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CONTRIBUTION

From:	General Secretariat of the Council
To:	Working Party on Telecommunications and Information Society
Subject:	Artificial Intelligence Act - NL comments (doc. 14278/21)

Delegations will find in annex the NL comments on Artificial Intelligence Act (doc. 14278/21).

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).

Presidency compromise text	Drafting Suggestions	Comments
Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS (Text with EEA relevance)		
CHAPTER 4		
NOTIFYING AUTHORITIES AND NOTIFIED BODIES		

Presidency compromise text	Drafting Suggestions	Comments
Article 30 Notifying authorities		
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.		
2. Member States may designate a national accreditation body referred to in Regulation (EC) No 765/2008 as a notifying authority.		
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.		

Presidency compromise text	Drafting Suggestions	Comments
4. Notifying authorities shall be organised in such a way that decisions relating to the notification of conformity assessment bodies are taken by competent persons different from those who carried out the assessment of those bodies.		
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.		
6. Notifying authorities shall safeguard the confidentiality of the information they obtain.	Insofar the information obtained by the notifying authorities must be considered confidential , the notifying authorities shall safeguard the confidentiality of the information they obtain this information, except when disclosure is required by Union or national law.	We propose to first test whether the information obtained is indeed confidential. If not, the information can be shared freely. If the answer is yes, confidentiality must be safeguarded, except when disclosure is required by Union or national law.
7. Notifying authorities shall have a sufficient number of competent personnel at	Member States shall ensure that the notifying authorities have a sufficient number of	More firm commitments necessary. The word 'proper' is too vague.

Presidency compromise text	Drafting Suggestions	Comments
their disposal for the proper performance of their tasks.	competent personnel at their disposal for the proper performance of their tasks.	
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.		
<i>Article 31</i> <i>Application of a conformity assessment body for notification</i>		
1. Conformity assessment bodies shall submit an application for notification to the notifying authority of the Member State in which they are established.		

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<p>2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 33. Any valid document related to existing designations of the applicant notified body under any other Union harmonisation legislation shall be added.</p>		
<p>3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the</p>	<p>3. Conformity assessment bodies should preferably provide an accreditation certificate to demonstrate compliance with the requirements laid down in Article 33. Only where the conformity assessment body concerned cannot provide an accreditation certificate, it shall</p>	<p>We suggest specifying in Art. 31.3 that accreditation should be the starting point. Exceptions should only be possible in case of compelling reasons.</p>

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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.	provide the notifying authority with the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 33. For notified bodies which are designated under any other Union harmonisation legislation, all documents and certificates linked to those designations may be used to support their designation procedure under this Regulation, as appropriate.	
<i>Article 32</i> <i>Notification procedure</i>		There is no paragraph dedicated to the consequences of an objection and whether this triggers the processes described in article 36 or article 37.
1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 33.		

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<p>2. Notifying authorities shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.</p>	<p>using the electronic notification tool [reference needed] developed and managed by the Commission.</p>	<p>Is this is a new tool based on existing tools in other areas, please provide a reference to that or explain how this tool will be developed.</p>
<p>3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies concerned.</p>	<p>The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies concerned and the relevant attestation of competence.</p> <p>Where a notification is not based on an accreditation certificate as referred to in Article 31 (2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 33.</p>	<p>We would suggest adding a paragraph on notifications that are not based on accreditation certificates in order to better ensure competence and compliance with Art. 33.</p>

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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.	The conformity assessment body concerned may perform the activities of a notified body as referred to in article 31/recital 64 only where no objections are raised by the Commission or the other Member States within one month of a notification within two weeks of the notification where it includes an accreditation certificate referred to in Article 31 paragraph 2 or within two months of the notification where it includes documentary evidence referred to in Article 31 paragraph 3.	Suggestion to clarify to which activities this article refers, is this article 31? We would suggest making a distinction between notifications based on accreditation certificates and notifications based on other documentary evidence. The latter would require more intensive investigation. Also we would suggest clarifying that only assessment bodies that have been notified without any objections being raised may be considered notified bodies.
5. Notifying authorities shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.	Notifying authorities shall notify the Commission and the other Member States of any subsequent relevant changes to the notification referred to in paragraph 2.	Minor specification.
<i>Article 33</i> <i>Notified bodies</i>		We noticed that no presumption of conformity has been introduced in this article for notified bodies that demonstrate conformity with applicable harmonized standards that cover the

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		requirements set out in this Regulation. We would suggest to consider including such a presumption of conformity.
1. Notified bodies shall verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43.		What conformity of high risk AI shall the notified bodies exactly verify (production, use, etc.)?
2. Notified bodies shall satisfy the organisational, quality management, resources and process requirements that are necessary to fulfil their tasks.		
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.		

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4. Notified bodies shall be independent of the provider of a high-risk AI system in relation to which it performs conformity assessment activities. Notified bodies shall also be independent of any other operator having an economic interest in the high-risk AI system that is assessed, as well as of any competitors of the provider.	Notified bodies shall be independent of the provider of a high-risk AI system in relation to which it performs conformity assessment activities . Notified bodies shall ensure there is no conflict of interest and 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.	Overall independence seems a better way. Added ‘no conflict of interest’ to make sure that what is not mentioned here is also covered.
5. Notified bodies shall be organised and operated so as to safeguard the independence, objectivity and impartiality of their activities. Notified bodies shall document and implement a structure and procedures to safeguard impartiality and to promote and apply the principles of impartiality throughout their organisation, personnel and assessment activities.	Notified bodies shall be organised and operated so as to safeguard the independence, objectivity and impartiality of their activities. Notified bodies shall document and implement a structure and procedures to safeguard impartiality and to promote and apply the principles of impartiality throughout their organisation, personnel and assessment activities. The remuneration of the top level management and the personnel responsible for carrying out the conformity assessments tasks	Addition to ensure impartiality at top level management.

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	shall not depend on the number of conformity assessments carried out or on the results of those assessments.	
6. Notified bodies shall have documented procedures in place ensuring that their personnel, committees, subsidiaries, subcontractors and any associated body or personnel of external bodies respect the confidentiality of the information which comes into their possession during the performance of conformity assessment activities, except when disclosure is required by law. The staff of notified bodies shall be bound to observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the notifying authorities of the Member State in which their activities are carried out.	except in relation to the notifying and national authorities of the Member State in which their activities are carried out.	Suggestion for minor specification to enable information sharing with national authorities.

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7. Notified bodies shall have procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the AI system in question.		
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.	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 in the notifying Member State or that Member State is itself directly responsible for the conformity assessment.	For clarification: Is liability insurance not a matter of responsibility of notifying bodies themselves, why is it in the article?
9. Notified bodies shall be capable of carrying out all the tasks falling to them under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by notified bodies		

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themselves or on their behalf and under their responsibility.		
10. Notified bodies shall have sufficient internal competences to be able to effectively evaluate the tasks conducted by external parties on their behalf. To that end, at all times and for each conformity assessment procedure and each type of high-risk AI system in relation to which they have been designated, the notified body shall have permanent availability of sufficient administrative, technical and scientific personnel who possess experience and knowledge relating to the relevant artificial intelligence technologies, data and data computing and to the requirements set out in Chapter 2 of this Title.	who possess experience and knowledge relating to the relevant artificial intelligence technologies, data and data computing, fundamental rights, health and safety risks and to the requirements set out in Chapter 2 of this Title.	In addition to technical knowledge, notified bodies should have substantive expertise relating to fundamental rights, in order to be able to appropriately assess whether the manner in which chapter 2 of this title is applied, effectively safeguards against fundamental rights risks and health and safety risks.
11. Notified bodies shall participate in coordination activities as referred to in Article 38. They shall also take part directly or be		

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represented in European standardisation organisations, or ensure that they are aware and up to date in respect of relevant standards.		
12. Notified bodies shall make available and submit upon request all relevant documentation, including the providers' documentation, to the notifying authority referred to in Article 30 to allow it to conduct its assessment, designation, notification, monitoring and surveillance activities and to facilitate the assessment outlined in this Chapter.		
<i>Article 34</i> <i>Subsidiaries of and subcontracting by notified bodies</i>		
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		More general question: is it necessary to make use of subcontracting. If the answer is yes, than describing in which circumstances this is

Presidency compromise text	Drafting Suggestions	Comments
subsidiary meets the requirements laid down in Article 33 and shall inform the notifying authority accordingly.		allowed and/or in which not could give a more clear and transparent picture.
2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.		
3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the provider.	3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the provider. The establishment and the supervision of internal procedures, general policies, codes of conduct or other internal rules, the assignment of personnel to specific tasks and the decision on certification may not be delegated to a subcontractor or a subsidiary.	Given the ongoing discussions about subcontracting we would suggest specifying the desired scope of activities that may be subcontracted or carried out by a subsidiary. Some activities are not suited for subcontracting in our view.
4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the		

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qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.		
<i>Article 35</i> <i>Identification numbers and lists of notified bodies designated under this Regulation</i>		
1. The Commission shall assign an identification number to notified bodies. It shall assign a single number, even where a body is notified under several Union acts.		
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.		

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<i>Article 36</i> <i>Changes to notifications</i>		
<p>1. Where a notifying authority has suspicions or has been informed that a notified body no longer meets the requirements laid down in Article 33, or that it is failing to fulfil its obligations, that authority shall without delay investigate the matter with the utmost diligence. In that context, it shall inform the notified body concerned about the objections raised and give it the possibility to make its views known. If the notifying authority comes to the conclusion that the notified body investigation no longer meets the requirements laid down in 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.</p>		

Presidency compromise text	Drafting Suggestions	Comments
2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying authority shall take appropriate steps to ensure that the files of that notified body are either taken over by another notified body or kept available for the responsible notifying authorities at their request.		
<i>Article 37</i> <i>Challenge to the competence of notified bodies</i>		
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.	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 and other requirements and responsibilities to which it is subject.	We would prefer a more specific approach in order to ensure compliance.

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2. The Notifying authority shall provide the Commission, on request, with all relevant information relating to the notification of the notified body concerned.		
3. The Commission shall ensure that all confidential information obtained in the course of its investigations pursuant to this Article is treated confidentially.		
4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements laid down in Article 33, it shall adopt a reasoned decision requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(2).		

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<i>Article 38</i> <i>Coordination of notified bodies</i>		
<p>1. The Commission shall ensure that, with regard to the areas covered by this Regulation, appropriate coordination and cooperation between notified bodies active in the conformity assessment procedures of AI systems pursuant to this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.</p>		
<p>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.</p>		
<i>Article 39</i> <i>Conformity assessment bodies of third countries</i>		<p>Suggestion to specify the procedure with third countries, referencing to existing agreements regarding conformity assessment bodies where possible and clarifying how this relates to the</p>

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		judgment that accreditation of a notified body must be done by the national accreditation body (located in the European Union) (C-142/20 - Analisi G. Caracciolo).
Conformity assessment bodies established under the law of a third country with which the Union has concluded an agreement may be authorised to carry out the activities of notified Bodies under this Regulation.	Conformity assessment bodies established under the law of a third country with which the Union has concluded an agreement may be authorised to carry out the activities of notified Bodies under this Regulation, provided that they meet the requirements in Article 33.	Minor suggestion for specification, agreement need further elaboration with possible references to existing type of agreements. Furthermore we suggest to include a procedure when it is suspected that the notified body in a third country does not meet/no longer meets the requirements laid down in Article 33.
CHAPTER 5		
STANDARDS, CONFORMITY ASSESSMENT, CERTIFICATES, REGISTRATION		

Presidency compromise text	Drafting Suggestions	Comments
<i>Article 40</i> <i>Harmonised standards</i>		<p>The standards mentioned here should solely be of genuinely technical aspects. The overall authority to set standards and perform oversight of issues that are not purely technical, such as bias mitigation, should remain in the remit of the legislative process guaranteeing parliamentary scrutiny and multistakeholder engagement.</p>
<p>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.</p>		
<i>Article 41</i> <i>Common specifications</i>		

Presidency compromise text	Drafting Suggestions	Comments
<p>1. Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns, the Commission may, by means of implementing acts, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).</p>		
<p>2. The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant bodies or expert groups established under relevant sectorial Union law.</p>	<p>The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant bodies or expert groups established under relevant sectorial Union law, and member states.</p>	<p>As common standards and specifications translate important requirements that aim to protect fundamental rights, member states should be at least consulted.</p>

Presidency compromise text	Drafting Suggestions	Comments
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.		
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.		
<i>Article 42</i> <i>Presumption of conformity with certain requirements</i>		
1. Taking into account their intended purpose, high-risk AI systems that have been trained and tested on data concerning the	1. — Taking into account their intended purpose, high-risk AI systems that have been trained and tested on data concerning the	We propose to delete this paragraph because we find that it does not increase clarity in relation to article 10(4).

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specific geographical, behavioural and functional setting within which they are intended to be used shall be presumed to be in compliance with the requirement set out in Article 10(4).	specific geographical, behavioural and functional setting within which they are intended to be used shall be presumed to be in compliance with the requirement set out in Article 10(4).	
2. High-risk AI systems that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 of the European Parliament and of the Council ¹ and the references of which have been published in the Official Journal of the European Union shall be presumed to be in compliance with the cybersecurity requirements set out in Article 15 of this Regulation in so far as the cybersecurity certificate or statement of conformity or parts thereof cover those requirements.		

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).

Presidency compromise text	Drafting Suggestions	Comments
Article 43 Conformity assessment		
1. For high-risk AI systems listed in point 1 of Annex III, where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider has applied harmonised standards referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall follow one of the following procedures:		
(a) the conformity assessment procedure based on internal control referred to in Annex VI;		We underline the importance of the effectiveness of conformity assessments in case of both self- and third party assessments. We are currently considering and studying the option that the same procedural requirements for point 1 of Annex III would also be the preferred option for certain other points in Annex III.

Presidency compromise text	Drafting Suggestions	Comments
(b) the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation, with the involvement of a notified body, referred to in Annex VII.		
Where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider has not applied or has applied only in part harmonised standards referred to in Article 40, or where such harmonised standards do not exist and common specifications referred to in Article 41 are not available, the provider shall follow the conformity assessment procedure set out in Annex VII.		
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	However, when the system is intended to be put into service by law enforcement, immigration or asylum authorities or judicial authorities as well as EU institutions, bodies or agencies, the	Add judicial authorities in line with the suggested change in article 63. Reference to article 63 must also be changed accordingly.

Presidency compromise text	Drafting Suggestions	Comments
into service by law enforcement, immigration or asylum authorities as well as EU institutions, bodies or agencies, the market surveillance authority referred to in Article 63(5) or (6), as applicable, shall act as a notified body.	market surveillance authority referred to in Article 63(5) or (6), as applicable, shall act as a notified body.	
2. For high-risk AI systems referred to in points 2 to 8 of Annex III, providers shall follow the conformity assessment procedure based on internal control as referred to in Annex VI, which does not provide for the involvement of a notified body. For high-risk AI systems referred to in point 5(b) of Annex III, placed on the market or put into service by credit institutions regulated by Directive 2013/36/EU, the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to 101 of that Directive.		The CRD doesn't regulate the offering of (consumer) credit, this is regulated by the CCD and MCD. Should this article therefore not refer to the CDD and the MCD instead of the CRD? How does the commission see the difference in this regulation between banks offering credit and other non-bank parties that offer credit?
3. For high-risk AI systems, to which legal acts listed in Annex II, section A, apply, the		

Presidency compromise text	Drafting Suggestions	Comments
<p>provider shall follow the relevant conformity assessment as required under those legal acts.</p> <p>The requirements set out in Chapter 2 of this Title shall apply to those high-risk AI systems and shall be part of that assessment. Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII shall also apply.</p>		
<p>For the purpose of that assessment, notified bodies which have been notified under those legal acts shall be entitled to control the conformity of the high-risk AI systems with the requirements set out in Chapter 2 of this Title, provided that the compliance of those notified bodies with requirements laid down in Article 33(4), (9) and (10) has been assessed in the context of the notification procedure under those legal acts.</p>		
<p>Where the legal acts listed in Annex II, section A, enable the manufacturer of the product to opt</p>		

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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.		
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.		
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	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	

Presidency compromise text	Drafting Suggestions	Comments
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.	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, except if they have an impact on fundamental rights.	
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.		
6. The Commission is empowered to adopt delegated acts to amend paragraphs 1 and 2 in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex VII or parts thereof. The Commission shall adopt		

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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.		
<i>Article 44</i> <i>Certificates</i>		
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.		

Presidency compromise text	Drafting Suggestions	Comments
<p>2. Certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the provider, the validity of a certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures.</p>		<p>What is the validity period for the conformity assessment based on the Annex VI procedure (internal control)?</p>
<p>3. Where a notified body finds that an AI system no longer meets the requirements set out in Chapter 2 of this Title, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it, unless compliance with those requirements is ensured by appropriate corrective action taken by the provider of the system within an appropriate deadline set by the notified body. The notified body shall give reasons for its decision.</p>		<p>What is ‘an appropriate deadline’ for measures taken by the provider to take appropriate corrective action?</p>

Presidency compromise text	Drafting Suggestions	Comments
<i>Article 45</i> <i>Appeal against decisions of notified bodies</i>		
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.		Suggestion to explicate that civil society organisations are considered as ‘party having a legitimate interest’.
<i>Article 46</i> <i>Information obligations of notified bodies</i>		
1. Notified bodies shall inform the notifying authority of the following:		
(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;		

Presidency compromise text	Drafting Suggestions	Comments
(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;		
(c) any circumstances affecting the scope of or conditions for notification;		
(d) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;		
(e) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.		

Presidency compromise text	Drafting Suggestions	Comments
2. Each notified body shall inform the other notified bodies of:		
(a) quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued;		
(b) EU technical documentation assessment certificates or any supplements thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or supplements thereto which it has issued.		
3. Each notified body shall provide the other notified bodies carrying out similar conformity assessment activities covering the same artificial intelligence technologies with relevant information on issues relating to negative and, on request, positive conformity assessment results.		

Presidency compromise text	Drafting Suggestions	Comments
<i>Article 47</i> <i>Derogation from conformity assessment procedure</i>		
<p>1. By way of derogation from Article 43, any market surveillance authority may authorise the placing on the market or putting into service of specific high-risk AI systems within the territory of the Member State concerned, for exceptional reasons of public security or the protection of life and health of persons, environmental protection and the protection of key industrial and infrastructural assets. That authorisation shall be for a limited period of time, while the necessary conformity assessment procedures are being carried out, and shall terminate once those procedures have been completed. The completion of those procedures shall be undertaken without undue delay.</p>	<p>(..) 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, and only to the extent that such authorisation is appropriate and necessary.</p>	<p>NL would like to add a definition of ‘key industrial and infrastructural assets’.</p>

Presidency compromise text	Drafting Suggestions	Comments
<p>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.</p>		
<p>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.</p>		
<p>4. Where, within 15 calendar days of receipt of the notification referred to in paragraph 2, objections are raised by a Member State against</p>		

Presidency compromise text	Drafting Suggestions	Comments
<p>an authorisation issued by a market surveillance authority of another Member State, or where the Commission considers the authorisation to be contrary to Union law or the conclusion of the Member States regarding the compliance of the system as referred to in paragraph 2 to be unfounded, the Commission shall without delay enter into consultation with the relevant Member State; the operator(s) concerned shall be consulted and have the possibility to present their views. In view thereof, the Commission shall decide whether the authorisation is justified or not. The Commission shall address its decision to the Member State concerned and the relevant operator or operators.</p>		
<p>5. If the authorisation is considered unjustified, this shall be withdrawn by the market surveillance authority of the Member State concerned.</p>		

Presidency compromise text	Drafting Suggestions	Comments
<p>6. By way of derogation from paragraphs 1 to 5, for high-risk AI systems intended to be used as safety components of devices, or which are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746, Article 59 of Regulation (EU) 2017/745 and Article 54 of Regulation (EU) 2017/746 shall apply also with regard to the derogation from the conformity assessment of the compliance with the requirements set out in Chapter 2 of this Title.</p>		
<p><i>Article 48</i> <i>EU declaration of conformity</i></p>		
<p>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</p>	<p>A copy of the EU declaration of conformity shall be given submitted to the relevant national competent authorities upon request.</p>	<p>It is important that companies must be able to submit (changes to) data and registrations (digitally) as simple as possible.</p>

Presidency compromise text	Drafting Suggestions	Comments
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.		
2. The EU declaration of conformity shall state that the high-risk AI system in question meets the requirements set out in Chapter 2 of this Title. The EU declaration of conformity shall contain the information set out in Annex V and shall be translated into an official Union language or languages required by the Member State(s) in which the high-risk AI system is made available.		
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		

Presidency compromise text	Drafting Suggestions	Comments
declaration shall contain all the information required for identification of the Union harmonisation legislation to which the declaration relates.		
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.		
5. The Commission shall be empowered to adopt delegated acts in accordance with Article 73 for the purpose of updating the content of the EU declaration of conformity set out in Annex V in order to introduce elements that become necessary in light of technical progress.		
<i>Article 49</i> <i>CE marking of conformity</i>		

Presidency compromise text	Drafting Suggestions	Comments
<p>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.</p>		
<p>2. The CE marking referred to in paragraph 1 of this Article shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.</p>		
<p>3. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 43. The identification number shall also be indicated in any promotional material which mentions that the high-risk AI system fulfils the requirements for CE marking.</p>		

Presidency compromise text	Drafting Suggestions	Comments
Article 50 Document retention		
The provider shall, for a period ending 10 years after the AI system has been placed on the market or put into service, keep at the disposal of the national competent authorities:	The provider shall, for a period ending 10 5 years after the high-risk AI system has been placed on the market or put into service if no longer in use, keep at the disposal of the national competent authorities:	The keeping of records, documentation and, where relevant, data sets should be limited for specific and identified high risk AI-systems only and for a limited time to to avoid burdensome and costly data storage requirements. 10 year is not proportionate for SME's, suggestion to limit the document retention period.
(a) the technical documentation referred to in Article 11;		
(b) the documentation concerning the quality management system referred to Article 17;		
(c) the documentation concerning the changes approved by notified bodies where applicable;		

Presidency compromise text	Drafting Suggestions	Comments
(d) the decisions and other documents issued by the notified bodies where applicable;		
(e) the EU declaration of conformity referred to in Article 48.		
<i>Article 51</i> <i>Registration</i>		
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.		
TITLE IV		

Presidency compromise text	Drafting Suggestions	Comments
TRANSPARENCY OBLIGATIONS FOR CERTAIN AI SYSTEMS		
<i>Article 52</i> <i>Transparency obligations for certain AI systems</i>		
1. Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that natural persons are informed that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences, unless those systems are available for the public to report a criminal offence.	<p>Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that natural persons are informed that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use.</p> <p>This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences insofar and as long as appropriate, proportional and necessary for these purposes, also considering any rights under international law, Union law or national law that can supersede these purposes</p>	Transparency should be aspired as long as it does not harm the detection prevention, investigation and prosecution of criminal offences. At all times, international human rights law must be complied with.

Presidency compromise text	Drafting Suggestions	Comments
2. Users of an emotion recognition system or a biometric categorisation system shall inform of the operation of the system the natural persons exposed thereto. This obligation shall not apply to AI systems used for biometric categorisation, which are permitted by law to detect, prevent and investigate criminal offences.	2. Users of an emotion recognition system or a biometric categorisation system shall inform of the operation of the system the natural persons exposed thereto. This obligation shall not apply to AI systems used for biometric categorisation, which are permitted by law to detect, prevent and , investigate and prosecute criminal offences insofar and as long as appropriate, proportional and necessary for these purposes also considering any rights under international law, Union law or national law that can supersede these purposes.	See 52(1).
3. Users of an AI system that generates or manipulates image, audio or video content that appreciably resembles existing persons, objects, places or other entities or events and would falsely appear to a person to be authentic or truthful ('deep fake'), shall disclose that the	(...) shall disclose that the content has been artificially generated or manipulated in a clear and visible manner.	NL wonders why deep fakes are not considered a high risk AI system. They can have an impact on fundamental rights and security. NL is in favour of creating transparency labels to aid citizens that encounter a 'deep fake' to help them determine the trustworthiness of the

Presidency compromise text	Drafting Suggestions	Comments
<p>content has been artificially generated or manipulated.</p>		<p>content. We do have some questions about article 52.3:</p> <ul style="list-style-type: none"> - Will there be a standard / minimum requirements to disclose that the content has been artificially generated or manipulated? Not all such “labels” are as effective. Uniformity can furthermore help citizens recognise such labels. <p>The article should make more clear that it requires the <i>producer</i> of such deep fake content to disclose that the content has been artificially generated or manipulated.</p>
<p>However, the first subparagraph shall not apply where the use is authorised by law to detect, prevent, investigate and prosecute criminal offences or it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, and subject to appropriate safeguards for the rights and freedoms of third parties.</p>	<p>However, the first subparagraph shall not apply where the use is authorised by law to detect, prevent, investigate and prosecute criminal offences insofar and as long as appropriate, proportionate and necessary for these purposes, also considering any rights under international law, Union law or national law that can supersede these purposes, or it is appropriate and necessary for the exercise of the right to</p>	<p>In exercising the right to freedom of expression it shall not impede with the rights of others guaranteed to third parties, like the right to privacy or family life.</p>

Presidency compromise text	Drafting Suggestions	Comments
	freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, and subject to appropriate safeguards for the rights and freedoms of third parties.	
4. Paragraphs 1, 2 and 3 shall not affect the requirements and obligations set out in Title III of this Regulation.		
TITLE IV_A		
GENERAL PURPOSE AI SYSTEMS		
<i>Article 52a</i>		
<i>General purpose AI systems</i>		NL supports the inclusion of general purpose AI systems, but needs time to study this specific proposal. Also, a specific definition for ‘general purpose AI systems’ lacks in the current text.

Presidency compromise text	Drafting Suggestions	Comments
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.		
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.		
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		

Presidency compromise text	Drafting Suggestions	Comments
an AI system whose intended purpose makes it subject to the provisions of this Regulation.		
4. The provisions of this Article shall apply irrespective of whether the general purpose AI system is open source software or not.		
TITLE V		
MEASURES IN SUPPORT OF INNOVATION		
Article 53 AI regulatory sandboxes		
1. AI regulatory sandboxes established by one or more Member States competent authorities or the European Data Protection Supervisor shall provide a controlled	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	As now formulated, the focus of the sandboxes is on ensuring compliance with the requirements of this Regulation and other Union and Member State legislation monitored within the sandbox.

Presidency compromise text	Drafting Suggestions	Comments
<p>environment that facilitates the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan. This shall take place under the direct supervision and guidance by the competent authorities with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.</p>	<p>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. The sandbox will enable technical, organisational experimentation and legal testing 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, enhancing legal certainty as well as understanding emerging risks and impact of AI-systems.</p>	<p>It is important to broaden the stated objective of the sandboxes, also enabling increased understanding about risks and impacts as well as enhancing legal certainty, and bringing the article more in line with the stated objectives in recital 72.</p> <p>Furthermore, to achieve a trusted and expert-driven testing environment, it is important that all competent authorities, including those with domain specific expertise, can be involved in regulatory sandboxes. We suggest to amend the relevant recitals and definitions for increase clarity about the difference between ‘competent authorities’ including a wide range of supervisory organisations and the ‘national competent authority’ as defined in article 3.</p>
<p>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</p>		<p>Please clarify that the GDPR applies.</p>

Presidency compromise text	Drafting Suggestions	Comments
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.		
3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. Any significant risks to health and safety and fundamental rights identified during the development and testing of such systems shall result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place.	The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. Any significant risks to health and safety and fundamental rights identified during the development and testing of such systems shall result in immediate mitigation and, failing that, in the suspension or ending of the development and testing process until such mitigation takes place.	Suspension is sufficient until mitigation, but if it doesn't occur, there should be a possibility to end.
4. Participants in the AI regulatory sandbox shall remain liable under applicable Union and Member States liability legislation for any harm inflicted on third parties as a result from the experimentation taking place in the sandbox.		

Presidency compromise text	Drafting Suggestions	Comments
5. Member States' competent authorities that have established AI regulatory sandboxes shall coordinate their activities and cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results from the implementation of those scheme, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application of this Regulation and other Union legislation supervised within the sandbox.		
6. The modalities and the conditions of the operation of the AI regulatory sandboxes, including the eligibility criteria and the procedure for the application, selection, participation and exiting from the sandbox, and the rights and obligations of the participants shall be set out in implementing acts. Those	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, the termination of regulatory sandboxes and the rights and obligations of the participants shall be	

Presidency compromise text	Drafting Suggestions	Comments
implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).	set out in implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).	
<p><i>Article 54</i></p> <p><i>Further processing of personal data for developing certain AI systems in the public interest in the AI regulatory sandbox</i></p>		<p>Questions:</p> <ul style="list-style-type: none"> - Why is the article (and recital 72) related to article 6(4) of the GDPR and related specifically to further processing? Why is it not posed as a separate (new) legal base? What are the advantages of this approach? - Do we assume correctly that the proposal only functions as a legal ground for personal data, and not for LED-data? This with regard to recital 72 and the specific mention of the need for a legal basis in MS law in article 54(1)(a)(i). - Do we assume correctly that the goal of article 54(2) is to make sure that MS can still by law limit further processing for specific purposes, even though it would be allowed under article 54(1)? So MS law restricting further processing of e.g. certain health data precludes the possibility created in article 54(1)(a)(ii)?

Presidency compromise text	Drafting Suggestions	Comments
		<p>Suggestions:</p> <ul style="list-style-type: none"> - The NL believes that if this article is to be seen as a horizontal legal ground for processing, it requires further specification. This might include (not exhaustive): <ul style="list-style-type: none"> o the categories of data used; (e.g. also article 9/10 categories of data?) o a limited retention period (the duration of the project in the sandbox seems to general) o further specification of the goals (e.g. public safety and health still seems to be rather general) - Explicit reference to the GDPR and its requirements (e.g. data protection principles, DPIA, security measures of article 35) could be made. - Especially if the aim is to process special categories of data, we are not yet convinced that this horizontal approach is feasible. It might be necessary to exclude these types of data from the scope of the legal ground.

Presidency compromise text	Drafting Suggestions	Comments
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:		
(a) the innovative AI systems shall be developed for safeguarding substantial public interest in one or more of the following areas:		
(i) the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security, under the control and responsibility of the competent authorities. The processing shall be based on Member State or Union law;		
(ii) public safety and public health, including disease prevention, control and treatment;		

Presidency compromise text	Drafting Suggestions	Comments
(iii) a high level of protection and improvement of the quality of the environment;		
(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;		
(c) there are effective monitoring mechanisms to identify if any high risks to the fundamental rights of the data subjects may arise during the sandbox experimentation as well as response mechanism to promptly mitigate those risks and, where necessary, stop the processing;		
(d) any personal data to be processed in the context of the sandbox are in a functionally separate, isolated and protected data processing		

Presidency compromise text	Drafting Suggestions	Comments
environment under the control of the participants and only authorised persons have access to that data;		
(e) any personal data processed are not be transmitted, transferred or otherwise accessed by other parties;		
(f) any processing of personal data in the context of the sandbox do not lead to measures or decisions affecting the data subjects;		
(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;		
(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		

Presidency compromise text	Drafting Suggestions	Comments
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;		
(i) complete and detailed description of the process and rationale behind the training, testing and validation of the AI system is kept together with the testing results as part of the technical documentation in Annex IV;		
(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.		
2. Paragraph 1 is without prejudice to Union or Member States legislation excluding processing for other purposes than those explicitly mentioned in that legislation.		

Presidency compromise text	Drafting Suggestions	Comments
Article 55 <i>Measures for SME small-scale providers and users</i>		NL supports the change from small scale to SME.
1. Member States shall undertake the following actions:	1. Member States and the European Commission shall undertake the following actions:	The Netherlands would like to introduce a shared effort by member states and the European Commission to support SMEs across the EU. This improves the level playing field for SMEs as a result of synchronized guidance.
(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;	(a) ensure that competent authorities and the EDPS 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;	Sandboxes are established by competent authorities according to article 53 and this amendment ensures that priority access will be designed to fit into the modalities and the conditions of the operation of the AI regulatory sandboxes that will be established based on the procedure in article 53.6.
(b) organise specific awareness raising activities about the application of this	(b) organise specific awareness raising activities about the application of this Regulation and the opportunities to engage in the European Digital	This proposal establishes a concrete relation between the AI Act and the important opportunities offered to promote and enable

Presidency compromise text	Drafting Suggestions	Comments
Regulation tailored to the needs of the small-scale SME providers and users;	Innovation Hubs and the Testing and Experimentation Facilities under the Digital Europe Programme , tailored to the needs of the small-scale SME providers and users;	innovation via the Digital Europe Programme and underlined in the coordinated action plan on AI, echoing recital 74.
(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 users and other innovators to provide guidance and respond to queries about the implementation of this Regulation.	
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 to their size and market size.		
	3. The European Commission provides guidance to member states to support SMEs with implementation of this Regulation in the form of workshops, guidance documents and tools.	NL proposes to include some specific services by the European Commission to help member states to support SME providers to implement the regulation, increase common understanding and promote innovation.

Presidency compromise text	Drafting Suggestions	Comments
TITLE VI		
GOVERNANCE		
CHAPTER 1		
EUROPEAN ARTIFICIAL INTELLIGENCE BOARD		
<i>Article 56</i> <i>Establishment of the European Artificial Intelligence Board</i>		
1. A ‘European Artificial Intelligence Board’ (the ‘Board’) is established.		
2. The Board shall provide advice and assistance to the Commission in order to:		

Presidency compromise text	Drafting Suggestions	Comments
(a) contribute to the effective cooperation of the national supervisory authorities and the Commission with regard to matters covered by this Regulation;		
(b) coordinate and contribute to guidance and analysis by the Commission and the national supervisory authorities and other competent authorities on emerging issues across the internal market with regard to matters covered by this Regulation;		
(c) assist the national supervisory authorities and the Commission in ensuring the consistent application of this Regulation.		
<i>Article 57</i> <i>Structure of the Board</i>		
1. The Board shall be composed of the national supervisory authorities, who shall be	and the European Data Protection Supervisor. The EDPS functions as a the competent	In this article is not really clear what the role is of the EDPS. Therefore, we suggest to refer to

Presidency compromise text	Drafting Suggestions	Comments
represented by the head or equivalent high-level official of that authority, and the European Data Protection Supervisor. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.	authority for their supervision as per article 59.8 and article 71	article 59.8 and 71, where the role of the EDPS is described.
2. The Board shall adopt its rules of procedure by a simple majority of its members, following the consent of the Commission. The rules of procedure shall also contain the operational aspects related to the execution of the Board's tasks as listed in Article 58. The Board may establish sub-groups as appropriate for the purpose of examining specific questions.	The Board shall adopt its rules of procedure by a simple qualified majority of its members, following the consent of in allignment with the Commission. The rules of procedure shall also contain the operational aspects related to the execution of the Board's tasks as listed in Article 58. The Board may establish sub-groups as appropriate for the purpose of examining specific questions.	<p>In case of a simple majority, there is a major risk that almost half the MS might not agree with certain guidance. Especially with very disputable issues, a simple majority is undesirable. With a much larger majority, sufficient acceptance of guidance will be received.</p> <p>Besides, if we read this article correctly, the article assigns a veto-right to the Commission regarding the rules of procedure. This seems to go beyond the usual set-up for this type of Boards in other regulations. Do we interpret this correctly, and if yes, why is this deemed necessary?</p>

Presidency compromise text	Drafting Suggestions	Comments
		The rules of procedure will also cover the voting rules of the Board, through the above veto-right the Commission has the opportunity to de facto dictate the voting rules.
3. The Board shall be chaired by the Commission. The Commission shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. The Commission shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.	The Board shall be chaired by the Commission one of the NSA (it can be rotated every 6 months) . The Commission chair shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. The Commission shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation	The Board is also an advisory board for the EC and the Commission is also the secretary. This already makes the role of the Commission towards the Board quite strong. The role of the Board and its independence is better served by a NSA as the chair.
4. The Board may invite external experts and observers to attend its meetings and may hold exchanges with interested third parties to inform		

Presidency compromise text	Drafting Suggestions	Comments
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.		
<i>Article 58</i> <i>Tasks of the Board</i>		
When providing advice and assistance to the Commission in the context of Article 56(2), the Board shall in particular:		
(a) collect and share expertise and best practices among Member States;		
(b) contribute to uniform administrative practices in the Member States, including for the functioning of regulatory sandboxes referred to in Article 53;		

Presidency compromise text	Drafting Suggestions	Comments
(c) issue opinions, recommendations or written contributions on matters related to the implementation of this Regulation, in particular		
(i) on technical specifications or existing standards regarding the requirements set out in Title III, Chapter 2,		
(ii) on the use of harmonised standards or common specifications referred to in Articles 40 and 41,		
(iii) on the preparation of guidance documents, including the guidelines concerning the setting of administrative fines referred to in Article 71-;		
(d) issue an advisory opinion on the need for amendment of Annex I and Annex III, including in light of available evidence.		
CHAPTER 2		

Presidency compromise text	Drafting Suggestions	Comments
NATIONAL COMPETENT AUTHORITIES		
<i>Article 59</i> <i>Designation of national competent authorities</i>		
1. National competent authorities shall be established or designated by each Member State for the purpose of ensuring the application and implementation of this Regulation. National competent authorities shall be organised so as to safeguard the objectivity and impartiality of their activities and tasks.		
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		

Presidency compromise text	Drafting Suggestions	Comments
administrative reasons to designate more than one authority.		
3. Member States shall inform the Commission of their designation or designations and, where applicable, the reasons for designating more than one authority.	Member States shall inform the Commission of their designation or designations and, where applicable, the reasons for designating more than one authority.	
4. Member States shall ensure that national competent authorities are provided with adequate financial and human resources to fulfil their tasks under this Regulation. In particular, national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements.	In particular, national competent authorities shall have a sufficient number of human resources available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements.	There needs to be some flexibility regarding sharing of expertise between national competent authorities (such as resource pools). Restricting human resources to ‘personnel’ and requiring that staff is ‘permanently’ available is unnecessarily prescriptive.

Presidency compromise text	Drafting Suggestions	Comments
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 shall transmit that information to the Board for discussion and possible recommendations.		
6. The Commission shall facilitate the exchange of experience between national competent authorities.		
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 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,		

Presidency compromise text	Drafting Suggestions	Comments
as appropriate. Member States may also establish one central contact point for communication with operators.		
8. When Union institutions, agencies and bodies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as the competent authority for their supervision.		
TITLE VII		
EU DATABASE FOR STAND-ALONE HIGH-RISK AI SYSTEMS		
<i>Article 60</i> <i>EU database for stand-alone high-risk AI systems</i>		Please specify when the data base should be filled, modified, etc. and how the responsibilities are arranged in particular with regards to the responsibility of the member states.

Presidency compromise text	Drafting Suggestions	Comments
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.	to in Article 6(2) which are registered in accordance with Article 51. This obligation shall not apply to AI systems used by law enforcement to detect, prevent, investigate and prosecute criminal offences including the safeguarding against and the prevention of threats to public security, under the control and responsibility of the competent authorities when publication may hinder criminal prosecution or ongoing investigations, insofar and as long as, proportional, appropriate and necessary for these purposes.	Maximum transparency should also be aimed for in the context of law enforcement (LEA). However, the publication of AI-systems used within the LEA-context should not be disclosed to the public if this could lead to the hindering of criminal prosecution, ongoing investigations etc. (e.g. gaming the system). Examples are tools for specific projects with a limited time scope.
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.		For law enforcement authorities, no personal data should be entered in the database in case the LEA is a provider.

Presidency compromise text	Drafting Suggestions	Comments
3. Information contained in the EU database shall be accessible to the public.		
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.	<p><i>Option 1</i></p> <p>4. The EU database shall contain no personal data, except for the information as listed in Annex VIII 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.</p> <p><i>Option 2</i></p> <p>4. The EU database shall contain no personal data, only insofar as necessary for collecting and processing information in accordance with this Regulation. That information which shall include the names and contact details of natural persons who are responsible for registering the</p>	<p>The suggestions for the database not to include any personal data, except for what is listed in Annex VIII follows from the principle of data minimisation from the GDPR.</p> <p>How does the exemption ‘this information shall not be provided for high-risk AI systems in the areas of law enforcement (...)’ relate to the exception regarding tax and customs authorities, laid down in preamble no. 38? Publication of these electronic instructions of use by tax and custom authorities might encourage misuse (‘gaming the system’).</p>

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	system and have the legal authority to represent the provider.	
5. The Commission shall be the controller of the EU database. It shall also ensure to providers adequate technical and administrative support.		
TITLE VIII		
POST-MARKET MONITORING, INFORMATION SHARING, MARKET SURVEILLANCE		
CHAPTER 1		
POST-MARKET MONITORING		

Presidency compromise text	Drafting Suggestions	Comments
<p><i>Article 61</i></p> <p><i>Post-market monitoring by providers and post-market monitoring plan for high-risk AI systems</i></p>		<p>For post-market monitoring, it is important that the impact and feasibility of the proposed obligation is clear. Oftentimes, AI systems, especially when integrated in a product, is hard to monitor. Against this background, a post-market monitoring obligation laid down in art. 61 should focus on requirements that are necessary to provide appropriate level of protection against risks and can be met by a provider of high-risk AI systems.</p>
<p>1. Providers shall establish and document a post-market monitoring system in a manner that is proportionate to the nature of the artificial intelligence technologies and the risks of the high-risk AI system.</p>		
<p>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</p>		

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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.		
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.		
4. For high-risk AI systems covered by the legal acts referred to in Annex II, where a post-market monitoring system and plan is already established under that legislation, the elements described in paragraphs 1, 2 and 3 shall be		

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integrated into that system and plan as appropriate.		
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.		
CHAPTER 2		
SHARING OF INFORMATION ON SERIOUS INCIDENTS AND MALFUNCTIONING		
<i>Article 62</i> <i>Reporting of serious incidents and of malfunctioning</i>		
1. Providers of high-risk AI systems placed on the Union market shall report any serious	1. Providers of high-risk AI systems placed on the Union market shall report any serious	To be consistent and clear, and the reference to Article 3(44)(c) is also made in paragraph 2.

Presidency compromise text	Drafting Suggestions	Comments
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.	incident referred to in Article 3(44)(c), including incidents involving a violation of fundamental rights' 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.	
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 .		
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		

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<p>relevant market surveillance authority shall inform the national public authorities or bodies referred to in Article 64(3). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1. That guidance shall be issued 12 months after the entry into force of this Regulation, at the latest.</p>		
<p>3. For high-risk AI systems referred to in point 5(b) of Annex III which are placed on the market or put into service by providers that are credit institutions regulated by Directive 2013/36/EU and for high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746, the notification of serious incidents or malfunctioning shall be limited to those referred to in Article 3(44)(c)that that</p>		

Presidency compromise text	Drafting Suggestions	Comments
constitute a breach of obligations under Union law intended to protect fundamental rights.		
CHAPTER 3		
ENFORCEMENT		
<i>Article 63</i> <i>Market surveillance and control of AI systems in the Union market</i>		
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:		Does “ this Regulation” refer to the AI-Act? Does “AI-systems” this mean that Regulation (EU) 2019/1020 is applicable to all AI-systems covered by the AI-Act (and not high risk systems only)?
(a) any reference to an economic operator under Regulation (EU) 2019/1020 shall be understood as including all operators identified		

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in Title III, Chapter 3 Article 2 of this Regulation;		
(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.		
2. The national supervisory authority shall report to the Commission on a regular basis the outcomes of relevant market surveillance activities. The national supervisory authority shall report, without delay, to the Commission and relevant national competition authorities any information identified in the course of market surveillance activities that may be of potential interest for the application of Union law on competition rules.		First sentence requires clarification.
3. For high-risk AI systems, related to products to which legal acts listed in Annex II,		

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section A apply, the market surveillance authority for the purposes of this Regulation shall be the authority responsible for market surveillance activities designated under those legal acts.		
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.		
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	For AI systems 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 placed on the market, put into service or used by law enforcement, immigration or	NL proposes here to use a similar formulation as for par. 4

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authorities under Directive (EU) 2016/680, or Regulation 2016/679 or the national competent authorities supervising the activities of the law enforcement, immigration or asylum authorities putting into service or using those systems.	asylum authorities agencies, the market surveillance authorities for the purposes of this Regulation shall be 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 law enforcement, immigration or asylum authorities putting into service or using those systems.	
6. Where Union institutions, agencies and bodies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as their market surveillance authority.	6. For AI systems placed on the market, put into service or used by judicial authorities, the market surveillance authorities for the purpose of this Regulation shall be the national competent authority supervising the activities of the judicial authorities	We suggest to add extra paragraph to protect the independency of the judiciary
7. Member States shall facilitate the coordination between market surveillance authorities designated under this Regulation and other relevant national authorities or bodies		

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which supervise the application of Union harmonisation legislation listed in Annex II or other Union legislation that might be relevant for the high-risk AI systems referred to in Annex III.		
<i>Article 64</i> <i>Access to data and documentation</i>		
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 means and tools enabling remote access.	Access to data and documentation in the context of their activities, where strictly necessary for their task 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. Additional safeguards or restrictions may be in place in case these datasets are used to detect, prevent, investigate	<p>The AI Act should not provide for an unlimited legal basis for sharing personal data with surveillance authorities. This should be limited to their respective tasks. Additional safeguards should be in place in case of personal data used by LEA's.</p> <p>The access to data in article 64(1) and 64(2) seems rather restricted, in practice access to other information than the data sources highlighted here might be necessary. The wording needs to provide room for authorities to</p>

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	and prosecute criminal offences insofar and as long as necessary for these purposes.	access all information necessary for their tasks, while at the same time acknowledging that unnecessary sharing of operational data should be avoided. It would be good to stress that the amount of information requested should be proportionate to the risks involved and take account of the size of the organisation.
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.		See above, in practice access to other types of information might be needed just as well. This seems very limitative.
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		

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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.		
4. By 3 months after the entering into force of this Regulation, each Member State shall identify the public authorities or bodies referred to in paragraph 3 and make a list publicly available on the website of the national supervisory authority. Member States shall notify the list to the Commission and all other Member States and keep the list up to date.		
5. Where the documentation referred to in paragraph 3 is insufficient to ascertain whether a breach of obligations under Union law intended		

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<p>to protect fundamental rights has occurred, the public authority or body referred to paragraph 3 may make a reasoned request to the market surveillance authority to organise testing of the high-risk AI system through technical means. The market surveillance authority shall organise the testing with the close involvement of the requesting public authority or body within reasonable time following the request.</p>		
<p>6. Any information and documentation obtained by the national public authorities or bodies referred to in paragraph 3 pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.</p>		
	<p>NEW Article 64A</p> <p>Right to Complain</p> <p>1. Without prejudice to any other administrative or judicial remedy, every natural person exposed to an AI system shall have the right to lodge a complaint with a supervisory authority,</p>	<p>The current proposal currently lacks any inclusion of end/natural persons in its provisions, as redress is left to pending proposals and domain specific regulation. However, to increase legal protection and</p>

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	<p>in particular in the Member State of his or her habitual residence, place of work or place of the alleged infringement if the data subject considers that the use of AI systems affecting him or her infringes this Regulation or poses a serious risk to his or her fundamental rights.</p> <p>2. The supervisory authority with which the complaint has been lodged shall inform the complainant on the progress and the outcome of the complaint including the possibility of a judicial remedy.</p>	strengthen governance, a right to complain is necessary and inspired by the GDPR.
<p><i>Article 65</i></p> <p><i>Procedure for dealing with AI systems presenting a risk at national level</i></p>		<p>We presume a high risk AI-system will be evaluated against Title II, chapter 2 and 3. But what would the evaluation criteria be for a) prohibited systems (b) AI-systems meant in art. 52 (c) any other low/no risk systems AI-system?</p>
<p>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 to the health or</p>	<p>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 and as product presenting a risk to the protection of</p>	<p>This is the first time the notion of risk is explained a bit more. Article 3.19 of Reg 2019/1020 does not mention fundamental rights, so it seems to be insufficient for the purposes of this regulation. We propose to include a more</p>

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safety or to the protection of fundamental rights of persons are concerned.	fundamental rights of persons are concerned in article 3. [...].	fitting description of product presenting a risk in the definitions part of the regulation, which gives the appropriate attention to fundamental rights risks, as well as risks for harms at a societal level, rather than an individual level.
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 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	When risks to the protection of fundamental rights are present,	

Presidency compromise text	Drafting Suggestions	Comments
national public authorities or bodies referred to in Article 64(3).		
Where, in the course of that evaluation, the market surveillance authority finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without delay require the relevant operator to take all appropriate 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.	Where, in the course of that evaluation, the market surveillance authority finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without delay require the relevant operator to take all appropriate 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 or withdraw it, commensurate with the nature of the risk, as it may prescribe.	If the AI system cannot be corrected it should be able to withdraw it.
The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph.		

Presidency compromise text	Drafting Suggestions	Comments
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.	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 within a reasonable time of the results of the evaluation and of the actions which it has required the operator to take.	To prevent long delays/ lack of information or doubling of evaluations.
4. The operator shall ensure that all appropriate corrective action is taken in respect of all the AI systems concerned that it has made available on the market throughout the Union.		
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.		
6. The information referred to in paragraph 5 shall include all available details, in particular the data necessary for the identification of the non-compliant AI system, the origin of the AI system, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to one or more of the following:		
(a) a failure of the AI system to meet requirements set out in Title III, Chapter 2;		
(b) shortcomings in the harmonised standards or common specifications referred to in Articles		

Presidency compromise text	Drafting Suggestions	Comments
40 and 41 conferring a presumption of conformity.		
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.		
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		

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without prejudice to the procedural rights of the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020.		
9. The market surveillance authorities of all Member States shall ensure that appropriate restrictive measures are taken in respect of the product concerned, such as withdrawal of the product from their market, without delay.		
<i>Article 66</i> <i>Union safeguard procedure</i>		
1. Where, within three months of receipt of the notification referred to in Article 65(5), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall without delay enter into consultation with the relevant Member State and operator or operators		<p>What happens with the system during this time of talks and investigations?</p> <p>Regarding: “objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall without delay enter</p>

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<p>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.</p>		<p>into consultation with the relevant Member State and operator or operators and shall evaluate the national measure.”</p> <p>There can be two situations: another member state does not agree with the decision of the member state to approve the AI system, or to disapprove the AI system. However, Article 66 (2) and (3) only covers the latter situation. What if other member states object to an admission of an AI system to the internal market by another member state? Is this situation deliberately left out? Is there a remedy against the decision of the Commission?</p>
<p>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</p>		

Presidency compromise text	Drafting Suggestions	Comments
accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.		
3. Where the national measure is considered justified and the non-compliance of the AI system is attributed to shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.		
<i>Article 67</i> <i>Compliant AI systems which present a risk</i>		
1. Where, having performed an evaluation under Article 65, the market surveillance authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a risk to the health or	to the compliance with obligations under Union or national law intended to protect fundamental rights	It is unclear what is meant with ‘obligations under Union or national law intended to protect fundamental rights’. Does this for instance cover the Charter of Fundamental Rights? Also, there may be (unacceptable) risks to

Presidency compromise text	Drafting Suggestions	Comments
<p>safety of persons, to the compliance with obligations under Union or national law intended to protect fundamental rights or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.</p>		<p>fundamental rights which are not yet covered by national or Union law.</p>
<p>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.</p>		

Presidency compromise text	Drafting Suggestions	Comments
<p>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.</p>		
<p>4. The Commission shall without delay enter into consultation with the Member States and the relevant operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.</p>		
<p>5. The Commission shall address its decision to the Member States.</p>		

Presidency compromise text	Drafting Suggestions	Comments
Article 68 Formal non-compliance		
1. Where the market surveillance authority of a Member State makes one of the following findings, it shall require the relevant provider to put an end to the non-compliance concerned:		
(a) the conformity marking has been affixed in violation of Article 49;		
(b) the conformity marking has not been affixed;		
(c) the EU declaration of conformity has not been drawn up;		
(d) the EU declaration of conformity has not been drawn up correctly;		

Presidency compromise text	Drafting Suggestions	Comments
(e) the identification number of the notified body, which is involved in the conformity assessment procedure, where applicable, has not been affixed;		
2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the high-risk AI system being made available on the market or ensure that it is recalled or withdrawn from the market.		
TITLE IX		
CODES OF CONDUCT		
<i>Article 69</i> <i>Codes of conduct</i>		

Presidency compromise text	Drafting Suggestions	Comments
<p>1. The Commission and the Member States shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to AI systems other than high-risk AI systems of the requirements set out in Title III, Chapter 2 on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems.</p>		
<p>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 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</p>		

Presidency compromise text	Drafting Suggestions	Comments
clear objectives and key performance indicators to measure the achievement of those objectives.		
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.		
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.		
TITLE X		

Presidency compromise text	Drafting Suggestions	Comments
CONFIDENTIALITY AND PENALTIES		
<i>Article 70</i> <i>Confidentiality</i>		
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:		
(a) intellectual property rights, and confidential business information or trade secrets of a natural or legal person, including source code, except the cases referred to in Article 5 of Directive 2016/943 on the protection of undisclosed know-how and		

Presidency compromise text	Drafting Suggestions	Comments
business information (trade secrets) against their unlawful acquisition, use and disclosure apply.		
(b) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits;(c) public and national security interests;		
(c) integrity of criminal or administrative proceedings.	integrity of criminal investigations and or administrative proceedings.	
2. Without prejudice to paragraph 1, information exchanged on a confidential basis between the national competent authorities and between national competent authorities and the Commission shall not be disclosed without the prior consultation of the originating national competent authority and the user when high-risk AI systems referred to in points 1, 6 and 7 of Annex III are used by law enforcement, immigration or asylum authorities, when such	Without prejudice to paragraph 1, information exchanged on a confidential basis between the national competent authorities and between national competent authorities and the Commission shall not be disclosed without the prior consultation of the originating national competent authority and the user when high-risk AI systems referred to in points 1, 6 and 7 of Annex III are used by law enforcement, immigration or asylum authorities, when such	Supervision might go further than only the category of high risk AI systems. We propose to delete the reference to Annex III, the exception for law enforcement would then still be intact.

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disclosure would jeopardise public and national security interests.	disclosure would jeopardise public and or national security interests or jeopardise the detection, prevention, investigation and prosecution of criminal offences, including the safeguarding against and the prevention of threats to public security.	
When the law enforcement, immigration or asylum authorities are providers of high-risk AI systems referred to in points 1, 6 and 7 of Annex III, the technical documentation referred to in Annex IV shall remain within the premises of those authorities. Those authorities shall ensure that the market surveillance authorities referred to in Article 63(5) and (6), as applicable, can, upon request, immediately access the documentation or obtain a copy thereof. Only staff of the market surveillance authority holding the appropriate level of security clearance shall be allowed to access that documentation or any copy thereof.		<p>A definition of '<i>premises</i>' would be helpful. This could either be a physical location (e.g. offices) or could be digitally stored in a private cloud environment (e. g. a data center) which can be located off-premise.</p> <p>Should there not be a distinction between law enforcement and immigration and asylum authorities in this context?</p>

Presidency compromise text	Drafting Suggestions	Comments
3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to the exchange of information and the dissemination of warnings, nor the obligations of the parties concerned to provide information under criminal law of the Member States.		
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.	The Commission and Member States may, notwithstanding paragraphs 1 and 2 , 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	
<i>Article 71</i> <i>Penalties</i>		

Presidency compromise text	Drafting Suggestions	Comments
<p>1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests of small-scale SME providers, including and start-up, and their economic viability.</p>		
<p>2. The Member States shall notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.</p>		
<p>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</p>		

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% of its total worldwide annual turnover for the preceding financial year, whichever is higher:		
(a) non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;		
(b) non-compliance of the AI system with the requirements laid down in Article 10.		
4. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to 20 000 000 EUR or, if the offender is a company, up to 4 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.		
5. The supply of incorrect, incomplete or misleading information to notified bodies and		

Presidency compromise text	Drafting Suggestions	Comments
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.		
6. When deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:		
(a) the nature, gravity and duration of the infringement and of its consequences;		
(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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(c) the size and market share of the operator committing the infringement;		
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.		
8. Depending on the legal system of the Member States, the rules on administrative fines may be applied in such a manner that the fines are imposed by competent national courts of other bodies as applicable in those Member States. The application of such rules in those Member States shall have an equivalent effect.		
<i>Article 72</i> <i>Administrative fines on Union institutions, agencies and bodies</i>		

Presidency compromise text	Drafting Suggestions	Comments
1. The European Data Protection Supervisor may impose administrative fines on Union institutions, agencies and bodies falling within the scope of this Regulation. When deciding whether to impose an administrative fine and deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:		
(a) the nature, gravity and duration of the infringement and of its consequences;		
(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		

Presidency compromise text	Drafting Suggestions	Comments
agency or body concerned with regard to the same subject matter;		
(c) any similar previous infringements by the Union institution, agency or body;		
2. The following infringements shall be subject to administrative fines of up to 500 000 EUR:		
(a) non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;		
(b) non-compliance of the AI system with the requirements laid down in Article 10.		
3. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in		

Presidency compromise text	Drafting Suggestions	Comments
Articles 5 and 10, shall be subject to administrative fines of up to 250 000 EUR.		
<p>4. Before taking decisions pursuant to this Article, the European Data Protection Supervisor shall give the Union institution, agency or body which is the subject of the proceedings conducted by the European Data Protection Supervisor the opportunity of being heard on the matter regarding the possible infringement. The European Data Protection Supervisor shall base his or her decisions only on elements and circumstances on which the parties concerned have been able to comment. Complainants, if any, shall be associated closely with the proceedings.</p>		
<p>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</p>		

Presidency compromise text	Drafting Suggestions	Comments
Supervisor's file, subject to the legitimate interest of individuals or undertakings in the protection of their personal data or business secrets.		
6. Funds collected by imposition of fines in this Article shall be the income of the general budget of the Union.		
TITLE XI		
DELEGATION OF POWER AND COMMITTEE PROCEDURE		
<i>Article 73</i> <i>Exercise of the delegation</i>		
1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.		

Presidency compromise text	Drafting Suggestions	Comments
2. The delegation of power referred to in Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall be conferred on the Commission for an a indeterminate period of time five years from <i>[entering into force of the Regulation]</i> .	2. The delegation of power referred to in Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall be conferred on the Commission for an a indeterminate period of time five years from <i>[entering into force of the Regulation]</i> .	The Netherlands is of the opinion that articles 4, 7(1) and 43(6) should contain references to implementing acts rather than delegated acts as the nature of Annexes I, III and the decision about the conformity assessment procedures are of <i>essential</i> nature and require involvement of co-legislators.
The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the 5 year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.		
3. The delegation of power referred to in Article 4, Article 7(1), Article 11(3), Article	3. The delegation of power referred to in Article 4, Article 7(1), Article 11(3), Article	See 73.1

Presidency compromise text	Drafting Suggestions	Comments
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 <i>Official Journal of the European Union</i> or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	43(5) and (6) and Article 48(5) may be revoked at any time by the European Parliament or by the Council	
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		
5. Any delegated act adopted pursuant to Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall enter into force only if no objection has been expressed by either the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the	Any delegated act adopted pursuant to Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall	See 73.1

Presidency compromise text	Drafting Suggestions	Comments
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.		
<i>Article 74</i> <i>Committee procedure</i>		
1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.		
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.		
TITLE XII		

Presidency compromise text	Drafting Suggestions	Comments
FINAL PROVISIONS		
<i>Article 75</i> <i>Amendment to Regulation (EC) No 300/2008</i>		
In Article 4(3) of Regulation (EC) No 300/2008, the following subparagraph is added:		
“When adopting detailed measures related to technical specifications and procedures for approval and use of security equipment concerning Artificial Intelligence systems in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Chapter 2, Title III of that Regulation shall be taken into account.”		

Presidency compromise text	Drafting Suggestions	Comments
* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...).”		
<i>Article 76</i> <i>Amendment to Regulation (EU) No 167/2013</i>		
In Article 17(5) of Regulation (EU) No 167/2013, the following subparagraph is added:		
“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.		

Presidency compromise text	Drafting Suggestions	Comments
* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...).”		
<i>Article 77</i> <i>Amendment to Regulation (EU) No 168/2013</i>		
In Article 22(5) of Regulation (EU) No 168/2013, the following subparagraph is added:		
“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.		

Presidency compromise text	Drafting Suggestions	Comments
* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...).”		
<i>Article 78</i> <i>Amendment to Directive 2014/90/EU</i>		
In Article 8 of Directive 2014/90/EU, the following paragraph is added:		
“4. For Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, when carrying out its activities pursuant to paragraph 1 and when adopting technical specifications and testing standards in accordance with paragraphs 2 and 3, the Commission shall take into account the requirements set out in Title III, Chapter 2 of that Regulation.		

Presidency compromise text	Drafting Suggestions	Comments
* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...).”.		
<i>Article 79</i> <i>Amendment to Directive (EU) 2016/797</i>		
In Article 5 of Directive (EU) 2016/797, the following paragraph is added:		
“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.		

Presidency compromise text	Drafting Suggestions	Comments
* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...).”.		
<i>Article 80</i> <i>Amendment to Regulation (EU) 2018/858</i>		
In Article 5 of Regulation (EU) 2018/858 the following paragraph is added:		
“4. When adopting delegated acts pursuant to paragraph 3 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council *, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.		

Presidency compromise text	Drafting Suggestions	Comments
* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...).”.		
<i>Article 81</i> <i>Amendment to Regulation (EU) 2018/1139</i>		
Regulation (EU) 2018/1139 is amended as follows:		
(1) In Article 17, the following paragraph is added:		
“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 [<i>on Artificial Intelligence</i>] 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.		

Presidency compromise text	Drafting Suggestions	Comments

* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...).”		
(2) In Article 19, the following paragraph is added:		
“4. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.”		
(3) In Article 43, the following paragraph is added:		

Presidency compromise text	Drafting Suggestions	Comments
“4. When adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.”		
(4) In Article 47, the following paragraph is added:		
“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.”		
(5) In Article 57, the following paragraph is added:		

Presidency compromise text	Drafting Suggestions	Comments
“When adopting those implementing acts concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.”		
(6) In Article 58, the following paragraph is added:		
“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.”.		

Presidency compromise text	Drafting Suggestions	Comments
Article 82 Amendment to Regulation (EU) 2019/2144		
In Article 11 of Regulation (EU) 2019/2144, the following paragraph is added:		
“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 of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.		

* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...).”.		

Presidency compromise text	Drafting Suggestions	Comments
<p><i>Article 83</i></p> <p><i>AI systems already placed on the market or put into service</i></p>		
<p>1. This Regulation shall not apply to the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before <i>[12 months after the date of application of this Regulation referred to in Article 85(2)]</i>, 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.</p>		
<p>The requirements laid down in this Regulation shall be taken into account, where applicable, in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX</p>		

Presidency compromise text	Drafting Suggestions	Comments
to be undertaken as provided for in those respective acts.		
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 [<i>date of application of this Regulation referred to in Article 85(2)</i>], only if, from that date, those systems are subject to significant changes in their design or intended purpose.		
<i>Article 84</i> <i>Evaluation and review</i>		
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.		
1a. The Commission shall assess the need for amendment of the list in Annex I every 24		

Presidency compromise text	Drafting Suggestions	Comments
<p>months following the entry into force of this Regulation and until the end of the period of the delegation of power. The findings of that assessment shall be presented to the European Parliament and the Council.</p>		
<p>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 European Parliament and the Council.</p>		
	<p>1c The Commission will establish a multistakeholder expert group to assist with the evaluation of Annexes I and III.</p>	<p>The amendments of annexes I and III need consultation of all relevant stakeholders to ensure that the regulation reflects the latest insights by a wide range of actors and remains effective. The High Level Expert Group could serve as example.</p>

Presidency compromise text	Drafting Suggestions	Comments
2. By [<i>three years after the date of application of this Regulation referred to in Article 85(2)</i>] 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.		
3. The reports referred to in paragraph 2 shall devote specific attention to the following:		
(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;		
(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.		

Presidency compromise text	Drafting Suggestions	Comments
<p>4. Within [<i>three years after the date of application of this Regulation referred to in Article 85(2)</i>] and every four years thereafter, the Commission shall evaluate the impact and effectiveness of codes of conduct to foster the application of the requirements set out in Title III, Chapter 2 and possibly other additional requirements for AI systems other than high-risk AI systems.</p>		
<p>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.</p>		
<p>6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 43 the Commission shall take into account the positions and findings of the Board, of the</p>		

Presidency compromise text	Drafting Suggestions	Comments
European Parliament, of the Council, and of other relevant bodies or sources.		
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.		
<i>Article 85</i> <i>Entry into force and application</i>		
1. This Regulation shall enter into force on the twentieth day following that of its publication in the <i>Official Journal of the European Union</i> .		
2. This Regulation shall apply from [24 months following the entering into force of the Regulation].		

Presidency compromise text	Drafting Suggestions	Comments
3. By way of derogation from paragraph 2:		
(a) Title III, Chapter 4 and Title VI shall apply from [three months following the entry into force of this Regulation];		
(b) Article 71 shall apply from [twelve months following the entry into force of this Regulation].		
This Regulation shall be binding in its entirety and directly applicable in all Member States.		
Done at Brussels,		
<i>For the European Parliament</i> <i>For the Council</i>		
<i>The President</i> <i>The President</i>		

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

Presidency compromise text	Drafting Suggestions	Comments
(c) the versions of relevant software or firmware and any requirement related to version update;		
(d) the description of all forms in which the AI system is placed on the market or put into service;		
(e) the description of hardware on which the AI system is intended to run;		
(f) where the AI system is a component of products, photographs or illustrations showing external features, marking and internal layout of those products;		
(g) instructions of use for the user and, where applicable installation instructions;		

Presidency compromise text	Drafting Suggestions	Comments
2. A detailed description of the elements of the AI system and of the process for its development, including:		
(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;		
(b) the design specifications of the system, namely the general logic of the AI system and of the algorithms; the key design choices including the rationale and assumptions made, also with regard to persons or groups of persons on which the system is intended to be used; the main classification choices; what the system is designed to optimise for and the relevance of the different parameters; the decisions about any possible trade-off made regarding the technical		

Presidency compromise text	Drafting Suggestions	Comments
solutions adopted to comply with the requirements set out in Title III, Chapter 2;		
(c) the description of the system architecture explaining how software components build on or feed into each other and integrate into the overall processing; the computational resources used to develop, train, test and validate the AI system;		
(d) where relevant, the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used, including information about the provenance of those data sets, their scope and main characteristics; how the data was obtained and selected; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection);		

Presidency compromise text	Drafting Suggestions	Comments
(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);		
(f) where applicable, a detailed description of pre-determined changes to the AI system and its performance, together with all the relevant information related to the technical solutions adopted to ensure continuous compliance of the AI system with the relevant requirements set out in Title III, Chapter 2;		
(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 compliance with other relevant requirements set out in Title III,		

Presidency compromise text	Drafting Suggestions	Comments
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).		
<p>3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system; the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the</p>		

Presidency compromise text	Drafting Suggestions	Comments
interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate;		
4. A detailed description of the risk management system in accordance with Article 9;		
5. A description of any change made to the system through its lifecycle;		
6. A list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union; where no such harmonised standards have been applied, a detailed description of the solutions adopted to meet the requirements set out in Title III, Chapter 2, including a list of other relevant standards and technical specifications applied;		

Presidency compromise text	Drafting Suggestions	Comments
7. A copy of the EU declaration of conformity;		
8. A detailed description of the system in place to evaluate the AI system performance in the post-market phase in accordance with Article 61, including the post-market monitoring plan referred to in Article 61(3).		
ANNEX V		
EU DECLARATION OF CONFORMITY		
The EU declaration of conformity referred to in Article 48, shall contain all of the following information:		
1. AI system name and type and any additional unambiguous reference allowing identification and traceability of the AI system;		

Presidency compromise text	Drafting Suggestions	Comments
2. Name and address of the provider or, where applicable, their authorised representative;		
3. A statement that the EU declaration of conformity is issued under the sole responsibility of the provider;		
4. A statement that the AI system in question is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity;		
5. References to any relevant harmonised standards used or any other common specification in relation to which conformity is declared;		
6. Where applicable, the name and identification number of the notified body, a		

Presidency compromise text	Drafting Suggestions	Comments
description of the conformity assessment procedure performed and identification of the certificate issued;		
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.		
ANNEX VI CONFORMITY ASSESSMENT PROCEDURE BASED ON INTERNAL CONTROL		
1. The conformity assessment procedure based on internal control is the conformity assessment procedure based on points 2 to 4.		
2. The provider verifies that the established quality management system is in compliance with the requirements of Article 17.		

Presidency compromise text	Drafting Suggestions	Comments
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.		
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.		
ANNEX VII CONFORMITY BASED ON ASSESSMENT OF QUALITY MANAGEMENT SYSTEM AND ASSESSMENT OF TECHNICAL DOCUMENTATION		
1. Introduction		

Presidency compromise text	Drafting Suggestions	Comments
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.		
2. Overview		
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 specified in point 5. The technical documentation of the AI system shall be examined in accordance with point 4.		
3. Quality management system		
3.1. The application of the provider shall include:		

Presidency compromise text	Drafting Suggestions	Comments
(a) the name and address of the provider and, if the application is lodged by the authorised representative, their name and address as well;		
(b) the list of AI systems covered under the same quality management system;		
(c) the technical documentation for each AI system covered under the same quality management system;		
(d) the documentation concerning the quality management system which shall cover all the aspects listed under Article 17;		
(e) a description of the procedures in place to ensure that the quality management system remains adequate and effective;		

Presidency compromise text	Drafting Suggestions	Comments
(f) a written declaration that the same application has not been lodged with any other notified body.		
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.		
The decision shall be notified to the provider or its authorised representative.		
The notification shall contain the conclusions of the assessment of the quality management system and the reasoned assessment decision.		
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.		

Presidency compromise text	Drafting Suggestions	Comments
3.4. Any intended change to the approved quality management system or the list of AI systems covered by the latter shall be brought to the attention of the notified body by the provider.		
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.		
The notified body shall notify the provider of its decision. The notification shall contain the conclusions of the examination of the changes and the reasoned assessment decision.		
4. Control of the technical documentation.		
4.1. In addition to the application referred to in point 3, an application with a notified body of		

Presidency compromise text	Drafting Suggestions	Comments
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 on the market or put into service and which is covered by the quality management system referred to under point 3.		
4.2. The application shall include:		
(a) the name and address of the provider;		
(b) a written declaration that the same application has not been lodged with any other notified body;		
(c) the technical documentation referred to in Annex IV.		
4.3. The technical documentation shall be examined by the notified body. To this purpose, the notified body shall be granted full access to		

Presidency compromise text	Drafting Suggestions	Comments
the training and testing datasets used by the provider, including through application programming interfaces (API) or other appropriate means and tools enabling remote access.		
<p>4.4. In examining the technical documentation, the notified body may require that the provider supplies further evidence or carries out further tests so as to enable a proper assessment of conformity of the AI system with the requirements set out in Title III, Chapter 2.</p> <p>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.</p>		
4.5. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the notified body shall also be		

Presidency compromise text	Drafting Suggestions	Comments
granted access to the source code of the AI system.		
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.		
Where the AI system is in conformity with the requirements set out in Title III, Chapter 2, an EU technical documentation assessment certificate shall be issued by the notified body. The certificate shall 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.		
The certificate and its annexes shall contain all relevant information to allow the conformity of		

Presidency compromise text	Drafting Suggestions	Comments
the AI system to be evaluated, and to allow for control of the AI system while in use, where applicable.		
Where the AI system is not in conformity with the requirements set out in Title III, Chapter 2, the notified body shall refuse to issue an EU technical documentation assessment certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.		
Where the AI system does not meet the requirement relating to the data used to train it, re-training of the AI system will be needed prior to the application for a new conformity assessment. In this case, the reasoned assessment decision of the notified body refusing to issue the EU technical documentation assessment certificate shall contain specific considerations on the quality		

Presidency compromise text	Drafting Suggestions	Comments
data used to train the AI system, notably on the reasons for non-compliance.		
<p>4.7. Any change to the AI system that could affect the compliance of the AI system with the requirements or its intended purpose shall be approved by the notified body which issued the EU technical documentation assessment certificate. The provider shall inform such notified body of its intention to introduce any of the above-mentioned changes or if it becomes otherwise aware of the occurrence of such changes. The intended changes shall be assessed by the notified body which shall decide whether those changes require a new conformity assessment in accordance with Article 43(4) or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the provider of its decision and, where the changes</p>		

Presidency compromise text	Drafting Suggestions	Comments
are approved, issue to the provider a supplement to the EU technical documentation assessment certificate.		
5. Surveillance of the approved quality management system.		
5.1. The purpose of the surveillance carried out by the notified body referred to in Point 3 is to make sure that the provider duly fulfils the terms and conditions of the approved quality management system.		
5.2. 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.		

Presidency compromise text	Drafting Suggestions	Comments
<p>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.</p>		
<p>ANNEX VIII</p> <p>INFORMATION TO BE SUBMITTED</p> <p>UPON THE REGISTRATION OF HIGH-RISK AI SYSTEMS IN ACCORDANCE</p> <p>WITH ARTICLE 51</p>		
<p>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.</p>		

Presidency compromise text	Drafting Suggestions	Comments
1. Name, address and contact details of the provider;	1. Title position Name, address and contact details of the provider;	People often change jobs, and the name used in the database may not be up to date anymore. Referring to the position/job of someone is more resistant to changes.
2. Where submission of information is carried out by another person on behalf of the provider, the name, address and contact details of that person;	2. Where submission of information is carried out by another person on behalf of the provider, the title position name, address and contact details of that person;	People often change jobs, and the name used in the database may not be up to date anymore. Referring to the position/job of someone is more resistant to changes.
3. Name, address and contact details of the authorised representative, where applicable;	3. Title position Name, address and contact details of the authorised representative, where applicable;	People often change jobs, and the name used in the database may not be up to date anymore. Referring to the position/job of someone is more resistant to changes.
	3a. Title position Name, address and contact details of the user, where applicable;	Besides the provider, it should be clear also which organisations are using these systems.
4. AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system;		

Presidency compromise text	Drafting Suggestions	Comments
5. Description of the intended purpose of the AI system;	Description of the intended purpose of the AI system, the context and actual purpose of deployment (if different from intended purpose), and the designation of impacted persons;	Intended purpose could differ from actual use
6. Status of the AI system (on the market, or in service; no longer placed on the market/in service, recalled);		
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;		
8. A scanned copy of the certificate referred to in point 7, when applicable;		
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;		

Presidency compromise text	Drafting Suggestions	Comments
10. A copy of the EU declaration of conformity referred to in Article 48;		
11. Electronic instructions for use; this information shall not be provided for high-risk AI systems in the areas of law enforcement and migration, asylum and border control management referred to in Annex III, points 1, 6 and 7.		How does the exemption ‘this information shall not be provided for high-risk AI systems in the areas of law enforcement (...)’ relate to the exception regarding tax and customs authorities, laid down in preamble no. 38?
12. URL for additional information (optional).		
ANNEX IX UNION LEGISLATION ON LARGE-SCALE IT SYSTEMS IN THE AREA OF FREEDOM, SECURITY AND JUSTICE		
1. Schengen Information System		
(a) Regulation (EU) 2018/1860 of the European Parliament and of the Council of 28		

Presidency compromise text	Drafting Suggestions	Comments
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).		
(b) Regulation (EU) 2018/1861 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of border checks, and amending the Convention implementing the Schengen Agreement, and amending and repealing Regulation (EC) No 1987/2006 (OJ L 312, 7.12.2018, p. 14)		
(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,		

Presidency compromise text	Drafting Suggestions	Comments
amending and repealing Council Decision 2007/533/JHA, and repealing Regulation (EC) No 1986/2006 of the European Parliament and of the Council and Commission Decision 2010/261/EU (OJ L 312, 7.12.2018, p. 56).		
2. Visa Information System		
(a) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 767/2008, Regulation (EC) No 810/2009, Regulation (EU) 2017/2226, Regulation (EU) 2016/399, Regulation XX/2018 [Interoperability Regulation], and Decision 2004/512/EC and repealing Council Decision 2008/633/JHA - COM(2018) 302 final. To be updated once the Regulation is adopted (April/May 2021) by the co-legislators.		
3. Eurodac		

Presidency compromise text	Drafting Suggestions	Comments
<p>(a) Amended proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the establishment of 'Eurodac' for the comparison of biometric data for the effective application of Regulation (EU) XXX/XXX [Regulation on Asylum and Migration Management] and of Regulation (EU) XXX/XXX [Resettlement Regulation], for identifying an illegally staying third-country national or stateless person and on requests for the comparison with Eurodac data by Member States' law enforcement authorities and Europol for law enforcement purposes and amending Regulations (EU) 2018/1240 and (EU) 2019/818 – COM(2020) 614 final.</p>		
4. Entry/Exit System		
<p>(a) Regulation (EU) 2017/2226 of the European Parliament and of the Council of 30</p>		

Presidency compromise text	Drafting Suggestions	Comments
November 2017 establishing an Entry/Exit System (EES) to register entry and exit data and refusal of entry data of third-country nationals crossing the external borders of the Member States and determining the conditions for access to the EES for law enforcement purposes, and amending the Convention implementing the Schengen Agreement and Regulations (EC) No 767/2008 and (EU) No 1077/2011 (OJ L 327, 9.12.2017, p. 20).		
5. European Travel Information and Authorisation System		
(a) Regulation (EU) 2018/1240 of the European Parliament and of the Council of 12 September 2018 establishing a European Travel Information and Authorisation System (ETIAS) and amending Regulations (EU) No 1077/2011, (EU) No 515/2014, (EU) 2016/399, (EU)		

Presidency compromise text	Drafting Suggestions	Comments
2016/1624 and (EU) 2017/2226 (OJ L 236, 19.9.2018, p. 1).		
(b) Regulation (EU) 2018/1241 of the European Parliament and of the Council of 12 September 2018 amending Regulation (EU) 2016/794 for the purpose of establishing a European Travel Information and Authorisation System (ETIAS) (OJ L 236, 19.9.2018, p. 72).		
6. European Criminal Records Information System on third-country nationals and stateless persons		
(a) Regulation (EU) 2019/816 of the European Parliament and of the Council of 17 April 2019 establishing a centralised system for the identification of Member States holding conviction information on third-country nationals and stateless persons (ECRIS-TCN) to supplement the European Criminal Records		

Presidency compromise text	Drafting Suggestions	Comments
Information System and amending Regulation (EU) 2018/1726 (OJ L 135, 22.5.2019, p. 1).		
7. Interoperability		
(a) Regulation (EU) 2019/817 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of borders and visa (OJ L 135, 22.5.2019, p. 27).		
(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).		
	End	End

