaluation under Article 65, the market surveillance authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons or to the environment, to the compliance with obligations	The definition of a relevant risk should extend to environmental risks, as described regarding Article 65 (1). Given the large differences across the Union in terms of geographies, infrastructures, landscapes, climatic conditions and many other

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	AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons, to the compliance with obligations under Union or national law intended to protect fundamental rights or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it within a	under Union or national law intended to protect fundamental rights or to other aspects of public interest, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.	factors influencing the functioning of an AI system, it is possible that systems developed and proven compliant in one location represents a risk in a different context.

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	reasonable period, commensurate with the nature of the risk, as it may prescribe.		
637.			
638.	2. The provider or other relevant operators shall ensure that corrective action is taken in respect of all the AI systems concerned that they have made available on the market throughout the Union within the timeline prescribed by the market surveillance authority of the Member State referred to in paragraph 1.		
639.			

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640.	3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.		
641.			
642.	4. The Commission shall without delay enter into consultation with the Member States and the		

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	relevant operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.		
643.			
644.	5. The Commission shall address its decision to the Member States.		
645.			
646.	*Article 68* *Formal non-compliance*		
647.			
648.	1. Where the market surveillance authority of a	Where, having performed an evaluation under Article 65, the market surveillance authority of a	Clarification.

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	Member State makes one of the following findings, it shall require the relevant provider to put an end to the non-compliance concerned:	Member State makes one of the following findings, it shall require the relevant provider to put an end to the non-compliance concerned:	
649.			
650.	(a) the conformity marking has been affixed in violation of Article 49;		
651.			
652.	(b) the conformity marking has not been affixed;		
653.			
654.	(c) the EU declaration of conformity has not been drawn up;		
655.			

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656.	(d) the EU declaration of conformity has not been drawn up correctly;		
657.			
658.	(e) the identification number of the notified body, which is involved in the conformity assessment procedure, where applicable, has not been affixed;		
659.			
660.	2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the high-risk AI system being made		

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	available on the market or ensure that it is recalled or withdrawn from the market.		
661.			
662.	**TITLE IX**		
663.			
664.	**CODES OF CONDUCT**		
665.			
666.	*Article 69* *Codes of conduct*		.
667.			
668.	1. The Commission and the Member States shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to	1. The Commission and the Member States shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to AI systems other than high-risk AI systems of the requirements set out in Title III, Chapter 2 this Regulationon the basis of harmonised standards or	Taking into account other requirements, e. g. quality management system, post-market-surveilliance system, etc.

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	AI systems other than high-risk AI systems of the requirements set out in Title III, Chapter 2 on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems.	common ~~technical~~ specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems.	Not “specifications” should be used, but the existing harmonised standards or common specifications.
669.			
670.	2. The Commission and the Board shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to AI systems of requirements related for example to	The Commission and the Board shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to AI systems of requirements related for example to environmental sustainability, e.g. energy-efficient programming, accessibility for persons with a disability, stakeholders participation in the design and development of the AI systems and diversity of	Clarification. Codes of conduct should set requirements for AI systems for ecological sustainability and thus contribute to a strong brand "Sustainable AI - Made in Europe". A strong signal should be sent to make the opportunities of sustainable AI systems, e.g. for the environment and climate, even more visible as a competitive advantage.

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	environmental sustainability, accessibility for persons with a disability, stakeholders participation in the design and development of the AI systems and diversity of development teams on the basis of clear objectives and key performance indicators to measure the achievement of those objectives.	development teams on the basis of clear objectives and key performance indicators to measure the achievement of those objectives. BMFSFJ: The Commission and the Board shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to AI systems of requirements related for example to environmental sustainability, accessibility for persons with a disability, prevention of discrimination, e.g. gender discrimination, stakeholder participation.	The term 'environmental sustainability' encompasses a broad range of aspects, such as environmental impact assessments, life cycle analysis, or reusability and recyclability of hardware. The proposed addition 'energy-efficient programming' not only gives a precise example of an environmental concern, it also supports the broader call for a more energy-efficient AI development, e.g. expressed in debates on 'Green AI' complementing 'Red AI', that would allow for more inclusivity and diversity in the corporate AI landscape as the high costs for computing power keep small actors out of the market.
671.			At this point we underline that accessibility for persons with disabilities shouldn´t be a voluntary requirement but an obligation. We refer to the Convention of the United Nations on

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			the rights of persons with disabilities ratified by the EU.
672.	3. Codes of conduct may be drawn up by individual providers of AI systems or by organisations representing them or by both, including with the involvement of users and any interested stakeholders and their representative organisations. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems.		
673.			

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674.	4. The Commission and the Board shall take into account the specific interests and needs of ~~the small scale~~ **SME** providers, including ~~and~~ start-ups**,** when encouraging and facilitating the drawing up of codes of conduct.		
675.			
676.	**TITLE X**		
677.			
678.	**CONFIDENTIALITY AND PENALTIES**		
679.			
680.	*Article 70* *Confidentiality*		
681.			

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682.	1. National competent authorities and notified bodies involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:		
683.			
684.	(a) intellectual property rights, and confidential business information or trade secrets of a natural or legal person, including source code, except the cases referred to in Article 5 of Directive 2016/943 on		

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	the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure apply.		
685.			
686.	(b) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits;(c) public and national security interests;		
687.			
688.	(c) integrity of criminal or administrative proceedings.	.	
689.			

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690.		(d) the integrity of information classified in accordance with Member States' respective laws as well EU classified information.	
691.			
692.	2. Without prejudice to paragraph 1, information exchanged on a confidential basis between the national competent authorities and between national competent authorities and the Commission shall not be disclosed without the prior consultation of the originating national competent authority and the user when high-risk AI systems referred to in points 1, 6 and 7 of Annex		

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	III are used by law enforcement, immigration or asylum authorities, when such disclosure would jeopardise public and national security interests.		
693.			
694.	When the law enforcement, immigration or asylum authorities are providers of high-risk AI systems referred to in points 1, 6 and 7 of Annex III, the technical documentation referred to in Annex IV shall remain within the premises of those authorities. Those authorities shall ensure that the market surveillance		

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	authorities referred to in Article 63(5) and (6), as applicable, can, upon request, immediately access the documentation or obtain a copy thereof. Only staff of the market surveillance authority holding the appropriate level of security clearance shall be allowed to access that documentation or any copy thereof.		
695.			
696.	3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to the exchange		

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	of information and the dissemination of warnings, nor the obligations of the parties concerned to provide information under criminal law of the Member States.		
697.			
698.	4. The Commission and Member States may exchange, where necessary, confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of confidentiality.		

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699.			
700.	*Article 71* *Penalties*		Art. 71 stipulates administrative fines in case of violations of the provisions of the regulation. According to Art. 25 (2) (a) and (b) and 27 (5), representatives, importers and distributors are obliged to provide certain information to the authorities. This raises the question regarding compliance with the nemo tenetur principle. What is the Commission's assessment? Should a right to withhold information be added in the legal text or should Member States at least be explicitly allowed to introduce a right to withhold information in their national laws?
701.			
702.	1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on		

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	penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests of ~~small-scale~~ **SME** providers**, including** ~~and~~ start-up**,** and their economic viability.		
703.			
704.	2. The Member States shall notify the Commission of those rules		

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	and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.		
705.			
706.	3. The following infringements shall be subject to administrative fines of up to 30 000 000 EUR or, if the offender is company, up to 6 % of its total worldwide annual turnover for the preceding financial year, whichever is higher:		
707.			
708.	(a) non-compliance with the prohibition of the artificial intelligence		

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	practices referred to in Article 5;		
709.			
710.	(b) non-compliance of the AI system with the requirements laid down in Article 10.		
711.			
712.	4. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to 20 000 000 EUR or, if the offender is a company, up to 4 % of its total worldwide annual turnover for the preceding		

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	financial year, whichever is higher.		
713.			
714.	5. The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to 10 000 000 EUR or, if the offender is a company, up to 2 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.		
715.			
716.	6. When deciding on the amount of the		

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	administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:		
717.			
718.	(a) the nature, gravity and duration of the infringement and of its consequences;		
719.			
720.	(b) whether administrative fines have been already applied by other market surveillance authorities to the same operator for the same infringement.		

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721.			
722.	(c) the size and market share of the operator committing the infringement;		
723.			
724.	7. Each Member State shall lay down rules on whether and to what extent administrative fines may be imposed on public authorities and bodies established in that Member State.		
725.			
726.	8. Depending on the legal system of the Member States, the rules on administrative fines may be applied in such a		

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	manner that the fines are imposed by competent national courts of other bodies as applicable in those Member States. The application of such rules in those Member States shall have an equivalent effect.		
727.			
728.			
729.			
730.	*Article 72* *Administrative fines on Union institutions, agencies and bodies*		
731.			
732.	1. The European Data Protection Supervisor may impose administrative fines on Union institutions,		

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	agencies and bodies falling within the scope of this Regulation. When deciding whether to impose an administrative fine and deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:		
733.			
734.	(a) the nature, gravity and duration of the infringement and of its consequences;		
735.			

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736.	(b) the cooperation with the European Data Protection Supervisor in order to remedy the infringement and mitigate the possible adverse effects of the infringement, including compliance with any of the measures previously ordered by the European Data Protection Supervisor against the Union institution or agency or body concerned with regard to the same subject matter;		
737.			
738.	(c) any similar previous infringements by the Union institution, agency or body;		

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739.			
740.	2. The following infringements shall be subject to administrative fines of up to 500 000 EUR:		
741.			
742.	(a) non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;		
743.			
744.	(b) non-compliance of the AI system with the requirements laid down in Article 10.		
745.			
746.	3. The non-compliance of the AI system with any		

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	requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to 250 000 EUR.		
747.			
748.	4. Before taking decisions pursuant to this Article, the European Data Protection Supervisor shall give the Union institution, agency or body which is the subject of the proceedings conducted by the European Data Protection Supervisor the opportunity of being heard on the matter regarding the		

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	possible infringement. The European Data Protection Supervisor shall base his or her decisions only on elements and circumstances on which the parties concerned have been able to comment. Complainants, if any, shall be associated closely with the proceedings.		
749.			
750.	5. The rights of defense of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the European Data Protection Supervisor's file, subject to the		

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	legitimate interest of individuals or undertakings in the protection of their personal data or business secrets.		
751.			
752.	6. Funds collected by imposition of fines in this Article shall be the income of the general budget of the Union.		
753.			
754.		7. This article shall not apply to the European Union Military Committee, the European Union Military Staff, the Military Planning and Conduct Capability within the European External Action Service, the European Defence Agency, and any missions or operations established in the framework of the Common Security and Defence Policy.	
755.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
756.	**TITLE XI**		
757.			
758.	**DELEGATION OF POWER AND COMMITTEE PROCEDURE**		
759.			
760.	*Article 73* *Exercise of the delegation*		
761.			
762.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.		
763.			
764.	2. The delegation of power referred to in Article		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall be conferred on the Commission for ~~an~~ **a** ~~indeterminate~~ period of ~~time~~ **five years** from [*entering into force of the Regulation*].		
765.			
766.	**The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the 5 year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the**		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	European Parliament or the Council opposes such extension not later than three months before the end of each period.		
767.			
768.	3. The delegation of power referred to in Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following that of its publication in the *Official*		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.		
769.			
770.			
771.	4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		
772.			
773.	5. Any delegated act adopted pursuant to Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall	5. Any delegated act adopted pursuant to Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall enter into force only if no objection has been expressed by either the European	The regulatory matters that are provided for in this regulation for delegated acts, especially regarding Art. 3 and Art. 7, are very complex, so that a regularly longer consulting time is required to deal with a possible objection.

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	enter into force only if no objection has been expressed by either the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.	Parliament or the Council within a period of three five months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.	
774.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
775.	*Article 74* *Committee procedure*		
776.			
777.	1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.		
778.			
779.	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.		
780.			
781.	**TITLE XII**		
782.			
783.	**FINAL PROVISIONS**		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
784.			
785.	*Article 75* *Amendment to Regulation (EC) No 300/2008*		
786.			
787.	In Article 4(3) of Regulation (EC) No 300/2008, the following subparagraph is added:		
788.			
789.	"When adopting detailed measures related to technical specifications and procedures for approval and use of security equipment concerning Artificial Intelligence systems in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence]		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	of the European Parliament and of the Council*, the requirements set out in Chapter 2, Title III of that Regulation shall be taken into account.”		
790.			
791.	_____		
792.			
793.	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”		
794.			
795.	*Article 76* *Amendment to Regulation (EU) No 167/2013*		
796.			
797.	In Article 17(5) of Regulation (EU) No		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	167/2013, the following subparagraph is added:		
798.			
799.	“When adopting delegated acts pursuant to the first subparagraph concerning artificial intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.		
800.			
801.	_____		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
802.			
803.	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”		
804.			
805.	*Article 77* *Amendment to Regulation (EU) No 168/2013*		
806.			
807.	In Article 22(5) of Regulation (EU) No 168/2013, the following subparagraph is added:		
808.			
809.	“When adopting delegated acts pursuant to the first subparagraph concerning Artificial Intelligence systems which are safety components in the meaning		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	of Regulation (EU) YYY/XX on [Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.		
810.			
811.	_____		
812.			
813.	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”		
814.			
815.	*Article 78* *Amendment to Directive 2014/90/EU*		
816.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
817.	In Article 8 of Directive 2014/90/EU, the following paragraph is added:		
818.			
819.	“4. For Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, when carrying out its activities pursuant to paragraph 1 and when adopting technical specifications and testing standards in accordance with paragraphs 2 and 3, the Commission shall take into		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	account the requirements set out in Title III, Chapter 2 of that Regulation.		
820.			
821.	_____		
822.			
823.	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”.		
824.			
825.	*Article 79* *Amendment to Directive (EU) 2016/797*		
826.			
827.	In Article 5 of Directive (EU) 2016/797, the following paragraph is added:		
828.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
829.	"12. When adopting delegated acts pursuant to paragraph 1 and implementing acts pursuant to paragraph 11 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.		
830.			
831.	_____		
832.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
833.	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”.		
834.			
835.	*Article 80* *Amendment to Regulation (EU) 2018/858*		
836.			
837.	In Article 5 of Regulation (EU) 2018/858 the following paragraph is added:		
838.			
839.	“4. When adopting delegated acts pursuant to paragraph 3 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU)		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council *, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.		
840.			
841.	_____		
842.			
843.	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”.		
844.			
845.	*Article 81* *Amendment to Regulation (EU) 2018/1139*		
846.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
847.	Regulation (EU) 2018/1139 is amended as follows:		
848.			
849.	(1) In Article 17, the following paragraph is added:		
850.			
851.	“3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [*on Artificial Intelligence*] of the European Parliament and of the Council*, the		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.		
852.			
853.	_____		
854.			
855.	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …)."		
856.			
857.	(2) In Article 19, the following paragraph is added:		
858.			
859.	"4. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account."		
860.			
861.	(3) In Article 43, the following paragraph is added:		
862.			
863.	"4. When adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU)		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account."		
864.			
865.	(4) In Article 47, the following paragraph is added:		
866.			
867.	"3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account."		
868.			
869.	(5) In Article 57, the following paragraph is added:		
870.			
871.	"When adopting those implementing acts concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	Regulation shall be taken into account.”		
872.			
873.	(6) In Article 58, the following paragraph is added:		
874.			
875.	“3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] , the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.”.		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
876.			
877.	*Article 82* *Amendment to Regulation (EU) 2019/2144*		
878.			
879.	In Article 11 of Regulation (EU) 2019/2144, the following paragraph is added:		
880.			
881.	"3. When adopting the implementing acts pursuant to paragraph 2, concerning artificial intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.		
882.			
883.	_____		
884.			
885.	* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”.		
886.			
887.	*Article 83* *AI systems already placed on the market or put into service*		
888.			
889.	1. This Regulation shall not apply to the AI systems which are components of		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before *[12 months after the date of application of this Regulation referred to in Article 85(2)]*, unless the replacement or amendment of those legal acts leads to a significant change in the design or intended purpose of the AI system or AI systems concerned.		
890.			
891.	The requirements laid down in this Regulation shall be taken into account, where applicable, in the		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts.		
892.			
893.	2. This Regulation shall apply to the high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [*date of application of this Regulation referred to in Article 85(2)*], only if, from that date, those systems are subject to significant		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	changes in their design or intended purpose.		
894.			
895.	*Article 84* *Evaluation and review*		
896.			
~~897.~~	~~1. The Commission shall assess the need for amendment of the list in Annex III once a year following the entry into force of this Regulation.~~		
~~898.~~			
899.	**1a. The Commission shall assess the need for amendment of the list in Annex I every 24 months following the entry into force of this Regulation and until the end of the**		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	period of the delegation of power. The findings of that assessment shall be presented to the European Parliament and the Council.		
900.			
901.	**1b. The Commission shall assess the need for amendment of the list in Annex III every 24 months following the entry into force of this Regulation and until the end of the period of the delegation of power. The findings of that assessment shall be presented to the**		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	European Parliament and the Council.		
902.			
903.	2. By [*three years after the date of application of this Regulation referred to in Article 85(2)*] and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The reports shall be made public.		
904.			
905.	3. The reports referred to in paragraph 2 shall devote specific attention to the following:		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
906.			
907.	(a) the status of the financial and human resources of the national competent authorities in order to effectively perform the tasks assigned to them under this Regulation;		
908.			
909.	(b) the state of penalties, and notably administrative fines as referred to in Article 71(1), applied by Member States to infringements of the provisions of this Regulation.	the state of penalties, and notably administrative fines as referred to in Article 71(1), applied by Member States to infringements of the provisions of this Regulation~~.~~;	
910.		(new) the status of the EU database for stand-alone high-risk AI systems and planned developments;	

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
911.		(new) the state of measures in support of innovation, in particular measures for SME providers;	
912.		(new) the state of the code of conduct and the application to AI systems other than high-risk AI systems.	
913.			
914.	4. Within [*three years after the date of application of this Regulation referred to in Article 85(2)*] and every four years thereafter, the Commission shall evaluate the impact and effectiveness of codes of conduct to foster the application of the requirements set out in Title III, Chapter 2 and possibly other additional		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	requirements for AI systems other than high-risk AI systems.		
915.			
916.	5. For the purpose of paragraphs 1 to 43 the Board, the Member States and national competent authorities shall provide the Commission with information on its request.		
917.			
918.	6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4**3** the Commission shall take into account the positions and findings of the Board, of the European Parliament, of the Council,		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	and of other relevant bodies or sources.		
919.			
920.	7. The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology and in the light of the state of progress in the information society.		
921.			
922.	*Article 85* *Entry into force and application*		
923.			
924.	1. This Regulation shall enter into force on the twentieth day following		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	that of its publication in the *Official Journal of the European Union*.		
925.			
926.	2. This Regulation shall apply from [24 months following the entering into force of the Regulation].		
927.			
928.	3. By way of derogation from paragraph 2:		
929.			
930.	(a) Title III, Chapter 4 and Title VI shall apply from [three months following the entry into force of this Regulation];		
931.			
932.	(b) Article 71 shall apply from [twelve months		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	following the entry into force of this Regulation].		
933.			
934.	This Regulation shall be binding in its entirety and directly applicable in all Member States.		
935.			
936.	Done at Brussels,		
937.			
938.	*For the European Parliament For the Council*		
939.			
940.	*The President The President*		
941.			
942.			
943.			
944.	**ANNEX IV TECHNICAL**		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	DOCUMENTATION referred to in Article 11(1)		
945.			
946.	The technical documentation referred to in Article 11(1) shall contain at least the following information, as applicable to the relevant AI system:		
947.			
948.	1. A general description of the AI system including:		
949.			
950.	(a) its intended purpose, the person/s developing the system the date and the version of the system;		
951.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
952.	(b) how the AI system interacts or can be used to interact with hardware or software that is not part of the AI system itself, where applicable;		
953.			
954.	(c) the versions of relevant software or firmware and any requirement related to version update;		
955.			
956.	(d) the description of all forms in which the AI system is placed on the market or put into service;		
957.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
958.	(e) the description of hardware on which the AI system is intended to run;		
959.			
960.	(f) where the AI system is a component of products, photographs or illustrations showing external features, marking and internal layout of those products;		
961.			
962.	(g) instructions of use for the user and, where applicable installation instructions;		
963.			
964.	2. A detailed description of the elements of the AI system and of the		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	process for its development, including:		
965.			
966.	(a) the methods and steps performed for the development of the AI system, including, where relevant, recourse to pre-trained systems or tools provided by third parties and how these have been used, integrated or modified by the provider;		
967.			
968.	(b) the design specifications of the system, namely the general logic of the AI system and of the algorithms; the key design choices including		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	the rationale and assumptions made, also with regard to persons or groups of persons on which the system is intended to be used; the main classification choices; what the system is designed to optimise for and the relevance of the different parameters; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Title III, Chapter 2;		
969.			
970.	(c) the description of the system architecture		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	explaining how software components build on or feed into each other and integrate into the overall processing; the computational resources used to develop, train, test and validate the AI system;		
971.			
972.	(d) where relevant, the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used, including information about the provenance of those data sets, their scope and main characteristics; how the data was obtained and		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	selected; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection);		
973.			
974.	(e) assessment of the human oversight measures needed in accordance with Article 14, including an assessment of the technical measures needed to facilitate the interpretation of the outputs of AI systems by the users, in accordance with Articles 13(3)(d);		
975.			
976.	(f) where applicable, a detailed description of pre-		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	determined changes to the AI system and its performance, together with all the relevant information related to the technical solutions adopted to ensure continuous compliance of the AI system with the relevant requirements set out in Title III, Chapter 2;		
977.			
978.	(g) the validation and testing procedures used, including information about the validation and testing data used and their main characteristics; metrics used to measure accuracy, robustness, cybersecurity and		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	compliance with other relevant requirements set out in Title III, Chapter 2 as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point (f).		
979.			
980.	3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for	Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended	Unintended outcomes and sources of risks to the environment may include environmental damages provoked by the foreseeable misrecognition of e.g. technical defects due to imperfect accuracy. As illustration, the introduction of an AI-based defect detection system in chemicals production plants may entail a reduction of workforce to monitor plant

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system; the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI	outcomes and sources of risks to health and safety, fundamental rights, the environment and discrimination in view of the intended purpose of the AI system; (…)	behavior as well as a heavier reliance on the AI system. If the AI system would now miss to correctly identify a defect such as the leakage of harmful chemicals, the leakage might remain unnoticed for longer as less people are charged with monitoring tasks. While AI systems can significantly improve the detection of plant malfunctioning and the intended purpose of such a system presents a large benefit to the environment, the foreseable unintented outcome should nevertheless be thought through beforehand and idealy be complemented by precautionary measures.

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	systems by the users; specifications on input data, as appropriate;		
981.			
982.	4. A detailed description of the risk management system in accordance with Article 9;		
983.			
984.	5. A description of any change made to the system through its lifecycle;		
985.			
986.	6. A list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union; where no		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	such harmonised standards have been applied, a detailed description of the solutions adopted to meet the requirements set out in Title III, Chapter 2, including a list of other relevant standards and technical specifications applied;		
987.			
988.	7. A copy of the EU declaration of conformity;		
989.			
990.	8. A detailed description of the system in place to evaluate the AI system performance in the post-market phase in accordance with Article 61,		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	including the post-market monitoring plan referred to in Article 61(3).		
991.			
992.	**ANNEX V** **EU DECLARATION OF CONFORMITY**		
993.			
994.	The EU declaration of conformity referred to in Article 48, shall contain all of the following information:		
995.			
996.	1. AI system name and type and any additional unambiguous reference allowing identification and traceability of the AI system;		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
997.			
998.	2. Name and address of the provider or, where applicable, their authorised representative;		
999.			
1000.	3. A statement that the EU declaration of conformity is issued under the sole responsibility of the provider;		
1001.			
1002.	4. A statement that the AI system in question is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	issuing of an EU declaration of conformity;		
1003.			
1004.	5. References to any relevant harmonised standards used or any other common specification in relation to which conformity is declared;		
1005.			
1006.	6. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate issued;		
1007.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
1008.	7. Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.		
1009.			
1010.	**ANNEX VI CONFORMITY ASSESSMENT PROCEDURE BASED ON INTERNAL CONTROL**		
1011.			
1012.	1. The conformity assessment procedure based on internal control is the conformity assessment		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	procedure based on points 2 to 4.		
1013.			
1014.	2. The provider verifies that the established quality management system is in compliance with the requirements of Article 17.		
1015.			
1016.	3. The provider examines the information contained in the technical documentation in order to assess the compliance of the AI system with the relevant essential requirements set out in Title III, Chapter 2.		
1017.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
1018.	4. The provider also verifies that the design and development process of the AI system and its post-market monitoring as referred to in Article 61 is consistent with the technical documentation.		
1019.			
1020.	**ANNEX VII CONFORMITY BASED ON ASSESSMENT OF QUALITY MANAGEMENT SYSTEM AND ASSESSMENT OF TECHNICAL DOCUMENTATION**		
1021.			
1022.	1. Introduction		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
1023.			
1024.	Conformity based on assessment of quality management system and assessment of the technical documentation is the conformity assessment procedure based on points 2 to 5.		
1025.			
1026.	2. Overview		
1027.			
1028.	The approved quality management system for the design, development and testing of AI systems pursuant to Article 17 shall be examined in accordance with point 3 and shall be subject to surveillance as		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	specified in point 5. The technical documentation of the AI system shall be examined in accordance with point 4.		
1029.			
1030.	3. Quality management system		
1031.			
1032.	3.1. The application of the provider shall include:		
1033.			
1034.	(a) the name and address of the provider and, if the application is lodged by the authorised representative, their name and address as well;		
1035.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
1036.	(b) the list of AI systems covered under the same quality management system;		
1037.			
1038.	(c) the technical documentation for each AI system covered under the same quality management system;		
1039.			
1040.	(d) the documentation concerning the quality management system which shall cover all the aspects listed under Article 17;		
1041.			
1042.	(e) a description of the procedures in place to ensure that the quality		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	management system remains adequate and effective;		
1043.			
1044.	(f) a written declaration that the same application has not been lodged with any other notified body.		
1045.			
1046.	3.2. The quality management system shall be assessed by the notified body, which shall determine whether it satisfies the requirements referred to in Article 17.		
1047.			
1048.	The decision shall be notified to the provider or		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	its authorised representative.		
1049.			
1050.	The notification shall contain the conclusions of the assessment of the quality management system and the reasoned assessment decision.		
1051.			
1052.	3.3. The quality management system as approved shall continue to be implemented and maintained by the provider so that it remains adequate and efficient.		
1053.			
1054.	3.4. Any intended change to the approved quality		

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	management system or the list of AI systems covered by the latter shall be brought to the attention of the notified body by the provider.		
1055.			
1056.	The proposed changes shall be examined by the notified body, which shall decide whether the modified quality management system continues to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.		
1057.			
1058.	The notified body shall notify the provider of its		

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	decision. The notification shall contain the conclusions of the examination of the changes and the reasoned assessment decision.		
1059.			
1060.	4. Control of the technical documentation.		
1061.			
1062.	4.1. In addition to the application referred to in point 3, an application with a notified body of their choice shall be lodged by the provider for the assessment of the technical documentation relating to the AI system which the provider intends to place		

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	on the market or put into service and which is covered by the quality management system referred to under point 3.		
1063.			
1064.	4.2. The application shall include:		
1065.			
1066.	(a) the name and address of the provider;		
1067.			
1068.	(b) a written declaration that the same application has not been lodged with any other notified body;		
1069.			
1070.	(c) the technical documentation referred to in Annex IV.		

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1071.			
1072.	4.3. The technical documentation shall be examined by the notified body. To this purpose, the notified body shall be granted full access to the training and testing datasets used by the provider, including through application programming interfaces (API) or other appropriate means and tools enabling remote access.		
1073.			
1074.	4.4. In examining the technical documentation, the notified body may require that the provider		

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	supplies further evidence or carries out further tests so as to enable a proper assessment of conformity of the AI system with the requirements set out in Title III, Chapter 2. Whenever the notified body is not satisfied with the tests carried out by the provider, the notified body shall directly carry out adequate tests, as appropriate.		
1075.			
1076.	4.5. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	and upon a reasoned request, the notified body shall also be granted access to the source code of the AI system.		
1077.			
1078.	4.6. The decision shall be notified to the provider or its authorised representative. The notification shall contain the conclusions of the assessment of the technical documentation and the reasoned assessment decision.		
1079.			
1080.	Where the AI system is in conformity with the requirements set out in		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	Title III, Chapter 2, an EU technical documentation assessment certificate shall be issued by the notified body. The certificate shall indicate the name and address of the provider, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for the identification of the AI system.		
1081.			
1082.	The certificate and its annexes shall contain all relevant information to allow the conformity of the AI system to be evaluated, and to allow for control of		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	the AI system while in use, where applicable.		
1083.			
1084.	Where the AI system is not in conformity with the requirements set out in Title III, Chapter 2, the notified body shall refuse to issue an EU technical documentation assessment certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.		
1085.			
1086.	Where the AI system does not meet the requirement relating to the data used to train it, re-training of the AI system will be needed		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	prior to the application for a new conformity assessment. In this case, the reasoned assessment decision of the notified body refusing to issue the EU technical documentation assessment certificate shall contain specific considerations on the quality data used to train the AI system, notably on the reasons for non-compliance.		
1087.			
1088.	4.7. Any change to the AI system that could affect the compliance of the AI system with the requirements or its		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	intended purpose shall be approved by the notified body which issued the EU technical documentation assessment certificate. The provider shall inform such notified body of its intention to introduce any of the above-mentioned changes or if it becomes otherwise aware of the occurrence of such changes. The intended changes shall be assessed by the notified body which shall decide whether those changes require a new conformity assessment in accordance with Article 43(4) or whether they		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the provider of its decision and, where the changes are approved, issue to the provider a supplement to the EU technical documentation assessment certificate.		
1089.			
1090.	5. Surveillance of the approved quality management system.		
1091.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
1092.	5.1. The purpose of the surveillance carried out by the notified body referred to in Point 3 is to make sure that the provider duly fulfils the terms and conditions of the approved quality management system.		
1093.			
1094.	5.2. For assessment purposes, the provider shall allow the notified body to access the premises where the design, development, testing of the AI systems is taking place. The provider shall further share with the notified body all necessary information.		It is suggested to specify that this applies only to the final AI system, as AI systems currently consist of different components developed internationally so that uniform access is not possible. In addition, leading AI companies sometimes operate 'remote', i.e. without open premises.

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
1095.			
1096.	5.3. The notified body shall carry out periodic audits to make sure that the provider maintains and applies the quality management system and shall provide the provider with an audit report. In the context of those audits, the notified body may carry out additional tests of the AI systems for which an EU technical documentation assessment certificate was issued.		
1097.			
1098.	**ANNEX VIII INFORMATION TO BE SUBMITTED UPON**		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	THE REGISTRATION OF HIGH-RISK AI SYSTEMS IN ACCORDANCE WITH ARTICLE 51		
1099.			
1100.	The following information shall be provided and thereafter kept up to date with regard to high-risk AI systems to be registered in accordance with Article 51.	The following information shall be provided and thereafter kept up to date with regard to ~~high-risk~~ AI systems to be registered in accordance with Article 51.	
1101.			
1102.	1. Name, address and contact details of the provider;		
1103.		1. a) Name, address and contact details of the public authority using an AI system;	To ensure greater public oversight of AI-systems and to access information about in which contexts AI-systems are put in operation, the framework must be complemented by the

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
			information, which public authority is deploying the high risk AI-system.
1104.	2. Where submission of information is carried out by another person on behalf of the provider, the name, address and contact details of that person;		
1105.			
1106.	3. Name, address and contact details of the authorised representative, where applicable;		
1107.			
1108.	4. AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system;		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
1109.			
1110.	5. Description of the intended purpose of the AI system;		
1111.			
1112.	6. Status of the AI system (on the market, or in service; no longer placed on the market/in service, recalled);		.
1113.			
1114.	7. Type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body, when applicable;		
1115.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
1116.	8. A scanned copy of the certificate referred to in point 7, when applicable;		
1117.			
1118.	9. Member States in which the AI system is or has been placed on the market, put into service or made available in the Union;		
1119.			
1120.	10. A copy of the EU declaration of conformity referred to in Article 48;		
1121.			
1122.	11. Electronic instructions for use; this information shall not be provided for high-risk AI systems in the areas of law		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	enforcement and migration, asylum and border control management referred to in Annex III, points 1, 6 and 7.		
1123.			
1124.	12. URL for additional information (optional).		
1125.			
1126.	**ANNEX IX UNION LEGISLATION ON LARGE-SCALE IT SYSTEMS IN THE AREA OF FREEDOM, SECURITY AND JUSTICE**		
1127.			
1128.	1. Schengen Information System		
1129.			

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
1130.	(a) Regulation (EU) 2018/1860 of the European Parliament and of the Council of 28 November 2018 on the use of the Schengen Information System for the return of illegally staying third-country nationals (OJ L 312, 7.12.2018, p. 1).		
1131.			
1132.	(b) Regulation (EU) 2018/1861 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of border checks, and		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	amending the Convention implementing the Schengen Agreement, and amending and repealing Regulation (EC) No 1987/2006 (OJ L 312, 7.12.2018, p. 14)		
1133.			
1134.	(c) Regulation (EU) 2018/1862 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of police cooperation and judicial cooperation in criminal matters, amending and repealing Council		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	Decision 2007/533/JHA, and repealing Regulation (EC) No 1986/2006 of the European Parliament and of the Council and Commission Decision 2010/261/EU (OJ L 312, 7.12.2018, p. 56).		
1135.			
1136.	2. Visa Information System		
1137.			
1138.	(a) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 767/2008, Regulation (EC) No 810/2009, Regulation		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	(EU) 2017/2226, Regulation (EU) 2016/399, Regulation XX/2018 [Interoperability Regulation], and Decision 2004/512/EC and repealing Council Decision 2008/633/JHA - COM(2018) 302 final. To be updated once the Regulation is adopted (April/May 2021) by the co-legislators.		
1139.			
1140.	3. Eurodac		
1141.			
1142.	(a) Amended proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	THE COUNCIL on the establishment of 'Eurodac' for the comparison of biometric data for the effective application of Regulation (EU) XXX/XXX [Regulation on Asylum and Migration Management] and of Regulation (EU) XXX/XXX [Resettlement Regulation], for identifying an illegally staying third-country national or stateless person and on requests for the comparison with Eurodac data by Member States' law enforcement authorities and Europol for law		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	enforcement purposes and amending Regulations (EU) 2018/1240 and (EU) 2019/818 – COM(2020) 614 final.		
1143.			
1144.	4. Entry/Exit System		
1145.			
1146.	(a) Regulation (EU) 2017/2226 of the European Parliament and of the Council of 30 November 2017 establishing an Entry/Exit System (EES) to register entry and exit data and refusal of entry data of third-country nationals crossing the external borders of the Member States and determining the		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	conditions for access to the EES for law enforcement purposes, and amending the Convention implementing the Schengen Agreement and Regulations (EC) No 767/2008 and (EU) No 1077/2011 (OJ L 327, 9.12.2017, p. 20).		
1147.			
1148.	5. European Travel Information and Authorisation System		
1149.			
1150.	(a) Regulation (EU) 2018/1240 of the European Parliament and of the Council of 12 September 2018 establishing a		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	European Travel Information and Authorisation System (ETIAS) and amending Regulations (EU) No 1077/2011, (EU) No 515/2014, (EU) 2016/399, (EU) 2016/1624 and (EU) 2017/2226 (OJ L 236, 19.9.2018, p. 1).		
1151.			
1152.	(b) Regulation (EU) 2018/1241 of the European Parliament and of the Council of 12 September 2018 amending Regulation (EU) 2016/794 for the purpose of establishing a European Travel Information and		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	Authorisation System (ETIAS) (OJ L 236, 19.9.2018, p. 72).		
1153.			
1154.	6. European Criminal Records Information System on third-country nationals and stateless persons		
1155.			
1156.	(a) Regulation (EU) 2019/816 of the European Parliament and of the Council of 17 April 2019 establishing a centralised system for the identification of Member States holding conviction information on third-country nationals and		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	stateless persons (ECRIS-TCN) to supplement the European Criminal Records Information System and amending Regulation (EU) 2018/1726 (OJ L 135, 22.5.2019, p. 1).		
1157.			
1158.	7. Interoperability		
1159.			
1160.	(a) Regulation (EU) 2019/817 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of		

Lfd Nr	Presidency compromise text	Drafting Suggestions	Comments
	borders and visa (OJ L 135, 22.5.2019, p. 27).		
1161.			
1162.	(b) Regulation (EU) 2019/818 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of police and judicial cooperation, asylum and migration (OJ L 135, 22.5.2019, p. 85).		
1163.			
1164.		**End**	**End**