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WORKING PAPER

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CONTRIBUTION

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

Delegations will find in annex the IE 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)		<i>Overall comment: “Ireland very much welcomes the compromise text for the AIA and supports a harmonised regulatory environment across the EU in relation to AI technology. It is important that the approach is proportionate but at the same time instils trust in AI Systems and that the individual is protected”.</i>
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.		

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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.		
7. Notifying authorities shall have a sufficient number of 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		

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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.		
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		

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<p>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 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</p>		

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designation procedure under this Regulation, as appropriate.		
<i>Article 32</i> <i>Notification procedure</i>		
1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 33.		
2. Notifying authorities shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.		
3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies concerned.		

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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.		
5. Notifying authorities shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.		
<i>Article 33</i> <i>Notified bodies</i>		
1. Notified bodies shall verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43.		

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<p>2. Notified bodies shall satisfy the organisational, quality management, resources and process requirements that are necessary to fulfil their tasks.</p>		
<p>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.</p>		
<p>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.</p>		

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<p>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.</p>		
<p>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</p>		

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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.		
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.		
9. Notified bodies shall be capable of carrying out all the tasks falling to them under		

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<p>this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by notified bodies themselves or on their behalf and under their responsibility.</p>		
<p>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.</p>		

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11. Notified bodies shall participate in coordination activities as referred to in Article 38. They shall also take part directly or be represented in European standardisation organisations, or ensure that they are aware and up to date in respect of relevant standards.		
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>		

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<p>1. Where a notified body subcontracts specific tasks connected with the conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements laid down in Article 33 and shall inform the notifying authority accordingly.</p>		
<p>2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.</p>		
<p>3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the provider.</p>		
<p>4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the</p>		

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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.		
2. The Notifying authority shall provide the Commission, on request, with all relevant		

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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).		
<i>Article 38</i> <i>Coordination of notified bodies</i>		

Presidency compromise text	Drafting Suggestions	Comments
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.		
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.		
<i>Article 39</i> <i>Conformity assessment bodies of third countries</i>		
Conformity assessment bodies established under the law of a third country with which the Union has concluded an agreement may be authorised		

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to carry out the activities of notified Bodies under this Regulation.		
CHAPTER 5		
STANDARDS, CONFORMITY ASSESSMENT, CERTIFICATES, REGISTRATION		
<i>Article 40</i> <i>Harmonised standards</i>		<i>IE notes that Cion intends to devote significant efforts, along with MS, to make maximum use of international standards and IE welcomes this.</i>
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		

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the extent those standards cover those requirements.		
<i>Article 41</i> <i>Common specifications</i>		
1. Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns, the Commission may, by means of implementing acts, adopt 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).		
2. The Commission, when preparing the common specifications referred to in paragraph		

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1, shall gather the views of relevant bodies or expert groups established under relevant sectorial Union law.		
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>		

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1. Taking into account their intended purpose, high-risk AI systems that have been trained and tested on data concerning the specific geographical, behavioural and functional setting within which they are intended to be used shall be presumed to be in compliance with the requirement set out in Article 10(4).		
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		

¹ Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 1).

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of this Regulation in so far as the cybersecurity certificate or statement of conformity or parts thereof cover those requirements.		
<i>Article 43</i> <i>Conformity assessment</i>		
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;		

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(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		

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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.		
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.		
3. For high-risk AI systems, to which legal acts listed in Annex II, section A, apply, the		

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<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		

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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.		
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 such delegated acts taking into account the		

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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.		
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		

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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.		
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.		
<i>Article 45</i> <i>Appeal against decisions of notified bodies</i>		

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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.		
<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;		
(b) any refusal, restriction, suspension or withdrawal of a Union technical documentation assessment certificate or a quality management		

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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.		
2. Each notified body shall inform the other notified bodies of:		

Presidency compromise text	Drafting Suggestions	Comments
(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.		

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<p><i>Article 47</i></p> <p><i>Derogation from conformity assessment procedure</i></p>		
<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>		

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<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>		

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<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>		

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<p>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.</p>		
<p>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.</p>		
<p>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</p>		

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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>		

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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.		Our understanding is that instances where CE marking cannot be affixed to the packaging, can instead be done on the accompanying documentation would include systems that are deployed in an online domain. IE seeks clarification that this interpretation is correct.
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.		
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		

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the high-risk AI system fulfils the requirements for CE marking.		
<i>Article 50</i> <i>Document retention</i>		
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:		
(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;		

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(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		
TRANSPARENCY OBLIGATIONS FOR CERTAIN AI SYSTEMS		

Presidency compromise text	Drafting Suggestions	Comments
<p><i>Article 52</i></p> <p><i>Transparency obligations for certain AI systems</i></p>		
<p>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>		
<p>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</p>		

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categorisation, which are permitted by law to detect, prevent and investigate criminal offences.		
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 content has been artificially generated or manipulated.		
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,		

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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>		
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.		

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<p>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.</p>		
<p>3. Paragraph 2 shall apply, mutatis mutandis, to any person who integrates a general purpose AI system made available on the market, with or without modifying it, into an AI system whose intended purpose makes it subject to the provisions of this Regulation.</p>		
<p>4. The provisions of this Article shall apply irrespective of whether the general</p>		

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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 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		

Presidency compromise text	Drafting Suggestions	Comments
<p>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>2. Member States shall ensure that to the extent the innovative AI systems involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the national data protection authorities and those other national authorities are associated to the operation of the AI regulatory sandbox.</p>		
<p>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</p>		

Presidency compromise text	Drafting Suggestions	Comments
<p>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.</p>		
<p>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.</p>		
<p>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</p>		

Presidency compromise text	Drafting Suggestions	Comments
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 implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).		
<i>Article 54</i> <i>Further processing of personal data for developing certain AI systems in the public interest in the AI regulatory sandbox</i>		

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;		

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(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		

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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 Measures for SME small-scale providers and users		<i>It would be important to ensure the engagement of SMEs (including Start-ups) would not be hindered by undue administrative burden on these enterprises who are vital to growth and innovation in the AI ecosystem.</i>
1. Member States shall undertake the following actions:		
(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;		
(b) organise specific awareness raising activities about the application of this Regulation tailored to the needs of the small-scale SME providers and users;		
(c) where appropriate, establish a dedicated channel for communication with small-scale		

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SME providers and user 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.		
TITLE VI		
GOVERNANCE		
CHAPTER 1		
EUROPEAN ARTIFICIAL INTELLIGENCE BOARD		

Presidency compromise text	Drafting Suggestions	Comments
Article 56 <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:		
(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;		

Presidency compromise text	Drafting Suggestions	Comments
(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 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.		
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		

Presidency compromise text	Drafting Suggestions	Comments
the Board's tasks as listed in Article 58. The Board may establish sub-groups as appropriate for the purpose of examining specific questions.		
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.		
4. The Board may invite external experts and observers to attend its meetings and may hold exchanges with interested third parties to inform its activities to an appropriate extent. To that end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups.		

Presidency compromise text	Drafting Suggestions	Comments
Article 58 Tasks of the Board		
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;		
(c) issue opinions, recommendations or written contributions on matters related to the implementation of this Regulation, in particular		

Presidency compromise text	Drafting Suggestions	Comments
(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		
NATIONAL COMPETENT AUTHORITIES		

Presidency compromise text	Drafting Suggestions	Comments
<p><i>Article 59</i></p> <p><i>Designation of national competent authorities</i></p>		<p><i>Adequate support and time will be needed for Market Surveillance Authorities, particularly where they have no previous experience in testing high risk AI systems and will need to be upskilled to implement the requirements of the draft AI regulation.</i></p>
<p>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.</p>		
<p>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</p>		

Presidency compromise text	Drafting Suggestions	Comments
unless a Member State has organisational and 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.		
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.		

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		

Presidency compromise text	Drafting Suggestions	Comments
under that Union legislation shall be consulted, 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>		

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.		<p><i>With respect to the transparency obligations for AI systems intended to interact with natural persons as outlined under article 52, the exemption for AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences takes account of security and public safety concerns.</i></p> <p><i>We would welcome clarification that the inclusion of details of such systems in an EU database for stand-alone high-risk AI systems takes into account similar concerns.</i></p>
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.		
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		

Presidency compromise text	Drafting Suggestions	Comments
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.		
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		

Presidency compromise text	Drafting Suggestions	Comments
POST-MARKET MONITORING		
<i>Article 61</i> <i>Post-market monitoring by providers and post-market monitoring plan for high-risk AI systems</i>		
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.		
2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate		

Presidency compromise text	Drafting Suggestions	Comments
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 integrated into that system and plan as appropriate.		

Presidency compromise text	Drafting Suggestions	Comments
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 incident or any malfunctioning of those systems which constitutes a breach of obligations under Union law intended to protect fundamental		

Presidency compromise text	Drafting Suggestions	Comments
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 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		

Presidency compromise text	Drafting Suggestions	Comments
paragraph 1. That guidance shall be issued 12 months after the entry into force of this Regulation, at the latest.		
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 constitute a breach of obligations under Union law intended to protect fundamental rights.		
CHAPTER 3		

Presidency compromise text	Drafting Suggestions	Comments
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:		
(a) any reference to an economic operator under Regulation (EU) 2019/1020 shall be understood as including all operators identified in Title III, Chapter 3 Article 2 of this Regulation;		
(b) any reference to a product under Regulation (EU) 2019/1020 shall be understood		

Presidency compromise text	Drafting Suggestions	Comments
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.		
3. For high-risk AI systems, related to products to which legal acts listed in Annex II, section A apply, the market surveillance authority for the purposes of this Regulation shall be the authority responsible for market surveillance activities designated under those legal acts.		

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

Presidency compromise text	Drafting Suggestions	Comments
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.		
7. Member States shall facilitate the coordination between market surveillance authorities designated under this Regulation and other relevant national authorities or bodies which supervise the application of Union harmonisation legislation listed in Annex II or other Union legislation that might be relevant for the high-risk AI systems referred to in Annex III.		
<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		

Presidency compromise text	Drafting Suggestions	Comments
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.		
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.		This may be difficult to implement with complications arising from data sharing rules and Intellectual property risk to producer of product / service. IE suggests that mitigating ways, such as safeguards as to non-disclosure of data and respect for confidentiality/intellectual property should be included in the regulation so as not to discourage AI producers from operating in European territory
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-		

Presidency compromise text	Drafting Suggestions	Comments
<p>risk AI systems referred to in Annex III shall have the power to request and access any documentation created or maintained under this Regulation when access to that documentation is necessary for the fulfilment of the competences under their mandate within the limits of their jurisdiction. The relevant public authority or body shall inform the market surveillance authority of the Member State concerned of any such request.</p>		
<p>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.</p>		

Presidency compromise text	Drafting Suggestions	Comments
<p>5. Where the documentation referred to in paragraph 3 is insufficient to ascertain whether a breach of obligations under Union law intended to protect fundamental rights has occurred, the public authority or body referred to paragraph 3 may make a reasoned request to the market surveillance authority to organise testing of the high-risk AI system through technical means. The market surveillance authority shall organise the testing with the close 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>		

Presidency compromise text	Drafting Suggestions	Comments
<p><i>Article 65</i></p> <p><i>Procedure for dealing with AI systems presenting a risk at national level</i></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 safety or to the protection of fundamental rights of persons are concerned.</p>		
<p>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</p>		

Presidency compromise text	Drafting Suggestions	Comments
relevant national public authorities or bodies referred to in Article 64(3). The relevant operators shall cooperate as necessary with the market surveillance authorities and the other national public authorities or bodies referred to in Article 64(3).		
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.		
The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to		

Presidency compromise text	Drafting Suggestions	Comments
the measures referred to in the second subparagraph.		
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.		
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		

Presidency compromise text	Drafting Suggestions	Comments
market, to withdraw the product from that market or to recall it. That authority shall inform the Commission and the other Member States, without delay, of those measures.		
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;		

Presidency compromise text	Drafting Suggestions	Comments
(b) shortcomings in the harmonised standards or common specifications referred to in Articles 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		

Presidency compromise text	Drafting Suggestions	Comments
provisional measure taken by a Member State, that measure shall be deemed justified. This is without prejudice to the procedural rights of the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020.		
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		

Presidency compromise text	Drafting Suggestions	Comments
without delay enter into consultation with the relevant Member State and operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not within 9 months from the notification referred to in Article 65(5) and notify such decision to the Member State concerned.		
2. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant AI system is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.		
3. Where the national measure is considered justified and the non-compliance of the AI		

Presidency compromise text	Drafting Suggestions	Comments
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 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		

Presidency compromise text	Drafting Suggestions	Comments
<p>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>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>		
<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</p>		

Presidency compromise text	Drafting Suggestions	Comments
the AI system, the nature of the risk involved and the nature and duration of the national measures taken.		
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.		
5. The Commission shall address its decision to the Member States.		
<i>Article 68</i> <i>Formal non-compliance</i>		
1. Where the market surveillance authority of a Member State makes one of the following		

Presidency compromise text	Drafting Suggestions	Comments
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;		
(e) the identification number of the notified body, which is involved in the conformity assessment procedure, where applicable, has not been affixed;		

Presidency compromise text	Drafting Suggestions	Comments
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>		
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		Where a provider chooses to create a code of conduct to voluntarily apply the mandatory requirements for high- risk AI systems, will they be able to select certain requirements voluntarily or have to apply all requirements if they choose to create a code of conduct?

Presidency compromise text	Drafting Suggestions	Comments
specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems.		
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 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		

Presidency compromise text	Drafting Suggestions	Comments
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		
CONFIDENTIALITY AND PENALTIES		
<i>Article 70</i> <i>Confidentiality</i>		

Presidency compromise text	Drafting Suggestions	Comments
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 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;		

Presidency compromise text	Drafting Suggestions	Comments
(c) integrity of criminal 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 disclosure would jeopardise public and national security interests.		
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		

Presidency compromise text	Drafting Suggestions	Comments
<p>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>		
<p>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.</p>		
<p>4. The Commission and Member States may exchange, where necessary, confidential information with regulatory authorities of third</p>		

Presidency compromise text	Drafting Suggestions	Comments
countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of confidentiality.		
<i>Article 71</i> <i>Penalties</i>		
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.		

Presidency compromise text	Drafting Suggestions	Comments
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.		
3. The following infringements shall be subject to administrative fines of up to 30 000 000 EUR or, if the offender is company, up to 6 % of its total worldwide annual turnover for the preceding financial year, whichever is higher:		Fines proposed are at higher level of fines and therefore would not be in line with current penalties for breaches of market surveillance regulations. We note the difference and are consulting with stakeholders.
(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		

Presidency compromise text	Drafting Suggestions	Comments
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 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:		

Presidency compromise text	Drafting Suggestions	Comments
(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.		
(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		

Presidency compromise text	Drafting Suggestions	Comments
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>		
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;		

Presidency compromise text	Drafting Suggestions	Comments
(b) the cooperation with the European Data Protection Supervisor in order to remedy the infringement and mitigate the possible adverse effects of the infringement, including compliance with any of the measures previously ordered by the European Data Protection Supervisor against the Union institution or agency or body concerned with regard to the same subject matter;		
(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;		

Presidency compromise text	Drafting Suggestions	Comments
(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 Articles 5 and 10, shall be subject to administrative fines of up to 250 000 EUR.		
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.		

Presidency compromise text	Drafting Suggestions	Comments
Complainants, if any, shall be associated closely with the proceedings.		
5. The rights of defense of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the European Data Protection Supervisor's file, subject to the 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		

Presidency compromise text	Drafting Suggestions	Comments
<p><i>Article 73</i></p> <p><i>Exercise of the delegation</i></p>		
<p>1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.</p>		
<p>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>.</p>		
<p>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</p>		

Presidency compromise text	Drafting Suggestions	Comments
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 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.		
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		

Presidency compromise text	Drafting Suggestions	Comments
<p>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 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.</p>		
<p><i>Article 74</i></p> <p><i>Committee procedure</i></p>		
<p>1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.</p>		

Presidency compromise text	Drafting Suggestions	Comments
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.		
TITLE XII		
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		

Presidency compromise text	Drafting Suggestions	Comments
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.”		

* 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		

Presidency compromise text	Drafting Suggestions	Comments
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 ...).”		
<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		

Presidency compromise text	Drafting Suggestions	Comments
requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.		

* 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		

Presidency compromise text	Drafting Suggestions	Comments
paragraphs 2 and 3, the Commission shall take into account the requirements set out in Title III, Chapter 2 of that Regulation.		

* 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		

Presidency compromise text	Drafting Suggestions	Comments
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 ...).”.		
<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		

Presidency compromise text	Drafting Suggestions	Comments
requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.		

* 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		

Presidency compromise text	Drafting Suggestions	Comments
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.		

* 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.”		

Presidency compromise text	Drafting Suggestions	Comments
(3) In Article 43, the following paragraph is added:		
“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		

Presidency compromise text	Drafting Suggestions	Comments
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:		
“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)		

Presidency compromise text	Drafting Suggestions	Comments
YYY/XX [on Artificial Intelligence] , the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.”.		
<i>Article 82</i> <i>Amendment to Regulation (EU) 2019/2144</i>		
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.		

Presidency compromise text	Drafting Suggestions	Comments
* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...).”.		
<i>Article 83</i> <i>AI systems already placed on the market or put into service</i>		
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.		
The requirements laid down in this Regulation shall be taken into account, where applicable, in		

Presidency compromise text	Drafting Suggestions	Comments
the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts.		
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.		

Presidency compromise text	Drafting Suggestions	Comments
1a. The Commission shall assess the need for amendment of the list in Annex I every 24 months following the entry into force of this Regulation and until the end of the period of the delegation of power. The findings of that assessment shall be presented to the European Parliament and the Council.		
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.		
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		IE considers that a period of 4 years between the submission of the Commission's report on the evaluation and review of the Regulation is quite long and would propose that this be either

Presidency compromise text	Drafting Suggestions	Comments
evaluation and review of this Regulation to the European Parliament and to the Council. The reports shall be made public.		reduced or an interim review be conducted to capture any weaknesses in the system at as early a stage as possible.
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.		
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,		

Presidency compromise text	Drafting Suggestions	Comments
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.		
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.		
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 European Parliament, of the Council, and of other relevant bodies or sources.		
7. The Commission shall, if necessary, submit appropriate proposals to amend this		

Presidency compromise text	Drafting Suggestions	Comments
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].		
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];		Why do the provision on notified bodies and governance structures apply from three months but the provisions for penalties apply from 12

Presidency compromise text	Drafting Suggestions	Comments
		months? We would propose that 12 months for the development of both structures would be more coherent.
(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>		
ANNEX IV TECHNICAL DOCUMENTATION referred to in Article 11(1)		

Presidency compromise text	Drafting Suggestions	Comments
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;		
(c) the versions of relevant software or firmware and any requirement related to version update;		

Presidency compromise text	Drafting Suggestions	Comments
(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;		
2. A detailed description of the elements of the AI system and of the process for its development, including:		

Presidency compromise text	Drafting Suggestions	Comments
(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 solutions adopted to comply with the requirements set out in Title III, Chapter 2;		

Presidency compromise text	Drafting Suggestions	Comments
(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);		
(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		

Presidency compromise text	Drafting Suggestions	Comments
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, Chapter 2 as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including		

Presidency compromise text	Drafting Suggestions	Comments
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 interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate;</p>		

Presidency compromise text	Drafting Suggestions	Comments
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;		
7. A copy of the EU declaration of conformity;		

Presidency compromise text	Drafting Suggestions	Comments
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;		
2. Name and address of the provider or, where applicable, their authorised representative;		

Presidency compromise text	Drafting Suggestions	Comments
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 description of the conformity assessment procedure performed and identification of the certificate issued;		

Presidency compromise text	Drafting Suggestions	Comments
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.		
3. The provider examines the information contained in the technical documentation in order to assess the compliance of the AI system		

Presidency compromise text	Drafting Suggestions	Comments
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		
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.		

Presidency compromise text	Drafting Suggestions	Comments
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:		
(a) the name and address of the provider and, if the application is lodged by the authorised representative, their name and address as well;		

Presidency compromise text	Drafting Suggestions	Comments
(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;		
(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		

Presidency compromise text	Drafting Suggestions	Comments
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.		
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.		

Presidency compromise text	Drafting Suggestions	Comments
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 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.		

Presidency compromise text	Drafting Suggestions	Comments
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 the training and testing datasets used by the provider, including through application programming interfaces (API) or other appropriate means and tools enabling remote access.		

Presidency compromise text	Drafting Suggestions	Comments
<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>		
<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 granted access to the source code of the AI system.</p>		
<p>4.6. The decision shall be notified to the provider or its authorised representative. The notification shall contain the conclusions of the</p>		

Presidency compromise text	Drafting Suggestions	Comments
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 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,		

Presidency compromise text	Drafting Suggestions	Comments
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 data used to train the AI system, notably on the reasons for non-compliance.		
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		

Presidency compromise text	Drafting Suggestions	Comments
<p>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 are approved, issue to the provider a supplement to the EU technical documentation assessment certificate.</p>		
<p>5. Surveillance of the approved quality management system.</p>		

Presidency compromise text	Drafting Suggestions	Comments
<p>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.</p>		
<p>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.</p>		
<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.</p> <p>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>		

Presidency compromise text	Drafting Suggestions	Comments
ANNEX VIII INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF HIGH- RISK AI SYSTEMS IN ACCORDANCE WITH ARTICLE 51		
The following information shall be provided and thereafter kept up to date with regard to high-risk AI systems to be registered in accordance with Article 51.		
1. Name, address and contact details of the provider;		
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;		

Presidency compromise text	Drafting Suggestions	Comments
3. Name, address and contact details of the authorised representative, where applicable;		
4. AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system;		
5. Description of the intended purpose of the AI system;		
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;		

Presidency compromise text	Drafting Suggestions	Comments
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;		
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.		
12. URL for additional information (optional).		
ANNEX IX UNION LEGISLATION ON LARGE-SCALE IT SYSTEMS IN THE AREA OF FREEDOM, SECURITY AND JUSTICE		

Presidency compromise text	Drafting Suggestions	Comments
1. Schengen Information System		
(a) Regulation (EU) 2018/1860 of the European Parliament and of the Council of 28 November 2018 on the use of the Schengen Information System for the return of illegally staying third-country nationals (OJ L 312, 7.12.2018, p. 1).		
(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)		

Presidency compromise text	Drafting Suggestions	Comments
<p>(c) Regulation (EU) 2018/1862 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of police cooperation and judicial cooperation in criminal matters, amending and repealing Council 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).</p>		
<p>2. Visa Information System</p>		
<p>(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</p>		

Presidency compromise text	Drafting Suggestions	Comments
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		
(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		

Presidency compromise text	Drafting Suggestions	Comments
Regulations (EU) 2018/1240 and (EU) 2019/818 – COM(2020) 614 final.		
4. Entry/Exit System		
(a) Regulation (EU) 2017/2226 of the European Parliament and of the Council of 30 November 2017 establishing an Entry/Exit System (EES) to register entry and exit data and refusal of entry data of third-country nationals crossing the external borders of the Member States and determining the conditions for access to the EES for law enforcement purposes, and amending the Convention implementing the Schengen Agreement and Regulations (EC) No 767/2008 and (EU) No 1077/2011 (OJ L 327, 9.12.2017, p. 20).		
5. European Travel Information and Authorisation System		

Presidency compromise text	Drafting Suggestions	Comments
(a) Regulation (EU) 2018/1240 of the European Parliament and of the Council of 12 September 2018 establishing a European Travel Information and Authorisation System (ETIAS) and amending Regulations (EU) No 1077/2011, (EU) No 515/2014, (EU) 2016/399, (EU) 2016/1624 and (EU) 2017/2226 (OJ L 236, 19.9.2018, p. 1).		
(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		

Presidency compromise text	Drafting Suggestions	Comments
(a) Regulation (EU) 2019/816 of the European Parliament and of the Council of 17 April 2019 establishing a centralised system for the identification of Member States holding conviction information on third-country nationals and stateless persons (ECRIS-TCN) to supplement the European Criminal Records Information System and amending Regulation (EU) 2018/1726 (OJ L 135, 22.5.2019, p. 1).		
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		

Presidency compromise text	Drafting Suggestions	Comments
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