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CONTRIBUTION

From:	General Secretariat of the Council
To:	Working Party on Telecommunications and Information Society
Subject:	Artificial Intelligence Act - Consolidated table of comments from : ES, IE, SK, BE, PT, BG, LV, SI, LT, PL, MT, IT, HR, SE, FI, CZ, EE, HU, DK, NL, AT - (Articles 30-85, Annexes V-IX) (doc. 14278/21)

Delegations will find in annex the AIA consolidated table of comments from : ES, IE, SK, BE, PT, BG, LV, SI, LT, PL, MT, IT, HR, SE, FI, CZ, EE, HU, DK, NL, AT - (Articles 30-85, Annexes V-IX) (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)

Comments from: ES IE SK BE PT BG LV SI LT PL MT IT HR SE FI CZ EE HU DK NL AT

LAST UPDATE: 25 January 2022

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
<p>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</p> <p>(Text with EEA relevance)</p>	<p>ES:</p> <p>(Comments):</p> <p>We miss mentions to the protection of whistleblowers (directive 2019/1937) in the chain of AI systems.</p> <p>IE:</p> <p>(Comments):</p> <p><i>Overall comment: "Ireland very much welcomes the compromise text for the ALA and supports a harmonised regulatory environment across the EU in relation to AI technology. It is important that the</i></p>

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	<p><i>approach is proportionate but at the same time instils trust in AI Systems and that the individual is protected”.</i></p> <p>BE:</p> <p>(Comments):</p> <p>Belgium believes, in coherence with the Belgian position paper on the 2030 Digital Compass, that the EU must play a leading international role in setting standards for the responsible, secure and innovative use of AI, whilst also considering fundamental rights and environmental impact.</p> <p>A prerequisite of adequate consideration of fundamental rights and environmental impact is first that the list of high risk AI systems in Annex III is (and remains) a</p>

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	<p>coherent and complete list of those use cases deemed qualifying as high risk according to Art. 7. <u>In this regard, this list remains obviously incoherent and incomplete.</u> By way of illustration, we consider that AI systems used for AML/CFT purposes could have deleterious effects and increase cases of de-risking (in this case, more difficult to identify as they would result from the complex interaction of multiple algorithms), or even de-banking and financial exclusion, by depriving some people of access to a bank account and related services. This is obviously a harm which is by far more severe than that of a credit refusal based on credit scoring, and could become more and more probable due to the implementation of de-risking</p>

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	<p>strategies by credit institutions. Furthermore, there are no fully effective legal measures to redress the potential risks entailed by those systems. Similarly, we cannot ignore the data protection challenges that the use of such AI systems for AML/CFT purposes could create, which should deserve specific attention as to (a.o.) articulation of the AIA with EU data protection laws.</p> <p>Another illustration concerns AI systems used in the field of insurance. We agree to include the insurance sector in Annex III and to also view certain insurance use cases as high-risk AI systems. This would indeed improve the level-playing field within the financial sector and treat bank and insurance</p>

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	<p>AI systems consistently. However, we observe that all AI systems in insurance (related to claims management, pricing and underwriting) are included in the proposed compromise text contrary to banking AI systems where it is limited to credit scoring and towards natural persons and small service providers are excluded. We would therefore propose to incorporate similar proportionality measures for insurance:</p> <p>Firstly, we would propose proportionality at the level of the insurance market by limiting the scope of high risk AI systems to the most material insurance products (similarly to bank where it is limited to credits towards natural persons). This would imply to limit the scope to Life, Health, Fire</p>

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	<p>and Motor insurance with respect to natural persons. As to other products with more limited materiality, in line with art. 7.d) and e) the extent and potential extent of harm will be limited and will not affect a large number of persons or policy holders.</p> <p>Secondly, we would propose proportionality at the level of the insurance undertaking by excluding small undertakings from the scope of Annex III. Under Solvency II, a threshold of 15 mio EUR premium income is put forward to be considered a low-risk undertaking. A consistency could be foreseen here.</p> <p>Thirdly, it would be useful to introduce proportionality at the level of the (AI)</p>

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	<p>techniques (Annex I). We understand that the aim of the proposed AIA is to protect fundamental rights which could be caused unknowingly by untransparent AI systems. However, the current scope of AI systems also incorporates simple statistical techniques (e.g. linear model, chainladder etc.) which are used for decades in insurance to calculate technical provisions, premiums etc. Given the high transparency that these techniques offer, it would be useful to limit the scope of the AIA to new machine learning and deep learning techniques which are less transparent by nature and to exclude the aforementioned already existing statistical techniques from the scope of the act. This remark is clearly linked to the comment we previously made</p>

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	<p>on the definition of an 'AI system' in Art. 3 (1), namely that it may be too broad, since it could potentially include more traditional/conventional software systems or analytical processing, that should not fall under the scope of the AIA. Even the new refined definition of an 'AI system' (in the first partial compromise proposal) may still be too broad as it has not substantially changed.</p> <p>Another prerequisite of adequate consideration of fundamental rights and environmental impact is that the requirements of the AIA (especially those concerning high risk systems) should be sufficiently specific. The operationalisation of such requirements through harmonised</p>

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	<p>standards should be a mere “operationalisation” thereof rather than a rulemaking of itself with the potential of weakening the norms outside the legislative process (see our examples and comments below relative to article 40 et seq.). We believe the EU should play it’s leading role internationally in alliance with like-minded partners in a broad array of international organizations and bodies, dealing with various aspects of AI such as norms and standards, innovation, etc.</p> <p>SI:</p> <p>(Comments):</p> <p>The Republic of Slovenia welcomes the proposal to regulate the development and use of AI, which brings about a systemic way of regulating the various impacts and</p>

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	<p>challenges that the introduction of AI brings to society. The Republic of Slovenia agrees with the need to achieve the identified four specific objectives of the Regulation.</p> <p>The Republic of Slovenia supports the preparation of a single horizontal AI regulation at EU level in order to establish a coherent framework for the future development and use of AI, in particular high-risk AI systems in such a way that regulation does not start from scratch, but rather builds and ensures coherence on the basis of existing legislation.</p> <p>The Republic of Slovenia agrees with a risk-based approach, which does not regulate the technology, but rather its use by defining a hierarchy of different application segments according to potential risks and by defining appropriate regulatory requirements for different segments, clearly defining what and where special attention is needed in this context. It also agrees with the identification of the main problems of ensuring an adequate regulatory regime for AI, i.e. the risk of violation of human rights</p>

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	<p>and freedoms, as well as risks to the safety of products and services, and in this context the need to ensure clarity and predictability of legislation regarding the responsibilities of individual stakeholders. The Republic of Slovenia will advocate those solutions to the proposal aimed at providing a legal framework that guarantees respect for human rights and fundamental freedoms in the development and use of AI systems.</p> <p>The Republic of Slovenia welcomes the use of the OECD definition of AI system, a clear and internationally harmonised and accepted definition of AI system at technical level, as the basis for the definition of AI in the Regulation.</p> <p>The Republic of Slovenia supports open and flexible arrangements to adapt to future developments and solutions of AI and to support the environment to stimulate innovation, the future development of AI, especially by small and medium-sized enterprises. In this context, the Republic of Slovenia supports the establishment of regulatory sandboxes, which enables the development and production of prototypes within regulatory sandboxes.</p>

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	<p>The Republic of Slovenia advocates a clear definition of the criteria for determining cases of AI applications that require stricter evaluation and supervision, i.e. high-risk AI and, in this context, a clear definition of the categories of AI methods actually covered by the Regulation, which must be specifically reflected in the criteria for defining high-risk AI. In this regard, the Republic of Slovenia has previously drawn attention to the need to separate requirements and criteria relating to the AI system itself (e.g. requirements on input data, learning models, decision models, end result and response of the system) and requirements related to the environment in which the AI system operates (e.g. human supervision, record keeping and data keeping, information, etc.).</p> <p>The Republic of Slovenia is committed to addressing the problem of explainability of different AI models and algorithms, which is crucial in the specific context of the use of AI, where explanations of AI-system decisions are a key prerequisite (legal or technical) for the use of AI system results in certain contexts (fields) of use.</p>

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	<p>Particular attention should be paid to the effective and efficient use of AI systems to ensure public safety. Without the use of new technologies such as artificial intelligence for these purposes, the level of public security will decrease, e.g. in terms of preventing malicious use of AI systems. In doing so, the use of AI must reflect European values and principles and uphold and ensure respect for human rights and fundamental freedoms.</p> <p>The Republic of Slovenia encourages the use of the existing system for checking the compliance of AI systems, which includes accreditation, certification and supervision systems, which already exist in the EU and, above all, at national levels.</p> <p>The Republic of Slovenia will seek to improve AI regulation in terms of greater clarity, consistency and predictability for all relevant stakeholders.</p> <p>LT:</p>

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	<p>(Comments):</p> <p>SE:</p> <p>(Comments):</p> <p>There is a need to review the proposal to ascertain that the obligations aimed at the targeted stakeholders (eg. companies, public authorities etc) are proportionate to the aim of the legislation. Many of the articles contain in themselves or in combination with other articles and the annexes far reaching and detailed demands on the targeted stakeholders. As a consequence these stakeholders (providers, users etc.) will be subject to a significantly increased administrative burden and other types of</p>

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	<p>costs. Other aspects of concern are e.g. the wide definition of AI in combination with the wide definition of what encompasses high-risk AI and the procedure (e.g. through delegated acts) for adding to the areas covered by the regulation. SE also have concerns regarding the extensive reporting requirements and the handling of this information which include confidential and other proprietary information. It is important to limit the amount of such information that needs to be reported to a minimum. It is also important to ensure that the confidentiality of such information is safeguarded in all instances where stakeholders are required to document and share information. Important to ensure that the AI board does not get too far reaching.</p>

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	<p>mandate.</p> <p>It is of great importance that the regulation is predictable and easy to apply.</p> <p>DK:</p> <p>(Comments):</p> <p>As a general comment, we are supportive of the aim with the Commission's proposal of establishing a horizontal regulatory framework for AI, as this can facilitate a genuinely single market for trustworthy, human-centric, safe and secure AI.</p> <p>In our view, further work and discussion are needed on some of the key elements of the proposal in order to achieve a proportionate, risk-based approach which strikes the balance between setting the right</p>

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	<p>requirements and safeguards, while at the same time facilitating and promoting innovation.</p> <p>Therefore, while aiming for substantial progress on the file, we would still underline the need to as a starting point focus the discussion on finding common ground in terms of scope as well as the definition of AI.</p> <p>As national coordination is still ongoing and due to our scrutiny reservation, our following comments and proposals will merely be of a preliminary nature and we have focus on the for us most important elements. Furthermore, assessment of the partial compromise proposal of the Slovenian presidency is still ongoing. In this respect, we reserve the right to submit</p>

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	further comments and proposals concerning these articles at a later stage.
CHAPTER 4	<p>SK:</p> <p>(Comments):</p> <p><u>For both Chapter 4 and Chapter 5:</u> As outlined in Slovakia's non-paper distributed on 13 December 2021 (see governance variant no. 2 in the Annex to the non-paper), Slovakia believes it needs to be considered whether conformity assessments/certifications and the corresponding governance structures are really suitable for stand-alone AI systems due to the systems' dynamic and evolving nature. Under the non-paper's variant no. 2</p>

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	<p>Chapters 4 and 5 below (as well as art. 19, 26, 27 etc.) would not apply to stand-alone AI systems.</p> <p>HR:</p> <p>(Comments):</p> <p>The European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS) stated in its Joint opinion on the Proposal of the AIA* that some provisions of the Proposal defining the tasks and powers of the different competent authorities under the AI regulation, their relationships, their nature and the guarantee of their independence seem unclear at this stage. Whereas Regulation 2019/1020 states that market surveillance authority must be independent, the draft regulation does not require Supervisory authorities to be independent, and even requires them to report to the</p>

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	<p>Commission on certain tasks carried out by market surveillance authorities, which can be different institutions. The EDPB and the EDPS therefore recommended that the cooperation mechanisms between national supervisory authorities be specified in the future AI Regulation. The EDPB and EDPS suggest to impose a mechanism guaranteeing a single point of contact for individuals concerned by the legislation as well as for companies, for each AI system, and that for organisations whose activity covers more than half of the Member States of the EU.</p> <p>*https://edpb.europa.eu/system/files/2021-06/edpb_edps_joint_opinion_ai_regulation_en.pdf</p> <p>As the Proposal for a Regulation envisages the introduction of new bodies at European and national level or the addition of roles to some existing national bodies, the Republic</p>

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	<p>of Croatia considers it necessary to describe in more detail the imaginary organizational structure and relationship of these bodies. In particular, it is necessary to include in the text a clearer description of the hierarchical relationship between the competent authority, the notified body and the conformity assessment body and their relation with competent EU bodies.</p> <p>CZ:</p> <p>(Comments):</p> <p>As regards Chapter 4, the provisions should be as much as possible aligned with the NLF provisions established primarily in Reference Decision No 768/2008/EC.</p> <p>Comments bellow do focus on various</p>

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	<p>provisions in more detail.</p> <p>EE:</p> <p>(Comments):</p> <p>Accreditation process is well described in Regulation (EC) No 765/2008, therefore the purpose of Chapter 4 in its current form remains somewhat unclear. While the current Regulation 765/2008 is rather flexible and provides for the possibility to turn to an accreditation body in another MS (if the MS itself lacks competences), the AIA proposal places a clear resource-intensive obligation on each MS to create these accreditation competences. In smaller countries, it can be difficult to find experts required to fill these roles.</p>

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	<p>The specific roles of notified bodies, notifying bodies and conformity assessment bodies is unclear. The system for assessment is very bureaucratic taking account the small number of systems it applies to. We propose simplifying the process and combining some of these roles. We prefer reliance on DECISION No 768/2008/EC (Chapter R4 Notification of conformity assessment bodies) rather than creating duplicating processes in the current Act.</p>
<p>NOTIFYING AUTHORITIES AND NOTIFIED BODIES</p>	<p>SE:</p> <p>(Comments):</p> <p>IMPORTANT TO CONSIDER</p>

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	<p>PROPORTIONALITY OF THE REGULATION AND OBLIGATIONS IT PUTS ON PRIVATE ACTORS N MK (MARIE – TEXTEN SKA INTE VARA I VERSALER MEN LYCKADES INTE BYTA)</p>
	<p>CZ:</p> <p>(Drafting):</p> <p>Notification</p> <p>Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this ... [act].</p> <p>CZ:</p>

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	<p>(Comments):</p> <p>Chapter 4 corresponds to the Chapter R4 (Notification of Conformity Assessment Bodies) of Reference Decision No 768/2008/EC but the Article R13 is missing. CZ proposes adding the provision laying down the obligation of MS to notify to this Chapter.</p>
<p><i>Article 30</i> <i>Notifying authorities</i></p>	<p>SE:</p> <p>(Comments):</p> <p>Terminology and processes should be aligned with the Cybersecurity Act. E.g. “National accreditation bodies” and “Conformity assessment bodies”.</p> <p>CZ:</p>

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	<p>(Comments):</p> <p>This Article corresponds to Articles R14 and R15 of reference Decision No 768/2008/EC which it brings together in a single article entitled Notifying Authorities. However, it does not contain paragraphs 3 and 4 of reference Article R14: CZ proposes adding these paragraphs to Article 30 or welcomes the explanation why these provisions were not introduced in AIA proposal as follows.</p> <p><i>“Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a</i></p>

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	<p><i>legal entity and shall comply mutatis mutandis with the requirements laid down in Article [R15(1) to (6)]. In addition, it shall have arrangements to cover liabilities arising out of its activities.</i></p> <p><i>The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3."</i></p>
<p>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.</p>	<p>IT:</p> <p>(Comments):</p> <p>It shall be evaluated whether independent private auditors - whose professional conduct is also subject to supervision by EU or national authority - can play a role as in the European System of Financial</p>

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	<p>Supervision. This to better cope with the dynamic nature of AI technology and data flows.</p> <p>SE:</p> <p>(Comments):</p> <p>Art. 30-39: The regulation of "notifying authorities" and "notifying bodies" is very detailed and difficult to understand. It is important that this administrative procedure does not become unnecessarily or disproportionately burdensome. It also needs to be clarified what role and what mandate competent national authorities, national regulatory authorities and the European AI Board have in relation to</p>

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	<p>existing national regulatory authorities and bodies at EU level, not least with regard to data protection issues.</p> <p>FI:</p> <p>(Comments):</p> <ul style="list-style-type: none"> - Why is the headline in plural? Can there be many Notifying authorities in one member state? - The article seems a bit confusing. How many different Notified bodies can there be or are all the Notified bodies always Conformity assessment bodies? <p>CZ:</p> <p>(Drafting):</p>

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	<p>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, including compliance with the provisions of Article 34.</p> <p>CZ:</p> <p>(Comments):</p> <p>CZ proposes (in accordance with Decision No 768/2008/EC) adding the reference to Article 34 on Subsidiaries of and subcontracting by notified bodies.</p>

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<p>2. Member States may designate a national accreditation body referred to in Regulation (EC) No 765/2008 as a notifying authority.</p>	<p>ES:</p> <p>(Drafting):</p> <p>2. Member States may designate a national accreditation body referred to in Regulation (EC) No 765/2008 as a notifying authority. The accreditation body may be designated to perform one or more of the functions described in article 30.1: assessment, designation or notification. Assessment functions will be performed with an adequate level of demand, as established in the guidance provided by the Commission and the European Artificial Intelligence Board.</p> <p>ES:</p>

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	<p>(Comments):</p> <p>After exploring accreditation bodies, Spain sees that they do not share this writing.</p> <p>They do not want to close their role to that assigned to the Notifying Authority. In this regard:</p> <ul style="list-style-type: none">- A notifying authority has three functions: assessment, designation and notification of conformity assessment bodies. The accreditation bodies affirm that their legal status in several EU countries may impede to accept functions such as designating or notifying.- In Spain, accreditation bodies are subject to private law and therefore, they should not notify the Commission (a public body should this), ergo, they can't be a notifying authority.- Moreover, they insist that the threshold for accepting a Notified Body must be set by a public authority, since

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	<p>different levels of demand may be foreseen by the different notifying authorities.</p> <p>It is necessary that the text offers the possibility to appoint an accreditation body only for certain functions of the notifying authority, but not all of them. The rest of the functions would be performed by the notifying authority itself. This would be a more similar approach to any of the NLF regulations previously approved.</p> <p>Also, more research should be done on the three functions explained before: Would it be possible to perform them by accreditation bodies across the EU? At least in Spain it does not seem feasible.</p> <p>IT:</p>

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	<p>(Comments):</p> <p>Both Independent Authorities and Public Agencies shall fit the provision.</p> <p>CZ:</p> <p>(Drafting):</p> <p>2. Member States may designate decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body referred to within the meaning of and in accordance with Regulation (EC) No 765/2008 as a notifying authority.</p> <p>CZ:</p> <p>(Comments):</p>

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	<p>The wording is different from the reference paragraph 2 of Article R14 of 768/2008/EC.</p> <p>This may have a major impact on the establishment and tasks of the notifying authority. By way of derogation from the NLF, either the notifying authority will only itself assess, control and notify the conformity assessment bodies or everything will be transferred to the accreditation body. When the accreditation body is designated as a notifying authority, it would be able to notify only the accredited bodies. The wording could also prevent the use of accreditation by a notifying body other than the accreditation body according Article 31(2).</p>

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	<p>AT:</p> <p>(Drafting):</p> <p>2. Member States may designate a national accreditation body referred to in Regulation (EC) No 765/2008 as a notifying authority.</p> <p>AT:</p> <p>(Comments):</p> <p>Deletion suggested.</p> <p>We think there is no need to deviate from the usual New Legal Framework approach. Accreditation only confirms the competence of a body, it never includes authorisation or designation. The separation between accreditation and notification should</p>

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	therefore be maintained.
	<p>EE:</p> <p>(Drafting):</p> <p>Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.</p> <p>EE:</p> <p>(Comments):</p> <p>Please consider adding this provision. This would pre-empt the obligation for each MS to establish an assessment body.</p>

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<p>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.</p>	<p>IT:</p> <p>(Comments):</p> <p>Absence of conflict of interest as well as impartiality and objectivity shall be deemed as essential prerequisites for the relevant designation.</p>
<p>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.</p>	<p>IT:</p> <p>(Comments):</p> <p>Separation of powers shall be emphasised. Reference to “competent persons different from those who carried out...” only risks being inadequate.</p>
<p>5. Notifying authorities shall not offer or</p>	<p>IT:</p>

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provide any activities that conformity assessment bodies perform or any consultancy services on a commercial or competitive basis.	(Comments): Notifying authorities shall be banned from performing consultancy services.
6. Notifying authorities shall safeguard the confidentiality of the information they obtain.	IT: (Comments): Confidentiality shall be safeguarded at statutory level and at personal level. SE: (Drafting): Notifying authorities shall, with respect to national law, safeguard the confidentiality of the information they obtain. / I ESD SE:

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	<p>(Comments):</p> <p>SE would like clarification as to what is referred to with regards to “confidentiality” and make a reference to Union and national law.</p> <p>FI:</p> <p>(Comments):</p> <ul style="list-style-type: none"> - Article 30(6) and Article 37, paragraph 3: <ul style="list-style-type: none"> o what is meant by “confidential information”. Would this mean business secrets, etc. or would this also include personal data? - Point 6 should be an exception to the rule which is the publicity of government activities and public

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	<p>access to documents.</p> <p>NL:</p> <p>(Drafting):</p> <p>Insofar the information obtained by the notifying authorities must be considered confidential , the notifying authorities shall safeguard the confidentiality of the information they obtain this information, except when disclosure is required by Union or national law.</p> <p>NL:</p> <p>(Comments):</p> <p>We propose to first test whether the information obtained is indeed confidential. If not, the information can be shared freely.</p>

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	If the answer is yes, confidentiality must be safeguarded, except when disclosure is required by Union or national law.
7. Notifying authorities shall have a sufficient number of competent personnel at their disposal for the proper performance of their tasks.	<p>PT:</p> <p>(Comments):</p> <p>For the case of Medical Devices Regulations - referred in Annex II, Section A, points 11 and 12 of this AI Regulation - we would like to emphasise that the Commission Implementing Regulation 2017/2185 establishes the codes for the designation of notified bodies in medical devices under Regulation (EU) 2017/745 and in vitro diagnostic medical devices under Regulation (EU) 2017/746. These</p>

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	<p>codes are primarily used by designating authorities to define the notified body scope of designation, but they are also used by the notified body to: 1) describe the individual qualification of the NBs staff members 2) describe the qualification required for assessing a device...Our question is, cumulatively to that does the Commission foreseen or plan to introduce new notified bodies codes addressing AI technologies under AIA? How will that codes be combined with the sectorial ones? Should apply for expansion of scope by NB – new codes under AIA will be added for MD NBs?</p> <p>IT:</p>

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	<p>(Comments):</p> <p>Italy suggests referring to an “adequate” number instead of a “sufficient” number.</p> <p>NL:</p> <p>(Drafting):</p> <p>Member States shall ensure that the notifying authorities have a sufficient number of competent personnel at their disposal for the proper performance of their tasks.</p> <p>NL:</p> <p>(Comments):</p> <p>More firm commitments necessary. The word 'proper' is too vague.</p>

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<p>8. Notifying authorities shall make sure that conformity assessments are carried out in a proportionate manner, avoiding unnecessary burdens for providers and that notified bodies perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of the AI system in question.</p>	<p>BG:</p> <p>(Comments):</p> <p>We will come back with comments on this paragraph at a later stage, it might be a challenging task for notifying authorities while it makes more sense for notified bodies</p> <p>LT:</p> <p>(Drafting):</p> <p>Notifying authorities shall make sure that conformity assessments are carried out in a proportionate and timely manner, avoiding unnecessary burdens for providers and that notified bodies perform their activities</p>

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	<p>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.</p> <p>LT:</p> <p>(Comments):</p> <p>Adding timely manner would indicate that all necessary procedures should be carried out without delay. Such amendment would increase clarity for businesses. Furthermore, strictly defined time framework, e.g. within 60 days etc, would be more welcome.</p> <p>PL:</p> <p>(Comments):</p> <p>We will come back with comments on this</p>

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	<p>paragraph at a later stage, it might be a challenging task for notifying authorities while it makes more sense for notified bodies</p> <p>IT:</p> <p>(Comments):</p> <p>Excessive burdens shall be avoided in line with the principle of proportionality.</p> <p>SE:</p> <p>(Comments):</p> <p>Taking into account the size of the company does not conform to the standard SS EN 17065. The issue is also discussed in the proposal for the forthcoming Machinery Regulation.</p>

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	<p>How will “size”, “sector” and “structure” effect the burdens and what does structure mean within these regards? Might help with clarification on “proportionate manner” and “unnecessary burdens”.</p> <p>CZ:</p> <p>(Comments):</p> <p>CZ is of the opinion that the notifying authority does not have the means to ensure these obligations and this should be a responsibility of a notified body.</p> <p>EE:</p> <p>(Comments):</p> <p>How to comply with this obligation? Could</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>you please provide some examples, especially how should the size of the undertaking be taken into account?</p> <p>How to guarantee the uniform application of this obligation and equal treatment of SMEs across the internal market?</p> <p>AT:</p> <p>(Drafting):</p> <p>8. — Notifying authorities shall make sure that conformity assessments are carried out in a proportionate manner, avoiding unnecessary burdens for providers and that notified bodies perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>the AI system in question:</p> <p>AT:</p> <p>(Comments):</p> <p>The provision of Art 30 para 8 is an obligation of the notified body to be taken into account in the course of the conformity assessment activities, but not - as currently provided - an obligation of a notifying authority. Therefore, deletion of the paragraph is suggested. However, such an obligation of notified bodies could be included in Art 33.</p> <p>The deletion from Art 30 para 8 and the inclusion in Art 33 as an obligation of notified bodies is also in line with other</p>

Presidency compromise text	Drafting Suggestions Comments
	applicable EU regulations, such as Art 32 of Regulation (EU) 2016/425, but also the current proposal for a regulation on machinery products in Art 36 para 2.
<p><i>Article 31</i> <i>Application of a conformity assessment body for notification</i></p>	<p>IT: (Comments): Italy wonders if and to which extent independent private auditors can be involved to better cope with the dynamic nature of AI technology and data flows.</p> <p>AT: (Comments): In the event of the introduction of such a provision, the Commission should bear in</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>mind that such an approach would entail the allocation of considerable resources. In this respect, the appropriateness of the provision in question is questioned.</p>
<p>1. Conformity assessment bodies shall submit an application for notification to the notifying authority of the Member State in which they are established.</p>	
<p>2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists,</p>	<p>PT:</p> <p>(Drafting):</p> <p>2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules</p>

Presidency compromise text	Drafting Suggestions Comments
<p>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>and the artificial intelligence technologies for which the conformity assessment body claims to be competent, in accordance with Annex I, 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>PT:</p> <p>(Comments):</p> <p>See previous comment (article 30 (7))</p> <p>SE:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>What is a module/modules, an example would clarify?</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 designation procedure under this Regulation, as</p>	<p>SE:</p> <p>(Drafting):</p> <p>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.</p> <p>For notified bodies which are designated under any other Union harmonisation</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
<p>appropriate.</p>	<p>legislation, all documents and certificates linked to those designations may be used to support their designation procedure under this Regulation, as appropriate.</p> <p>SE:</p> <p>(Comments):</p> <p>SE prefers that accreditation in accordance with (EU) Regulation 765/2008 is the only tool to be used to assess the competence of the conformity assessment bodies. If not, there is a risk for a high degree of variation in terms of competence.</p> <p>Designation/-s should be changed to notification/-s. If not notified bodies according to Mutual Recognition Agreements.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>NL:</p> <p>(Drafting):</p> <p>3. Conformity assessment bodies should preferably provide an accreditation certificate to demonstrate compliance with the requirements laid down in Article 33. Only where the conformity assessment body concerned cannot provide an accreditation certificate, it shall 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</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>linked to those designations may be used to support their designation procedure under this Regulation, as appropriate.</p> <p>NL:</p> <p>(Comments):</p> <p>We suggest specifying in Art. 31.3 that accreditation should be the starting point. Exceptions should only be possible in case of compelling reasons.</p>
<p><i>Article 32</i> <i>Notification procedure</i></p>	<p>NL:</p> <p>(Comments):</p> <p>There is no paragraph dedicated to the consequences of an objection and whether</p>

Presidency compromise text	Drafting Suggestions Comments
	this triggers the processes described in article 36 or article 37.
1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 33.	
2. Notifying authorities shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.	SE: (Drafting): Notifying authorities shall notify the European Artificial Intelligence Board, using the electronic notification tool developed by the Commission and managed by the European Artificial Intelligence Board.

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>NL:</p> <p>(Drafting):</p> <p>using the electronic notification tool [reference needed] developed and managed by the Commission.</p> <p>NL:</p> <p>(Comments):</p> <p>Is this is a new tool based on existing tools in other areas, please provide a reference to that or explain how this tool will be developed.</p>
<p>3. The notification shall include full details of the conformity assessment activities, the conformity assessment</p>	<p>PT:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
<p>module or modules and the artificial intelligence technologies concerned.</p>	<p>See previous comment (article 30 (7))</p> <p>IT:</p> <p>(Comments):</p> <p>It would be useful to have a detailed report on the conformity assessment activities (together with the assessment module)</p> <p>CZ:</p> <p>(Comments):</p> <p>Paragraph 3 builds on the relevant paragraph of Article R23 of 768/2008/EC and provides that the notification shall include (inter alia) information on the AI technologies concerned. Unlike Article R23, however, notification must not contain the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>relevant attestation of competence.</p> <p>CZ proposes adding a requirement for the relevant attestation of competence, which is a basic document.</p> <p>NL:</p> <p>(Drafting):</p> <p>The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies concerned and the relevant attestation of competence.</p> <p>Where a notification is not based on an accreditation certificate as referred to in Article 31 (2), the notifying authority shall provide the Commission and the other</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 33.</p> <p>NL:</p> <p>(Comments):</p> <p>We would suggest adding a paragraph on notifications that are not based on accreditation certificates in order to better ensure competence and compliance with Art. 33.</p>
4. The conformity assessment body	SE:

Presidency compromise text	Drafting Suggestions Comments
<p>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.</p>	<p>(Drafting):</p> <p>where no objections are raised by the European Artificial Intelligence Board, within one month of a notification</p> <p>CZ:</p> <p>(Comments):</p> <p>Paragraph 4 corresponds to paragraph 5 of Article R23 of 768/2008/EC, but unlike those two paragraphs, it does not distinguish between two time limits for objections where an accreditation certificate is used (two weeks) and in case where accreditation is not used (two months). The deadline for objections in the draft AIA is within one month of notification. In contrast to the paragraph of Article R23, the following</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>sentence is also missing: <i>"Only such a body shall be considered a notified body for the purposes of this ... [act]."</i></p> <p>The provisions and related deadlines should be aligned to those established in 768/2008/EC. Otherwise, it might undermine the efforts of the Commission and MS, including the Czech Republic, to support the use of accreditation. There is also context in relation to the above comments regarding unclear possibilities of using accreditation.</p> <p>HU:</p> <p>(Drafting):</p> <p>The conformity assessment body concerned may perform the activities of a notified</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>body only where no objections are raised by the Commission or the other Member States within one month of a notification of the notifying authority.</p> <p>HU:</p> <p>(Comments):</p> <p>For clarification purposes only.</p> <p>NL:</p> <p>(Drafting):</p> <p>The conformity assessment body concerned may perform the activities of a notified body as referred to in article 31/recital 64 only where no objections are raised by the Commission or the other Member States within one month of a notification within</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>two weeks of the notification where it includes an accreditation certificate referred to in Article 31 paragraph 2 or within two months of the notification where it includes documentary evidence referred to in Article 31 paragraph 3.</p> <p>NL:</p> <p>(Comments):</p> <p>Suggestion to clarify to which activities this article refers, is this article 31?</p> <p>We would suggest making a distinction between notifications based on accreditation certificates and notifications based on other documentary evidence. The latter would require more intensive investigation.</p> <p>Also we would suggest clarifying that only</p>

Presidency compromise text	Drafting Suggestions Comments
	assessment bodies that have been notified without any objections being raised may be considered notified bodies.
<p>5. Notifying authorities shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.</p>	<p>SE:</p> <p>(Drafting):</p> <p>Notifying authorities shall notify the European Artificial Intelligence Board</p> <p>HU:</p> <p>(Drafting):</p> <p>Notifying authorities shall notify the Commission and the other Member States of any subsequent relevant changes to the notification within one month after becoming aware of the changes.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>HU:</p> <p>(Comments):</p> <p>We recommend setting a unified deadline for notification.</p> <p>NL:</p> <p>(Drafting):</p> <p>Notifying authorities shall notify the Commission and the other Member States of any subsequent relevant changes to the notification referred to in paragraph 2.</p> <p>NL:</p> <p>(Comments):</p> <p>Minor specification.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>CZ:</p> <p>(Drafting):</p> <p>6. Where a notification is not based on an accreditation certificate as referred to in Article 31 (2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 33.</p> <p>CZ:</p> <p>(Comments):</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>CZ proposes adding this provision, otherwise the notification will not be complete and the Commission and MS will not be able to assess it sufficiently.</p>
<p><i>Article 33</i> <i>Notified bodies</i></p>	<p>HR:</p> <p>(Comments):</p> <p>There is a high number and wide diversity of situations where the use of AI systems is identified as problematic with respect to equality and fundamental rights, for example in the European Network of Equality Bodies' (Equinet) report⁹ so a risk-based approach strictly limited to particular sectors that are considered high-risk may not provide adequate protection against all potential rights violations by AI systems.</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>For the purpose of equality and fundamental rights protection, and for the prevention of unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination, the widest possible range of AI uses should be subject to compliance checks.</p> <p>*https://equineteurope.org/wp-content/uploads/2020/06/ai_report_digital.pdf</p> <p>CZ:</p> <p>(Comments):</p> <p>Article 33 is based on Articles R27 (Operational obligations of notified bodies) and R17 (Requirements relating to notified bodies) of 768/2008/EC and is adapted to</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>artificial intelligence.</p> <p>Grouping Articles R27 and R17 into a single article could, however, create confusion. The requirements for notified bodies shall be assessed before notifying a conformity assessment body and commencing its activities. The obligations relating to the activity relate only to its activity. There are also connections with accreditation and its possible scope. CZ proposes breaking this Article down according to the reference provisions concerned of 768/2008/EC.</p> <p>NL:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>We noticed that no presumption of conformity has been introduced in this article for notified bodies that demonstrate conformity with applicable harmonized standards that cover the requirements set out in this Regulation. We would suggest to consider including such a presumption of conformity.</p>
	<p>CZ:</p> <p>(Drafting):</p> <p>The notified body shall be established under national law and have legal personality.</p> <p>A notified body shall be a third-party body independent of the organisation or the product it assesses.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.</p> <p>CZ:</p> <p>(Comments):</p> <p>The paragraphs 2 and 3 of Article R 17 of 768/2008/EC are missing. CZ proposes adding these provisions, in particular <i>“The notified body shall be established under national law and have legal personality.”</i>, which is crucial for the functioning of</p>

Presidency compromise text	Drafting Suggestions Comments
	notified bodies, or asks the Commission for the explanation of the difference from NLF.
1. Notified bodies shall verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43.	NL: (Comments): What conformity of high risk AI shall the notified bodies exactly verify (production, use, etc.)?
2. Notified bodies shall satisfy the organisational, quality management, resources and process requirements that are necessary to fulfil their tasks.	
3. The organisational structure, allocation of responsibilities, reporting lines and operation of notified bodies shall be	

Presidency compromise text	Drafting Suggestions Comments
<p>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>	<p>IT: (Comments): It shall be clarified that notified bodies shall be legally and economically independent.</p> <p>CZ: (Comments): Paragraph 4 on the independence of the notified body corresponds in substance to paragraph 4 of Article R17 of 768/2008/EC,</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>but paragraph 4 of Article R17 formulates the principle of independence of the notified body in a more precise and detailed manner, including advisory services.</p> <p>AIA proposal also states: <i>“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.”</i> The draft AIA does not contain the second sentence of paragraph 4 of Article R17: <i>“This shall not preclude the use of assessed products which are necessary for the operation of the conformity assessment body or the use of such products for personal purposes.”</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Clarification as to why this option has been omitted, or consider addition would be welcome.</p> <p>NL:</p> <p>(Drafting):</p> <p>Notified bodies shall be independent of the provider of a high-risk AI system in relation to which it performs conformity assessment activities. Notified bodies shall ensure there is no conflict of interest and also be independent of any other operator having an economic interest in the high-risk AI system that is assessed, as well as of any competitors of the provider.</p> <p>NL:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>Overall independence seems a better way. Added ‘‘no conflict of interest’’ to make sure that what is not mentioned here is also covered.</p>
<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>IT:</p> <p>(Comments):</p> <p>Uniform guidelines and code of conducts shall be required in order to uniformly safeguard the independence, objectivity and impartiality of the activities.</p> <p>NL:</p> <p>(Drafting):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Notified bodies shall be organised and operated so as to safeguard the independence, objectivity and impartiality of their activities. Notified bodies shall document and implement a structure and procedures to safeguard impartiality and to promote and apply the principles of impartiality throughout their organisation, personnel and assessment activities. The remuneration of the top level management and the personnel responsible for carrying out the conformity assessments tasks shall not depend on the number of conformity assessments carried out or on the results of those assessments.</p> <p>NL:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	Addition to ensure impartiality at top level management.
<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 information obtained in carrying out their tasks under this Regulation, except in</p>	<p>CZ:</p> <p>(Comments):</p> <p>Paragraph 6, which lays down the obligations of professional confidentiality of the personnel of a conformity assessment body, corresponds to paragraph 10 of Article R17 of 768/2008/EC. However, it does not contain the sentence: <i>"Proprietary rights shall be protected."</i></p> <p>CZ would welcome clarification as to why this option has been omitted, or consider addition.</p>

Presidency compromise text	Drafting Suggestions Comments
<p>relation to the notifying authorities of the Member State in which their activities are carried out.</p>	<p>NL: (Drafting): except in relation to the notifying and national authorities of the Member State in which their activities are carried out.</p> <p>NL: (Comments): Suggestion for minor specification to enable information sharing with national authorities.</p>
<p>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,</p>	<p>IT: (Comments): Italy wonders whether minimum</p>

Presidency compromise text	Drafting Suggestions Comments
<p>the degree of complexity of the AI system in question.</p>	<p>standards shall be provided in order to avoid arbitrage.</p> <p>SE:</p> <p>(Comments):</p> <p>What does this mean in practice, the intention is good but might need further clarification, e.g. what is intended with “take due account”?</p> <p>CZ:</p> <p>(Comments):</p> <p>Paragraph 7 is based on paragraph 2 of Article R2 of 768/2008/EC7. Unlike R27, it does not contain: <i>“Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p><i>economic operators</i>” and also <i>“In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the product with the provisions of this ... [act]”</i>. CZ proposes adding the above mentioned 2 provisions and at the same time remove them from the obligations of the notifying authority, see the comment to Article 30(8).</p>
<p>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.</p>	<p>NL:</p> <p>(Drafting):</p> <p>Notified bodies shall take out appropriate liability insurance for their conformity assessment activities, unless liability is assumed by the Member State concerned in</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>accordance with national law in the notifying Member State or that Member State is itself directly responsible for the conformity assessment.</p> <p>NL:</p> <p>(Comments):</p> <p>For clarification:</p> <p>Is liability insurance not a matter of responsibility of notifying bodies themselves, why is it in the article?</p>
<p>9. Notified bodies shall be capable of carrying out all the tasks falling to them under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field,</p>	<p>SE:</p> <p>(Drafting):</p> <p>responsibility. Notified bodies shall when possible act proactively and give impartial</p>

Presidency compromise text	Drafting Suggestions Comments
<p>whether those tasks are carried out by notified bodies themselves or on their behalf and under their responsibility.</p>	<p>guidance.</p> <p>SE:</p> <p>(Comments):</p> <p>To further the use and development of AI, it is important that notified bodies work in an open and helpful manner, with due respect to their role.</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</p>	<p>PT:</p> <p>(Comments):</p> <p>See previous comment (article 30 (7))</p> <p>HR:</p> <p>(Comments):</p> <p>Personnel of notified bodies should also</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>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>	<p>have basic knowledge about discriminatory effects and fundamental rights impact of AI systems, and should make technical assessments about the presence and scope of potential discriminatory effects due to a particular AI application. They could be trained by for example equality bodies and other relevant regulators (e.g. data and consumer protection authorities, labour inspectorates, financial and health sector regulators) on the relevant legal standards.</p> <p>SE:</p> <p>(Drafting):</p> <p>Notified bodies shall have sufficient internal competences to be able to effectively evaluate the tasks conducted by external parties on</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>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> <p>SE:</p> <p>(Comments):</p> <p>The competence requirements of notified bodies needs to be satisfactory and sufficient in regard to their tasks and activities, both in the short and long term.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Too high technical competence requirements of notified bodies, in a technical domain that is developing quickly, could lead to protracted conformity assessment procedures and have a negative impact on the placement of AI-systems on the Union market.</p> <p>HU:</p> <p>(Drafting):</p> <p>To that end, at all times and for each conformity assessment procedure and each type of high-risk AI system in relation to which they have been designated, the notified body shall have permanent availability of sufficient administrative, technical, legal and scientific personnel who</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>possess experience and knowledge relating to the relevant artificial intelligence technologies, fundamental rights, data and data computing and to the requirements set out in Chapter 2 of this Title.</p> <p>HU:</p> <p>(Comments):</p> <p>We recommend that Article 33 (10) be amended so that notified bodies are required to have, in addition to the necessary administrative, technical, and scientific experts, a sufficient number of staff with human rights expertise to meet the minimum legal requirements. These fundamental rights experts, in consultation with technology experts, could ensure that</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>all human rights risks are identified and adequately mitigated in the design of the programme.</p> <p>DK:</p> <p>(Comments):</p> <p>In order to ensure impartiality a suggestion could be to add the following provision from the MDR art. 53(5): “Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>judgement or the results of their conformity assessment activities, especially as regards persons or groups with an interest in the results of those activities.”</p> <p>NL:</p> <p>(Drafting):</p> <p>who possess experience and knowledge relating to the relevant artificial intelligence technologies, data and data computing, fundamental rights, health and safety risks and to the requirements set out in Chapter 2 of this Title.</p> <p>NL:</p> <p>(Comments):</p> <p>In addition to technical knowledge, notified</p>

Presidency compromise text	Drafting Suggestions Comments
	bodies should have substantive expertise relating to fundamental rights, in order to be able to appropriately assess whether the manner in which chapter 2 of this title is applied, effectively safeguards against fundamental rights risks and health and safety risks.
<p>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.</p>	<p>CZ:</p> <p>(Comments):</p> <p>Paragraph 11 on participation in coordination activities and participation in the work of the European standardisation organisations is based on paragraph 11 of Article R17 of 768/2008/EC which states: <i>“Conformity assessment bodies shall</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p><i>participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Community harmonisation legislation and apply as general guidance the administrative decisions and documents produced as a result of the work of that group."</i></p> <p>CZ would propose aligning the paragraph of AIA with para 11 R17. Notified bodies need to follow the relevant decisions and documents of the Coordination Group. CZ would welcome the explanation from Commission why this does not need to be the case and whether there is therefore any</p>

Presidency compromise text	Drafting Suggestions Comments
	need for coordination at all in accordance with Article 38.
<p>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.</p>	<p>CZ:</p> <p>(Comments):</p> <p>Paragraph 12 provides for the making available and submission of relevant documentation to the notifying authority upon request.</p> <p>CZ considers the added paragraph to be unnecessary. The relevant obligations also arise from other provisions. Moreover, it is not clear what the difference is between <i>"monitoring and surveillance activities"</i>. CZ would like to ask for clarification.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>AT:</p> <p>(Drafting):</p> <p>13. Notified authorities shall make sure that conformity assessments are carried out in a proportionate manner, avoiding unnecessary burdens for providers and that notified bodies perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of the AI system in question.</p> <p>AT:</p> <p>(Comments):</p> <p>Reasoning see comments regarding Art 30 para 8.</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p><i>Article 34</i> <i>Subsidiaries of and subcontracting by notified bodies</i></p>	<p>FI:</p> <p>(Comments):</p> <ul style="list-style-type: none"> - We have reservations concerning this article. The subcontracting should be limited to ancillary or technical tasks only. It should be left for the Member States to decide whether subcontracting is possible under national law.
<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</p>	<p>IT:</p> <p>(Comments):</p> <p>Italy wonders whether a system of independent auditors could better fit the</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>in Article 33 and shall inform the notifying authority accordingly.</p>	<p>purpose.</p> <p>NL:</p> <p>(Comments):</p> <p>More general question: is it necessary to make use of subcontracting. If the answer is yes, than describing in which circumstances this is allowed and/or in which not could give a more clear and transparent picture.</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</p>	<p>BG:</p>

Presidency compromise text	Drafting Suggestions Comments
agreement of the provider.	<p>(Comments):</p> <p>Does the requirement for agreement of the provider cover only the provider that develops an AI system or also the one that has an AI system developed without developing it? Do both have to agree in case they are not the same entity/person?</p> <p>HU:</p> <p>(Drafting):</p> <p>Activities may be subcontracted or carried out by a subsidiary only with the agreement prior approval of the provider.</p> <p>HU:</p> <p>(Comments):</p>

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	<p>Since providers as defined in Article 3 (2) of the Proposal are those bearing the responsibility and compliance risk, we recommend putting them in a position to approve the outsourcing of the conformity assessment carried out with respect to the AI system they develop.</p> <p>NL:</p> <p>(Drafting):</p> <p>3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the provider. The establishment and the supervision of internal procedures, general policies, codes of conduct or other internal rules, the assignment of personnel to specific tasks</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>and the decision on certification may not be delegated to a subcontractor or a subsidiary.</p> <p>NL:</p> <p>(Comments):</p> <p>Given the ongoing discussions about subcontracting we would suggest specifying the desired scope of activities that may be subcontracted or carried out by a subsidiary. Some activities are not suited for subcontracting in our view.</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 subsidiary and the work</p>	<p>BG:</p> <p>(Comments):</p> <p>How long should be the relevant documents kept?</p>

Presidency compromise text	Drafting Suggestions Comments
carried out by them under this Regulation.	
<p><i>Article 35</i></p> <p><i>Identification numbers and lists of notified bodies designated under this Regulation</i></p>	
<p>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.</p>	<p>IT:</p> <p>(Comments):</p>
<p>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</p>	

Presidency compromise text	Drafting Suggestions Comments
the list is kept up to date.	
<i>Article 36</i> <i>Changes to notifications</i>	
	<p>PL:</p> <p>(Comments):</p> <p><i>It is recommended that the notifying authority should initiate an investigation into the failure of the notified body to meet the requirements set out in Art. 33 or incorrect performance of its duties. The proceedings are instituted ex officio or upon request. It is carried out with the utmost care.</i></p>
1. Where a notifying authority has suspicions or has been informed that a	PL:

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>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>	<p>(Drafting):</p> <p>Where a notifying authority has suspicious or has been informed that a notified body no longer meets the requirements laid down in Article 33 [...]</p> <p>PL:</p> <p>(Comments):</p> <p><i>Suggestion to cancel "suspicious or" because of superfluous. It is properly enough to keep one expression "has been informed". The authority acting by suspicions also previously got information, and finally has been informed.</i></p> <p>IT:</p> <p>(Comments):</p>

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	<p>Procedural safeguards and due process provisions shall be provided.</p> <p>SE:</p> <p>(Drafting):</p> <p>It shall also immediately inform the European Artificial Intelligence Board.</p> <p>CZ:</p> <p>(Comments):</p> <p>Paragraph 1 corresponds in substance to paragraph 1 of Article R25 of 768/2008/EC but governs the first-stage of notifying authority's procedure differently as Article R25 provides only for the following</p>

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	<p>procedure for the notifying authority in this matter (without investigation) – <i>“the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations.”</i></p> <p>The explanation of this difference from NLF would be welcome.</p> <p>HU:</p> <p>(Drafting):</p> <p>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</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>restrict, suspend or withdraw the notification as appropriate, depending on the seriousness of the failure.</p> <p>HU:</p> <p>(Comments):</p> <p>For clarification purposes only.</p>
<p>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.</p>	<p>CZ:</p> <p>(Comments):</p> <p>Paragraph 2 corresponds to paragraph 2 of Article R25 of 768/2008, however at the end of paragraph the following words of Article R25 are missing: <i>“and market surveillance authorities at their request.”</i></p> <p>The explanation of this difference from</p>

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	NLF or consideration of alignment of the text with NLF would be welcome.
<p><i>Article 37</i></p> <p><i>Challenge to the competence of notified bodies</i></p>	
<p>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.</p>	<p>IT:</p> <p>(Comments):</p> <p>Procedural safeguards and due process provisions shall be provided.</p> <p>SE:</p> <p>(Drafting):</p> <p>The European Artificial Intelligence Board shall</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>DK:</p> <p>(Drafting):</p> <p>The Commission shall in conjunction with relevant notifying and/or designating authorities, where necessary, investigate all cases where there are reasons to doubt whether a notified body complies with the requirements laid down in Article 33.</p> <p>DK:</p> <p>(Comments):</p> <p>In existing sector specific legislation, the Commission does not have a similar role. We find it more appropriate that the notifying and/or designation authorities in question are involved in the process.</p>

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	<p>NL:</p> <p>(Drafting):</p> <p>The Commission shall, where necessary, investigate all cases where there are reasons to doubt whether a notified body complies with the requirements laid down in Article 33 and other requirements and responsibilities to which it is subject.</p> <p>NL:</p> <p>(Comments):</p> <p>We would prefer a more specific approach in order to ensure compliance.</p>
<p>2. The Notifying authority shall provide the Commission, on request, with all</p>	<p>SE:</p>

Presidency compromise text	Drafting Suggestions Comments
relevant information relating to the notification of the notified body concerned.	(Drafting): shall provide the European Artificial Intelligence Board
3. The Commission shall ensure that all confidential information obtained in the course of its investigations pursuant to this Article is treated confidentially.	SE: (Drafting): The European Artificial Intelligence Board FI: (Comments): <ul style="list-style-type: none"> - What is meant by “confidential information” in point 3? Can it be personal data as well or only for example business related data? - Point 3 should be an exception to the rule which is the publicity of

Presidency compromise text	Drafting Suggestions Comments
	<p>government activities and public access to documents.</p> <p>DK:</p> <p>(Drafting):</p> <p>The Commission and relevant notifying and/or designating authorities shall ensure that all confidential information obtained in the course of its investigations pursuant to this Article is treated confidentially.</p> <p>DK:</p> <p>(Comments):</p> <p>In existing sector specific legislation, the Commission does not have a similar role. We find it more appropriate that the notifying and/or designation authorities in</p>

Presidency compromise text	Drafting Suggestions Comments
	question are involved in the process.
<p>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).</p>	<p>IT: (Comments): Reasoned decisions shall be subject to judicial review.</p> <p>SE: (Drafting): 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</p>

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	<p>necessary. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(2).</p> <p>SE:</p> <p>(Comments):</p> <p>This process should be in the hands of the member states in respect to the principle of subsidiarity, see art. 9, Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.</p> <p>Also note that the Commission may start an infringement procedure if a member states</p>

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	<p>fails to implement EU law. MS intervention and the infringement procedure should be sufficient measures for the purpose of the article.</p> <p>CZ:</p> <p>(Comments):</p> <p>Paragraph 4 corresponds to paragraph 4 of Article R26 of the 768/2008/EC. The paragraph 4 does not use an implementing act in case of a challenge to the competence of notified bodies. The explanation of the need for implementing act would be welcome.</p> <p>DK:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Drafting):</p> <p>Where the Commission, in conjunction with relevant notifying and/or designating authorities, 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).</p> <p>DK:</p> <p>(Comments):</p> <p>In existing sector specific legislation, the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Commission does not have a similar role. We find it more appropriate that the notifying and/or designation authorities in question are involved in the process.</p>
<p><i>Article 38</i> <i>Coordination of notified bodies</i></p>	<p>SE:</p> <p>(Comments):</p> <p>This article could be interpreted as in principle all police use of AI could be assessed as a high-risk system. Some AI systems, especially those that handle biometric data in real time and without human intervention, probably need to be considered as high-risk systems, but at present this type of system is not used and the human control factor is central to this</p>

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	type of system as well.
<p>1. The Commission shall ensure that, with regard to the areas covered by this Regulation, appropriate coordination and cooperation between notified bodies active in the conformity assessment procedures of AI systems pursuant to this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.</p>	<p>SE:</p> <p>(Comments):</p> <p>This might be better suited for the European Artificial Intelligence Board (EAIB)? Or the member states national authorities?</p> <p>CZ:</p> <p>(Comments):</p> <p>Article 38 almost literally corresponds to Article R30 of 768/2008/EC, also the title is the same (Coordination of notified bodies). They differ only in that the AIA proposal mentions one sectoral group of notified bodies. Article R30 provides: "... sectoral</p>

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	<p><i>or cross-sectoral groups of notified bodies.</i>"</p> <p>CZ proposes the alignment of the text with NLF or would welcome an explanation of the need for differences.</p>
<p>2. Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.</p>	
<p><i>Article 39</i> <i>Conformity assessment bodies of third countries</i></p>	<p>NL:</p> <p>(Comments):</p> <p>Suggestion to specify the procedure with third countries, referencing to existing agreements regarding conformity assessment bodies where possible and</p>

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	clarifying how this relates to the judgment that accreditation of a notified body must be done by the national accreditation body (located in the European Union) (C-142/20 - Analisi G. Caracciolo).
Conformity assessment bodies established under the law of a third country with which the Union has concluded an agreement may be authorised to carry out the activities of notified Bodies under this Regulation.	<p>BG: (Comments): We might provide comments to this article at a later stage</p> <p>LT: (Comments): What type of agreement does that mean? FTA?</p>

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	<p>IT:</p> <p>(Comments):</p> <p>Agreements with third countries shall be grounded on common principles and rules. Standards of reciprocity shall apply.</p> <p>HU:</p> <p>(Drafting):</p> <p>Conformity assessment bodies established under the law of a third country that fully respects the fundamental rights enshrined in the Charter and the relevant decisions of the Court of Justice of the European Union, with which the Union has concluded an agreement may be authorised to carry out</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>the activities of notified Bodies under this Regulation.</p> <p>HU:</p> <p>(Comments):</p> <p>With regard to the annulment of the Safe Harbour and subsequently the Privacy Shield agreements, it is of paramount importance that all such agreements concluded by the Commission must be fully compatible with the Charter and the relevant decisions of the Court of Justice of the European Union.</p> <p>We recommend clarifying here, who may authorise these conformity assessment bodies, and which notifying authority is</p>

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	<p>competent, if their seat/main establishment is in a third country.</p> <p>DK:</p> <p>(Comments):</p> <p>It is unclear what constitutes such agreements as well as whether such conformity assessment bodies will be able to become notified bodies. It is also unclear who would be responsible for negotiating and concluding such agreements. If they are able, the question is which entity shall be able to designate/notify these. If they are not, the question is whether article 32(4) will apply for these bodies and which entity will be responsible for ensuring their conformity with this regulation.</p>

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	<p>NL:</p> <p>(Drafting):</p> <p>Conformity assessment bodies established under the law of a third country with which the Union has concluded an agreement may be authorised to carry out the activities of notified Bodies under this Regulation, provided that they meet the requirements in Article 33.</p> <p>NL:</p> <p>(Comments):</p> <p>Minor suggestion for specification, agreement need further elaboration with possible references to existing type of agreements. Furthermore we suggest to</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>include a procedure when it is suspected that the notified body in a third country does not meet/no longer meets the requirements laid down in Article 33.</p>
<p>CHAPTER 5</p>	<p>SK:</p> <p>(Comments):</p> <p>As already mentioned in previous round of Slovakia's comments to the entire proposal and article 16, Slovakia believes that protection of health and fundamental rights should not be reduced to technical standards in situations where this is not feasible or adequate; at the same time, it appears impractical, ineffective and costly to burden</p>

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	<p>operators with additional obligation of <i>ex ante</i> fundamental rights/health impact assessments or triages which would amount <i>de facto</i> to a kind of decentralised <i>a priori</i> exercise of proportionality test in fundamental rights protection and assessment of possible impacts on health. Given the proposed full harmonisation approach, these <i>ex ante</i> assessments will be actually made via EU legislation under practices prohibited in article 5 and under the scope of use cases as covered under articles 6, 7 and Annex II and III (other practices and use cases being automatically deemed lawful, legitimate and proportionate). Therefore, we need to make sure that the EU legislation remains as flexible as possible and can be amended on</p>

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	<p>the basis of continuous policy prototyping regime (testbeds and test groups) operated within the overall AIA governance structure (see below comments to article 56).</p> <p>Slovakia also believes it is necessary to ensure participation of SMEs, civil organisations and other relevant stakeholders in the process of standards adoption in the relevant (private) bodies for technical standardisation.</p> <p>EE:</p> <p>(Comments):</p> <p>It seems to us that Chapter 5 duplicates, at least partially, what is already described in Regulation (EU) 1025/2012 on European standardisation; Regulation (EU) 765/2008</p>

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	on Accreditation and Market Surveillance; and Regulation 2019/881 (Cybersecurity Act).
STANDARDS, CONFORMITY ASSESSMENT, CERTIFICATES, REGISTRATION	<p>BE:</p> <p>(Drafting):</p> <p>BE:</p> <p>(Comments):</p> <p>In order to comply with the applicable requirements, harmonized standards give presumption of conformity for those requirements which are covered. However, these harmonized standards do not yet exist at present and we believe that it will take a</p>

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	<p>considerable effort from the ESO's for these standards to be finalized at the time of the entry into force of this proposed regulation. We encourage the Commission's wish to make the necessary efforts and hope that the ambitious targets and timetable can be met.</p> <p>At the other hand, the proposed legal architecture and normative approach raises fundamental concerns in terms of legal certainty, safeguards for fundamental rights, specificity to inform supervision, and governance. Indeed, certain rules applicable to high risk systems are vague and unclear. The ensuing delegation to standardisation organisations (which will not benefit from the same level of governance safeguards than legislation (e.g.,</p>

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	<p>adequate involvement of relevant stakeholders)) is far too wide. Failing sufficient and adequate specification of the requirements in the legislation, we understand that the state-of-the-art will be in essence determined by such organisations. For example, as mentioned in earlier comments, the (article 10) requirement that training, validation and testing data sets are to be relevant, representative, free of errors and complete needs to be further clarified and is to some extent conflicting with Recital (44). Another example is article 14(4) according to which human oversight measures shall enable the individuals to whom human oversight is assigned to “fully understand” the capacities and limitations of the high-risk AI system. Since a full</p>

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	<p>understanding is not possible, and harmonised standards deemed to clarify the “full understanding” requirement, the implicit assumption that harmonised standards will specify the state-of-the-art actually results in a (too) wide mandate to standardisation organisations to determine the (true) requirement itself and as the case may be to weaken it. Note that we would not agree to relaxing the principle requirements in the regulation (e.g. by referring in article 10(3) to <i>reliable data sets</i>), while maintaining the current wide delegation to standardisation organisations.</p> <p>In conclusion, the requirements effectively applicable to high-risk AI systems should be sufficiently specified <u>in the regulation itself</u></p>

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	<p><u>and/or other legislation</u>, having involved all relevant public stakeholders (similar to Level 2 regulation in the financial sector).</p> <p>Finally, any common specifications or harmonised standards should be without prejudice to (possibly stricter) sectoral legislation or guidance applicable to credit institutions. It should be noted, for example, that banking legislation provides for specific rules addressed to <u>users of AI systems</u>. By laying down obligations to mitigate the risks of AI systems for the provider in essence, the proposed regulation does the opposite. It is arguable that this is fully addressing fundamental rights concerns as the provider will not be able to consider all possible uses of the system when proceeding with its risk assessment</p>

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	<p>and designing the associated risk management system. Likewise, full delegation of human oversight measures with limited user obligations beyond the reference to instructions of use seems inadequate. This is why risk mitigation measures at the level of the user are deemed necessary. At the very least, the proposed regulation should in any event be <u>without prejudice to user obligations under banking legislation.</u></p>
<p><i>Article 40</i> <i>Harmonised standards</i></p>	<p>IE:</p> <p>(Comments):</p> <p><i>IE notes that Cion intends to devote significant efforts, along with MS, to make</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p><i>maximum use of international standards and IE welcomes this.</i></p> <p>BE:</p> <p>(Comments):</p> <p>Cf. our comment above and below (art. 41) <i>re</i> sufficient level of specification of the regulation as to Chapter II, as the case may be completed by implementing acts. A presumption of conformity to the requirements based on conformity to harmonised standards or part thereof results in a too wide mandate to standardisation organisations so long as the requirements are not sufficiently specific.</p> <p>EE:</p>

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	<p>(Comments):</p> <p>As per Art 40, the standardization process will have a material role in determining the quality requirements for high-risk AI systems. Thus, in light of its regulatory impact, art 40 should establish an explicit requirement to ensure involvement of all relevant stakeholders – including civil society organizations – in the standard-setting procedure.</p> <p>NL:</p> <p>(Comments):</p> <p>The standards mentioned here should solely be of genuinely technical aspects. The overall authority to set standards and</p>

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	<p>perform oversight of issues that are not purely technical, such as bias mitigation, should remain in the remit of the legislative process guaranteeing parliamentary scrutiny and multistakeholder engagement.</p>
	<p>PL:</p> <p>(Comments):</p> <p><i>How and when will the standards be published? Which specific requirements from type II will be concerned?</i></p>
<p>High-risk AI systems which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements set out in</p>	<p>PT:</p> <p>(Comments):</p> <p>Different standards may be harmonized under the Medical Device Regulations and the AI Act containing diverging definitions /</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>Chapter 2 of this Title, to the extent those standards cover those requirements.</p>	<p>technical requirements (e.g. regarding risk management). How can harmonised standards under AIA be considered, if they are not harmonised and referenced under the MDR / IVDR?</p> <p>IT:</p> <p>(Comments):</p> <p>NLF framework shall be considered and reference / coordination with it shall be included.</p> <p>A self-assessment procedure shall be included.</p> <p>Reference to “parts of” harmonised</p>

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	<p>standards risks being misleading. We suggest to integrate with “essential parts of”</p> <p>SE:</p> <p>(Comments):</p> <p>We are uncertain on the implication of this article, especially on the meaning of “... to the extent those standards cover those requirements.”. Is this article necessary?</p> <p>HU:</p> <p>(Comments):</p> <p>More legal certainty needs to be provided for providers and users of AI, but in</p>

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	<p>addition, clear, predictable and timely working plans for standardisation efforts need to be made available. Today there are no agreed benchmarks for the conformity assessment. Harmonised standards and common specifications can be developed over time as the industry and society gains knowledge and experience. The development of these standards should be mandated to European SDOs rather than developed by implementing acts, prepared or defined by the Commission as stated in Article 41. There should be a transition period foreseen, to make sure AI development and uptake is not unduly hampered due to the lack of those common benchmarks.</p> <p>Furthermore, the industry needs a process</p>

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	<p>design that focuses on clear and easy-to-handle requirements. It is important that, sector by sector, the relevant institutions are operational so as not to create additional delays in market access. We see a risk that the sum and overlap of requirements and obligations, including in parts vaguely defined high risk applications, and the associated legal uncertainty in operationalisation, creates a complexity and compliance burden that inhibits the development of AI applications in the area of high risk in the EU. As such, we recommend that lessons from data protection should be considered where overlapping competences lead to slow and contradicting decisions.</p>

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	<p>BG:</p> <p>(Drafting):</p> <p>(New) For the sake of ensuring a higher level of SMEs representation in the preparation of harmonised standards under paragraph 1, the participation of SMEs in the standards development processes shall be facilitated in accordance with Art. 6 of Regulation (EU) 1025/2012</p> <p>BG:</p> <p>(Comments):</p> <p><u>Justification</u>: very often SMEs are underrepresented in standardisation organisations and there is a likelihood that the standards will be written in a way that</p>

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	<p>will not be feasible and workable for SMEs. Therefore, it is very important to further foster already existing mechanisms for ensuring the active participation of SMEs in standards development processes by avoiding an “one-size-fits-all” approach. The aim is to ensure the proactive involvement of SMEs in the standardisation process as one of the supporting measures/incentives.</p> <p>Last remark under this article, it remains unclear what the approach will be towards the international standards and to what extent they will be taken into account; to what extent companies will be allowed to follow them. In our view, this issue should be clarified, it could be in a recital, as well</p>

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	<p>PL:</p> <p>(Drafting):</p> <p>(New addition) The participation of SMEs in the processes of developing harmonized standards is required in accordance with Art. 6 of Regulation (EU) 1025/2012.</p> <p>PL:</p> <p>(Comments):</p> <p>SMEs are underrepresented in standardisation organisations and there is a crucial need that the standards will be written in a way that will be feasible and workable for SMEs and finally not close them by “one-size-fits-all” approach in closed value chains and finally create</p>

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	innovation debt dependency.
<i>Article 41</i> <i>Common specifications</i>	
<p>1. Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns, the Commission may, by means of implementing acts, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).</p>	<p>ES:</p> <p>(Comments):</p> <p>Some concern has been raised here among ESOs and industry. It appears that limiting the existence of common specifications to a very extraordinary situation is more accepted, as they fear that common specification could be used as circumvention of harmonised standards or they could not take into account industry practices.</p>

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	<p>As we can't provide with alternative writing here, maybe being clearer on limiting Common specifications to very special situations could be useful. We offer, nevertheless, an idea as a new paragraph 3.</p> <p>BE:</p> <p>(Comments):</p> <p>Reference is made to "specific" fundamental rights concerns. The very purpose of most, if not all obligations of providers for high risk systems is the protection of fundamental rights; to the extent that obligations could not be sufficiently determined in the regulation (which we deem necessary in order to provide for legal certainty and safeguard</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>effective, adequate protection of fundamental rights and adequately inform supervisory judgement), common specifications (or other forms of legislative process involving all relevant public stakeholders) should be the rule rather than the exception.</p> <p>BG:</p> <p>(Drafting):</p> <p>“Where harmonised standards referred to in Article 40 do not exist and none of the European standardisation organisations are capable to develop them or where the Commission considers duly justifies that the relevant harmonised standards are insufficient or that there is a need to address</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>specific safety or fundamental right concerns and none of the European standardisation organisations are willing to take up the task, the Commission may,.....”</p> <p>BG:</p> <p>(Comments):</p> <p><u>Justification:</u> Our strong preference is for harmonized standards and their existence should not be weakened. However, if this provision remains, it would be better to further clarify the conditions when common specifications as part of an implementing act are possible and thus, avoid any subjective assessment. Furthermore, in our view, this provision should better reflect the</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>requirements of Art 22 of Regulation (EU) 1025/2012 and the comitology procedure under Art 5 of Regulation (EU) 182/2011 for the sake of better justifying the need for the implementing powers of the Commission.</p> <p>Next, how will be cases tackled when the European commission does not publish in the Official Journal the harmonised standards developed by the European standardisation organisations? This could be also one of the enumerated conditions justifying the need for an implementing act.</p> <p>LT:</p> <p>(Drafting):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>1. Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns, the Commission may, by means of implementing acts, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).</p> <p>LT:</p> <p>(Comments):</p> <p>Facing with specific safety concerns means</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>that relevant harmonised standards are insufficient. We consider that <i>safety concerns</i> covers harmonised standards insufficiency. Thus, avoiding duplication we suggest deleting <i>where the Commission considers that the relevant harmonised standards are insufficient</i> and left only a need to address specific safety or fundamental right concerns.</p> <p>IT:</p> <p>(Comments):</p> <p>Further clarification is needed with reference to the evaluation process to be followed when harmonized standards are insufficient.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>The section referring to “there is a need to address specific safety or fundamental rights concerns” risks making the underlying assessment to much discretionary.</p> <p>Timeline for the for the adoption of implementing acts shall be included.</p> <p>Transitory provisions applying pending the adoption shall be included.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>SE:</p> <p>(Drafting):</p> <p>1.—Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns, the Commission may, by means of implementing acts, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>SE:</p> <p>(Comments):</p> <p>Where the Commission considers relevant harmonised standards insufficient or that there is a need to address specific safety or fundamental right concerns, the commission should work together with relevant standardization organizations so that they may address the problem.</p> <p>There are different wordings on “common specification” in the proposal for a machine regulation, article 17(3). Risk of different procedures.</p> <p>CZ:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Given the established system of European standardization, there is a need to carefully consider the added value of this alternative of defining technical requirements as it does not guarantee the same level of participation, openness and transparency of stakeholder's involvement in the development of harmonized standards.</p> <p>Either way, conditions for its use should be clearly specified so that it is used only as a kind of fall-back option and not as a common alternative way of setting the technical specifications.</p> <p>EE:</p> <p>(Drafting):</p> <p>Where harmonised standards referred to in</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>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 technical specifications in respect of the requirements set out in Chapter 2 of this Title. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).</p> <p>EE:</p> <p>(Comments):</p> <p>We suggest using “technical specifications” instead of “common specifications” to</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>ensure consistency with Regulation (EU) No 1025/2012 where technical specifications is defined in Article 2 (4). Article 3 (28) of the proposal should be changed accordingly in order to avoid any inconsistency of definitions.</p> <p>HU:</p> <p>(Drafting):</p> <p>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</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>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). Such common specifications shall only remain in force until the lack of relevant harmonised standards has been resolved.</p> <p>DK:</p> <p>(Comments):</p> <p>We are generally supportive of the New Legislative Framework and pleased to see this regulation building on harmonised standards. While we understand the need for the Commission to have a fall-back option, in certain limited cases, we find this</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>provision too broad. It should be clear, that setting common specifications in implementing acts would be a measure of last resort. We do however welcome the use of the examination procedure in this regard. We have furthermore noticed similar articles in the legislative proposals on batteries and machinery. However, the articles are phrased differently in each proposal and therefore, we call for a horizontal discussion – and eventually horizontal formulation – rather than having separate discussions across different Council formations.</p>
<p>2. The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of</p>	<p>BE:</p>

Presidency compromise text	Drafting Suggestions Comments
<p>relevant bodies or expert groups established under relevant sectorial Union law.</p>	<p>(Comments):</p> <p>ECB/national competent authorities should be consulted in addition to relevant bodies or expert groups, where they concern AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score or AI systems used in the insurance sector.</p> <p>BG:</p> <p>(Drafting):</p> <p>“.....shall gather the views of stakeholders, including SMEs, relevant bodies....”</p> <p>BG:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>See our justification under Art 40</p> <p>SI:</p> <p>(Drafting):</p> <p>The Commission, when preparing the common specifications referred to in paragraph 1, shall conduct stakeholders' consultations with special attention put on relevant consumer organizations and organizations representing SMSs that are typically not well represented in standardization activities and gather the views of relevant bodies or expert groups established under relevant sectorial Union law.</p> <p>SI:</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>(Comments):</p> <p>When preparing harmonize standards or in their absence common specification by the Commission (article 41) it is crucial to include proper consultations of relevant stakeholder, specially consumer organizations and organizations representing SMSs that are typically not well represented in standardization activities. This is crucial for establishing public trust which is vital requirement for large and quick uptake of AI.</p> <p>IT:</p> <p>(Comments):</p> <p>Procedures and prerequisites of the members of the expert group shall be</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>specified.</p> <p>The risk of obsolescence of the defined specifications shall be considered.</p> <p>EE:</p> <p>(Drafting):</p> <p>2. The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant stakeholders and bodies or expert groups established under relevant sectorial Union law.</p> <p>EE:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>See our comment for Art 40.</p> <p>HU:</p> <p>(Drafting):</p> <p>The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of consult relevant bodies or expert groups established under relevant sectorial Union law.</p> <p>HU:</p> <p>(Comments):</p> <p>The common specifications provided for in Article 41 are not necessarily a suitable</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>alternative to the harmonised standards referred to in Article 40, because while standards are drawn up by specialised bodies, the Commission, under Article 41(1), adopts common specifications by means of implementing acts, which does not necessarily guarantee the same level of expertise as that of the standardisation bodies. It is therefore necessary to develop and ensure that the common specifications under Article 41, which are used in exceptional cases, also reflect technical requirements similar to standards.</p> <p>DK:</p> <p>(Comments):</p> <p>We welcome this consolation.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>NL:</p> <p>(Drafting):</p> <p>The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant bodies or expert groups established under relevant sectorial Union law, and member states.</p> <p>NL:</p> <p>(Comments):</p> <p>As common standards and specifications translate important requirements that aim to protect fundamental rights, member states should be at least consulted.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>ES:</p> <p>(Drafting):</p> <p>3. Common specifications will only be used as long as no other harmonised standards that address the safety of fundamental rights concerns are approved or valid for the purpose of addressing such concerns. In any case, common specifications development will take fully into account the views of European Standardization Organizations and stakeholders of the Artificial Intelligence/private sector.</p>
<p>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</p>	<p>ES:</p> <p>(Drafting):</p> <p>4</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>set out in Chapter 2 of this Title, to the extent those common specifications cover those requirements.</p>	<p>IT:</p> <p>(Comments):</p> <p>Self-assessment procedures shall be defined.</p> <p>SE:</p> <p>(Comments):</p> <p>If the common specifications must cover the requirements in chapter 2. How will this article compliment or add to chapter 2?</p>
<p>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.</p>	<p>ES:</p> <p>(Drafting):</p> <p>5</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>BG:</p> <p>(Comments):</p> <p>What is meant by “duly justify”?</p> <p>Could providers follow international technical solutions, as well? Do “technical solutions” cover international standards?</p> <p>IT:</p> <p>(Comments):</p> <p>The definition of equivalence shall be exploited and clarified.</p> <p>SE:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Drafting):</p> <p>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.</p> <p>SE:</p> <p>(Comments):</p> <p>There are plenty of ways to adhere to the Act. Too many different ways will lead to difficulties in foreseeability.</p> <p>Also, some companies might get an unfair competitive advantage by claiming (knowingly that they are likely or possibly likely to fall short when tested) that they have adopted technical solutions as stated in</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>the article and thus coming to the market faster and creating a customer base.</p> <p>DK:</p> <p>(Comments):</p> <p>We are wondering why it is an obligation for the provider to duly justify that it has adopted a technical solution which are equivalent to the common specification. This seems to part with the objective of having voluntary guiding tools such as harmonized standards or common specifications.</p>
<p><i>Article 42</i></p> <p><i>Presumption of conformity with certain requirements</i></p>	<p>BG:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>PL:</p> <p>(Comments):</p> <p>DK:</p> <p>(Comments):</p> <p>It could be relevant to introduce a possibility of updating the list, as further schemes etc. could be developed which could ensure presumption of conformity with certain requirements in the future.</p>
<p>1. Taking into account their intended purpose, high-risk AI systems that have been trained and tested on data concerning</p>	<p>SE:</p> <p>(Comments):</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
<p>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).</p>	<p>Is the specific setting (geographical, behavioural and functional) to be read as cumulative? Might need clarification.</p> <p>NL:</p> <p>(Drafting):</p> <p>4. — 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).</p> <p>NL:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>We propose to delete this paragraph because we find that it does not increase clarity in relation to article 10(4).</p>
	<p>BG:</p> <p>(Drafting):</p> <p>(New sentence at the end of paragraph 1)</p> <p>The requirements under this article shall not apply to training and testing on data when the intended purpose of the AI system is not for use in the EU.</p> <p>BG:</p> <p>(Comments):</p> <p>Justification: not to limit the export potential of the EU companies as in other regions the specific geographical etc. setting</p>

Presidency compromise text	Drafting Suggestions Comments
	might differ and different requirements for data might be applicable (however, our main preference is to have the exception under Art. 2)
<p>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 Council¹ and the references of which have been published in the Official Journal of the European Union shall be presumed to be in compliance with the cybersecurity requirements set out in Article 15 of this Regulation in so far as the cybersecurity certificate or statement of</p>	<p>SK:</p> <p>(Comments):</p> <p>The proposed act is aimed at safety, health and fundamental rights risks. Slovakia points out that we need to make sure that the proposed Act meaningfully interacts also with national and EU (cyber-)security measures, including systemic and hybrid security risks related to the deployment of AI. Article 42 (2) and article 15 do not appear to ensure this. Concrete possible</p>

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).

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>conformity or parts thereof cover those requirements.</p>	<p>interconnections between relevant pieces of EU legislation and relevant national competences need to be examined and introduced, based on the identified needs of effective (cyber-)security protection. ENISA should be consulted on this.</p> <p>BE:</p> <p>(Comments):</p> <p>Given the sensitive nature of the areas of application of high-risk systems, it would be useful to provide for an indication of the cybersecurity certificates required.</p> <p>BG:</p> <p>(Drafting):</p> <p>“.....shall be presumed to be in compliance</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>with the cybersecurity requirements set out in Article 15 of this Regulation, where applicable in so far as the cybersecurity certificate or statement of conformity or parts thereof when applied cover those requirements”</p> <p>BG:</p> <p>(Comments):</p> <p><u>Justification</u>: It is important to clarify that cybersecurity schemes are and remain voluntary in accordance with the Cybersecurity Act</p> <p>IT:</p> <p>(Comments):</p> <p>Essential parts shall be considered</p>

Presidency compromise text	Drafting Suggestions Comments
	instead.
<p><i>Article 43</i> <i>Conformity assessment</i></p>	<p>DK:</p> <p>(Comments):</p> <p>In general, we are supportive of requiring a conformity assessment in order to ensure compliance with high-risk AI. In this respect, it is positive that the proposal takes into account existing legislation and combines different procedures. At the same time, it is important to ensure effective procedures as well as sufficient capacity to certify high-risk AI. Particular attention should be paid to limit administrative burdens, in order to ensure that the process is manageable also for SMEs.</p>

Presidency compromise text	Drafting Suggestions Comments
<p>I. 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:</p>	<p>PL:</p> <p>(Comments):</p> <p><i>In the case of high-risk AI systems referred to in point 5 (a) of Annex III. b) placed on the market or put into service by credit or insurance institutions subject to the provisions of Directive 2013/36 / EU, the conformity assessment shall be carried out in the course of the procedure referred to in Art. 97-101 of this directive - it is not entirely clear how this assessment will be carried out, as well as how to read the said requirement and whether it is addressed directly to supervisory authorities (as indicated by the material scope of Articles</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p><i>97-101 CRD), or also to credit institutions.</i></p> <p>IT:</p> <p>(Comments):</p> <p>Clarifications on the conformity assessment, its conditions and duration shall be provided.</p> <p>It has to be specified that it is on the provider to choose which procedure to followed.</p> <p>HR:</p> <p>(Comments):</p> <p>Referred to in Article 33.- there has to be conformity assessment procedure for other</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>AI systems regarding their impact on fundamental rights and equality/non-discrimination.</p> <p>CZ:</p> <p>(Comments):</p> <p>It would be beneficial if the Commission presents a model example of how the company developing and providing a high-risk AI system should, step by step, demonstrate its compliance with conformity assessment according to requirements of the AI Act as well as other legislation such as GDPR, Cyber Security Act, etc. Further analysis based on this example might benefit the discussion in the Council.</p> <p>Guidelines for the providers on the basis of</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>this model example could be created later on. Any unnecessary duplications and parallel processes should be avoided.</p>
	<p>PL:</p> <p>(Comments):</p> <p><i>It is still unclear whether real-time remote biometric identification systems in public spaces for law enforcement purposes in one of the three exceptions set out in Art. 5 sec. 1 lit. (d) they will be subject to the conformity assessment provided for in Annex VI and the notified body will be the market surveillance authority referred to in Art. 63 (5)? Some ambiguity in this respect results from the fact that Art. 43 sec. 1 refers to general biometric identification</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p><i>systems (Annex III point 1) and not used for law enforcement / law enforcement?</i></p> <p><i>Which body should be designated as a notified body for conformity assessment of a system provided by a private body but intended for use by law enforcement authorities?</i></p>
<p>(a) the conformity assessment procedure based on internal control referred to in Annex VI;</p>	<p>SK:</p> <p>(Comments):</p> <p>As outlined in its Slovakia's non-paper, Slovakia prefers external (independent) controls for AI systems when no technical standards are applied or available.</p> <p>BE:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Please reconsider the merits of third-party review on top of internal control (cf. earlier comments).</p> <p>HU:</p> <p>(Drafting):</p> <p>(a) the conformity assessment procedure based on internal control referred to in Annex VI; or</p> <p>HU:</p> <p>(Comments):</p> <p>For clarification purposes only.</p> <p>NL:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>We underline the importance of the effectiveness of conformity assessments in case of both self- and third party assessments. We are currently considering and studying the option that the same procedural requirements for point 1 of Annex III would also be the preferred option for certain other points in Annex III.</p>
<p>(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.</p>	

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>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.</p>	<p>HU:</p> <p>(Drafting):</p> <p>For high-risk AI systems listed in point 1 of Annex III, where 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.</p> <p>HU:</p>

Presidency compromise text	Drafting Suggestions Comments
	(Comments): For clarification purposes only.
<p>For the purpose of the conformity assessment procedure referred to in Annex VII, the provider may choose any of the notified bodies. However, when the system is intended to be put into service by law enforcement, immigration or asylum authorities as well as EU institutions, bodies or agencies, the market surveillance authority referred to in Article 63(5) or (6), as applicable, shall act as a notified body.</p>	<p>NL:</p> <p>(Drafting):</p> <p>However, when the system is intended to be put into service by law enforcement, immigration or asylum authorities or judicial authorities as well as EU institutions, bodies or agencies, the market surveillance authority referred to in Article 63(5) or (6), as applicable, shall act as a notified body.</p> <p>NL:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	Add judicial authorities in line with the suggested change in article 63. Reference to article 63 must also be changed accordingly.
<p>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.</p>	<p>ES: (Comments): Spain suggested that in case new areas area allowed to be included in annex III upon delegated act (or other), this article should be modified. (points 2 to 8 [or more]) of Annex III).</p> <p>SK: (Comments): As outlined in its Slovakia's non-paper, Slovakia prefers external (independent)</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>controls for AI systems when no technical standards are applied or available.</p> <p>IT:</p> <p>(Comments):</p> <p>Please clarify how IA regulation and financial services regulations interact.</p> <p>NL:</p> <p>(Comments):</p> <p>The CRD doesn't regulate the offering of (consumer) credit, this is regulated by the</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>CCD and MCD. Should this article therefore not refer to the CDD and the MCD instead of the CRD?</p> <p>How does the commission see the difference in this regulation between banks offering credit and other non-bank parties that offer credit?</p> <p>AT:</p> <p>(Comments):</p> <p>We welcome the approach that a number of new requirements according to this Regulation shall be integrated into the existing obligations and procedures under Directive 2013/36/EU, as it is stipulated in Art. 9 (9), 17 (3), 18 (2), 19 (2), 20 (2), 29 (4) and (5), 43 (2), 61 (4) and 62 (3) of the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Regulation on AI.</p> <p>However, in the same context, it must be highlighted that it is more than probable that the Regulation on AI will not only be applicable to credit institutions but (at least eventually) also to a number of other financial service providers, such as for instance insurance undertakings or investment firms. Annex III No. 5 letter d of the Regulation, as it was added in the first Presidency compromise proposal, already introduces high-risk <i>“AI systems intended to be used for insurance premium setting, underwritings and claims assessments”</i> which subsequently results in the inclusion of insurance undertakings in the scope of the Regulation on AI. Moreover, according</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>to Art. 7 of the Regulation on AI, the Commission is able to extent Annex III which means that other financial service provider could as well become subject to the Regulation on AI any time in the future.</p> <p>As many other financial service providers (e.g. insurance undertakings, investment firms) have – similar to credit institutions according to Art. 74, 97 to 101 of Directive 2013/36/EU – corresponding requirements regarding their internal governance arrangements, processes and mechanisms and supervisory review procedures in their sectoral EU regulatory frameworks, these specific requirements should as well be referred to in Art. 9 (9), 17 (3), 18 (2), 19 (2), 20 (2), 29 (4) and (5), 43 (2), 61 (4) and</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>62 (3) of the Regulation on AI (and not only Directive 2013/36/EU). Such an approach would ensure a level playing field and equal treatment for all kind of financial service providers regulated by EU law as regards the application of the new rules on AI.</p> <p>Consequently, such modifications of the draftings should be done consistently in Art. 9 (9), 17 (3), 18 (2), 19 (2), 20 (2), 29 (4) and (5), 43 (2), 61 (4) and 62 (3) of the Regulation on AI.</p>
<p>3. For high-risk AI systems, to which legal acts listed in Annex II, section A, apply, the provider shall follow the relevant</p>	<p>ES: (Comments):</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>conformity assessment as required under those legal acts. The requirements set out in Chapter 2 of this Title shall apply to those high-risk AI systems and shall be part of that assessment. Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII shall also apply.</p>	<p>AI systems used in radio equipment should be subject to AI Requirements, but we wonder if it is truly necessary (in several cases, it seems excessive).</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>PT:</p> <p>(Comments):</p> <p>The intention of that sentence, in the case of medical devices, is to clarify that notified bodies designated under/MDR/IVDR would need to undergo an expansion of their scope in respect to AIA? Conformity assessment.</p>

Presidency compromise text	Drafting Suggestions Comments
<p>Where the legal acts listed in Annex II, section A, enable the manufacturer of the product to opt out from a third-party conformity assessment, provided that that manufacturer has applied all harmonised standards covering all the relevant requirements, that manufacturer may make use of that option only if he has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering the requirements set out in Chapter 2 of this Title.</p>	<p>EE:</p> <p>(Comments):</p> <p>What happens in cases when there are no harmonised standards nor technical specifications? Are the manufacturers still obliged to undergo a third-party conformity assessment despite this not being considered necessary regarding the main product?</p> <p>AT:</p> <p>(Comments):</p> <p>According to this subparagraph AI systems that do not need to undergo third-party conformity assessment (in those cases where the manufacturer opted for a self</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>conformity declaration) are still considered high risk.</p> <p>Art 6 para 2 (old Art 6 para 1 lit. b) requires third party conformity assessment for AI systems falling under the legislative acts of Annex II/A; thus a possible amendment of Art 6 para 2 (old Art 6 para 1 lit. b) may be necessary</p>
<p>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.</p>	<p>SK:</p> <p>(Comments):</p> <p>It should be clarified to what extent an adoption of new harmonised technical standards also requires new conformity assessments procedures (if adopted after previous placement on the market or putting</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>into service). Dynamic nature of AI systems may require that they be adapted even to newly adopted harmonised technical standards.</p> <p>BE:</p> <p>(Comments):</p> <p>The definition of “substantial modification” in Art. 3 (23) should be further specified. The articulation between the notion of substantial modification and the notion of “significant change” (which would be expected to capture substantially similar issues than the “substantial modification”, at the very least in the event of change of intended purpose) under article 83 should be clarified.</p>

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	<p>IT:</p> <p>(Comments):</p> <p>Please clarify what is meant by substantial modification.</p> <p>SE:</p> <p>(Comments):</p> <p>The definition of “substantial modification” under art. 3.23 might need further clarification, see Recital 66.</p> <p>According to the article, high-risk systems must undergo a new “conformity assessment” when they are “substantially modified”. Guidance is requested here regarding what should be considered such a</p>

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	<p>modification as it is unclear.</p> <p><i>CZ:</i></p> <p>(Comments):</p> <p>The term “substantial modification” should be better clarified, we need to make sure it is well understood by everyone. The definition of “substantial modification” (as proposed in Article 3(23)) might benefit from updating so as to make it clear that the modification of the AI system based on a standard software update following up-to-date market development within the scope of the intended purpose of the original AI system does not constitute a substantial modification. This is also how we understood the recitals but it is such an</p>

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	<p>important aspect that it should be established clearly within the definition itself.</p> <p>DK:</p> <p>(Comments):</p> <p>We agree that if a substantial modification is made, the system should be subject to a new conformity assessment. However, it is essential that pre-determined changes, updates or the like which are contained in the technical documentation should not be viewed as a substantial modification. In this respect, we find that this paragraph could be further specified in order to avoid a situation, where providers find themselves in a constant conformity assessment.</p>

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	<p>AT:</p> <p>(Comments):</p> <p>The term “substantial modification” has always been a much-discussed issue. It would be helpful to include concrete cases of modifications that are not considered a substantial modification for clarification.</p>
<p>For high-risk AI systems that continue to learn after being placed on the market or put into service, changes to the high-risk AI system and its performance that have been pre-determined by the provider at the moment of the initial conformity assessment and are part of the information contained in the technical documentation referred to in</p>	<p>ES:</p> <p>(Comments):</p> <p>We believe that in its current writing, this is hardly achievable. Maybe not all the changes are foreseeable and therefore, this would lead to a new conformity assesment. Has this been properly assessed?</p>

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<p>point 2(f) of Annex IV, shall not constitute a substantial modification.</p>	<p>SK:</p> <p>(Comments):</p> <p>“AI systems that continue to learn” – this notion needs to be defined in article 3 for the sake of legal clarity.</p> <p>IT:</p> <p>(Comments):</p> <p>Italy supports such approach if linear learning applies only.</p> <p>DK:</p> <p>(Comments):</p> <p>This paragraph seems to establish a new AI category in terms of “high-risk AI systems that continue to learn after being placed on</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>the market or put into service” and it would be essential to clarify that the beforementioned pre-determined changes are not viewed as substantial modification only for this category, but across the board of high-risk AI.</p> <p>NL:</p> <p>(Drafting):</p> <p>For high-risk AI systems that continue to learn after being placed on the market or put into service, changes to the high-risk AI system and its performance that have been pre-determined by the provider at the moment of the initial conformity assessment and are part of the information contained in the technical documentation referred to in</p>

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	point 2(f) of Annex IV, shall not constitute a substantial modification, except if they have an impact on fundamental rights.
<p>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.</p>	<p>BG:</p> <p>(Drafting):</p> <p>“.....in order to introduce update/amend elements of the conformity assessment procedures that become necessary or useless/obsolete in light of technical progress.”</p> <p>BG:</p> <p>(Comments):</p> <p><u>Justification</u>: more flexible wording in the light of the technological development, but</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>in general, we have a reservation on the delegated powers of the Commission on Annexes VI and VII as they are defined as part of NLF in Decision 768/2008 and that is why, we are not sure that any possible amendments should take place via delegated acts.</p> <p>PL:</p> <p>(Drafting):</p> <p>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</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>PL:</p> <p>(Comments):</p> <p><i>We prefer mechanism based not on delegated acts but on acts which are compliant with art 290 TFEU.</i></p> <p>SE:</p> <p>(Drafting):</p> <p>When formally asked by a simple majority of the member states the Commission is empowered to adopt delegated acts in accordance with Article 73 for the purpose of updating Annexes VI and Annex VII... /</p> <p>IESD</p> <p>SE:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>According to 43.5 and 43.6, the Commission is empowered to amend, add and update the requirements of VI and VII, which may cause additional administrative burden and adaptation time that goes beyond the pace of innovation, development and implementation of AI methods already based on the broad the definition has been identified as high risk.</p> <p>CZ:</p> <p>(Comments):</p> <p>Article 43(5) and (6) would grant the European Commission extensive power to change requirements for conformity assessment procedures set out in Annex VI</p>

Presidency compromise text	Drafting Suggestions Comments
	and Annex VII as well as Article 43(1) and (2). Those paragraphs should not allow to change fundamental procedures and requirements without thorough consultation and involvement of European Artificial Intelligence Board.
<p>6. The Commission is empowered to adopt delegated acts to amend paragraphs 1 and 2 in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex VII or parts thereof. The Commission shall adopt such delegated acts taking into account the effectiveness of the conformity assessment procedure based</p>	<p>SK: (Comments): Slovakia believes external (independent) assessment should be a rule, i.e. contained already in the act which renders the proposed delegated powers unnecessary. PL:</p>

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<p>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.</p>	<p>(Drafting):</p> <p>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.</p> <p>The Commission shall adopt such delegated acts taking into account the effectiveness of the conformity assessment procedure based on internal control referred to in Annex VI in preventing or minimizing the risks to health and safety and protection of fundamental rights posed by such systems as well as the availability of adequate capacities and resources among notified bodies.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>PL:</p> <p>(Comments):</p> <p><i>We prefer mechanism based not on delegated acts but on acts which are compliant with art 290 TFEU</i></p> <p>IT:</p> <p>(Comments):</p> <p>Clarifications on the delegated acts amending paragraphs 1 and 2 shall be provided in order to avoid excessive discretion.</p> <p>SE:</p> <p>(Drafting):</p> <p>When formally asked by a simple majority</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>of the member states the Commission is empowered to adopt delegated acts to amend paragraphs 1 and 2 in order to subject high...</p> <p>CZ:</p> <p>(Comments):</p> <p>Fundamentally, amending Annex III in the future without proper involvement of MS and other relevant actors creates a risk to a stable environment and legal clarity. The topic requires further discussion and careful consideration.</p> <p>EE:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Is it possible to change the obligations stemming from a regulation with a delegated act in this provision (art 43(6))?</p> <p>Could the CLS please provide their opinion on the use of delegated acts in this provision?</p> <p>HU:</p> <p>(Drafting):</p> <p>[...] The Commission shall initiate prior consultation with the European Artificial Intelligence Board and the European Data Protection Board before the adoption of such delegated acts.</p> <p>HU:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Article 43 (5) and (6) would give the Commission broad powers to amend the requirements for conformity assessment procedures set out in Annexes VI and VII and in Article 43 (1) and (2). We recommend amending this to ensure that the Commission cannot change the basic procedures and requirements without thorough consultation.</p> <p>DK:</p> <p>(Comments):</p> <p>We are still assessing the choice of delegated act in order to amend whether providers are subject to internal or third-party control. However, if such instrument is chosen and if the conformity assessment</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>procedure is changed, it would be relevant to discuss a transition period for both providers as well as for member states in terms of the possible establishment of relevant notified bodies.</p>
<p><i>Article 44</i> <i>Certificates</i></p>	<p>SE:</p> <p>(Comments):</p> <p>Need to clarify how certificates issued under AIA is related to certificates issued under CSA.</p>
	<p>PL:</p> <p>(Comments):</p> <p><i>In the area of certification, it is necessary to take into account the principle of the</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p><i>autonomy of the EU Member States and the principle of mutual recognition of certificates.</i></p> <p><i>There is a need for transparency in the application of uniform certification procedures based on e.g. a technical standard in the area of implementation</i></p>
<p>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.</p>	<p>BE:</p> <p>(Comments):</p> <p>Link with uncertainty about which general rules apply or do not apply to law enforcement - It is not sufficiently clear if the certificate system also applies for inhouse development and inhouse use of AI systems, when law enforcement itself is the developer and user of its AI system.</p>

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<p>2. Certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the provider, the validity of a certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures.</p>	<p>ES:</p> <p>(Comments):</p> <p>How have been these periods been established?</p> <p>IT:</p> <p>(Comments):</p> <p>More information on providers' demand, the relevant criteria and the timing of this process shall be provided. Besides, the five-year duration does not seem in line with the dynamics of IA innovation.</p> <p>Please clarify the interaction with the certification system introduced by the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Cybersecurity Act.</p> <p>NL:</p> <p>(Comments):</p> <p>What is the validity period for the conformity assessment based on the Annex VI procedure (internal control)?</p>
<p>3. Where a notified body finds that an AI system no longer meets the requirements set out in Chapter 2 of this Title, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it, unless compliance with those requirements is ensured by appropriate corrective action taken by the provider of the system within</p>	<p>IT:</p> <p>(Comments):</p> <p>A procedure shall be set up.</p> <p>NL:</p> <p>(Comments):</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>an appropriate deadline set by the notified body. The notified body shall give reasons for its decision.</p>	<p>What is 'an appropriate deadline' for measures taken by the provider to take appropriate corrective action?</p>
<p><i>Article 45</i> <i>Appeal against decisions of notified bodies</i></p>	
<p>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.</p>	<p>PL:</p> <p>(Comments):</p> <p><i>1. There must be a clear distinction between "legal interest" and factual interest. Which of them is relevant here?</i></p>

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	<p><i>2. It should also be clarified whether it is if are to determine the nature of the appeal and its effects? Is it a complaint procedure carried out by the certification body itself, administrative or judicial control in terms of formalities, or something else?</i></p> <p>IT:</p> <p>(Comments):</p> <p>An alternative dispute resolution system could be considered.</p> <p>SE:</p> <p>(Drafting):</p> <p>Member States shall ensure that an appeal procedure against decisions of the notified bodies is available to parties having a</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>legitimate interest in that decision.</p> <p>SE:</p> <p>(Comments):</p> <p>Such procedural laws is in the mandate of the national legislator.</p> <p>Different writing that that of the proposed machinery regulation (article 37). It is important that it is uniform. Becomes problematic with different processes.</p> <p>FI:</p> <p>(Comments):</p> <ul style="list-style-type: none">- Possibility for national derogations is absolutely needed. <p>DK:</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>(Comments):</p> <p>We would recommend defining legitimate interests, including which entities will decide on whether an interest is legitimate. This would ensure more legal clarity for both the notified bodies and the companies wishing to appeal.</p> <p>NL:</p> <p>(Comments):</p> <p>Suggestion to explicate that civil society organisations are considered as ‘party having a legitimate interest’.</p>
<p><i>Article 46</i></p> <p><i>Information obligations of notified bodies</i></p>	<p>SE:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>According to Article 46, the notified bodies have an obligation to provide information to the notifying authority, which may lead to excessive requirements regarding transparency regarding, for example, the working methods of the secret activity. Transparency and the obligation to provide information must be clearly defined in this respect, taking into account the specific nature of law enforcement authorities.</p>
<p>1. Notified bodies shall inform the notifying authority of the following:</p>	<p>CZ:</p> <p>(Comments):</p> <p>Paragraph 1 corresponds to paragraph 1 of Article R28 of 768/2008/EC, except for</p>

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	paragraph 1(a), which provides for the obligation for notified bodies to inform the notifying authority. CZ would welcome explanation of this difference from NLF.
(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 system approval issued in accordance with the requirements of Annex VII;	

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>(c) any circumstances affecting the scope of or conditions for notification;</p>	
<p>(d) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;</p>	
<p>(e) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.</p>	
<p>2. Each notified body shall inform the other notified bodies of:</p>	<p>BE:</p> <p>(Comments):</p>

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	<p>Link with uncertainty about which general rules apply or do not apply to law enforcement - Is the exception for law enforcement, immigration or asylum authorities in Article 70 (2), also applicable here, and in the next point?</p>
<p>(a) quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued;</p>	
<p>(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.</p>	

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<p>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.</p>	<p>BE:</p> <p>(Comments):</p> <p>Link with uncertainty about which general rules apply or do not apply to law enforcement - Is the exception for law enforcement, immigration or asylum authorities in Article 70 (2), also applicable here? (see also comments on Article 46 (2)).</p>
<p><i>Article 47</i> <i>Derogation from conformity assessment procedure</i></p>	
<p>1. By way of derogation from Article 43, any market surveillance authority may</p>	<p>SK:</p>

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<p>authorise the placing on the market or putting into service of specific high-risk AI systems within the territory of the Member State concerned, for exceptional reasons of public security or the protection of life and health of persons, environmental protection and the protection of key industrial and infrastructural assets. That authorisation shall be for a limited period of time, while the necessary conformity assessment procedures are being carried out, and shall terminate once those procedures have been completed. The completion of those procedures shall be undertaken without undue delay.</p>	<p>(Comments):</p> <p>The exceptional reasons contained in the article appear too vague. As already proposed by Slovakia in relation to article 3, the notion of “public security” should be defined for the purposes of this act, also to make clear how it differentiates in practice from “national security” which does not fall under EU competences.</p> <p>BG:</p> <p>(Comments):</p> <p>We are not sure what exactly is meant by the last sentence of this paragraph and in particular, “...and shall terminate once those procedures have been completed”.</p> <p>In our view, if the conformity assessment</p>

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	<p>procedures prove compliance as soon as they are completed, the authorisation shall be terminated only when the exceptional reasons/circumstances are not present anymore.</p> <p>However, the authorisation shall be terminated as long as the conformity assessment procedures prove incompliance.</p> <p>Any possible contradictions with paragraph 2 of this article should be avoided and therefore, it would be advisable to revise it</p> <p>LT:</p> <p>(Drafting):</p> <p>By way of derogation from Article 43, any market surveillance authority may authorise the placing on the market or putting into</p>

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	<p>service of specific high-risk AI systems within the territory of the Member State concerned, for exceptional reasons of public security or the protection of life and health of persons, environmental protection and the protection of key industrial and infrastructural assets. That authorisation shall be for a limited period of time, while the necessary conformity assessment procedures are being carried out, and shall terminate once those procedures have been completed. The completion of those procedures shall be undertaken without undue delay.</p> <p>LT:</p> <p>(Comments):</p>

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	<p>Would be preferable to define those key industrial and infrastructural assets in order to avoid broad interpretations and ensure clarity.</p> <p>PL:</p> <p>(Comments):</p> <p><i>There is still a need of making clarification of the derogation from the conformity assessment procedure specified in Art. 43, since the authorization to place on the market specific high-risk systems, incl. for reasons of public security, it seems only after the market surveillance authority has determined that the system meets the requirements of type II and the standard procedure in Annex VI is internal control</i></p>

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	<p>MT:</p> <p>(Comments):</p> <p>Malta stresses that there is an important risk from a health point of view when thinking of the use of health data by insurance companies. Whilst there is an explicit reference to a ban on social scoring, there is a risk that insurance premia and credit ratings are based on one's health record through AI algorithms. We already see young people with chronic conditions being disproportionately and systematically barred from securing funding by banks to start a business on the basis of their chronic stable health condition. Many such loan providers require health policies which, in turn,</p>

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	<p>require disclosure of one's health records. As one's genomic profile becomes more accessible and within everyone's reach, this is likely to become part of the electronic health record in the near future, creating major social disadvantage based on one's genetic makeup.</p> <p>IT:</p> <p>(Comments):</p> <p>The term "limited period of time" should be clarified. For a correct management of the possibilities of derogation from Article 43, it would be appropriate to introduce a list of possible cases, specifying the maximum period of time in which it is possible to derogate from the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>general rule.</p> <p>DK:</p> <p>(Comments):</p> <p>We understand the need to have a derogation for exceptional circumstances. Nevertheless, we find this derogation very broad and vaguely formulated, which could lead to uncertainty and potential misuse. Particularly, it is unclear what is meant by the protection of “key industrial and infrastructural assets”. If this is referring to critical infrastructure, we would suggest clarifying that in order to have a clear scope – also having in mind that the aim of this regulation is to avoid a fragmented internal market. Furthermore it could be relevant to</p>

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	<p>formulate a set of criteria indicating when it would be warranted to use this derogation. This would also make it easier for other member states to evaluate, whether there is a need for them to object.</p> <p>NL:</p> <p>(Drafting):</p> <p>(..) for exceptional reasons of public security or the protection of life and health of persons, environmental protection and the protection of key industrial and infrastructural assets, and only to the extent that such authorisation is appropriate and necessary.</p> <p>NL:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>NL would like to add a definition of 'key industrial and infrastructural assets'.</p>
<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>SE:</p> <p>(Drafting):</p> <p>The market surveillance authority shall inform the European Artificial Intelligence Board of any authorisation issued pursuant to paragraph 1.</p> <p>SE:</p> <p>(Comments):</p> <p>15 days is a too long period if there are exceptional reasons that makes it necessary</p>

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	to use a specific AI-system.
<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>SE:</p> <p>(Drafting):</p> <p>Where, within 15 calendar days of receipt of the information referred to in paragraph 2, no objection has been raised by any of the members of the European Artificial Intelligence Board 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</p>	<p>SE:</p>

Presidency compromise text	Drafting Suggestions Comments
<p>paragraph 2, objections are raised by a Member State against an authorisation issued by a market surveillance authority of another Member State, or where the Commission considers the authorisation to be contrary to Union law or the conclusion of the Member States regarding the compliance of the system as referred to in paragraph 2 to be unfounded, the Commission shall without delay enter into consultation with the relevant Member State; the operator(s) concerned shall be consulted and have the possibility to present their views. In view thereof, the Commission shall decide whether the authorisation is justified or not. The Commission shall address its decision to the Member State concerned and the relevant</p>	<p>(Drafting):</p> <p>Where, within 15 calendar days of receipt of the notification referred to in paragraph 2, objections are raised by a Member State against an authorisation issued by a market surveillance authority of another Member State, or where the Commission considers the authorisation to be contrary to Union law or the conclusion of the Member States regarding the compliance of the system as referred to in paragraph 2 to be unfounded, the Commission shall without delay enter into consultation with the relevant Member State; the operator(s) concerned shall be consulted and have the possibility to present their views. In view thereof, the Commission shall decide whether the</p>

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operator or operators.	<p>authorisation is justified or not. The Commission shall address its decision to the Member State concerned and the relevant operator or operators.</p> <p>SE:</p> <p>(Comments):</p> <p>Article 47.4 transfers to the Commission and the Member States to decide whether or not a permit/approval is justified. If the regulation does not clearly define the requirements for approval, it can be problematic that different interpretations of both regulation and AI technology can delay the process even in important and exceptional cases.</p> <p>The infringement procedure should be</p>

Presidency compromise text	Drafting Suggestions Comments
	sufficient.
<p>5. If the authorisation is considered unjustified, this shall be withdrawn by the market surveillance authority of the Member State concerned.</p>	
<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</p>	<p>ES: (Comments): Why this provision specifically addressed to Medical Devices?</p>

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with the requirements set out in Chapter 2 of this Title.	
<p><i>Article 48</i> <i>EU declaration of conformity</i></p>	<p>SE:</p> <p>(Comments):</p> <p>Is the “EU declaration of conformity” similar to the “EU statement of conformity” according to the CSA? If yes, alignment as far as possible between the processes is needed.</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</p>	<p>BG:</p> <p>(Comments):</p> <p>As per Art 26 and 27 the importers and distributors are obliged to provide “all</p>

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<p>market or put into service. The EU declaration of conformity shall identify the AI system for which it has been drawn up. A copy of the EU declaration of conformity shall be given to the relevant national competent authorities upon request.</p>	<p>necessary information and documentation” to verify for instance, the presence of a declaration of conformity, but Art 48 implies that the declaration shall not be only drawn up by the provider, but also kept by that person/body. How then will the importers and distributors be able to fulfil their obligations for verification under Art 26 and Art 27 if they don’t have access to the declaration (it seems that access to it will be given only to national competent authorities upon request)? Is presence of CE marking conformity sufficient for fulfilment of the obligations (“all necessary information and documentation”) under Art 26 and Art 27?</p> <p>Last, to our knowledge such declaration</p>

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	<p>should be possessed by the manufacturer and not exactly by the provider. According to the new version of definitions in doc. 14278/21 still it is not clear whether the provider is also a manufacturer although the new definition for provider does not seem to exclude such possibility.</p> <p>PL:</p> <p>(Drafting):</p> <p>The provider shall draw up an EU electronic declaration of conformity (e-declaration) for each AI system and keep it at the disposal of the national competent authorities for 10 years after the AI system has been placed on the market or put into service. The EU declaration of conformity shall identify the AI system for which it has been drawn up.</p> <p>The EU declaration of conformity shall identify the AI system for which it has been</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>drawn up. A copy of the EU declaration of conformity shall be given to the relevant national competent authorities upon request</p> <p>PL:</p> <p>(Comments):</p> <p><i>Art. 48 is drafted in such a way as to take into account the production of a document in written and documentary form. It seems that these documents should be prepared only in electronic form (in documentary or electronic form within the meaning of the Code of Civil Procedure). Then the problem of copies (and certification for compliance) does not arise, as such electronic proof in the same form is kept by the manufacturer and can be made available to anyone.</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p>IT:</p> <p>(Comments):</p> <p>The provision seems grounded on linear innovative processes.</p> <p>Please clarify the procedure to follow in order to obtain the single UE declaration.</p> <p>Italy suggests to provide for online publications of Declaration of Conformity (e.g., such as in providers' web sites).</p> <p>NL:</p> <p>(Drafting):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>A copy of the EU declaration of conformity shall be given submitted to the relevant national competent authorities upon request.</p> <p>NL:</p> <p>(Comments):</p> <p>It is important that companies must be able to submit (changes to) data and registrations (digitally) as simple as possible.</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</p>	<p>PL:</p> <p>(Comments):</p> <p><i>Mandatory (ex lege) transmission immediately to the designated national authority is to be considered</i></p>

Presidency compromise text	Drafting Suggestions Comments
required by the Member State(s) in which the high-risk AI system is made available.	
<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 declaration shall contain all the information required for identification of the Union harmonisation legislation to which the declaration relates.</p>	
<p>4. By drawing up the EU declaration of conformity, the provider shall assume responsibility for compliance with the</p>	

Presidency compromise text	Drafting Suggestions Comments
<p>requirements set out in Chapter 2 of this Title. The provider shall keep the EU declaration of conformity up-to-date as appropriate.</p>	
<p>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.</p>	<p>PL: (Comments): The EC will have to develop a template for the e-declaration (Art. 48.5). SE: (Drafting): When formally asked by a simple majority of the member states the Commission</p>
	<p>LV:</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>(Comments):</p> <p>We call for an assessment of the possibility of supplementing Article 48 of the Regulation by establishing criteria for which an AI system, for which a declaration has been drawn under the provisions of the Regulation, is to be recognised as a new (other) AI system and thus a new declaration is to be made.</p>
<p><i>Article 49</i></p> <p><i>CE marking of conformity</i></p>	<p>CZ:</p> <p>(Comments):</p> <p>Article 49 does not contain paragraph 4 of Article R12 of 768/2008/EC on penalties for incorrect use of the CE marking.</p> <p>CZ would like to ask for clarification why</p>

Presidency compromise text	Drafting Suggestions Comments
	the provisions on penalties for incorrect use of CE marking were not included.
<p>1. The CE marking shall be affixed visibly, legibly and indelibly for high-risk AI systems. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it shall be affixed to the packaging or to the accompanying documentation, as appropriate.</p>	<p>IE:</p> <p>(Comments):</p> <p>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.</p> <p>BG:</p> <p>(Comments):</p> <p>Does this provision require to certify</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>retroactively currently running systems as a result of using e.g., statistical models and optimization algorithms in many critical systems in infrastructure, transportation, utilities, finance etc...? We assume that this should be the case only if there will be significant changes in the design and purpose of the AI systems, but we would appreciate a more explicit clarification in a recital, as well and in addition to Art 83 (2).</p> <p>Last, as other delegations pointed out during the meeting, the wording in the second sentence of this paragraph should be adjusted to software specifics.</p> <p>PL:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p><i>1. However, the appeal contained in point 2 indicates who can grant the CE certificate, it seems that the regulation itself should contain a clear indication in this regard.</i></p> <p><i>2. Such an obligation as specified in Art. 49 should be implemented, for the sake of consumer protection, in relation to all artificial intelligence systems, and not just "high-risk artificial intelligence systems".</i></p> <p>IT:</p> <p>(Comments):</p> <p>For the sake of clarity, it seems better to invert paragraph 1 with paragraph 2, in order to underline that CE marking of</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>conformity should be primarily consistent with the general principles set out in Article 30 of Regulation (EC) No 765/2008.</p> <p>For the same reason, CE marking of conformity and the Machine Regulation provisions shall be explicitly coordinated.</p> <p>SE:</p> <p>(Comments):</p> <p>A requirement of CE-marking will be burdensome for authorities developing high-risk AI for in-house use. Will the requirement of CE-marking be applicable such systems, or only for high-risk systems</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>intended for the market?</p> <p>HU:</p> <p>(Comments):</p> <p>Greater clarity is needed on the requirements for affixing and maintaining the CE marking. The text should provide further details on the process for placing the CE marking and the placing of the CE marking on software. It will be crucial for the Proposal to establish uniform rules on requirements and procedure, as this is the first time that CE marking is a requirement for software.</p>
<p>2. The CE marking referred to in paragraph 1 of this Article shall be subject</p>	

Presidency compromise text	Drafting Suggestions Comments
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 the high-risk AI system fulfils the requirements for CE marking.	
<i>Article 50</i> <i>Document retention</i>	SE: (Comments): The documentation that has to be

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>maintained for 10 years after the AI system has been put into use may possibly include personal data of a nature that needs to be in compliance with existing legislation on retention time.</p>
<p>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:</p>	<p>BG:</p> <p>(Comments):</p> <p>Will notified bodies assessing the conformity also have access to the retained documents or it is rather limited to national competent authorities? Next, if the documentation is kept only at the disposal of the national competent authorities, how will importers and distributors provide access to “all necessary information and</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>documentation” under Art 26 and Art 27? Is it possible to clarify their obligations for submission of information and documentation by avoiding ambiguous wording and limiting those to what is strictly necessary for an importer or distributor? What exactly is covered by “all necessary information and documentation” under Art. 26 and Art. 27?</p> <p>How does this 10-year period of document retention relates to AI systems that continue to learn? If the provider is not the same entity that puts the system into service who is obliged to retain the documentation, is it a shared responsibility?</p> <p>PL:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p><i>A similar problem as in Art. 48.1. - it is necessary to decide what is happening with the documentation in the event of bankruptcy or liquidation</i></p> <p>EE:</p> <p>(Drafting):</p> <p>The provider shall, for the whole-a period where the AI system is on the market or in service and for 10 years thereafter 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:</p> <p>EE:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>To ensure that the document retention period would not end in cases where the AI system is still in service after 10 years, it would be advisable to link the document retention period to the whole use-cycle of the AI system, plus a certain number of years thereafter.</p> <p>HU:</p> <p>(Comments):</p> <p>The obligations for providers and users of high-risk AI could result in being costly and excessive, with the consequence that innovation, development and investment are all chilled, or certain market actors fail to</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>fully comply, both of which would be detrimental to the stated aims of the legislative intervention, in particular the requirement to keep technical documentation for over 10 years, including pictures, the definition of residual risks in terms of risk management, and the record keeping of logs.</p> <p>In addition to the administrative burden brought by such obligations and its risk to innovation, there is an increased risk for professional secrets and IPR, in case of breach of confidentiality from regulators, market surveillance authorities or notified bodies. As such, requests by national authorities to prove compliance with Chapter II (Articles 8 to 16) should be based</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>on founded risks or concerns of non-compliance, otherwise developers could be subject to arbitrary requests leading to unjustified burden.</p> <p>NL:</p> <p>(Drafting):</p> <p>The provider shall, for a period ending 40 5 years after the high-risk AI system has been placed on the market or put into service if no longer in use, keep at the disposal of the national competent authorities:</p> <p>NL:</p> <p>(Comments):</p> <p>The keeping of records, documentation and, where relevant, data sets should be limited</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>for specific and identified high risk AI-systems only and for a limited time to to avoid burdensome and costly data storage requirements. 10 year is not proportionate for SME's, suggestion to limit the document retention period.</p>
<p>(a) the technical documentation referred to in Article 11;</p>	<p>HU:</p> <p>(Comments):</p> <p>AI value chains are complex, and it is important to avoid that the regulation creates disadvantages for the European AI industry. Therefore, we propose where possible the use of existing documentation systems for managing risks. Due to the</p>

Presidency compromise text	Drafting Suggestions Comments
	close links between data protection and AI, an extension of the GDPR risk management system with AI aspects should be considered instead of or as an alternative for an additional one for AI only. At a minimum, requirements in the various regulations (e.g., GDPR, AI Regulation, future EU mandatory environmental and human rights due diligence) must be congruent and aligned.
(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.	
<p><i>Article 51</i> <i>Registration</i></p>	<p><i>CZ:</i></p> <p>(Comments):</p> <p>It is important to further discuss and possibly clarify in the text the specificities of the registration, e.g. whether the product will have to appear in the database prior to its placing on the market or putting it into service or whether the simple act of</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>registering it will suffice. Who will handle the registrations and assess the information provided? How long will it take? Will there be any deadlines? What options the provider will have in case the submission is rejected – is there such possibility at all?</p>
<p>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.</p>	<p>PT: (Comments): In the case of AI system is medical device according to MDR/IVDR, how this registration will work, is there a connection between EU database for stand-alone high-risk AI systems (article 60) and the EUDAMED database? BG:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>If read together with the new version of Art. 6 (2) in doc. 14278/21, is the reference to Art. 6 (2) still correct? When should be the system registered exactly, before or after undergoing a third-party conformity assessment? If the latter applies then, should the system be registered while in operation or still before being placed on the market or put into service?</p> <p>SI:</p> <p>(Drafting):</p> <p>Before placing on the market or putting into service a high-risk AI system referred to in Article 6(32), the provider or, where applicable, the authorised representative shall register that system in the EU database</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>referred to in Article 60.</p> <p>SI:</p> <p>(Comments):</p> <p>Incorrect reference in article 51.</p> <p>PL:</p> <p>(Comments):</p> <p><i>In connection with art. 60 - in the case of high-risk systems used for law enforcement purposes, if the system provider is a public entity, eg the Police, it needs to be considered whether it is justified to enter a natural person - an authorized representative in the register. The description of the purpose of the system for these systems should be limited.</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p>FI:</p> <p>(Comments):</p> <p>It must be assessed whether the registration of high-risk AI systems is based on a real need and provides added-value.</p> <p>AT:</p> <p>(Drafting):</p> <p>Before placing on the market or putting into service a high-risk AI system referred to in Annex II and III the provider or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60. Regarding Annex II only high-risk AI systems shall be registered where the AI-system is the main</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>component and has possible direct effect on the user (e.g. toys).</p> <p>AT:</p> <p>(Comments):</p> <p>Suggestion to also include AI systems referred to in Art 6 para 1 (If the rationale behind including only AI systems referred to in Art 6 para 3 is that these AI systems are only subject to internal control and no third-party conformity assessment).</p>
<p>TITLE IV</p>	
<p>TRANSPARENCY</p> <p>OBLIGATIONS FOR CERTAIN</p> <p>AI SYSTEMS</p>	<p>BE:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Belgium supports the obligation of providers of AI systems that interact with natural persons, to ensure that these systems are designed and developed in such a way that natural persons are informed transparently about the fact that they are interacting with an ai system. Moreover, Belgium estimates that natural persons should also be able to understand the possible implications of this interaction with the AI system. However, the references made to ‘manipulation of image, audio or video content’ under this title are not defined in the AIA and thus should be further explained by the Commission.</p> <p>HR:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>Transparency of AI systems is key to preventing and monitoring discriminatory effects. Without a sufficient level of transparency, there can be no determination (or at least not an adequately reliable one) whether a given AI application complies with the law (EU law, national law, international law), including equality law, and as a result, users of AI systems could not claim their rights through the usual legal redress channels. Also, if there is no sufficient level of transparency independent oversight bodies will not have sufficient evidence to enforce the law. Thus, ensuring sufficient level of transparency is essential for enabling effective access to justice. Without a legal reform that</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>secures adequate transparency and the related explainability of AI systems, access to justice by persons whose rights are affected by AI systems is effectively blocked or at least severely limited. This aim could be also achieved by mapping the uses of AI within EU MS, possibly through a proposal for a legal requirement of transparency through the creation of publicly accessible national registers for the uses of AI.</p> <p>AT:</p> <p>(Drafting):</p> <p>TRANSPARENCY</p> <p>OBLIGATIONS FOR CERTAIN AI SYSTEMS POSING TRANSPARENCY OR FAIRNESS</p>

Presidency compromise text	Drafting Suggestions Comments
	RISKS
	<p>AT:</p> <p>(Drafting):</p> <p>NEW Article 51a</p> <p>Compliance with the obligations</p> <p>1. This Title includes obligations for AI systems where one or both of the following conditions are fulfilled:</p> <p>(a) use of the AI system involves a risk of confusion between AI system and humans, or their operations or activities, where such confusion might harm the legitimate interests of persons exposed to the AI system;</p> <p>(b) use of the AI system leads to a decision with regard to a person that involves a</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>material degree of evaluation or discretion and thus involves a fairness risk for the affected person.</p> <p>2. The obligations of users of AI systems under this Title shall apply also to users who do not operate the AI system under their own authority but who solicit the services of another party using the AI system.</p> <p>3. Providers of AI system whose intended use includes use within the meaning of paragraph 1 shall ensure that AI systems are designed and developed in such a way that users are able to comply with their obligations under this Title.</p> <p>4. None of the provisions under this Title shall affect any prohibitions or restrictions for AI systems following from Title II or</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Title IIa or any requirements or obligations set out for high-risk AI systems in Title III of this Regulation.</p> <p>AT:</p> <p>(Comments):</p> <p>It is suggested not to leave individual rights entirely to the GDPR, first, because it is not likely that the GDPR will be changed in the near future and the gaps filled (e.g. with regard to AI systems merely recommending action to a human) and, second, because AI-related individual rights are rather misplaced in the GDPR. The reason for the latter is that these individual rights are not focussed on the processing of input data relating specifically to the affected data</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>subject but on the output data, which may have been generated with the help of (training etc.) data relating to very different data subjects, or with the help of non-personal data. This is why it is suggested to give Title IV of the AIA a new focus on individual rights in the context of AI systems that present either a transparency or a fairness risk,</p> <p>and also to rephrase the existing Article 52 on transparency obligations in the light of this new focus and clarify its application to social bots that merely generate content.</p>
<p><i>Article 52</i> <i>Transparency obligations for certain AI systems</i></p>	<p>PL:</p> <p>(Comments):</p> <p><i>It is necessary to clarify Art. 52. It does not</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p><i>follow from it whether the project ensures transparency each time a person is subjected to emotional analysis or is general information sufficient, eg in a contract template? It should also be indicated that this information is to be provided in a clear and comprehensible manner, separately from other information. Moreover, it should be considered whether the solution provided for in Art. 52 is sufficient, i.e. whether, in relation to the analysis of emotions, the person should be strengthened with the right not to be subjected to such analysis. If the provisions of the GDPR were to be sufficient in this regard, it is worth clarifying the relationship between these acts</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p>EE:</p> <p>(Comments):</p> <p>In order to protect the human dignity, tackle the spread of AI-generated fake news, reduce spamming and harassment by social media bots and in general ensure further transparency concerning synthetic content, we propose expanding the transparency obligations in art 52 to users who publish AI-generated text content. Certain limitations from the transparency obligation may be justified, such as excluding AI-generated translations or summarizations.</p> <p>DK:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Transparency should be our point of departure in order to promote trust. We are positive in terms of enhancing transparency through establishing simple transparency obligations in this Regulation. However, our aim must always be to provide added value and ensure good user experiences. The transparency obligations should not interrupt or hinder the user experience. In this respect, we see a need to clarify the scope of applications covered by article 52. At the moment, it is difficult to assess how many applications would be covered. Also, we would underline the need to pay greater attention to technology neutrality in this article. For example, article 52(3) is referring to production or manipulation of image, audio or video content, but</p>

Presidency compromise text	Drafting Suggestions Comments
	transparency obligationsn could also be relevant for other forms of technology or software.
<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>LT:</p> <p>(Comments):</p> <p>There is a requirement to inform consumers when they interact with an AI-system, but with regard to the use of AI in a wide range of services, it remains unclear whether, for example, the use of AI in search engines also falls into situations where such information is mandatory and at the same time meaningful.</p> <p>PL:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p><i>it is worth considering the clarification of the concept of "interaction with natural persons"</i></p> <p>IT:</p> <p>(Comments):</p> <p>Informative procedures shall be included.</p> <p>FI:</p> <p>(Comments):</p> <p>The relation between this Article's transparency obligations to those of the GDPR should be clarified.</p> <p>CZ:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Drafting):</p> <ol style="list-style-type: none">1. Providers shall ensure that all 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>CZ:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>We suggest that the information that this provision applies to all AI systems which intend to interact with natural persons, irrespective of whether they qualify as high-risk or not, is incorporated into the main text.</p> <p>EE:</p> <p>(Comments):</p> <p>It remains unclear how to determine if it is obvious from the circumstances and the context of use that a natural person is interacting with an AI system. What is „obvious“ to a tech-savvy person may not be to someone who is not. Thus, we would like to understand further how this</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>exemption applies in practice.</p> <p>At minimum, the exemption should be further clarified in the article text or recitals to ensure that the human dignity and fundamental rights of people who lack knowledge and exposure as regards to AI systems could not be systematically undermined via this exemption.</p> <p>NL:</p> <p>(Drafting):</p> <p>Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that natural persons are informed that they are interacting with an AI system, unless this is obvious from the circumstances and the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>context of use.</p> <p>This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences insofar and as long as appropriate, proportional and necessary for these purposes, also considering any rights under international law, Union law or national law that can supersede these purposes</p> <p>NL:</p> <p>(Comments):</p> <p>Transparency should be aspired as long as it does not harm the detection prevention, investigation and prosecution of criminal offences. At all times, international human</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>rights law must be complied with.</p> <p>AT:</p> <p>(Drafting):</p> <p>Users of an AI system that interacts with natural persons 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>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>AT:</p> <p>(Comments):</p> <p>No sufficient explanation available under which circumstances and in which context the use of AI systems is "obvious" for natural persons, therefore deletion is suggested (or further explanation in recitals).</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 categorisation, which are permitted by law to detect, prevent and</p>	<p>SK:</p> <p>(Comments):</p> <p>This article should be adjusted as Slovakia believes these systems should be covered by and included in article 5 (1) (d) – see Slovakia's comments to article 5.</p>

Presidency compromise text	Drafting Suggestions Comments
investigate criminal offences.	<p>BG:</p> <p>(Comments):</p> <p>“Inform” only or rather “inform before” or even “use such systems after expressed consent by the exposed natural persons”?</p> <p>PL:</p> <p>(Comments):</p> <p>HR:</p> <p>(Comments):</p> <p>Transparency obligations have been defined for certain artificial intelligence systems in</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>order to prevent certain risks of manipulation. Transparency obligations will apply to systems that interact with people, detect emotions or establish links with certain (social) categories based on biometric data or generate or manipulate content ("deep fakes"). If people interact with an artificial intelligence system or their emotions or characteristics are recognized automatically, people must be informed.</p> <p>SE:</p> <p>(Comments):</p> <p>In Article 52.2 there's an exception to inform the exposed persons of the use of AI systems used for biometric categorization, but this exception does not apply to emotion</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>recognition systems. Although we welcome the Commissions proposal that exempts AI systems used for biometric categorisation permitted by law to detect, prevent and investigate criminal offences, the logic behind why emotion recognition systems are not exempted is unclear to us.</p> <p>CZ:</p> <p>(Comments):</p> <p>CZ supports this provision.</p> <p>However, as regards “biometric categorisation system”, it is necessary to reconsider changes made to definition of “biometric data” in Art. 3(33). Pursuant to recital 7) and for practical reasons,</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>definitions should not diverge from GDPR and the identification function should be kept. Otherwise, the definition will be so broad to be meaningless (height of a person would qualify). For the purposes of “biometric categorisation”, a broader term should be used. By reference to Art. 4(4) GDPR, we suggest “biometric aspects”. That would let us improve definition in Art. 3(35) where aspects such as eye colour are confused with categories:</p> <p>‘biometric categorisation system’ means an AI system for the purpose of assigning natural persons to specific categories, such as sex, age, hair colour, eye colour, tattoos, health, personal traits, ethnic origin or sexual or political orientation, on the basis</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>of their biometric aspects, such as hair colour, eye colour, tattoos, or their biometric data;</p> <p>NL:</p> <p>(Drafting):</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 categorisation, which are permitted by law to detect, prevent and, investigate and prosecute criminal offences insofar and as long as appropriate, proportional and necessary for these purposes also considering any rights under</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>international law, Union law or national law that can supersede these purposes.</p> <p>NL:</p> <p>(Comments):</p> <p>See 52(1).</p> <p>AT:</p> <p>(Drafting):</p> <p>Users of an emotion recognition system or a biometric categorisation system shall inform of the operation of the system the natural persons exposed thereto. This obligation shall not apply to AI systems used for biometric categorisation, which are permitted by law to detect, prevent and investigate criminal offences. an AI system</p>

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	<p>that creates content or engages in [online] activities that are normally engaged in by natural persons ('bot') shall disclose that the content was created, or the [online] activities performed, by an AI system, unless the source of the content or [online] activities cannot reasonably be expected to matter to natural persons exposed thereto</p> <p>AT:</p> <p>(Comments):</p> <p>An emotion recognition system is qualified as high risk and was inserted in Annex III/1b (see last table transferred to the Slovene Presidency).</p> <p>See last sentence of comments to Art 51a.</p>

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<p>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.</p>	<p>SK:</p> <p>(Comments):</p> <p>Textual content generated or manipulated by AI systems should also be included in the scope of this provision.</p> <p>PL:</p> <p>(Comments):</p> <p><i>Art. 52 sec. 3 imposes an obligation to inform about changes in the objective reality by the user of artificial intelligence. Apart from obviously undesirable situations (e.g. deep fake), introducing changes to the presented reality may have various, thoroughly positive motivations - artistic,</i></p>

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	<p><i>functional, explanatory, educational, quoting, polemical, etc. Moreover, it can be assumed that it is precisely these situations that constitute the majority of cases of "manipulating" the real image. The imposition of the obligation to inform about the introduced change in each case, even in the slightest dimension, could significantly impede the conduct of journalistic, artistic or, more broadly, creative activity. The second paragraph of the indicated point only slightly eliminates this risk. It should be clarified whether each change should be marked according to the rule.</i></p> <p>FI:</p> <p>(Comments):</p>

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	<p>Does generating or manipulating image also cover manipulating text?</p> <p>CZ:</p> <p>(Comments):</p> <p>Given that appropriate safeguards are required in both situations, it is not clear why deep fakes for law enforcement purposes are considered high risk and deep fakes for mass media (standard public platforms) are not.</p> <p>EE:</p> <p>(Comments):</p> <p>The recitals or the article text should clarify when the use of deep fakes is “necessary”</p>

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	<p>for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences as referred to in Art 52(3) second paragraph. It should furthermore be clarified which are the “appropriate safeguards” for protecting the rights and freedoms of third parties. As a general remark, it remains unclear which particular risk or concern is mitigated by the freedom of expression and the freedom of the arts and sciences exemption in art 52(3) second paragraph.</p> <p>HU:</p> <p>(Drafting):</p> <p>Users of an AI system that generates or manipulates image, audio or video content</p>

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	<p>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 immediately before presenting such content, or, in case of audio and video, at the start at latest.</p> <p>HU:</p> <p>(Comments):</p> <p>The proposed addendum serves the purpose of transparency. This prior notification obligation should be fulfilled immediately before showing such content:</p> <ul style="list-style-type: none"> - before showing the image, or - in case of audio and video at latest at the start (e.g., the deepfake's

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	<p>greeting "I'm a deep fake", "This is deep fake").</p> <p>Displaying this information at the end of the audio/video is not sufficient, as many users do not watch/listen until the end.</p> <p>NL:</p> <p>(Drafting):</p> <p>(...) shall disclose that the content has been artificially generated or manipulated in a clear and visible manner.</p> <p>NL:</p> <p>(Comments):</p> <p>NL wonders why deep fakes are not considered a high risk AI system. They can have an impact on fundamental rights and</p>

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	<p>security.</p> <p>NL is in favour of creating transparency labels to aid citizens that encounter a 'deep fake' to help them determine the trustworthiness of the content. We do have some questions about article 52.3:</p> <ul style="list-style-type: none">- Will there be a standard / minimum requirements to disclose that the content has been artificially generated or manipulated? Not all such "labels" are as effective. Uniformity can furthermore help citizens recognise such labels. <p>The article should make more clear that it requires the <i>producer</i> of such deep fake content to disclose that the content has been artificially generated or manipulated.</p>

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<p>However, the first subparagraph shall not apply where the use is authorised by law to detect, prevent, investigate and prosecute criminal offences or it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, and subject to appropriate safeguards for the rights and freedoms of third parties.</p>	<p>SK:</p> <p>(Comments):</p> <p>The provision does not contain a reference to international instruments in the field of fundamental rights by which member states are bound and national constitutions protecting fundamental rights which will be exercised exercised also outside of the scope of EU law and the Charter.</p> <p>Appropriate safeguards for their exercise should be included in this respect and an explicit reference to national law and international law should be included.</p> <p>PL:</p>

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	<p>(Comments):</p> <p><i>Moreover, it is necessary to balance the need for a natural person to know how his data is used (See Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016) The right to privacy is one of the basic and fundamental human rights. A natural person has the right to decide whether the artificial intelligence system used by a private entity is to have access to a range of information and the possibility of using this data for its own purposes - including business purposes. In addition, in application of the provisions on respect for private life, the information obligation for consumers / natural persons should be implemented in</i></p>

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	<p><i>relation to all types of artificial intelligence - not only this "high risk". A natural person should know what risks and consequences are associated with it in order to be able to make a rational decision before the purchase / use or other activity that may have legal consequences for him. Even if the change is relatively small, it may affect that person's rights and freedoms</i></p> <p>NL:</p> <p>(Drafting):</p> <p>However, the first subparagraph shall not apply where the use is authorised by law to detect, prevent, investigate and prosecute criminal offences insofar and as long as appropriate, proportionate and necessary for</p>

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	<p>these purposes, also considering any rights under international law, Union law or national law that can supersede these purposes, or it is appropriate and necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, and subject to appropriate safeguards for the rights and freedoms of third parties.</p> <p>NL:</p> <p>(Comments):</p> <p>In excersing the right to freedom of expression it shall not impade with the rights of others guaranteed to third parties, like the right to privacy or family life.</p>

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	<p>AT:</p> <p>(Drafting):</p> <p>3a. Paragraphs 1, 2 and 3 However, the first subparagraph shall not apply where the use is authorised by law to detect, prevent, investigate and prosecute criminal offences or it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, and subject to appropriate safeguards for the rights and freedoms of third parties</p>
	<p>LV:</p> <p>(Drafting):</p> <p>5. AI system should always warn user if</p>

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	user's actions can harm oneself, other individuals, property, or the environment.
4. Paragraphs 1, 2 and 3 shall not affect the requirements and obligations set out in Title III of this Regulation.	<p>AT:</p> <p>(Drafting):</p> <p>Paragraphs 1, 2 and 3 shall not be read as legitimising the use of AI systems referred to beyond what is permitted by other law affect the requirements and obligations set out in Title III of this Regulation.</p>
TITLE IVA	
GENERAL PURPOSE AI SYSTEMS	<p>DK:</p> <p>(Comments):</p> <p>We are still assessing this new adjustment.</p>

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	<p>We very much welcome the discussion concerning this element, as AI is a technology which could have multiple purposes, thereby challenging the value chain as well as who should be responsible for different obligations.</p> <p>On the one hand, it makes sense that a person cannot be responsible for how the next person in the value chain integrates or uses a system. We must find a balance where the obligations follow the right actor in the value chain.</p> <p>On the other hand, we see a risk of creating a loophole, if too many systems are defined as general purpose AI systems as well as a risk of creating a loophole, if the original provider can leave the bulk of the obligations for the next person in the value</p>

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	<p>chain, thereby also leaving the conformity assessment for the new provider. In many cases, especially for a SME, going through an entire conformity assessment could be a heavy burden, thereby discouraging the SME from using such systems in high risk areas.</p> <p>In this respect, we are still reflecting on this new article.</p>
<p><i>Article 52a</i></p>	<p>SE:</p> <p>(Comments):</p> <p>This article should be integrated under article 2 or at least “general purpose AI system” should be stated under article 2 and possible defined under article 3.</p>

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	<p>AT:</p> <p>(Drafting):</p> <p><i>Article 52aa</i></p>
<p><i>General purpose AI systems</i></p>	<p>SE:</p> <p>(Comments):</p> <p>SE are positive to the addition article 52a (with recital 70 b) as many AI-systems could be used for various different purposes and it is the purpose (and outcome) of the system that should be considered under this regulation. This will simplify for businesses and public administration as it enables them to test systems for different uses.</p> <p>However there remains some ambiguity in</p>

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	<p>relation to the current proposal and the addition needs further analysis. One example of ambiguity in need of further analysis may be the requirements put forth for high risk AI-systems such as representative data for the intended purpose as the data the general purpose AI was trained on might not be considered relevant for the same purpose. If this is the case then the general purpose AI systems converted to intended purpose AI systems risk contradicting the requirements by default rendering them unusable for practical purposes.</p> <p>CZ:</p> <p>(Comments):</p>

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	<p>For the sake of legal clarity, and to avoid potential loopholes, the definition of a general purpose AI system should be provided, accompanied by further justification why a general purpose AI system does not fall under the scope of the regulation. The Commission should provide member states with practical impacts (e.g. market impact) of this article and real examples.</p> <p>NL:</p> <p>(Comments):</p> <p>NL supports the inclusion of general purpose AI systems, but needs time to study this specific proposal. Also, a specific definition for 'general purpose AI systems'</p>

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	lacks in the current text.
<p>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.</p>	<p>LT: (Comments): We suggest including definition of general purpose AI systems under Article 3 (Definitions)</p> <p>SE: (Comments):</p> <p>HU: (Comments): The introduction of the concept of “<i>general purpose AI systems</i>” would necessitate the</p>

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	<p>inclusion of the concept in the definitions as well.</p> <p>HU agrees with the approach of distinguishing between AI systems based on their intended purpose and outcome rather than their capabilities alone, however we are concerned that the term "<i>general purpose</i>" could lead to legal ambiguity by way of too broad interpretation.</p>
<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</p>	<p>LV:</p> <p>(Drafting):</p> <p>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</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>subject to the provisions of this Regulation.</p>	<p>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>LV:</p> <p>(Comments):</p> <p>Trademark may be registered by any person and therefore person should not be responsible for the AI system.</p> <p>SE:</p> <p>(Comments):</p> <p>To what extent can the provider of the high-risk AI-system count on the cooperation of the provider of the general purpose AI to</p>

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	<p>ensure compliancy with the AI Act? Recital 70a states they will cooperate “as appropriate”, what does that mean?</p> <p>DK:</p> <p>(Comments):</p> <p>The formulation in this paragraph is very unclear and creates confusion as to if and potentially when the user can become the provider in terms of obligations.</p> <p>Furthermore, it seems confusing to refer to “an intended purpose” for a general purpose AI system, as it can be very difficult to determine what the intended purpose is.</p>
<p>3. Paragraph 2 shall apply, mutatis mutandis, to any person who integrates a</p>	

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<p>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 purpose AI system is open source software or not.</p>	
	<p>ES:</p> <p>(Drafting):</p> <p>5. The publication of a general purpose AI system for its use for third parties will entail providing with all relevant information that any provider will need</p>

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	<p>for the purpose of complying with this Regulation.</p> <p>ES:</p> <p>(Comments):</p> <p>Spain welcomes this new article. Nevertheless, we see that it is important that any general purpose AI system is accompanied with relevant information that could be of interest for providers to comply with regulation.</p> <p>We offer a writing, even though we know that other options for expressing what is said in this comment could be also appropriate or even better than the one proposed.</p>

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	<p>AT:</p> <p>(Drafting):</p> <p>New</p> <p>Article 52a</p> <p>Scrutiny of individual decision-making</p> <p>1. No decision which produces legal affects concerning a person, or which similarly significantly affects that person, is taken by the user on the basis of the output from an AI system unless the appropriateness and fairness of this decision has been verified by means htat are appropriate to the nature and the significance of the decision and the role of the AI system in the decision-making process.</p> <p>2. Unless otherwise specified by Union or</p>

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	<p>Member State law, verification within the meaning of paragraph 1 may, in particular, consist in meaningful scrutiny, before the decision is taken, by a natural person who is equipped with the appropriate competence.</p> <p>(a) Abilities, training and decision-making authority;</p> <p>(b) Information with regard to the individual case; and</p> <p>(c) Safeguards against automation bias.</p> <p>3. The user may replace ex-ante verification within the meaning of paragraphs 1 and 2 by equivalent other measures where the affected person has given explicit consent or where ex-ante verification is impossible or would cause unreasonable effort and is not</p>

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	<p>strictly necessary for safeguarding the affected person's rights and freedoms and legitimate interests. Unless otherwise specified by Union or Member State law, such equivalent other measures may, in particular, consist in the right to</p> <ul style="list-style-type: none"> (a) Obtain human intervention that satisfies the requirement under paragraph 2; (b) Provide additional information and express his or her point of view; and (c) Contest the decision with a meaningful chance of having it revised. <p>Article 52b</p> <p>Explanation of individual decision-making</p> <p>1. A decision which is taken by the user on the basis of the output from an AI system</p>

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	<p>and which produces legal effects concerning a person, or which similarly significantly affects that person, shall be accompanied by a meaningful explanation that allows the user to fully understand the decision-making process.</p> <p>(a) the role of the AI system in the decision-making process;</p> <p>(b) the logic involved, the main parameters of decision making, and their relative weight; and</p> <p>(c) the input data relating to the affected person and each of the main parameters on the basis of which the decision was made.</p> <p>For information on input data under point (c) to be meaningful it must include an</p>

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	<p>easily understandable description of inferences drawn from other data if it is the inference that relates to a main parameter.</p> <p>2. Paragraph 1 shall not apply to the use of AI systems</p> <p>(a) that have only minor influence within the decision-making process;</p> <p>(b) that are authorised by law to detect, prevent, investigate and prosecute criminal offences or other unlawful behaviour;</p> <p>(c) for which exceptions from, or restrictions to, the obligation under paragraph 1 follow from Union or Member State law, which lays down appropriate other safeguards for the affected person's rights and freedoms and legitimate interests;</p>

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	<p>or</p> <p>(d) where the affected person has given explicit consent not to receive an explanation.</p> <p>3. The explanation within the meaning of paragraph 1 shall be provided at the time when the decision is communicated to the affected person. However, the user may provide the explanation only at a later point upon the affected person's request, where providing the explanation immediately is not strictly necessary for safeguarding the affected person's rights and freedoms and legitimate interests, in which case the user shall inform the affected person of the right under this Article and how it can be exercised.</p>

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	<p>4. Paragraph 2 should be applied accordingly prior to the conclusion of a consumer purchase or service contract regarding a product which contains an AI system or is the AI system itself.</p> <p>AT:</p> <p>(Comments):</p> <p>A central part of the revised Title IV should be two additional provisions that mirror and adapt Article 22 GDPR (right to scrutiny of individual decision-making) as well as the respective information duties in Articles 13 to 15 GDPR (right to explanation of individual decision-making) in a way tailored to the specific situation of AI-driven decision-making. Major benefits for affected persons would include that these individual rights do</p>

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	<p>not only apply for fully automated decisions, but also to decisions recommended to humans, and that the right to receive an explanation would be much more explicit and include, in particular, the main parameters of decision-making and their relative weight as well as an easily understandable explanation of inferences drawn if the inference itself is a main parameter.</p> <p>According to paragraph 4 the same kind of explanation which is foreseen in paragraph 2 should apply, when consumers buy products which either contain AI systems or are the AI system itself. Consumers will be affected by the product after purchase and they should be informed before the purchase about the logic and parameters of the system in order to be able to take an informed contractual decision.</p>

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TITLE V	HR: (Comments): It is necessary to further clarify how the financing of activities related to UI regulatory sandboxes, certification and risk assessment of UI systems, financing provided through the envelope of the Digital Europe 2021-2027 (DEP) program, is intended. Also it is necessary to clearly define the criteria for reducing the financial burden for SMEs and start-ups.

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MEASURES IN SUPPORT OF INNOVATION	BE: (Comments): We welcome the specific support measures envisaged for SMEs and start-ups, as these constitute the core of the AI ecosystem. Regulatory requirements for risk management and compliance represent costs and constraints that can be obstacles for SMEs or start-ups wishing to develop or implement AI solutions (in particular due to the lack of human and financial resources). However, we also believe that measures to support innovation should not be conditioned only on the size of the company, but should also consider other criteria such as the societal and

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	<p>environmental impact of current AI systems.</p> <p>Ensuring AI adoption of smaller businesses is also crucial for advancing innovation in Europe and working towards digital sovereignty. Belgium therefore supports complementary policy options that would create a facilitating environment and facilitate the development and uptake of AI. Regulatory measures such as skills development, financial support, capacity building and standardization shall be envisaged. In particular, granting businesses better access to data and/or developing the framework for industry-driven standardization in APIs (Application Programming Interface) and data formats are welcome.</p>

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	<p>SE:</p> <p>(Comments):</p> <p>Covers mainly exempts for processing personal data in support of certain innovation. The head-line gives an impression that is not met in the articles.</p> <p>To take measures in support of innovation the para 2.7 regarding R&D should be clarified. Now it could be interpreted that R&D that in the end leads to placing an AI-system on the market is covered by this act.</p> <p>This would effectively exclude all R&D activities performed by companies, hence be a hinder to innovation and be an extra cost affecting European companies only.</p>

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<p><i>Article 53</i> <i>AI regulatory sandboxes</i></p>	<p>SK:</p> <p>(Comments):</p> <p>Slovakia has doubts about the attractiveness of sandboxes for operators as the sandboxes are proposed to operate strictly under the binding applicable rules under the proposed act and other relevant EU and national legislation. Room for experimentation and possibilities policy feedback appears too narrow. We need a more flexible framework for sandboxes.</p> <p>Clear rules for accessibility of sanboxes to private operators should be defined.</p> <p>At the same time, sandboxes should be used also to upgrade public services, so public entities should also be entitled to participate.</p>

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	<p>BE:</p> <p>(Comments):</p> <p>While it is positive that the Commission is urging Member States to put in place regulatory sandboxes, this process should be further formalized and coordinated at EU level in order to avoid resulting in a fragmented landscape between Member States as to the conditions of use of these sandboxes. National competent authorities, like national data protection authorities, need to strengthen their skills and experience in this area, and should be supported by the Commission in this regard.</p> <p>Having a proper environment to test AI</p>

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	<p>systems that prevents any harm and enables consistent and robust results is crucial; however, we believe that flexibility is needed regarding preliminary work and that regulatory sandboxes should remain optional in AI testing phases.</p> <p>PT:</p> <p>(Comments):</p> <p>As the article goes beyond the concept of high-risk AI, it would be important to understand if these articles should be in this regulation, or if the regulation that MS are developing and putting into practice (Technological Free Zones in Portugal) are sufficient to regulate this type of activity</p> <p>SE:</p>

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	<p>(Comments):</p> <p>Regulatory sandboxes enable in a real-life environment the testing of innovative technologies, products, services or approaches, which are not fully compliant with the existing legal and regulatory framework. They are operated for a limited time and in a limited part of a sector or area. The purpose of regulatory sandboxes is to learn about the opportunities and risks that a particular innovation carries and to develop the right regulatory environment to accommodate it.</p> <p>Based on above the definition of regulatory sandboxes in article 53 is not clear. For example why is it necessary to prioritise SME for access to the sandboxes? Each</p>

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	<p>sandbox is established for its own purpose. Article 53 needs to better describe how the AI regulatory sandboxes is supposed to work.</p> <p>It is important that sandboxes do not incur too high cost to SMEs so that they remain competitive.</p> <p>In order to train AI, large amounts of data are sometimes required and according to Article 10.3, the training, validation and testing data set must be "relevant, representative, free of errors and complete."</p> <p>Given that this often involves large amounts of data, it can be difficult to fully meet all the requirements in advance. When examining a new type of criminal activity, for example, the relevance of the information needs to be assessed in order to</p>

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	<p>map and develop hypotheses in order to prevent, deter and detect the criminal activity. It is essential that AI in the future can be trained appropriately to be a tool and support in such an assessment.</p> <p>FI:</p> <p>(Comments):</p> <p>It should be clearly regulated which activities can be performed within AI regulatory sandboxes and what are the rights and obligations of the participants in the sandboxes.</p> <p>CZ:</p> <p>(Comments):</p>

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	<p>Use of regulatory sandboxes might prove to be very beneficial. If well set and implemented, it might enable testing of AI systems and more targeted and safe development of innovations in the EU. However, the specifics of the regulatory sandboxes should be further discussed, also in light of the Joint Opinion of the EDPB and the EDPS 5/2021 on the proposal of Artificial Intelligence Act. Furthermore, testing should be allowed directly on the market and in real operation, where feasible. This is what the Council Conclusions on Regulatory sandboxes from November 2020 emphasize. Otherwise, it would not have a desired effect and would not provide a real relief for small businesses, especially not for</p>

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	<p>start-ups, when launching AI systems. We therefore see the need to work on these provisions further to make sure they bring the desired effect into practise while taking necessary precautions and safeguarding the process.</p> <p>DK:</p> <p>(Comments):</p> <p>We are very supportive of initiatives which can promote and support innovation, including the establishment of regulatory sandboxes. To safeguard the internal market and the level palying field it is important that the requirements for conditions of operation, eligibility criteria etc. are set at EU level. We therefore welcome an</p>

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	implementing act, but would recommend to include more details in this article, to ensure that the implementing act contains the relevant measures and ensures the needed support for innovative companies, in particular for SMEs and start-up.
<p>1. AI regulatory sandboxes established by one or more Member States competent authorities or the European Data Protection Supervisor shall provide a controlled environment that facilitates the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan. This shall take place under the direct supervision and guidance by the competent</p>	<p>ES: (Drafting):</p> <p>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</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>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>before their placement on the market or putting into service pursuant to a specific plan. This shall take place under the direct supervision and guidance by the competent authorities with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox. They may also be useful for identifying risks to health and safety and fundamental rights, as well as testing mitigation measures for identified risks, demonstrating the prevention of such risks.</p> <p>ES:</p> <p>(Comments):</p>

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	<p>Modification in order to give a more finalist approach.</p> <p>PL:</p> <p>(Comments):</p> <p><i>Regulatory sandboxes in the proposed regulation are practically the only form of support for SMEs. However, support limited to the regulatory layer without financial support (which would reduce the costs of new AI solutions by experimenting and testing in sandboxes) will be an empty norm and will not support the development of the European AI market. It is important to ensure the autonomy of nation states in determining the conditions of availability and the cost of validation.</i></p>

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	<p>IT:</p> <p>(Comments):</p> <p>Reference to the European Data Protection Supervisor shall be erased.</p> <p>HR:</p> <p>(Drafting):</p> <p>AI regulatory sandboxes established by SMEs, large enterprises and other organizations and institutions dealing with artificial intelligence or one or more Member States competent authorities or the European Data Protection Supervisor shall provide a controlled environment that facilitates the safe development, testing and validation of innovative AI systems for a</p>

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	<p>limited time before their placement on the market or putting into service pursuant to a specific plan. For Member States competent authorities or the European Data Protection Supervisor, this shall take place under the direct supervision and guidance by the competent authorities with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.</p> <p>For SMEs, large enterprises and other organizations and institutions dealing with artificial intelligence, this shall take place independently from supervising authorities, while following rules and regulations established in cooperation with Member State competent authorities.</p>

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	<p>HR:</p> <p>(Comments):</p> <p>The AI Act needs to give more autonomy to SMEs, large enterprises and other organizations and institutions dealing with artificial intelligence to establish their own AI sandboxes, following rules and regulations drawn up in collaboration with Member States. If the presumption is that AI sandboxes, a cornerstone of AI innovation, can only be established by a state run body, this will create two negative effects: on the one hand, a backlog of AI sandbox requests will stifle any form of innovation and overburden governments. On the other, it will create a counter effect</p>

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	<p>by forcing innovators to either test their prototypes in third countries or it will create a grey zone of unregulated and unreported innovation.</p> <p>SE:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Drafting):</p> <p>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.</p> <p>SE:</p> <p>(Comments):</p> <p>We do not see the need to limit the use of regulatory sandboxes to pre-market.</p> <p>Regulatory sandboxes could, as an example,</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>be highly relevant to use if actors are thinking of substantially modify the system.</p> <p>CZ:</p> <p>(Comments):</p> <p>The measures should be in accordance with the Council Conclusions (11/2020) and incorporate experimentation clauses that are already used in many MS' legal frameworks. These clauses should be activated on a case-by-case basis in order to guarantee flexibility.</p> <p>EE:</p> <p>(Comments):</p> <p>It remains unclear what is the aim of these</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>regulatory sandboxes, is it to test innovation against the legal order or to test the legal order against the innovation. It should be possible to make necessary exceptions in the applicable rules in order to test innovative solutions. Otherwise, regulatory sandboxes could only be used by operators in order to test whether their system complies with all the applicable rules. One of the goals of regulatory sandboxes should be to test innovative solutions not in full conformity with the existing rules in order to assess whether these rules should be changed, whether the legal order is up to date and enables and fosters new innovative solutions.</p> <p>HU:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>We welcome the emphasis of the Proposal on the support of innovation, in particular regulatory sandboxes. This is a positive development, but the text could be more ambitious still in favour of innovation. The Proposal only establishes rules and regulatory oversight mechanisms for regulatory sandboxes but does not require Member States to establish any regulatory sandbox. It would be desirable to further encourage Member States to include the establishment of regulatory sandboxes in their national AI strategy.</p> <p>DK:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>When it comes to supervision and guidance, we see a need to broaden this paragraph in order to not just include the requirements of this regulation. Supervision and guidance on this aspect is of course essential, but due to the rapid development, other aspects, such as cybersecurity or data ethics, could become important in the future, thereby, calling for a flexible framework in terms of regulatory sandboxes.</p> <p>NL:</p> <p>(Drafting):</p> <ol style="list-style-type: none">1. AI regulatory sandboxes established by one or more Member States competent

Presidency compromise text	Drafting Suggestions Comments
	<p>authorities or the European Data Protection Supervisor shall provide a controlled environment that facilitates the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan. This shall take place under the direct supervision and guidance by the competent authorities. The sandbox will enable technical, organisational experimentation and legal testing with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox, enhancing legal certainty as well as understanding emerging risks and impact of AI- systems.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>NL:</p> <p>(Comments):</p> <p>As now formulated, the focus of the sandboxes is on ensuring compliance with the requirements of this Regulation and other Union and Member State legislation monitored within the sandbox. It is important to broaden the stated objective of the sandboxes, also enabling increased understanding about risks and impacts as well as enhancing legal certainty, and bringing the article more in line with the stated objectives in recital 72.</p> <p>Furthermore, to achieve a trusted and expert-driven testing environment, it is important that all competent authorities,</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>including those with domain specific expertise, can be involved in regulatory sandboxes. We suggest to amend the relevant recitals and definitions for increase clarity about the difference between 'competent authorities' including a wide range of supervisory organisations and the 'national competent authority' as defined in article 3.</p> <p>AT:</p> <p>(Comments):</p> <p>The scope of this provision (and Art. 54 and 55) is not clear for us, i.e. we would need further information which structures would be considered as "AI regulatory sandbox". A number of EU</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Member States (including AT), respectively their national financial supervisory authorities, have already introduced so called “Regulatory Sandboxes” to promote the introduction of innovative financial products, financial services or business models (in this context, please see also the European Commission’s March 2018 “FinTech Action Plan”); such innovative financial products, financial services or business models could in some cases as well have a link to AI systems.</p> <p>In this context, we would need further explanation/information whether Art. 53-55 will be applicable only to “Regulatory</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>sandboxes” which will be established in future to exclusively deal with new AI systems or whether Art. 53-55 of the Regulation will be applicable as well to already existing “Regulatory sandboxes” (which were established by financial supervisory authorities with a different purpose and a different focus, namely on the promotion of innovative financial services/financial products/business models) in case such innovative financial services/financial products/business models are linked to the application of AI systems?</p>
<p>2. Member States shall ensure that to the extent the innovative AI systems involve the processing of personal data or otherwise fall</p>	<p>LT: (Comments):</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>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>Recital 72 of the AI Act provides that participants in pilot projects shall ensure adequate safeguards and cooperate with the competent authorities, including taking into account guidance provided by them.</p> <p>According to Art. 53(2) of the Artificial Intelligence Act, Member States shall ensure that national data protection authorities and other national authorities are associated in the functioning of AI pilot projects. It is not clear from the text how this involvement of the national data protection authority and other national authorities in the operation of the pilot projects would occur.</p> <p>HR:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Drafting):</p> <p>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 established by one or more Member States competent authorities or the European Data Protection Supervisor. SMEs, large enterprises and other organizations and institutions dealing with artificial intelligence may request access to personal data from relevant national</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>authorities to be used in their AI sandbox under the guidelines defined through Member State rules and regulations .</p> <p>HR:</p> <p>(Comments):</p> <p>It should be emphasised that the risk is not only on processing personal data but potentially affects fundamental rights and equality.</p> <p>FI:</p> <p>(Comments):</p> <p>Art. 53 ensure that operators, even when developing AI systems in regulatory sandboxes, comply fully with GDPR.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>We would kindly ask for more information on what kind of cooperation would be required from the data protection authorities (including the budgetary impacts to the data protection authorities)?</p> <p>HU:</p> <p>(Comments):</p> <p>It is necessary to lay down basic rules such as 1) who designs the sandbox, 2) who operates the sandbox, 3) who can use it and under what conditions. It is currently unclear whether these regulatory testbeds will be provided by the Member State authorities themselves or by the EDPS,</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>EAIB, or whether the task will be outsourced to private companies.</p> <p>NL:</p> <p>(Comments):</p> <p>Please clarify that the GDPR applies.</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 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>IT:</p> <p>(Comments):</p> <p>Please clarify when a risk is considered significant and which mitigation measures should be taken during the test development.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>SE:</p> <p>(Drafting):</p> <p>, failing that, in the suspension of the development and testing process until such mitigation takes place. For the purpose of pure research purposes the actors may still continue to use the sandbox.</p> <p>SE:</p> <p>(Comments):</p> <p>The para. should be split in two and “the competent authorities.” to make it easier to read.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>EE:</p> <p>(Comments):</p> <p>Unclear what is meant under the first sentence, what kind of supervisory and corrective powers could the competent authorities exercise. Do these powers also include enforcement powers? Could the authorities impose fines even if the non-compliance with the existing rules is the novel innovation being tested in the AI regulatory sandbox, e.g., could a self-driving car be fined for the absence of a steering wheel if they are testing alternative manoeuvring systems?</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>This provision should not affect the regulators' ability to make necessary exceptions in order to test innovative solutions. It should be clarified what is meant under "supervisory and corrective powers", that authorities should be able to oversee the testing, make suggestions and intervene when necessary. Nevertheless, it should be taken into account that one of the goals of regulatory sandboxes is to test innovative solutions not in full conformity with the existing rules in order to assess whether these rules should be changed, whether the legal order is up to date and enables and fosters new innovative solutions.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>DK:</p> <p>(Comments):</p> <p>The suspension of the development and testing process might have a negative effect on the demand in terms of participation. Furthermore, the question is whether this would create an unequal situation where actors outside of the regulatory sandbox would not be required to halt development or testing completely. A more proportionate requirement could be that further participation in the specific sandbox would be suspended until the mitigation has taken place.</p> <p>NL:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Drafting):</p> <p>The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. Any significant risks to health and safety and fundamental rights identified during the development and testing of such systems shall result in immediate mitigation and, failing that, in the suspension or ending of the development and testing process until such mitigation takes place.</p> <p>NL:</p> <p>(Comments):</p> <p>Suspension is sufficient until mitigation, but if it doesn't occur, there should be a</p>

Presidency compromise text	Drafting Suggestions Comments
	possibility to end.
<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>HU:</p> <p>(Drafting):</p> <p>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>HU:</p> <p>(Comments):</p> <p>Sandboxes are controlled testing environments that allow developing, testing and re-testing of AI systems. As such, one</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>aim of the sandbox is to identify potential issues and gaps, and as a second step, to solve the issues (be it with training data, coding, or proposed application), and establish the compliant ways of functioning of the AI systems. Developers of AI systems could easily be discouraged from participation knowing that they remain fully liable for an AI system in a test environment.</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</p>	<p>SI:</p> <p>(Drafting):</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</p>

Presidency compromise text	Drafting Suggestions Comments
<p>from the implementation of those scheme, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application of this Regulation and other Union legislation supervised within the sandbox.</p>	<p>Artificial Intelligence Board. They shall publish annual reports on their website and submit them to the Board and the Commission on the results from the implementation of those scheme, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application of this Regulation and other Union legislation supervised within the sandbox. Based on the annual reports the Board shall publish a summary of good practices, lessons learnt and recommendations on its website.</p> <p>SI:</p> <p>(Comments):</p> <p>It is important to communicate the project and its intermediate results to those outside the regulatory sandbox and to the public. Such transparent reporting and other forms</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>of external reporting in the press, radio, social media, forums contribute to better acceptance of the project and transfer of knowledge gained within the sandbox participants to those outside. This is also important in order to minimize risks to the level playing field.</p> <p>IT:</p> <p>(Comments):</p> <p>Some indicators shall be defined (coherently with EU approach, maybe in the attempt to “contribute” to the Digital Economy and Society Index (DESI) which summarises indicators on Europe’s digital performance and tracks the progress of EU countries.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>CZ:</p> <p>(Drafting):</p> <p>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.</p> <p>They shall may submit annual reports to the Board and the Commission on the results from the implementation of those scheme, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application of this Regulation and other Union legislation supervised within the sandbox.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>CZ:</p> <p>(Comments):</p> <p>Creation of the annual report should be construed as an option not as a requirement. Most of the time it will be a repetitive exercise without added value.</p>
	<p>HR:</p> <p>(Comments):</p> <p>Member States should be encouraged to share personal data with innovators, but under the supervision of relevant competent authorities.</p>
<p>6. The modalities and the conditions of the operation of the AI regulatory sandboxes, including the eligibility criteria</p>	<p>ES:</p> <p>(Drafting):</p>

Presidency compromise text	Drafting Suggestions Comments
<p>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).</p>	<p>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 and will be accompanied with proper guidance documentation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).</p> <p>BG:</p> <p>(Drafting):</p> <p>“....including the eligibility criteria and the procedure for the application, selection,</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>participation and exiting from the sandbox..."</p> <p>BG:</p> <p>(Comments):</p> <p><u>Justification</u>: Member States should be free to decide who should participate depending on market specifics, incl., market demand and also taking into account the availability of resources</p> <p>SI:</p> <p>(Drafting):</p> <p>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,</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>participation and exiting from the sandbox, monitoring and assessment process 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).</p> <p>SI:</p> <p>(Comments):</p> <p>In addition open communication regarding outcomes of the sandboxes with MSs and other stakeholders by Board is crucial in order to establish learning culture and level playing field for all stakeholders in EU..</p> <p>HR:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>Request for further clarification: when are the implementing acts expected to be drafted? Who will supervise their creation? Who can get involved?</p> <p>SE:</p> <p>(Comments):</p> <p>Will it be possible to appeal? For example, if an SME perceives that the selection process was unfair or if the selection criteria were biased.</p> <p>Can the exclusion of an actor from a regulatory sandbox be seen as denial of market access?</p> <p>FI:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Drafting):</p> <p>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).</p> <p>FI:</p> <p>(Comments):</p> <p>The essential parts of the regulation should</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>be laid down in the basic act, not in the implementing acts. We would suggest that at least the rights and obligations of the participants shall be set out in the basic act, instead of implementing acts.</p> <p><i>CZ:</i></p> <p>(Comments):</p> <p>It should be up to MS competent authorities how they will set up their sandboxes.</p> <p><i>NL:</i></p> <p>(Drafting):</p> <p>The modalities and the conditions of the operation of the AI regulatory sandboxes, including the eligibility criteria and the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>procedure for the application, selection, participation and exiting from the sandbox, the termination of regulatory sandboxes and the rights and obligations of the participants shall be set out in implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).</p> <p>AT:</p> <p>(Comments):</p> <p>In case Art. 53-55 apply as well to already existing "Regulatory Sandboxes" in the area of financial services, it would be of utmost importance that the current remit of such already existing "Regulatory Sandboxes" remains unchanged and that such already</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>existing “Regulatory Sandboxes” can continue with their current functions, tasks and procedures in order to promote technical innovation in the area of financial services.</p> <p>Consequently, such already existing “Regulatory Sandboxes” should at least be excluded from the application of Art. 53 para. 6.</p>
	<p>ES:</p> <p>(Drafting):</p> <p>7. The modalities referred to in Article 53(6) shall ensure proper participation of small-scale providers in the sandbox, including their preliminary registration. The</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>different modalities will also include support and guidance methods for the participating companies, as well as access to relevant elements of the European Union initiatives on Artificial Intelligence.</p> <p>Sandboxes will be organised in a way that they are all accessible via a single information point.</p> <p>ES:</p> <p>(Comments):</p> <p>With this paragraph, we try to add value for companies (specially small scale ones) to participate.</p> <p>This should include regulatory confort, guidance (bespoken or not) and certainty.</p> <p>LV:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Drafting):</p> <p>7. AI regulatory sandboxes shall provide virtual environment for virtual tests/certification and investigations of incidents. Virtual environment shall be able to simulate wide spectrum of environments/conditions and load log data to virtually restore incident situation.</p> <p>EE:</p> <p>(Drafting):</p> <p>Article 53 shall not apply to AI regulatory sandboxes intended for testing AI systems that are developed or used exclusively for military or national security purposes.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>EE:</p> <p>(Comments):</p> <p>It is very likely that AI regulatory sandboxes are developed also in the sphere of national security and defence. Hence, for avoidance of any doubt and for the legal clarity, it should be explicitly stated that such AI regulatory sandboxes are exempted from the scope of this regulation. This would be in line with art 4 (2) of the Treaty on European Union, which states that national security remains the sole responsibility of each Member State.</p>
<p><i>Article 54</i> <i>Further processing of personal data for</i></p>	<p>SK:</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p><i>developing certain AI systems in the public interest in the AI regulatory sandbox</i></p>	<p>(Comments):</p> <p>See comments to article 53 above.</p> <p>BG:</p> <p>(Drafting):</p> <p><i>Article 54 Further processing of personal data for developing certain AI systems upon request of public authorities in the public interest in the AI regulatory sandbox</i></p> <p>BG:</p> <p>(Comments):</p> <p><u>Justification:</u> Who decides whether there is a need to develop certain AI systems in the public interest? From the proposed provision it is not clear whose the initiative is. If the intention is to address the public</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>interest then the public bodies should have the leading role in the process</p> <p>PL:</p> <p>(Comments):</p> <p><i>The indicated provision on the protection of personal data should be specified in terms of relation to the GDPR. In particular, the obligations of the data processor for the preparation of the artificial intelligence system have not been specified in relation to the persons who are processed. The information obligation arises from the GDPR. It is important to assess the impact of the processing of personal data, not the act of processing itself</i></p> <p>FI:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>It should be ensured that further processing of personal data in Article 54 complies with GDPR and the principle of purpose limitation (Article 8 of the Charter of Fundamental Rights; Article 5(1)(b) of GDPR).</p> <p>Requires more clarification: whether Article 54 would provide for more specific rules than GDPR (Article 5(1)(b); article 6 paragraphs 2-4 GDPR).</p> <p>In addition, it should be clarified whether it might include processing personal data referred to in Articles 9 and 10 of the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>General data protection Regulation, (in which case e.g. the legal basis in Article 9(2), should be identified.</p> <p>DK:</p> <p>(Comments):</p> <p>If the article is intended to complement the existing provisions in the GDPR, as the Commission previously has explained, it is uncertain with the current formulations what the added value with this provisions will actually be, especially as recital 41 states that the AI Act will not provide for legal ground of processing personal data.</p> <p>Member states are already able to establish regulatory sandboxes, therefore, the added value of this provision needs to be clarified.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Furthermore, we see a need to further clarify the relationship between this article and the existing data protection legislation.</p> <p>NL:</p> <p>(Comments):</p> <p>Questions:</p> <ul style="list-style-type: none">- Why is the article (and recital 72) related to article 6(4) of the GDPR and related specifically to further processing? Why is it not posed as a separate (new) legal base? What are the advantages of this approach?- Do we assume correctly that the proposal only functions as a legal ground for personal data, and not for LED-data? This with regard to recital 72 and the specific mention of the need for a legal basis in MS law in article 54(1)(a)(i).- Do we assume correctly that the goal of article 54(2) is to make sure that

Presidency compromise text	Drafting Suggestions Comments
	<p>MS can still by law limit further processing for specific purposes, even though it would be allowed under article 54(1)? So MS law restricting further processing of e.g. certain health data precludes the possibility created in article 54(1)(a)(ii)?</p> <p>Suggestions:</p> <ul style="list-style-type: none"> - The NL believes that if this article is to be seen as a horizontal legal ground for processing, it requires further specification. This might include (not exhaustive): <ul style="list-style-type: none"> o the categories of data used; (e.g. also article 9/10 categories of data?) o a limited retention period (the duration of the project in the sandbox seems to general) o further specification of the goals (e.g. public safety and health still seems to be rather general)

Presidency compromise text	Drafting Suggestions Comments
	<ul style="list-style-type: none"> - Explicit reference to the GDPR and its requirements (e.g. data protection principles, DPIA, security measures of article 35) could be made. - Especially if the aim is to process special categories of data, we are not yet convinced that this horizontal approach is feasible. It might be necessary to exclude these types of data from the scope of the legal ground.
<p>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:</p>	<p>BG:</p> <p>(Drafting):</p> <p>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</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>systems upon request of public authorities, in the sandbox under the following conditions:</p> <p>LT:</p> <p>(Comments):</p> <p>The question arises as to the relationship between Art. 54(1) of the Artificial Intelligence Act and Regulation 2016/679 and Directive 2016/680 — whether Art. 54(1) of the Artificial Intelligence Act allows the processing of personal data collected for other purposes in the development and testing of pilot projects, while fully complying with the provisions of Regulation 2016/679 and Directive 2016/680 under strict conditions (e.g. on the use of special categories of personal data in</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>accordance with Article 9 of Regulation 2016/679; on ensuring transparency in accordance with Article 5 of Regulation 2016/679).</p> <p>IT:</p> <p>(Comments):</p> <p>Please provide further clarification on the relationship with GDPR, since the provisions on the processing of personal data seem to limit the spread of the sandboxes.</p> <p>SE:</p> <p>(Drafting):</p> <p>In the AI regulatory sandbox personal data lawfully collected for other purposes may</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>be processed for the purposes of developing and...</p> <p>SE:</p> <p>(Comments):</p> <p>The relationship between this article and GDPR/LED needs to be clarified.</p> <p>Which are the rights and responsibilities of individuals whose data is used in the regulatory sandbox?</p> <p>HU:</p> <p>(Drafting):</p> <p>1. In the AI regulatory sandbox personal data lawfully collected for other purposes shall be processed for the purposes of</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>developing and testing certain innovative AI systems in the sandbox under the following joint conditions:</p> <p>HU:</p> <p>(Comments):</p> <p>As this is a high risk case, we recommend to avoid any possible misunderstanding that the conditions are joint, otherwise some providers may interpret it as only needing any one of the listed conditions.</p> <p>AT:</p> <p>(Drafting):</p> <p>Member States shall adopt sector-specific legislation to authorise the processing of certain categories of personal data in certain</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>contexts for the purposes of developing and testing certain innovative AI systems in the sandbox under the following conditions:</p> <p>AT:</p> <p>(Comments):</p> <p>As AT mentioned before, we are very sceptical of this blanket authorisation for processing any lawfully collected personal data in the context of regulatory sandboxes. The fact that there are limitations for the establishment of regulatory sandboxes in Articles 53 and 54, i.e. the framework in which personal data is processed, is not sufficient in our opinion to comply with existing data protection law.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>We would argue that the principle of purpose limitation according to Art. 5 para 1 lit b GDPR restricts the processing of personal data for purposes other than the initial purpose.</p> <p>If it is argued that Article 54 para 1 is a case of further compatible use according to Article 6 para 4 GDPR it has to be noted that the question of the interpretation of Article 6 para 4 GDPR is still divisive. Regardless of the interpretation of Article 6 para 4 GDPR we would argue that it does not serve as a legal basis for blanket authorisations for the processing of personal data, let alone special categories of personal data, in the context of regulatory sandboxes.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>If it is argued that the processing of lawfully collected personal data for the purpose of developing AI systems in the context of a regulatory sandbox is always compatible with any initial purpose because it is a form of scientific research, we have to point out that AI systems which are specifically developed and put into service for the sole purpose of scientific research and development are excluded from the scope of the AIA according to Article 2 para 6. Furthermore, according to Article 2 para 7 any limitations of the AIA do not apply to research and development activities regarding AI systems in so far as such activity does not lead to or entail placing an AI system on the market or putting it into service.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>As a result, Article 54 only applies to the development of AI systems, which are meant to be placed on the market or put into service.</p> <p>Therefore, we would argue that a blanket authorisation for the processing of any lawfully collected personal data solely for the commercial interests of the developer is not compatible with the principle of purpose limitation according to Article 5 para 1 lit. b GDPR.</p> <p>Furthermore, it does not comply with the principles of transparency and data minimisation according to Article 5 para 1 lit. a and c GDPR and data subjects are not made aware of the processing of their</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>personal data, which was collected in a completely different context.</p> <p>The provision is also in violation of Articles 9 and 10 GDPR because it does not fulfil the requirements for the processing of special categories of personal data and personal data relating to criminal convictions and offences, as it does not distinguish between general personal data and special categories of personal data.</p> <p>Lastly, it could be questioned whether a blanket authorisation for the processing of any lawfully collected personal data solely for the commercial interests of the developer is proportionate in accordance with Article 8 CFR.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>We therefore suggest that the provision should be converted into an opening clause for Member States to allow for sector-specific national and Union legislation to authorise the processing of certain categories of personal data in certain contexts according to their national law.</p>
<p>(a) the innovative AI systems shall be developed for safeguarding substantial public interest in one or more of the following areas:</p>	<p>SE: (Comments):</p> <p>What is the definition of “innovative AI system”? To foster innovation, it would be helpful to broaden the areas here.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>AT:</p> <p>(Drafting):</p> <p>[...] shall only be developed [...]</p> <p>AT:</p> <p>(Comments):</p> <p>The current wording should be clarified.</p>
	<p>SE:</p> <p>(Drafting):</p> <p>(i) a more efficient public administration</p>
<p>(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</p>	<p>AT:</p> <p>(Comments):</p> <p>Does the last sentence mean that the processing of personal data in the context of</p>

Presidency compromise text	Drafting Suggestions Comments
<p>security, under the control and responsibility of the competent authorities. The processing shall be based on Member State or Union law;</p>	<p>a regulatory sandbox developed for law enforcement purposes needs to be based on Member States or Union law? In our opinion all processing within the context of a regulatory sandbox needs to be based on sector specific Member States or Union laws.</p>
<p>(ii) public safety and public health, including disease prevention, control and treatment;</p>	<p>IT: (Comments): Healthcare systems improvement shall be included. EE: (Drafting):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(ii) public safety, public order and public health, including disease prevention, control and treatment;</p> <p>EE:</p> <p>(Comments):</p> <p>How is “public safety” defined? Does this include dispatching of emergency response?</p> <p>Further data processing in sandboxes should be applicable also for development of AI systems to identify violations of public order, such as traffic violations.</p> <p>HU:</p> <p>(Drafting):</p> <p>(ii) public administration, public safety</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>and public health, including disease prevention, control and treatment;</p> <p>HU:</p> <p>(Comments):</p> <p>We propose allowing the collection of data on artificial intelligence for administrative purposes as well by supplementing point (1) (a) (ii).</p>
(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	<p>SE:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
<p>2 where those requirements cannot be effectively fulfilled by processing anonymised, synthetic or other non-personal data;</p>	<p>Should this exempt instead be included in EU 2016/679? Now the AI Act makes exempts from GDPR, which directives and regulations will make exempts from the AI Act? As the number of criss-crossing exempts increase it will be difficult to see the full picture of how GDPR is implemented. That could in turn mean that codes-of-conduct implemented in relation to GDPR are not updated to reflect exempts made in other EU directives and regulations. Vice versa, if other rules make exempts to the AI Act, how will affected parties know to act accordingly in terms of code-of-conduct and compliancy?</p>
<p>(c) there are effective monitoring mechanisms to identify if any high risks to</p>	<p>SE:</p>

Presidency compromise text	Drafting Suggestions Comments
<p>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;</p>	<p>(Drafting):</p> <p>there are effective monitoring mechanisms to identify if any high substantial risks to the fundamental rights and non-discrimination of the data subjects</p>
<p>(d) any personal data to be processed in the context of the sandbox are in a functionally separate, isolated and protected data processing environment under the control of the participants and only authorised persons have access to that data;</p>	<p>SE:</p> <p>(Comments):</p> <p>What does “participants” refer to? Does it cover national competent authorities, do they have the prerequisites to handle the data in an appropriate way? Do they want to? Are the individuals that the data represent count as participants?</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>EE:</p> <p>(Drafting):</p> <p>(d) any personal data to be processed in the context of the sandbox are in a functionally separate, isolated and protected data processing environment under the control of the participants and only authorised persons authorised by competent authorities have access to that data;</p> <p>EE:</p> <p>(Comments):</p> <p>It is unclear who the participants are. Private parties who act under a contract with a competent authority should be able to</p>

Presidency compromise text	Drafting Suggestions Comments
	access the data.
(e) any personal data processed are not be transmitted, transferred or otherwise accessed by other parties;	<p>EE:</p> <p>(Comments):</p> <p>It should be possible to involve third parties, including companies, in the development of certain AI systems in the public interest in the AI regulatory sandbox.</p>
(f) any processing of personal data in the context of the sandbox do not lead to measures or decisions affecting the data subjects;	<p>CZ:</p> <p>(Drafting):</p> <p>any processing of personal data in the context of the sandbox do not lead to measures or decisions affecting the data subjects, not including provision of products</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>or services provided during the testing period;</p> <p>CZ:</p> <p>(Comments):</p> <p>Activities of the subject testing the system during the testing period might affect the data subjects. For example, providing loans that take longer to repay than the testing period. Generally speaking, it cannot be said that the testing does not affect people.</p>
<p>(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;</p>	

Presidency compromise text	Drafting Suggestions Comments
	<p>HU:</p> <p>(Drafting):</p> <p>(h) any personal data processed in the context of the sandbox is safeguarded with appropriate technical measures, such as encryption or anonymisation techniques.</p> <p>HU:</p> <p>(Comments):</p> <p>Since Article 55 is in itself a broad interpretation of the purpose compatibility as defined in Article 6 (1) b) and (4) in the GDPR, special attention should be taken to the application of technical safeguards for processing the personal data, that should be reiterated in this list.</p>

Presidency compromise text	Drafting Suggestions Comments
	We propose to add “anonymisation techniques” in order to remain technologically neutral, and not to cause confusion with the list of Annex I (as updated from time to time).
(h) the logs of the processing of personal data in the context of the sandbox are kept for the duration of the participation in the sandbox and 1 year after its termination, solely for the purpose of and only as long as necessary for fulfilling accountability and documentation obligations under this Article or other application Union or Member States legislation;	HU: (Drafting): (h) (i)
(i) complete and detailed description of the process and rationale behind the	HU:

Presidency compromise text	Drafting Suggestions Comments
training, testing and validation of the AI system is kept together with the testing results as part of the technical documentation in Annex IV;	(Drafting): ⊕ (j)
(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.	HU: (Drafting): ⊕ (k)
2. Paragraph 1 is without prejudice to Union or Member States legislation excluding processing for other purposes than those explicitly mentioned in that legislation.	AT: (Comments): Does this mean that, if a national law explicitly prohibits the processing of lawfully collected personal data for any other purpose, the personal data cannot be

Presidency compromise text	Drafting Suggestions Comments
	<p>used in the context of a regulatory sandbox?</p> <p>As mentioned above, we would argue that the principle of purpose limitation according to Art. 5 para 1 lit b GDPR already prohibits the processing of personal data for purposes other than the initial purpose.</p> <p>In case the argument arises that the processing of lawfully collected personal data for the purpose of developing an AI system in the context of a regulatory sandbox is always compatible with any lawful initial purpose because it is a form of scientific research, we would argue that the development of AI systems primarily serves the commercial interest of enterprises.</p> <p>However, AI systems which are specifically developed and put into service for the sole</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>purpose of scientific research and development are already excluded from the scope of the AIA according to Article 2 para 6.</p> <p>Furthermore, the limitations of the AIA do not apply to any research and development activities regarding AI systems in so far as such activity does not lead to or entail placing an AI system on the market or putting it into service according to Article 2 para 7.</p> <p>Article 54 therefore only applies to the development of AI systems which are meant to be placed on the market or put into service.</p> <p>Therefore we would argue that a blanket authorisation of processing of any lawfully</p>

Presidency compromise text	Drafting Suggestions Comments
	collected personal data for the commercial interests of the developer is not compatible with the principles of the GDPR.
	<p>HU:</p> <p>(Drafting):</p> <p>3. The further processing in Paragraph 1 may constitute the further processing of personal data for scientific research and statistical purposes based on Article 89 of Regulation (EU) No. 2016/679 if meeting the conditions thereof, and provided that such personal data is not further processed outside scientific research and statistical purposes.</p> <p>HU:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>The conflicts between the current text and the GDPR need to be resolved as regards to further processing personal data based on the same legal basis for compatible purposes only.</p> <p>An explicit reference to Article 89 of the GDPR in the text of the Proposal could be a solution to this.</p>
<p><i>Article 55</i></p> <p><i>Measures for SME small-scale providers and users</i></p>	<p>IE:</p> <p>(Comments):</p> <p><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</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p><i>the AI ecosystem.</i></p> <p>BG:</p> <p>(Drafting):</p> <p><i>Measures for SME small-scale providers, start-ups and users</i></p> <p>BG:</p> <p>(Comments):</p> <p><u>Justification:</u> Incentives should be for both SMEs and start-ups along with users. There should be flexibility for Member States to decide on the incentives and the ones that could benefit from them depending on the market demand. Next, there should be a link to the “Digital Europe” Programme Regulation and the EDIHs established under</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>that programme aiming at fostering the penetration of the AI and the digitalisation of businesses across the EU</p> <p>PL:</p> <p>(Comments):</p> <p>DK:</p> <p>(Comments):</p> <p>We very much welcome this adjustment, as this was also part of our written comments for article 1 to 29.</p> <p>NL:</p> <p>(Comments):</p> <p>NL supports the change from small scale to</p>

Presidency compromise text	Drafting Suggestions Comments
	SME.
<p>1. Member States shall undertake the following actions:</p>	<p>BG:</p> <p>(Drafting):</p> <p>1. Member States shall, where possible, through the European Digital Innovation Hubs, undertake the following actions:</p> <p>SE:</p> <p>(Comments):</p> <p>55.1 (a) Do small-scale suppliers and start-ups get priority access to the regulatory sandboxes? How are priority given to critical or particularly important systems that law enforcement activities need to develop within regulatory sandboxes?</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>DK:</p> <p>(Comments):</p> <p>We are questioning why this is solely directed at member states. For example, the European Data Protection Supervisor can also establish a regulatory sandbox and thereby be relevant in terms of providing priority access to this.</p> <p>NL:</p> <p>(Drafting):</p> <p>1. Member States and the European Commission shall undertake the following actions:</p> <p>NL:</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>(Comments):</p> <p>The Netherlands would like to introduce a shared effort by member states and the European Commission to support SMEs across the EU. This improves the level playing field for SMEs as a result of synchronized guidance.</p>
	<p>HR:</p> <p>(Comments):</p> <p>The AI Act should encourage Member States to establish their own AI sandboxes while at the same time allow them the autonomy to establish rules and regulations for AI sandboxes established by Member State based SMEs, large enterprises and</p>

Presidency compromise text	Drafting Suggestions Comments
	other organizations and institutions dealing with artificial intelligence.
(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;	<p>PL:</p> <p>(Comments):</p> <p><i>Please explain what it means in Art. 55 sec. 1 lit. a - priority rule? It seems that it would be important to facilitate, such as lowering the fees (or costs of use) from a sandbox, the possibility of issuing an order to admit a small provider to a sandbox organized / managed by a large company and means of appeal in the event of refusal to admit to such a sandbox</i></p> <p>FI:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>It must be ensured that providing certain providers with priority access to the AI regulatory sandboxes does not result in discriminatory treatment between different providers.</p> <p>NL:</p> <p>(Drafting):</p> <p>(a) ensure that competent authorities and the EDPS provide small-scale SME providers including and start-ups with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions;</p> <p>NL:</p> <p>(Comments):</p> <p>Sandboxes are established by competent</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>authorities according to article 53 and this amendment ensures that priority access will be designed to fit into the modalities and the conditions of the operation of the AI regulatory sandboxes that will be established based on the procedure in article 53.6.</p> <p>AT:</p> <p>(Comments):</p> <p>In case Art. 53-55 apply as well to already existing “Regulatory Sandboxes” in the area of financial services, it would be of utmost importance that the current remit of such already existing “Regulatory Sandboxes” remains unchanged and that such already existing “Regulatory Sandboxes” can</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>continue with their current functions, tasks and procedures in order to promote technical innovation in the area of financial services.</p> <p>Consequently, such already existing “Regulatory Sandboxes” should at least be excluded from the application of Art. 55 para. 1 letter a.</p>
	<p>BG:</p> <p>(Drafting):</p> <p>(New letter) foster the participation of SMEs in the standardisation development process;</p>
(b) organise specific awareness raising activities about the application of this	ES:

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>Regulation tailored to the needs of the small-scale SME providers and users;</p>	<p>(Drafting):</p> <p>(b) organise specific awareness raising and training activities about the application of this Regulation tailored to the needs of the small-scale SME providers and users;</p> <p>ES:</p> <p>(Comments):</p> <p>Bespoken guidance for companies is an important concept to foster. Training is a way of doing so.</p> <p>BG:</p> <p>(Drafting):</p> <p>(b) organise specific awareness raising and enhanced digital skills development activities about the application of this</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Regulation tailored to the needs of the small-scale SME providers, start-ups and users for instance, through the European Digital Innovation Hubs (EDIHs);</p> <p>NL:</p> <p>(Drafting):</p> <p>(b) organise specific awareness raising activities about the application of this Regulation and the opportunities to engage in the European Digital Innovation Hubs and the Testing and Experimentation Facilities under the Digital Europe Programme, tailored to the needs of the small-scale SME providers and users;</p> <p>NL:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>This proposal establishes a concrete relation between the AI Act and the important opportunities offered to promote and enable innovation via the Digital Europe Programme and underlined in the coordinated action plan on AI, echoing recital 74.</p>
<p>(c) where appropriate, establish a dedicated channel for communication with small-scale SME providers and user and other innovators to provide guidance and respond to queries about the implementation of this Regulation.</p>	<p>BG:</p> <p>(Drafting):</p> <p>c) where appropriate, establish a dedicated channel for communication with small-scale SME providers, including start-ups and user and other innovators to provide</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>guidance and respond to queries about the implementation of this Regulation.</p> <p>PL:</p> <p>(Comments):</p> <p><i>What does it mean „where appropriate“ – in the context of establishing a dedicated channel for communication with small-scale providers and user and other innovators? Is it, for example, a situation where particular support is required due to difficulties with implementation of this Regulation?</i></p> <p><i>What should be the form of „dedicated channel of communication“- should EU Member States have freedom in this area?</i></p> <p>NL:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Drafting):</p> <p>(c) where appropriate, establish a dedicated channel for communication with small-scale SME providers and users and other innovators to provide guidance and respond to queries about the implementation of this Regulation.</p>
	<p>ES:</p> <p>(Drafting):</p> <p>(d) Publication of specific guidelines about the implementation of this Regulation</p>
<p>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,</p>	<p>BG:</p> <p>(Drafting):</p> <p>2. The specific interests and needs of the</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>reducing those fees proportionately to their size and market size.</p>	<p>small-scale SME providers, including start-ups shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size, and market size and market demand.</p> <p>SE:</p> <p>(Comments):</p> <p>See comment on article 30.8</p> <p>EE:</p> <p>(Comments):</p> <p>How should the MS comply with this obligation? How to guarantee the uniform application of this obligation and equal treatment of SMEs across the internal</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>market?</p> <p>HU:</p> <p>(Drafting):</p> <p>The specific interests and needs of the small-scale SME providers in relation to their size, annual turnover or similar indicator 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.</p> <p>HU:</p> <p>(Comments):</p> <p>To achieve the objective set out in Article 55 (1) a), it is worth considering adding a threshold to Article 55(2) e.g., based on the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>number of employees or annual turnover, to exempt the smallest companies and entrepreneurs from paying any fees related to the conformity assessment requirements of the Regulation.</p>
	<p>NL:</p> <p>(Drafting):</p> <p>3. The European Commission provides guidance to member states to support SMEs with implementation of this Regulation in the form of workshops, guidance documents and tools.</p> <p>NL:</p> <p>(Comments):</p> <p>NL proposes to include some specific</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>services by the European Commission to help member states to support SME providers to implement the regulation, increase common understanding and promote innovation.</p>
TITLE VI	
GOVERNANCE	<p>SK:</p> <p>(Comments):</p> <p>Slovakia believes we need to consider the depth and significance of challenges we face in designing a proper operational governance for the evolving, general-purpose and converging technology that AI represents. Slovakia does not consider the proposed AI Board powers and powers of</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>the European Commission sufficient and adequate to secure an effective and uniform enforcement of the proposed Artificial Intelligence Act.</p> <p>Innovative private actors already integrate and interlink their various dynamic AI-driven services/products and technologies and expand to new markets. Market surveillance and public support and guidance for innovation must respond to these new complexities, new speeds, volumes and scales.</p> <p>To master the complexities on a Union-wide basis, we need to start building a common well-equipped EU team which will be in charge of the enforcement of rules for AI technologies underpinning and driving all the above areas. We should consider</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>building a common specialized EU team and provide it with strong institutional cooperation/communication links with relevant national and EU authorities.</p> <p>Last but not least, the enforcement of the GDPR has given all member states lessons that a decentralized, national level enforcement in cyberspace has its considerable limitations. To make AI work for the EU, we need to take these lessons seriously. Multi-level and multi-national EU governance must not be our weakness but our strength.</p> <p>In Slovakia's non-paper distributed on 13 December 2021, we have introduced a more detailed description of possible variants of the governance design which can be further elaborated or even combined. Variants 1A</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>and 1B contained therein build upon the current European Commission's proposal which takes the product safety framework as its basis. Variant 2 is included in case we decide, in the course of our negotiations, to deviate from the product safety framework and opt for a regulatory and governance model resembling more the current European System of Financial Supervision (ESFS). Variant 2 may better reflect the dynamic nature of AI technology and data flows, while keeping the advantages of product safety framework for AI systems embedded in products.</p> <p>Given the dynamic developments in the digital sphere, we expect that in the future we may decide to broaden the scope of the proposed governance model to cover</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>resources and infrastructures on which AI directly depends or which are underpinned and driven by AI systems (i.e. data governance and cloud, digital platforms, augmented and virtual reality, Internet of Things and Internet of People). Already now, these fields and agendas are in use, requiring deep knowledge and fast responses, and are all closely inter-connected.</p> <p>For this purpose, an establishment of a (new) independent EU authority may be considered, but for now incorporating the necessary powers in the proposed AI Board or the European Commission can be considered as well. Notwithstanding all the mentioned possible institutional options, Slovakia sees no legal obstacles for</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>establishing an independent EU regulator/supervisor. Such an independent institution could be accountable to the European Parliament or even the Council and its mandate could in line with requirements set out in C-270/12 (p. 41 – 45, 53, 65, 66, 79, 86, 104, 105, 107, 108, 117) and C-521/15 (p. 43), decisions and other acts being subject to judicial review by CJEU (including acts which have no binding legal effect – see C- 911/19, p. 67 – 69).</p>
CHAPTER 1	
EUROPEAN ARTIFICIAL INTELLIGENCE BOARD	BE:

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>As mentioned in earlier comments relating to Article 7, Belgium believes that the Commission's power to adopt delegated acts to update the list of high-risk AI systems in Annex III, in the light of Article 7, goes too far and hence, further clarification as to other possibilities to amend this Annex is needed. In any case, additional clarifications are required and should be duly specified in the AIA, in particular, as to the relevant criteria, consultation procedures and implementation process when making use of this power.</p> <p>In this regard, a role could be given to the EU AI Board to identify cases for amendment of Annex III and, for</p>

Presidency compromise text	Drafting Suggestions Comments
	example, trigger such an amendment.
<p><i>Article 56</i> <i>Establishment of the European Artificial Intelligence Board</i></p>	<p>SK: (Comments): See general comment to Title VI above.</p> <p>PT: (Comments): Suggestions based upon the SK non-paper on revamping the governance model of the Regulation</p> <p>HU: (Comments): It should be stressed that the ways of working of the EAIB must be coherent with</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>other EU level boards to ensure harmonisation of legislation and to reduce regulatory burden. Additionally, the AI Regulation should ensure that the EAIB works collaboratively with and does not duplicate or undermine the work of the EDPB or the European Data Innovation Board foreseen under the upcoming Digital Governance Act.</p> <p>The competences of the EDPB and the EAIB shall be clearly separated.</p> <p>DK:</p> <p>(Comments):</p> <p>We are supportive of establishing a European Artificial Intelligence Board, as the board in our view will play a key role in</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>ensuring effective implementation and enforcement.</p> <p>However, we find that the key objective of the board must be to ensure the consistent application of the regulation – no matter whether advice and assistance should be directed to the member states or the Commission. Therefore, we are questioning why article 56(2) is solely focusing on providing advice and assistance to the Commission.</p> <p>In our view, a similar structure as article 70 in the GDPR could be preferred, as it states that “The Board shall ensure the consistent application of this Regulation. To that end, the Board shall, on its own initiative or, where relevant, at the request of the Commission ...”, then proceeding with the</p>

Presidency compromise text	Drafting Suggestions Comments
	different tasks which among others include advice and assistance to the Commission.
<p>I. A 'European Artificial Intelligence Board' (the 'Board') is established.</p>	<p>SE:</p> <p>(Drafting):</p> <p>hereby established as a body of the Union and shall have legal personality.</p> <p>SE:</p> <p>(Comments):</p> <p>We propose that the AIA follows the same structure and intent as the GDPR so that the European Artificial Intelligence Board mirrors the European Data Protection Board. This will lead to a number of changes. We are in line with EDPB in this:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>EDPB & EDPS call for ban on use of AI for automated recognition of human features in publicly accessible spaces, and some other uses of AI that can lead to unfair discrimination European Data Protection Board (europa.eu)</p>
<p>2. The Board shall provide advice and assistance to the Commission in order to:</p>	<p>PT:</p> <p>(Drafting):</p> <p>2. The Board shall promote and supervise the correct application of this Regulation as well as provide advice and assistance to the Commission in order to:</p> <p>CZ:</p> <p>(Drafting):</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>CZ:</p> <p>(Comments):</p> <p>The role and competences of the Board requires further consideration and update. MS and the Board should be more directly involved in the process of amending the parts of this Regulation. Further discussion on how to achieve this and incorporate it to the text should take place.</p>
<p>(a) contribute to the effective cooperation of the national supervisory authorities and the Commission with regard to matters covered by this Regulation;</p>	

Presidency compromise text	Drafting Suggestions Comments
<p>(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;</p>	
<p>(c) assist the national supervisory authorities and the Commission in ensuring the consistent application of this Regulation.</p>	
	<p>ES:</p> <p>(Drafting):</p> <p>(d) Provide with guidance material to operators, in particular when they are SMEs or start-ups, regarding the compliance of the obligations set out in this Regulation.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(e) carry out annual reviews and analyses of the complaints sent to and findings by national competent authorities, of the serious incidents and malfunctioning reports referred to in Article 62, and of the new registration in the EU Database referred to in Article 60 to identify trends and potential emerging issues threatening the future health and safety and fundamental rights of citizens and not adequately addressed by this Regulation; to carry out biannual horizon scanning and foresight exercises to extrapolate the impact these trends and emerging issues can have on the Union; and to annually publish recommendations to the Commission, including but not limited to recommendations on the categorization of prohibited practices, high-risk systems, and</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>codes of conduct for AI systems that are not classified as high-risk.</p> <p>3. The Board will be able to count with personnel for assistance in the proper performance of their tasks.</p> <p>4. The Board shall be organised and operated so as to safeguard the independence, objectivity and impartiality of their activities. The Board shall document and implement a structure and procedures to safeguard impartiality and to promote and apply the principles of impartiality throughout its activities.</p> <p>ES:</p> <p>(Comments):</p> <p>- Guidance for operators is crucial for</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>companies to be able to comply with regulation.</p> <ul style="list-style-type: none"> - Reviews of information will help enforcement, to monitor the market and main risks and general information for improving any AIA related action. - The Board will need assistance for some of its duties. This assistance might be obtained from experts, academia, but also hiring consulting or support services.
<p><i>Article 57</i> <i>Structure of the Board</i></p>	<p>SK:</p> <p>(Comments):</p> <p>See general comment to Title VI above.</p>
<p>1. The Board shall be composed of the national supervisory authorities, who shall</p>	<p>IT:</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
<p>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.</p>	<p>(Comments):</p> <p>The European Data Protection Supervisor could be invited but shall not be part of the Board <i>per se</i>.</p> <p>SE:</p> <p>(Drafting):</p> <p>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, the European Data Protection Supervisor and the Commission.</p> <p>EE:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Could you please explain why high-level representation is necessary?</p> <p>NL:</p> <p>(Drafting):</p> <p>and the European Data Protection Supervisor. The EDPS functions as a the competent authority for their supervision as per article 59.8 and article 71</p> <p>NL:</p> <p>(Comments):</p> <p>In this article is not really clear what the role is of the EDPS. Therefore, we suggest to refer to article 59.8 and 71, where the role of the EDPS is described.</p>

Presidency compromise text	Drafting Suggestions Comments
<p>2. The Board shall adopt its rules of procedure by a simple majority of its members, following the consent of the Commission. The rules of procedure shall also contain the operational aspects related to the execution of the Board's tasks as listed in Article 58. The Board may establish sub-groups as appropriate for the purpose of examining specific questions.</p>	<p>DK:</p> <p>(Comments):</p> <p>We are questioning why the procedures of the board would need a subsequent consent of the Commission, if a simple majority between the members have already been established. This would in our view result in a veto right for the Commission which we do not find proportionate.</p> <p>NL:</p> <p>(Drafting):</p> <p>The Board shall adopt its rules of procedure by a simple qualified majority of its members, following the consent of in</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>alignment with the Commission. The rules of procedure shall also contain the operational aspects related to the execution of the Board's tasks as listed in Article 58. The Board may establish sub-groups as appropriate for the purpose of examining specific questions.</p> <p>NL:</p> <p>(Comments):</p> <p>In case of a simple majority, there is a major risk that almost half the MS might not agree with certain guidance. Especially with very disputable issues, a simple majority is undesirable. With a much larger majority, sufficient acceptance of guidance will be received.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Besides, if we read this article correctly, the article assigns a veto-right to the Commission regarding the rules of procedure. This seems to go beyond the usual set-up for this type of Boards in other regulations. Do we interpret this correctly, and if yes, why is this deemed necessary?</p> <p>The rules of procedure will also cover the voting rules of the Board, through the above veto-right the Commission has the opportunity to de facto dictate the voting rules.</p>
	<p>BG:</p> <p>(Drafting):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(New sentence at the end of the paragraph) Where relevant, stakeholders, including SMEs and smaller providers, shall take part in the work of the sub-groups.</p> <p>BG:</p> <p>(Comments):</p> <p><u>Justification:</u> a similar approach with the involvement of relevant stakeholders has been taken for the European Data Innovation Board under Data Governance Act. Moreover, as far as data requirements are concerned interaction between the two Boards should be envisaged.</p>
<p>3. The Board shall be chaired by the Commission. The Commission shall convene the meetings and prepare the</p>	<p>SE:</p> <p>(Drafting):</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>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.</p>	<p>The Board shall elect a chair and two deputy chairs from amongst its members by simple majority.</p> <p>The term of office of the Chair and of the deputy chairs shall be five years and be renewable once.</p> <p>HU:</p> <p>(Drafting):</p> <p>The Commission shall convene the meetings and prepare the draft agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure in due time for the Members of the Board to respond and propose additional items.</p> <p>HU:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>Article 57 (3) suggests that the EAIB does not have the competence to define its own agenda and issues to be discussed, as this task is given to the Commission. The Proposal should give broader autonomy to the EAIB as to what issues it may discuss in its meetings, which would increase the independence of the EAIB's procedure.</p> <p>NL:</p> <p>(Drafting):</p> <p>The Board shall be chaired by the Commission one of the NSA (it can be rotated every 6 months) . The Commission chair chair shall convene the meetings and</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>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</p> <p>NL:</p> <p>(Comments):</p> <p>The Board is also an advisory board for the EC and the Commission is also the secretary. This already makes the role of the Commission towards the Board quite strong. The role of the Board and its independence is better served by a NSA as the chair.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>SE:</p> <p>(Drafting):</p> <p>3 bis. The composition of the Board is to be gender balanced.</p> <p>SE:</p> <p>(Comments):</p> <p>According to adopted CCs on the impact of AI on Gender Equality in the Labour Market, the Commission is to promote gender balance in research, education and training and in employment in jobs that involve work in the field of AI.</p>
4. The Board may invite external experts and observers to attend its meetings and	HU:

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>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.</p>	<p>(Comments):</p> <p>The AI Regulation should specify the composition of the EAIB and the role of “<i>external experts</i>” in Article 57 (4) more precisely.</p> <p>DK:</p> <p>(Comments):</p> <p>Besides inviting external experts and observers to attend meetings, we would call for a more formal consultation procedure between the board and interested parties. Such a consultation could prove important, especially when it comes to issuing guidelines and recommendations within a fast-evolving technology as AI.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>ES:</p> <p>(Drafting):</p> <p>5. The Board may take into account the opinion of research centers, private actors and operators for the purpose of having a more comprehensive information when developing the tasks listed in article 58..</p> <p>6. For the purpose of developing the provisions established in article 74, the Board will act as the committee established in paragraph 1 of such article.</p>
<p><i>Article 58</i> <i>Tasks of the Board</i></p>	<p>SK:</p> <p>(Comments):</p> <p>See general comment to Title VI above.</p>

Presidency compromise text	Drafting Suggestions Comments
<p>When providing advice and assistance to the Commission in the context of Article 56(2), the Board shall in particular:</p>	<p>PT:</p> <p>(Drafting):</p> <p>When providing advice and assistance to the Commission in the context of Article 56(2), the Board shall in particular:</p> <p>SE:</p> <p>(Drafting):</p> <p>When providing advice and assistance to the Commission in the context of Article 56(2), the Board shall in particular:</p> <p>SE:</p> <p>(Comments):</p> <p>The tasks of the Board will need to be</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>adjusted in respect to the other proposed changes that involves the mandate and tasks of the Board, such as addressed in art. 32.</p> <p>DK:</p> <p>(Comments):</p> <p>We would again highlight that advice and assistance to the Commission should be part of the board's tasks but should not be the overlying focus. We would refer to our suggestion in article 56.</p> <p>Furthermore, the list of tasks should be further specified, especially in terms of guidance which is needed before the regulation is applicable.</p> <p>In general, preparation of practical guidance should be further reflected in the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>regulation. For example, one practical tool would be a horizontal assessment tool, especially targeted at SMEs, which would enable providers and users to quickly clarify whether they would be subject to the requirements of high-risk AI.</p>
<p>(a) collect and share expertise and best practices among Member States;</p>	<p>CZ: (Drafting): (a) collect and share expertise and best practices among Member States and relevant stakeholders;</p> <p>HU: (Drafting): "share technical and regulatory expertise"</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>HU:</p> <p>(Comments):</p> <p>It should be specified that the technical as well as from the regulatory views are considered.</p>
<p>(b) contribute to uniform administrative practices in the Member States, including for the functioning of regulatory sandboxes referred to in Article 53;</p>	<p>BG:</p> <p>(Drafting):</p> <p>“.....including for the functioning of regulatory sandboxes referred to in Article 53 and Article 54;</p> <p>BG:</p> <p>(Comments):</p> <p><u>Justification:</u> consistency, same approach</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>for all possible sandboxes</p> <p>HU:</p> <p>(Comments):</p> <p>It should be made clear whether Point b) of Article 58 means that, in fact, the EAIB becomes an “oversight body” of the regulatory sandboxes referred to in Article 53.</p>
<p>(c) issue opinions, recommendations or written contributions on matters related to the implementation of this Regulation, in particular</p>	<p>IT:</p> <p>(Comments):</p> <p>Opinions, recommendations and written contributions shall include proposals of delegated acts.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>HU:</p> <p>(Comments):</p> <p>It should be clarified, whether the EAIB's advice, recommendations, opinions, or any other form of assistance have any binding effect for the Commission.</p>
<p>(i) on technical specifications or existing standards regarding the requirements set out in Title III, Chapter 2,</p>	<p>ES:</p> <p>(Drafting):</p> <p>(i) on technical specifications, or existing standards and ways of reaching an appropriate compliance with regarding the requirements set out in Title III, Chapter 2,</p> <p>BG:</p>

Presidency compromise text	Drafting Suggestions Comments
	(Comments): PL: (Comments):
(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-;	

Presidency compromise text	Drafting Suggestions Comments
	<p>ES:</p> <p>(Drafting):</p> <p>(iv) on concrete procedures to be performed by operators under the implementation of this Regulation, in particular those regarding the documentation they have to deliver to notified bodies, the methods for performing the conformity assessment based on internal control and methods to provide authorities with other relevant information.</p> <p>ES:</p> <p>(Comments):</p> <p>There is a risk of SMEs not having capacity to comply with this Regulation and therefore, not participating in the development of certain AI systems. The difference between companies being able to put into market those systems or not is their</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>ability to pay expensive consultants. In this regard, putting at their service their board could dampen this effect.</p> <p>We know that this may seem redundant with other provisions, but there is a need for an important emphasis here.</p>
<p>(d) issue an advisory opinion on the need for amendment of Annex I and Annex III, including in light of available evidence.</p>	<p>BE:</p> <p>(Comments):</p> <p>Cf. our earlier comment on the possible role of the EU AI Board <i>re</i> triggering the modification of Annex III in addition to issuing an advisory opinion when such an amendment is proposed by the Commission.</p> <p>PT:</p> <p>(Drafting):</p> <p>(d) submit to the Commission proposed</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>delegated acts referred to in articles 4, 7, 11, 43 and 48 as well as implementing acts of this Regulation;</p> <p>CZ:</p> <p>(Comments):</p> <p>It goes in the right direction but the topic of further strengthening the role of the AI Board in relation to any amendments should be discussed in the future. Amending these important parts of the regulation is a sensitive point for numerous MS and it should be carefully considered.</p> <p>DK:</p> <p>(Comments):</p> <p>We are still assessing this adjustment. In our</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>view, it is part of the wider discussion on the definition and high-risk as well as the usage of delegated acts in order to find the right approach.</p>
	<p>PT:</p> <p>(Drafting):</p> <p>(e) participate in the derogation from conformity assessment procedures as per article 47, at the request of Member States or of its own initiative;</p> <p>(f) access the EU database referred to in Article 60;</p> <p>(g) analyse serious incidents and malfunctionings, referred to in article 62 and issue opinions thereabout;</p> <p>(h) take part in the procedures referred to in</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>articles 65, 66 and 67, alongside the Commission;</p> <p>(i) cooperate with relevant EU and national authorities in the fields of cybersecurity, competition, financial services, financial payments, cryptocurrencies, consumer protection, data and fundamental rights protection;</p> <p>(j) operate testbeds and test groups for continuous policy prototyping;</p> <p>(k) issue guidance and manuals for the proper implementation of this Regulation;</p> <p>(l) organise training sessions for staff of Member States involved in implementing this Regulation.</p>

Presidency compromise text	Drafting Suggestions Comments
CHAPTER 2	
NATIONAL COMPETENT AUTHORITIES	
<p><i>Article 59</i></p> <p><i>Designation of national competent authorities</i></p>	<p>IE:</p> <p>(Comments):</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>FI:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>What is the relation between this article and article 30?</p> <p>CZ:</p> <p>(Comments):</p> <p>When deciding about the date of application, various deadlines and assigning obligations for competent authorities, it will be necessary to take into account the amount of time needed for setting up a national authority, to find and train relevant experts and also the limited financial resources, especially in the disposal of middle-sized and small countries.</p> <p>Authorities are already busy with complying with obligations based on existing legislation with many more to come in the</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
	<p>near future.</p> <p>DK:</p> <p>(Comments):</p> <p>We are supportive that this is based – to a large extent - on existing national structures and it is important that member states retain the right to determine the best organization at national level.</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</p>	<p>PL:</p> <p>(Comments):</p> <p><i>It should be noted that the regulation is too succinct. The features of the authority should also be supplemented with independence- they should not be limited to</i></p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>activities and tasks.</p>	<p><i>objectivity and impartiality</i></p> <p>SE:</p> <p>(Comments):</p> <p>It is important that it remains the choice of each member state to designate (or establish) the national competent authorities.</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 unless a Member State has organisational and administrative reasons to designate more than one authority.</p>	<p>ES:</p> <p>(Drafting):</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
	<p>unless a Member State has organisational and administrative reasons to designate more than one authority. The national supervisory authority will be provided with the competence of coordinating the action of other national authorities with regards the compliance of this Regulation and its fit with other legislation in force. Additionally, the National Supervisory Authority may act as a one-stop-shop regarding information to be taken into account for complying with different legislation affecting the development of AI systems, and the cases where a product falls within the mandate of a given authority.</p> <p>ES:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>The risk for companies to receive overlapped requirements for public authorities is real. A coordination in this regard is required and the national supervisory authority is best placed for this purpose (coordination with data protection agencies, other bodies such as drug agencies – responsible in Spain for Medical Devices Regulation conformity assessments, or others).</p> <p>It is also important that the NSA provides all actors in the AI ecosystem regarding the obligations they have to fulfill with regards legislation.</p> <p>SK:</p> <p>(Comments):</p> <p>In order to ensure institutional flexibility for supervision of stand-alone AI systems, it should be possible for member states to designate as “market surveillance authorities” also national authorities other than those already designated under reg.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>2019/1020 and those under article 63 (3) – (5). Definition in article 3 subsection (26) should be adjusted accordingly.</p> <p>PL:</p> <p>(Comments):</p> <p><i>There is no reference to the authority's competence in terms of coherence of its activity in the EU - the coordination aspect of activities is a very important issue, especially in case of potential divergences in the interpretation of the provisions of the Regulation.</i></p> <p><i>Which authority may be designated as the national competent authority to ensure the application and implementation of this Regulation to high-risk systems in the area</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p><i>of law enforcement and migration, asylum and border control management? How should the impartiality of these authorities be understood in the face of the need to maintain the confidentiality of the activities of law enforcement, border and migration services, and to respect the protection and integrity of security and public order?</i></p> <p>SE:</p> <p>(Drafting):</p> <p>The national supervisory authority may shall act as notifying authority and market surveillance authority if above principles</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>can be ensured and unless a Member State has organisational and administrative reasons to designate more than one authority.</p> <p>SE:</p> <p>(Comments):</p> <p>This is contradictory to article 59.1, there must be a distinction between the notifying authority and the market surveillance authority in order to ensure objectivity and impartiality of their activities and tasks. Usually the notifying authority has the competence to designate the conformity assessment bodies through accreditation and separate from the market surveillance activities. In Sweden, the notifying authority</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>for most harmonised sectors is separate from the market surveillance authority.</p> <p>What is the role of the “national supervisory authority” in relation to the “notifying authority” regulated in art. 30?</p> <p>HU:</p> <p>(Comments):</p> <p>It should be ensured by the AI Regulation, that regardless the form of the national competent authorities (whether standalone, newly established organisation or part of an already existing one), all national competent authorities have the same competences to carry out the tasks set out in the AI Regulation, e.g., issuing binding guidelines or sanctioning powers.</p>

Presidency compromise text	Drafting Suggestions Comments
<p>3. Member States shall inform the Commission of their designation or designations and, where applicable, the reasons for designating more than one authority.</p>	<p>SE:</p> <p>(Drafting):</p> <p>3. Member States shall inform the Commission of their designation or designations and, where applicable, the reasons for designating more than one authority.</p> <p>NL:</p> <p>(Drafting):</p> <p>Member States shall inform the Commission of their designation or designations and, where applicable, the reasons for designating more than one</p>

Presidency compromise text	Drafting Suggestions Comments
	authority.
<p>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.</p>	<p>SK: (Comments): The estimated impacts in the EC's impact assessment (up to 25 FTE) are inadequate and underestimated. Slovakia requests these to be re-assessed and re-calculated.</p> <p>HR: (Comments): One can already envisage potential difficulties in countries where there are a great number of different national competent authorities regarding data, consumer, competition protection</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>authorities, labour inspectorates, financial and health sector regulators, equality body, etc. They have different competences and mandates and separate and different working methods and data bases. There should be joint databases concerning AI systems and their usage between competent authorities, as well as close and formalised cooperation.</p> <p>SE:</p> <p>(Drafting):</p> <p>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</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>technologies, data and data computing, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements.</p> <p>SE:</p> <p>(Comments):</p> <p>Is it not sufficient to ensure that competent authorities are provided with adequate resources to fulfil their tasks under this Regulation? The details concerning the <i>how</i> should not be controlled in the Regulation.</p> <p>DK:</p> <p>(Comments):</p> <p>We find the paragraph at hand as well as the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>following too detailed in terms of organisation, also when comparing to existing legislation.</p> <p>NL:</p> <p>(Drafting):</p> <p>In particular, national competent authorities shall have a sufficient number of human resources available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements.</p> <p>NL:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>There needs to be some flexibility regarding sharing of expertise between national competent authorities (such as resource pools). Restricting human resources to 'personnel' and requiring that staff is 'permanently' available is unnecessarily prescriptive.</p>
<p>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</p>	<p>SE:</p> <p>(Drafting):</p> <p>Member States shall report to the European Artificial Intelligence Board on an annual basis on the status of the financial and human resources of the national competent</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>recommendations.</p>	<p>authorities with an assessment of their adequacy. The Commission shall transmit that information to the Board for discussion and possible recommendations.</p> <p>SE:</p> <p>(Comments):</p> <p>Are these types of reports of such importance that they motivate the administrative burden put on the competent authorities?</p> <p>CZ:</p> <p>(Comments):</p> <p>Oversight over financial and human resources is normally done internally under the sole competence of MS in relation to</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Article 59(1). Added value of this provision is rather unclear.</p> <p>DK:</p> <p>(Comments):</p>
<p>6. The Commission shall facilitate the exchange of experience between national competent authorities.</p>	
<p>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</p>	<p>PL:</p> <p>(Comments):</p> <p><i>The relationship between the guidance and advice provided by national competent authorities and the "special communication</i></p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>advice with regard to an AI system in areas covered by other Union legislation, the competent national authorities under that Union legislation shall be consulted, as appropriate. Member States may also establish one central contact point for communication with operators.</p>	<p><i>channel" referred to in Art. 55, section 1, lit. c. Should they be understood as separate mechanisms and, if so, how should "used cases" requiring a dedicated communication channel be distinguished from the normal procedure for providing advice and guidance to actors on the implementation of the Regulation?</i></p> <p>SE:</p> <p>(Drafting):</p> <p>National competent authorities may shall provide guidance and advice on the implementation of this Regulation, including tailored to small-scale SME providers.</p> <p>SE:</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>(Comments):</p> <p>Due to the complexity of the regulation it is important that providers receive advice where needed with regards to implementation so that they may remain competitive.</p> <p>DK:</p> <p>(Comments):</p> <p>We welcome this adjustment to include all SME providers</p>
<p>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.</p>	

Presidency compromise text	Drafting Suggestions Comments
TITLE VII	
<p>EU DATABASE FOR STAND-ALONE HIGH-RISK AI SYSTEMS</p>	<p>BE:</p> <p>(Comments):</p> <p>The creation of a database for high-risk AI systems deployed in the EU is a welcomed development, as it provides for more transparency that can benefit both public and private enforcement of the AIA and of fundamental rights that can potentially be breached by the use of AI.</p>
<p><i>Article 60</i> <i>EU database for stand-alone high-risk AI systems</i></p>	<p>PL:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p><i>In connection with art. 51 - in the case of high-risk systems used for law enforcement purposes, if the system provider is a public entity, e.g. the Police, it needs to be considered whether it is justified to enter a natural person - an authorized representative in the EU database. The description of the purpose of the system for these systems should be limited.</i></p> <p>SE:</p> <p>(Comments):</p> <p>SE have concerns regarding the extensive reporting requirements and the handling of this information which include confidential and other proprietary information.</p> <p>Important to safeguard confidentiality of</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>proprietary information from e.g. competitors.</p> <p>CZ:</p> <p>(Comments):</p> <p>Due to security reasons, registration of AI systems in the areas of law enforcement and migration, asylum and border control management and AI systems used to manage and operate critical infrastructure should not be mandatory or, at least, should be more limited. Alternatively, public access should be limited. This concerns, in particular, the information pursuant to points 5 and 9 of Annex VIII. There are substantial operational reasons for restricting information on precise technical</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>capabilities of law enforcement.</p> <p>NL:</p> <p>(Comments):</p> <p>Please specify when the data base should be filled, modified, etc. and how the responsibilities are arranged in particular with regards to the responsibility of the member states.</p>
<p>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>	<p>IE:</p> <p>(Comments):</p> <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</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p><i>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> <p>PT:</p> <p>(Comments):</p> <p>See comment to article 51</p> <p>IT:</p> <p>(Comments):</p> <p>Could the Commission specify terms and procedures of developing the EU database ?</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>SE:</p> <p>(Comments):</p> <p>Dual-use high-risk AI systems developed or used for military or national security purposes will be registered in this database, since art. 2.3 only excludes "AI systems developed or used <u>exclusively</u> for military or national security purposes". This articles must be considered in relation to the writings in art. 2.3.</p> <p>DK:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>We are still assessing the different approaches between systems in annex 2 which do not have to register and systems in annex 3 which must register – also in terms of whether the same kind of information would be public accessible for both systems.</p> <p>However, it is important that the database is integrated with other existing databases establish by the Commission such as EUDAMED under the MDR. Otherwise, actors will be required to register in multiple places.</p> <p>NL:</p> <p>(Drafting):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>to in Article 6(2) which are registered in accordance with Article 51. This obligation shall not apply to AI systems used by law enforcement to detect, prevent, investigate and prosecute criminal offences including the safeguarding against and the prevention of threats to public security, under the control and responsibility of the competent authorities when publication may hinder criminal prosecution or ongoing investigations, insofar and as long as, proportional, appropriate and necessary for these purposes.</p> <p>NL:</p> <p>(Comments):</p> <p>Maximum transparency should also be</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>aimed for in the context of law enforcement (LEA). However, the publication of AI-systems used within the LEA-context should not be disclosed to the public if this could lead to the hindering of criminal prosecution, ongoing investigations etc. (e.g. gaming the system). Examples are tools for specific projects with a limited time scope.</p>
<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.</p>	<p>PT:</p> <p>(Drafting):</p> <p>2. The data listed in Annex VIII shall be entered into the EU database by the providers, or where applicable by the authorised representative. The Commission</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>shall provide them with technical and administrative support.</p> <p>PT:</p> <p>(Comments):</p> <p>The text in red was added to be in line with article 51</p> <p>IT:</p> <p>(Comments):</p> <p>Please specify who is in charge of entering the providers into the database and clarify</p> <p>which are the consequences, in the case of providers not entering the overall data requested.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>SE:</p> <p>(Comments):</p> <p>The registration of every high-risk AI-system across the whole Union could be of interest to malicious activities. Therefore, the technical and administrative data listed in Annex VIII that shall be entered into the EU database needs to be kept restrictive and relatively unmodified over time.</p> <p>FI:</p> <p>(Comments):</p> <p>Should point 2 be supplemented with a deadline?</p> <p>DK:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>In terms of information which the provider is required to register in the EU database, this also include information of member states in which the AI system is or has been placed on the market. We recognize that such information would be important in terms of enforcement, but the question is whether the provider would always know where the user will deploy the system.</p> <p>Furthermore, electronic instruction needs to be provided, whereas some areas such as law enforcement and migration, asylum and border control management are excluded from this requirement. However, we are wondering why some areas are excluded, whereas others are not, for example such as</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>critical infrastructure.</p> <p>NL:</p> <p>(Comments):</p> <p>For law enforcement authorities, no personal data should be entered in the database in case the LEA is a provider.</p>
<p>3. Information contained in the EU database shall be accessible to the public.</p>	<p>ES:</p> <p>(Drafting):</p> <p>3. Information contained in the EU database shall be accessible to the public, except for AI systems listed in point 1(a) in so far as the systems are used for law enforcement purposes, and points 6 and 7 of</p>

Presidency compromise text	Drafting Suggestions Comments
	<p data-bbox="745 440 887 469">Annex III.</p> <p data-bbox="745 509 801 537">ES:</p> <p data-bbox="745 596 920 625">(Comments):</p> <p data-bbox="745 668 1301 810">We believe that HRAIS used by Law Enforcement Authorities (LEAs) should of course be included in the data base.</p> <p data-bbox="745 834 1319 1086">Nevertheless, information of HRAIS used by LEAs should not be inherently accessible to the public. Its access should be restricted in order to preserve certain sensitive information.</p> <p data-bbox="745 1129 801 1158">BE:</p> <p data-bbox="745 1217 920 1246">(Comments):</p> <p data-bbox="745 1289 1319 1377">Link with uncertainty about which general rules apply or do not apply to law</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>enforcement - It is not clear which part (all?) of the information of the EU database shall be made public. For law enforcement, exceptions to publication of some information about registered AI systems should be possible, on initiative by the competent market surveillance authority.</p> <p>FI:</p> <p>(Comments):</p> <p>It must be ensured that the registration to a public database is safe taking into account the sensitive nature of high-risk AI systems.</p>
<p>4. The EU database shall contain personal data only insofar as necessary for collecting and processing information in</p>	<p>NL:</p> <p>(Drafting):</p>

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<p>accordance with this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider.</p>	<p><i>Option 1</i></p> <p>4. The EU database shall contain no personal data, except for the information as listed in Annex VIII only insofar as necessary for collecting and processing information in accordance with this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider.</p> <p><i>Option 2</i></p> <p>4. The EU database shall contain no personal data, only insofar as necessary for collecting and processing information in accordance with this Regulation. That information which shall include the names</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider.</p> <p>NL:</p> <p>(Comments):</p> <p>The suggestions for the database not to include any personal data, except for what is listed in Annex VIII follows from the principle of data minimalisation from the GDPR.</p> <p>How does the exemption 'this information shall not be provided for high-risk AI systems in the areas of law enforcement (...) ' relate to the exception regarding tax and customs authorities, laid down in</p>

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	preamble no. 38? Publication of these electronic instructions of use by tax and custom authorities might encourage misuse ('gaming the system').
5. The Commission shall be the controller of the EU database. It shall also ensure to providers adequate technical and administrative support.	IT: (Comments): Please clarify who is the subject responsible for maintenance and updating the database. Please clarify the role of the national authorities involved in.
TITLE VIII	

Presidency compromise text	Drafting Suggestions Comments
POST-MARKET MONITORING, INFORMATION SHARING, MARKET SURVEILLANCE	ES: (Drafting): POST-MARKET MONITORING, INFORMATION SHARING, MARKET SURVEILLANCE AND COMPLAINT PROCEDURE
CHAPTER 1	
POST-MARKET MONITORING	
<i>Article 61</i> <i>Post-market monitoring by providers and post-market monitoring plan for high-risk</i>	ES:

Presidency compromise text	Drafting Suggestions Comments
<i>AI systems</i>	<p>(Comments):</p> <p>LEAs should have a particular treatment in this article</p> <p>BE:</p> <p>(Comments):</p> <p>Link with uncertainty about which general rules apply or do not apply to law enforcement - It is not clear what the implications will be for law enforcement authorities when they use on-the shelf AI systems sold by providers, since there are legal restrictions for sharing law enforcement data and procedures.</p> <p>PL:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p><i>1. The imposition of the above-mentioned obligation on credit institutions (banks) seems excessive, considering that in relation to none of the other cases specified no such obligation is provided for in Annex III. It would also be appropriate to balance these obligations proportionally for institutions of public funds.</i></p> <p><i>2. In the case of high-risk systems dedicated to law enforcement and the management of migration, asylum and border control, post-market monitoring of the operation of the system may not be possible and appropriate due to the specific tasks performed by the competent national authorities in the field of security and public order and the risk of</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p><i>disclosure of information, e.g. on operational activities undertaken by officers. It is not clear how it would be appropriate to ensure the possibility of an artificial intelligence system provider to assess whether the system consistently meets the requirements of Chap. II, without revealing sensitive data or classified information, e.g. in the case of the system for migration services to analyze migration risks and migrant smuggling routes</i></p> <p>DK:</p> <p>(Comments):</p> <p>It is still unclear what such a system as well as plan are meant to consist of and how this would work in practice. It would be helpful</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>to receive some kind of examples which showcase this more in detail.</p> <p>NL:</p> <p>(Comments):</p> <p>For post-market monitoring, it is important that the impact and feasibility of the proposed obligation is clear. Oftentimes, AI systems, especially when integrated in a product, is hard to monitor. Against this background, a post-market monitoring obligation laid down in art. 61 should focus on requirements that are necessary to provide appropriate level of protection against risks and can be met by a provider of high-risk AI systems.</p>

Presidency compromise text	Drafting Suggestions Comments
<p>1. Providers shall establish and document a post-market monitoring system in a manner that is proportionate to the nature of the artificial intelligence technologies and the risks of the high-risk AI system.</p>	<p>EE:</p> <p>(Comments):</p> <p>How does this obligation relate to the obligation in the Article 9 to establish a risk management system?</p> <p>DK:</p> <p>(Comments):</p> <p>This formulation is unclear, as it both refers to the nature of AI technologies and the risks of the high-risk AI system. It should be clarified that the post-market monitoring system is solely meant to cover the high-risk system.</p>
<p>2. The post-market monitoring system</p>	<p>ES:</p>

Presidency compromise text	Drafting Suggestions Comments
<p>shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.</p>	<p>(Comments):</p> <p>AI systems used for Law enforcement/police should have a specific paragraph, in accordance with its nature.</p> <p>BE:</p> <p>(Comments):</p> <p>'Lifetime' of an AI system should be further specified.</p> <p>BG:</p> <p>(Drafting):</p> <p>"The post-market monitoring system shall actively and systematically include activities to receive, collect, document and</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>analyse relevant data provided by users under Art. 29 or ...and allow the provider to evaluate the continuous compliance of AI systems...”</p> <p>BG:</p> <p>(Comments):</p> <p><u>Justification:</u> According to Art. 29 users are tasked to inform the providers only in cases when the system presents a risk for “serious incidents/malfunctioning” and not on a regular basis throughout the lifetime of the system. At the same time, paragraph 2 of this article obliges the providers to proactively/actively and systematically collect, document, analyse relevant data provided by the users, but the initiative</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>belongs to the users. Therefore, excessive burden for providers should be avoided</p> <p>SE:</p> <p>(Drafting):</p> <p>2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.</p> <p>SE:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>It presents challenges to both design and develop a system that has the desired functions alone but to be able to also implement active collection and analytical features sets the bar to high and imposes difficulties. This is best done with an independent IT-system with the sole purpose of doing just that.</p> <p>Propose a new text that makes it more realistic to achieve the intent.</p> <p>HU:</p> <p>(Drafting):</p> <p>2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>sources on the performance of high-risk AI systems – excluding the high-risk AI systems performing in law enforcement – throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.</p> <p>The post-market monitoring system shall actively and systematically collect, document and analyse relevant data necessary for the assessment of the proper functioning of the AI system – if possible in anonymized form – provided by users or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>compliance of AI systems with the requirements set out in Title III, Chapter 2.</p> <p>HU:</p> <p>(Comments):</p> <p>The text should better define what is to be considered “<i>relevant data</i>” under Article 61 (2).</p> <p>The current text of Article 61 (2) the post-market monitoring system results in excessive collection and re-use of data, including personal data, therefore we propose to limit the scope of “<i>relevant data</i>”.</p> <p>DK:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>It is necessary to define how a system's lifetime is to be understood. Such definition would also be important in terms of for how long a provider would be required to have such a monitoring system and plan in place.</p>
	<p>BG:</p> <p>(Drafting):</p> <p>Art. 3 (25) "post-market monitoring" means all activities carried out by providers of AI systems to proactively receive, collect and review experience gained from.....</p>
<p>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</p>	<p>BG:</p> <p>(Drafting):</p> <p>"3. The post-market monitoring system shall be based on a post-market monitoring</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>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.</p>	<p>plan.”</p> <p>BG:</p> <p>(Comments):</p> <p><u>Justification:</u> There is no notion to “system” in the definition and hence, no need to make an explicit reference to it</p> <p>SE:</p> <p>(Comments):</p> <p>It is of great importance that the administrative burden be kept at a minimum.</p> <p>DK:</p> <p>(Comments):</p> <p>It is important that providers receive</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>guidance on how to comply with this requirement. In the medical device regulation, the elements of the surveillance plan – which is similar to the AI Act’s monitoring plan – is specified directly in an annex.</p>
<p>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.</p>	<p>BG: (Drafting):</p> <p>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.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>BG:</p> <p>(Comments):</p> <p>“Plan” should be enough although its availability depends on the information provided by the users</p> <p>HU:</p> <p>(Drafting):</p> <p>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 the post-market monitoring documentation as prepared under that</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>legislation shall be deemed sufficient.</p> <p>HU:</p> <p>(Comments):</p> <p>Given that sectoral legislation (as listed in Annex II) already provides for well-established, accepted and known post-market monitoring mechanisms, this obligation would put administrative burden on organisations already complying with said sectoral legislation.</p> <p>AT:</p> <p>(Comments):</p> <p>We welcome the approach that a number of new requirements according to this Regulation shall be integrated into the</p>

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	<p>existing obligations and procedures under Directive 2013/36/EU, as it is stipulated in Art. 9 (9), 17 (3), 18 (2), 19 (2), 20 (2), 29 (4) and (5), 43 (2), 61 (4) and 62 (3) of the Regulation on AI.</p> <p>However, in the same context, it must be highlighted that it is more than probable that the Regulation on AI will not only be applicable to credit institutions but (at least eventually) also to a number of other financial service providers, such as for instance insurance undertakings or investment firms. Annex III No. 5 letter d of the Regulation, as it was added in the first Presidency compromise proposal, already introduces high-risk “<i>AI systems intended to be used for insurance premium setting,</i></p>

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	<p><i>underwritings and claims assessments”</i> which subsequently results in the inclusion of insurance undertakings in the scope of the Regulation on AI. Moreover, according to Art. 7 of the Regulation on AI, the Commission is able to extend Annex III which means that other financial service provider could as well become subject to the Regulation on AI any time in the future.</p> <p>As many other financial service providers (e.g. insurance undertakings, investment firms) have – similar to credit institutions according to Art. 74, 97 to 101 of Directive 2013/36/EU – corresponding requirements regarding their internal governance arrangements, processes and mechanisms and supervisory review procedures in their</p>

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	<p>sectoral EU regulatory frameworks, these specific requirements should as well be referred to in Art. 9 (9), 17 (3), 18 (2), 19 (2), 20 (2), 29 (4) and (5), 43 (2), 61 (4) and 62 (3) of the Regulation on AI (and not only Directive 2013/36/EU). Such an approach would ensure a level playing field and equal treatment for all kind of financial service providers regulated by EU law as regards the application of the new rules on AI.</p> <p>Consequently, such modifications of the draftings should be done consistently in Art. 9 (9), 17 (3), 18 (2), 19 (2), 20 (2), 29 (4) and (5), 43 (2), 61 (4) and 62 (3) of the Regulation on AI.</p>
The first subparagraph shall also apply to	

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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	<p>SK:</p> <p>(Comments):</p> <p>Slovakia believes that the proposed self-reporting mechanism is not sufficient, not even in combination with article 65. As described in Slovakia's non-paper distributed on 13 December 2021, a more robust and sophisticated system of public supervision, based on targeted joint</p>

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	investigations and market inquiries could be created especially for stand-alone AI systems. See our general comment to Title VI above.
<p><i>Article 62</i> <i>Reporting of serious incidents and of</i> <i>malfunctioning</i></p>	<p>BE:</p> <p>(Comments):</p> <p>Article 62 only mentions the responsibility of the providers and the authorities in reporting serious incidents. The responsibilities for the user of the AI system in reporting incidents are not clear. (Is this anticipated in the post-market monitoring?). There is no mention of the responsibilities of the provider towards informing the users of incidents either.</p>

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	<p>FI:</p> <p>(Comments):</p> <p>Article 62 Reporting of serious incidents and of malfunctioning: Regarding serious incidents and malfunctions, we see the risk of unnecessary administrative burden. It is important to review the different notification obligations set for the providers in other ICT-related regulation and map the possibilities to replace these obligations by one EU-level contact point that would be responsible inform about the serious incidents and malfunctioning. Currently, actors in the financial sector are obligated to report about the same incident several times and in addition in several languages, which</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>creates unnecessary administrative costs, increases the risk of misunderstandings and at worst, has an adverse effect on the investigation of the issue and might result in delays in recovery.</p> <ul style="list-style-type: none">• In addition, it is unclear which serious incidents and malfunctions the obligation to report applies to? Article 62(3) (original text) “obligations intended to protect fundamental rights” Is objectively difficult to assess. If left in the original form, this could lead to a situation where market surveillance authorities might receive reports that are made “just in case”, that might result in increased administrative burden.

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	<p>Realistic opportunities to comply with the obligations should be ensured.</p> <p>Article 62 Reporting of serious incidents and of malfunctioning: What is the purpose of this change and how does it relate to the changes made in articles 1 to 7? “Malfunctioning” is still included in Article 3(44).</p> <p>CZ:</p> <p>(Comments):</p> <p>Clarification of the Article 62 in the compromise text regarding the difference between paragraph 1 and 3 is now understandable.</p>

Presidency compromise text	Drafting Suggestions Comments
	DK: (Comments): We welcome this clarification
<p>1. Providers of high-risk AI systems placed on the Union market shall report any serious incident or any malfunctioning of these systems which constitutes a breach of obligations under Union law intended to protect fundamental rights to the market surveillance authorities of the Member States where that incident or breach occurred.</p>	ES: (Drafting): 1. Providers and, if the serious incident can be noticed by users, users of high-risk AI systems placed on the Union market shall report any serious incident or any malfunctioning of these systems which constitutes a breach of obligations under Union law intended to protect fundamental rights to the market surveillance authorities of the Member States where that incident or

Presidency compromise text	Drafting Suggestions Comments
	<p>breach occurred.</p> <p>ES:</p> <p>(Comments):</p> <p>LEAs should have a particular treatment in this article:</p> <ul style="list-style-type: none">- What entity is the one to report (different law enforcement authorities exist up to date).<ul style="list-style-type: none">- A specific methodology for doing this report and transmitting the associated information. <p>LV:</p> <p>(Drafting):</p> <ol style="list-style-type: none">1. Providers of high-risk AI systems placed on the Union market shall report any serious incident to the market surveillance authorities of the Member States where that

Presidency compromise text	Drafting Suggestions Comments
	<p>incident occurred. In case of violations of the General Data Protection Regulation all incidents shall be reported.</p> <p>LV:</p> <p>(Comments):</p> <p><i>Article 33 Notification of a personal data breach to the supervisory authority of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46 EC (General Data Protection Directive) requires the controller to be obliged in the event of an infringement of personal data protection without undue</i></p>

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	<p>delay and, if possible, notify the supervisory authority of a personal data breach within 72 hours of the date on which the infringement became known. On the other hand, Article 62 of the proposal provides that providers of high-risk AI systems placed on the Union market for all serious incidents or malfunctioning of these systems, which include infringements of obligations under Union law aimed at protecting fundamental rights (including the right to the protection of personal data), shall report to the market surveillance authorities in the Member States where they have occurred.</p> <p>We would like to draw attention to the fact that the General Data Protection Regulation does not distinct the severity of the data</p>

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	<p>protection breach as a criterion for deciding whether it is necessary to report to the supervisory authority or not. It is also apparent from the wording of Article 62 of the proposal that, at each time, the controller should assess the severity and relevance of the personal data breach for reporting purposes, since the current version provides that only serious incidents which are contrary to the General Data Protection Regulation should be reported.</p> <p>LT:</p> <p>(Comments):</p> <p>obligation of the reporting of serious incidents under Article 62 (1) in conjunction with Article 63 (5) of the AI Regulation</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>shows that the recipient of incident information depends on the purposes of the AI systems, i.e. y. in cases where AI systems are used for law enforcement purposes, the recipient of such information will be the data protection supervisory authority and in other cases by other market surveillance authorities. Law enforcement authorities may use AI systems for both law enforcement and other purposes, which may lead to difficulties in selecting the appropriate recipient of information about such an incident. This issue should be clarified by defining in such cases, where the AI system is used for different purposes, including law enforcement purposes, both authorities are informed, or only the data protection supervisory authority, etc.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>IT:</p> <p>(Comments):</p> <p>For the sake of a clear and uniform concept of "serious incident", we suggest a scoring system of malfunctioning and incidents.</p> <p>NL:</p> <p>(Drafting):</p> <p>1. Providers of high-risk AI systems placed on the Union market shall report any serious incident referred to in Article 3(44)(c), including incidents involving a violation of fundamental rights' or any malfunctioning of those systems which constitutes a breach of obligations under</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Union law intended to protect fundamental rights to the market surveillance authorities of the Member States where that incident or breach occurred.</p> <p>NL:</p> <p>(Comments):</p> <p>To be consistent and clear, and the reference to Article 3(44)(c) is also made in paragraph 2.</p> <p>AT:</p> <p>(Comments):</p> <p>Suggestion to make it also possible for users to report any serious incident (to the providers) because they often receive more information than providers do.</p>

Presidency compromise text	Drafting Suggestions Comments
	Suggestion to extend group of addressees to notified bodies so that it can consider them in its conformity assessment procedure.
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 .	LV; (Drafting): Such notification shall be made immediately after the provider has established a causal link between the AI system and the serious incident 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. In case of violations of General Data Protection Regulation notification shall be made not later than 72

Presidency compromise text	Drafting Suggestions Comments
	<p>hours from the time the incident becomes known.</p> <p>LV:</p> <p>(Comments):</p> <p>Proposal provides that the notification should be made immediately after the procurer has established a causal link between AI system and the incident or malfunction, or a reasonable probability of such a link, and in any event not later than 15 days after the procurer has learned of a serious incident or malfunction, while the General Data Protection Regulation provides for the obligation of the controller to report on the breach of data protection without undue delay and, if possible, not</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>later than 72 hours from the time the irregularity becomes known. Consequently, we call for the time limits laid down in the proposal and the data regulation for the communication of personal data processing violations.</p> <p>LT:</p> <p>(Comments):</p> <p>In accordance with Article 63 (5) of the Regulation, an incident in law enforcement DI systems have to be reported to the data protection supervisory authority, we would suggest considering that the time for reporting an incident should be compatible with the deadlines for reporting a personal data breach set out in Directive (EU)</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>2016/680 and the Regulation.</p> <p>SE:</p> <p>(Drafting):</p> <p>Such notification shall be made immediately and no later than 24 hours from the point at which the provider detects 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. A report about the serious incident or of the malfunctioning shall be sent to the market surveillance authority within 72 hours from the point at</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>which the provider detects it.</p> <p>SE:</p> <p>(Comments):</p> <p>The proposed deadline (not later than 15 days) of notification of serious incidents or malfunctioning to the market surveillance authorities is far too extended in time. This appears to be inconsistent with the far-reaching safety regulations in other parts of the AIA.</p> <p>What is the responsibility of an “operator” who is not a “provider”?</p> <p>EE:</p> <p>(Drafting):</p> <p>Such notification shall be made immediately</p>

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	<p>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 72 hours 45 days after the providers becomes aware of the serious incident or of the malfunctioning.</p> <p>EE:</p> <p>(Comments):</p> <p>Providers should notify of serious incidents within 72 hours of becoming aware of such incident (as in the GDPR art 33).</p>
<p>2. Upon receiving a notification related to a serious incident referred to in Article</p>	<p>PT:</p>

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<p>3(44)(c) a breach of obligations under Union law intended to protect fundamental rights, the relevant market surveillance authority shall inform the national public authorities or bodies referred to in Article 64(3). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1. That guidance shall be issued 12 months after the entry into force of this Regulation, at the latest.</p>	<p>(Comments):</p> <p>As indicated on the point 3 of article 62, for cases where the AI systems are medical devices, it is indicated that notification of serious incident is limited to those referred to in Article 3(44)(c). However, considering that those are not reportable according under MDR/IVDR and, in this sense, also not communicated through EUDAMED, it should be clear in the text of this article, that serious incident referred to in Article 3(44)(c) of AIA should be notified/reported to national public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights in relation to the use of high-risk AI systems, referred to in Article</p>

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	<p>64(3).</p> <p>From the text of article 62 it is not clear to what authority should the serious incidents referred to in Article 3(44)c) be reported by the provider, if the high-risk AI systems is in the context of MDR/IVDR.</p> <p>LV:</p> <p>(Drafting):</p> <p>2. Upon receiving a notification related to a serious incident referred to in Article 3(44)(c), the relevant market surveillance authority shall inform the national public authorities or bodies referred to in Article 64(3). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1.</p>

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	<p>That guidance shall be issued intime-42 months after with the entry into force of this Regulation, at the latest and actualized 12 months after.</p> <p>LV:</p> <p>(Comments):</p> <p>Regulation stipulates that the guidelines shall be issued at the latest 12 months after the entry into force of the Regulation. In the view of Latvia, it would not be appropriate to postpone the elaboration of the above guidelines for the time when the Regulation had already entered into force, particularly because new, regulatory issues or uncertainties which should have been considered or included in Regulation could</p>

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	<p>be detected in the drafting of the guidelines.</p> <p>SE:</p> <p>(Drafting):</p> <p>The European Board of Artificial Intelligence shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1. That guidance shall be issued 12 months after the entry into force of this Regulation, at the latest.</p> <p>HU:</p> <p>(Drafting):</p> <p>The national supervisory authority shall report to the Commission on a regular an annual basis the outcomes of relevant</p>

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	<p>market surveillance activities.</p> <p>HU:</p> <p>(Comments):</p> <p>For clarification purposes, we believe that the reporting period shall be unified in all Member States and therefore we recommend defining it in the text.</p>
<p>3. For high-risk AI systems referred to in point 5(b) of Annex III which are placed on the market or put into service by providers that are credit institutions regulated by Directive 2013/36/EU and for high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulation (EU) 2017/745 and</p>	<p>PT:</p> <p>(Comments):</p> <p>See previous comment.</p> <p>AT:</p> <p>(Comments):</p> <p>We welcome the approach that a number of</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>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.</p>	<p>new requirements according to this Regulation shall be integrated into the existing obligations and procedures under Directive 2013/36/EU, as it is stipulated in Art. 9 (9), 17 (3), 18 (2), 19 (2), 20 (2), 29 (4) and (5), 43 (2), 61 (4) and 62 (3) of the Regulation on AI.</p> <p>However, in the same context, it must be highlighted that it is more than probable that the Regulation on AI will not only be applicable to credit institutions but (at least eventually) also to a number of other financial service providers, such as for instance insurance undertakings or investment firms. Annex III No. 5 letter d of the Regulation, as it was added in the first Presidency compromise proposal, already</p>

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	<p>introduces high-risk “<i>AI systems intended to be used for insurance premium setting, underwritings and claims assessments</i>” which subsequently results in the inclusion of insurance undertakings in the scope of the Regulation on AI. Moreover, according to Art. 7 of the Regulation on AI, the Commission is able to extend Annex III which means that other financial service provider could as well become subject to the Regulation on AI any time in the future.</p> <p>As many other financial service providers (e.g. insurance undertakings, investment firms) have – similar to credit institutions according to Art. 74, 97 to 101 of Directive 2013/36/EU – corresponding requirements regarding their internal governance</p>

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	<p>arrangements, processes and mechanisms and supervisory review procedures in their sectoral EU regulatory frameworks, these specific requirements should as well be referred to in Art. 9 (9), 17 (3), 18 (2), 19 (2), 20 (2), 29 (4) and (5), 43 (2), 61 (4) and 62 (3) of the Regulation on AI (and not only Directive 2013/36/EU). Such an approach would ensure a level playing field and equal treatment for all kind of financial service providers regulated by EU law as regards the application of the new rules on AI.</p> <p>Consequently, such modifications of the draftings should be done consistently in Art. 9 (9), 17 (3), 18 (2), 19 (2), 20 (2), 29 (4) and (5), 43 (2), 61 (4) and 62 (3) of the Regulation on AI.</p>

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	<p>AT:</p> <p>(Drafting):</p> <p>NEW</p> <p>CHAPTER 2A</p> <p>ADDITIONAL OBLIGATIONS FOR</p> <p>VERY LARGE PROVIDERS TO</p> <p>MANAGE SYSTEMIC RISKS</p> <p>Article 62a</p> <p>Very large providers</p> <p>1. This Chapter shall apply to providers of high-risk AI systems listed in Annex III for which both of the following conditions are fulfilled:</p> <p>(a) the provider has a share of [...] percent or above in the market for AI systems of the</p>

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	<p>relevant type, considering the AI system's core functionalities, with regard to the whole Union, or a share of [...] percent or above in the relevant market in at least three Member States; and</p> <p>(b) [...] percent or above of decision-making of the relevant kind listed in Annex III significantly relies on the use of that type of AI system.</p> <p>When calculating the share within the meaning of point (a), AI systems that are not placed on the market or put into service under the provider's own name or trademark, but that use the provider's AI system as a basis or component in a way that significantly influences any systemic risks presented by those AI systems, shall be included.</p>

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	<p>2. The Commission shall adopt delegated acts in accordance with Articles 73 and 74, after consulting the Board, to lay down a specific methodology for calculating the market share referred to in paragraph 1. In those delegated acts, the Commission may also define different percentages than referred to in paragraph 1 for particular high-risk AI systems where there is reason to believe that systemic risks resulting from that type of AI system are significantly higher or lower than for other AI systems listed in Annex III.</p> <p>3. The Board shall verify, at least once a year, whether the market shares of providers whose AI systems are used in the Union is equal to or higher than the shares referred to in paragraphs 1 and 2. On the basis of that</p>

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	<p>verification, it shall adopt a decision designating the provider as a very large provider for the purposes of this Regulation, or terminating that designation, and communicate that decision, without undue delay, to the provider concerned and to the Commission.</p> <p>4. The Commission shall ensure that the list of designated very large providers is published in the Official Journal of the European Union and keep that list updated. The obligations of this Chapter shall apply, or cease to apply, to the very large providers concerned from four months after that publication.</p> <p>Article 62b Systemic risk assessment</p>

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	<p>1. As part of the quality management system referred to in Article 17 and post-market monitoring system referred to in Article 61, very large providers shall identify, analyse and assess, at least once a year, any significant systemic risks stemming from the functioning and use made of the AI systems provided by them in the Union.</p> <p>2. This risk assessment shall be specific to the AI systems they provide and shall, in any case, include the following systemic risks:</p> <p>(a) any negative effects for the exercise of fundamental rights, for example respect for private and family life, data protection, the prohibition of discrimination, the rights of the child and access to an effective remedy</p>

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	<p>and a fair trial, as enshrined in Articles 7, 8, 21, 24 and 47 of the Charter respectively;</p> <p>(b) any negative effects for democracy, the rule of law, the functioning of state institutions, the stability of societies and economies, protection of the environment and the combat against climate change, and other important public interests;</p> <p>(c) any risks resulting from uniformity of decision-making, including for the emergence of new disadvantaged groups, the reduction of diversity in affected groups (e.g. recruited individuals), and a steering function for human behaviour as affected individuals adapt their behaviour to the parameters relied on by the AI system;</p> <p>(d) any risks resulting from a reduction in human skills and competences, including</p>

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	<p>for the ability to detect and correct errors and to act independently of the AI system where the system is unavailable;</p> <p>(e) risks of intentional manipulation of their AI system, including by means of targeted inauthentic behaviour of affected persons, malicious interference by third parties, or hybrid warfare, with an actual or foreseeable negative effect on important public or private interests.</p> <p>Article 62c Mitigation of systemic risks</p> <p>1. Very large providers shall put in place reasonable, proportionate and effective mitigation measures, tailored to the specific systemic risks identified pursuant to Article 62b. Such measures may include, where</p>

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	<p>applicable:</p> <ul style="list-style-type: none">(a) adapting AI systems, their decision-making processes, their features or functioning, or the instructions and specifications accompanying them;(b) reinforcing the internal processes or supervision of any of their activities in particular as regards detection of systemic risk;(c) ... <p>2. The Board, in cooperation with the Commission, shall publish comprehensive reports, once a year, which shall include the following:</p> <ul style="list-style-type: none">(a) identification and assessment of the most prominent and recurrent systemic risks reported by very large providers or identified through other information

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	<p>sources;</p> <p>(b) best practices for very large providers to mitigate the systemic risks identified.</p> <p>3. The Commission, in cooperation with the Board, may issue general guidelines on the application of paragraph 1 in relation to specific risks, in particular to present best practices and recommend possible measures, having due regard to the possible consequences of the measures on fundamental rights enshrined in the Charter of all parties involved. When preparing those guidelines the Commission shall organise public consultations.</p> <p>Article 62d</p> <p>Independent audit</p> <p>1. Very large providers shall be subject, at</p>

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	<p>their own expense and at least once a year, to audits to assess compliance with the following:</p> <ul style="list-style-type: none">(a) the obligations set out in Chapter 3 of Title III;(b) any commitments undertaken pursuant to the codes of conduct referred to in Article 69. <p>2. Audits performed pursuant to paragraph 1 shall be performed by organisations which:</p> <ul style="list-style-type: none">(a) are independent from the very large providers concerned;(b) have proven expertise in the area of risk management, technical competence and capabilities;(c) have proven objectivity and professional ethics, based in particular on adherence to codes of practice or appropriate standards.

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	<p>3. The organisations that perform the audits shall establish an audit report for each audit. The report shall be in writing and include at least the following:</p> <ul style="list-style-type: none">(a) the name, address and the point of contact of the very large provider subject to the audit and the period covered;(b) the name and address of the organisation performing the audit;(c) a description of the specific elements audited, and the methodology applied;(d) a description of the main findings drawn from the audit;(e) an audit opinion on whether the very large provider subject to the audit complied with the obligations and with the commitments referred to in paragraph 1, either positive, positive with comments or

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	<p>negative;</p> <p>(f) where the audit opinion is not positive, operational recommendations on specific measures to achieve compliance.</p> <p>4. Very large providers receiving an audit report that is not positive shall take due account of any operational recommendations addressed to them with a view to take the necessary measures to implement them. They shall, within one month from receiving those recommendations, adopt an audit implementation report setting out those measures. Where they do not implement the operational recommendations, they shall justify in the audit implementation report the reasons for not doing so and set out any alternative measures they may have taken to</p>

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	<p>address any instances of non-compliance identified.</p> <p>Article 62e Transparency reporting obligations for very large providers</p> <p>1. Very large providers shall make publicly available and transmit to the Board and the Commission, at least once a year and within 30 days following the adoption of the audit implementing report provided for in Article 62d(4):</p> <ul style="list-style-type: none">(a) a report setting out the results of the risk assessment pursuant to Article 62b;(b) the related risk mitigation measures identified and implemented pursuant to Article 62c;(c) the audit report provided for in Article

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	<p>62d(3);</p> <p>(d) the audit implementation report provided for in Article 62d(4).</p> <p>3. Where a very large provider considers that the publication of information pursuant to paragraph 2 may result in the disclosure of confidential information of that provider or of the users of the AI system, may cause significant vulnerabilities for the security of its AI system, may undermine public security or may harm users or affected individuals, the provider may remove such information from the reports. In that case, that provider shall transmit the complete reports to the Board and the Commission, accompanied by a statement of the reasons for removing the information from the public reports.</p>

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	<p>Article 62f Data access and scrutiny by vetted researchers</p> <p>1. Upon a reasoned request from the Commission, very large providers shall, within a reasonable period, as specified in the request, provide access to data to vetted researchers who meet the requirements in paragraphs 3 of this Article, for the sole purpose of conducting research that contributes to the detection, identification and understanding of systemic risks in the Union as set out in Article 62b(1), including as regards the adequacy, efficiency and impacts of the risk mitigation measures pursuant to Article 62c. In making a request, the Commission shall take due account of</p>

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	<p>the rights and interests of the providers and users of the AI system concerned, including the protection of personal data, the protection of confidential information, in particular trade secrets, and maintaining the security of their AI systems.</p> <p>2. Very large providers shall facilitate and provide access to data pursuant to paragraph 1 through appropriate interfaces specified in the request, including online databases or application programming interfaces.</p> <p>3. Upon a duly substantiated application from researchers, the Commission shall award them the status of vetted researchers and issue data access requests pursuant to paragraph 1, where the researchers demonstrate that they meet all of the following conditions:</p>

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	<p>(a) they are affiliated to a research organisation as defined in Article 2 (1) of Directive (EU) 2019/790 of the European Parliament and of the Council;</p> <p>(b) they are independent from commercial interests;</p> <p>(c) they are in a capacity to preserve the specific data security and confidentiality requirements corresponding to each request and to protect personal data, and they describe in their request the appropriate technical and organisational measures they put in place to this end;</p> <p>(d) the application submitted by the researchers justifies the necessity and proportionality for the purpose of their research of the data requested and the timeframes within which they request</p>

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	<p>access to the data, and they demonstrate the contribution of the expected research results to the purposes laid down in paragraph 1;</p> <p>(e) the planned research activities will be carried out for the purposes laid down in paragraph 1;</p> <p>(f) they carry their activities according to the procedures laid down in delegated acts referred to in paragraph 7;</p> <p>(g) they have not already filed the same application with the Commission.</p> <p>4. The Commission shall issue a decision terminating the access if it determines, following an investigation either on its own initiative or on the basis information received from third parties, that the vetted researcher no longer meets the conditions set out in paragraph 3. Before terminating</p>

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	<p>the access, the Commission shall allow the vetted researcher to react to the findings of its investigation and its intention to terminate the access.</p> <p>5. Upon completion of the research envisaged in paragraph 1, the vetted researchers shall make their research results available to the Commission free of charge. The Commission may make the research results publicly available, taking due account of the rights and interests of the providers and users of the AI system concerned, including the protection of personal data, the protection of confidential information, in particular trade secrets, and maintaining the security of their service.</p> <p>6. The Commission shall, after consulting the Board, adopt delegated acts laying down</p>

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	<p>the technical conditions under which providers of very large providers are to share data pursuant to paragraphs 1 and 2 and the purposes for which the data may be used. Those delegated acts shall lay down the specific conditions and relevant objective indicators, as well as procedures under which such sharing of data with vetted researchers can take place in compliance with Regulation (EU) 2016/679, taking into account the rights and interests of the providers and users of the AI system concerned, including the protection of confidential information, in particular trade secrets, and maintaining the security of their AI system.</p> <p>AT:</p>

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	<p>(Comments):</p> <p>In addition to including the AIA, or the relevant provisions thereof, in the list of legal instruments in Annex I to the Representative Actions Directive (RAD), it is recommended to include a new enforcement mechanism with regard to systemic risks. Systemic risks may arise, in particular, where a high-risk AI system that complies with the AIA has, in the light of its significant market coverage, the potential of changing our societies and economies, causing characteristic features and smaller deficiencies (that may be acceptable in an AI system when seen in isolation) to become a systemic risk. For example, bias in a system that is dominant on the relevant</p>

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	<p>market could cause new disadvantaged groups to emerge that can no longer be captured by non-discrimination law as it currently exists, or widespread use of an AI system could have detrimental effects on human skills and competences. The new enforcement mechanism suggested has been inspired by Articles 25 ff DSA, and it includes data access for vetted researchers.</p>
CHAPTER 3	
ENFORCEMENT	
<p><i>Article 63</i> <i>Market surveillance and control of AI systems in the Union market</i></p>	<p>PL: (Comments): <i>The obligation to report a serious incident</i></p>

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	<p><i>related to system operation rests with the user who reports it to the supplier and the supplier who reports it to market surveillance authorities. In the case of high-risk systems in the area of law enforcement, as well as migration, asylum and border control management, when the provider is a private entity and the user is a public entity, i.e. law enforcement agencies, consideration should be given to whether this two-stage process is adequate and necessary.</i></p>
<p>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:</p>	<p>NL: (Comments): Does “ this Regulation” refer to the AI-Act? Does “AI-systems” this mean that</p>

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	Regulation (EU) 2019/1020 is applicable to all AI-systems covered by the AI-Act (and not high risk systems only)?
(a) any reference to an economic operator under Regulation (EU) 2019/1020 shall be understood as including all operators identified in Title III, Chapter 3 Article 2 of this Regulation;	
(b) any reference to a product under Regulation (EU) 2019/1020 shall be understood as including all AI systems falling within the scope of this Regulation.	ES: (Comments): We understand that 'a priori' this is applicable to all AI Systems, not only high-risk.

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<p>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.</p>	<p>IT: (Comments): EU guidelines could be appropriate in order to clarify the boundaries of the potential interest.</p> <p>DK: (Drafting): The national supervisory authority shall report to the Commission on a regular basis by 31 March of each year, the outcomes of relevant market surveillance activities.</p> <p>DK: (Comments): It is unclear why this regulation should</p>

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	<p>introduce a new obligation for member states to report to the Commission, as article 25(6) of regulation 2019/1020 already has an obligation for member states to report to the Commission by 31 March every year. Therefore, at least, it would be beneficial to coordinate these requirements and thereby set out a similar timeframe in the AI Act for reporting to the Commission.</p> <p>Furthermore, the formulation concerning “that may be of potential interest” is rather vague which could make it difficult for national supervisory authorities to establish when they would need to report certain information.</p> <p>NL:</p>

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	(Comments): First sentence requires clarification.
<p>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.</p>	<p>ES:</p> <p>(Drafting):</p> <p>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. For the purpose of the compliance of this regulation, such authorities under the mentioned legal acts will collaborate with the national</p>

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	<p>supervisory authority, in order to know and monitor due market surveillance activities.</p> <p>ES:</p> <p>(Comments):</p> <p>If the national supervisory authority is to report to the Commission about market surveillance activities, it is crucial that it receives proper input from the different market surveillance authorities and that have sufficient competency to coordinate them all.</p> <p>BE:</p> <p>(Comments):</p> <p>This Article should remain sufficiently general so that the cooperation between the different market surveillance authorities for high-risk AI can be regulated at national level without any restrictions.</p>

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	<p>PL:</p> <p>(Comments):</p> <p><i>In addition, we suggest that in the case of Art. 63 sec. 3 also take into account the systems referred to in Annex III point 6 and 7, i.e. that reported incidents should be limited to cases of violation of EU law in the field of the protection of fundamental rights.</i></p> <p>SE:</p> <p>(Drafting):</p> <p>For high-risk AI systems, related to products to which legal acts listed in Annex II, section A apply, the a market surveillance authority for the purposes of this Regulation shall be the authority</p>

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	<p>responsible for market surveillance activities designated under those legal acts. appointed by member states.</p> <p>SE:</p> <p>(Comments):</p> <p>As there exists heterogeneity with regards to the modes of organization within EU and when taking into account the specific competencies required by the market surveillance authorities when regulating AI, SE views it as more suitable for member states to be able to appoint their own market surveillance authorities.</p>
4. For AI systems placed on the market, put into service or used by financial	ES:

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>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>(Drafting):</p> <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. For the purpose of the compliance of this regulation, such authority will collaborate with the national supervisory authority.</p> <p>AT:</p> <p>(Comments):</p> <p>A Member State option should be</p>

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	<p>inserted in this provision to provide Member States with the discretion to designate authorities different to the “relevant authority responsible for the financial supervision of those institutions under that legislation” as the “market surveillance authority” for financial institutions if this is deemed more appropriate by the relevant Member State, e.g. in order to further concentrate the expertise regarding the surveillance of AI-systems.</p> <p>In addition, this provision should be clarified concerning the following issues:</p> <ul style="list-style-type: none">- The wording “financial institutions regulated by Union legislation on financial

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>services” is too vague and has to be clarified respectively further defined. Currently, it is not sufficiently clear which financial institutions would be addressed by this provision, especially as some provisions of the Regulation – Recital 80 and Art. 9 (9), 17 (3), 18 (2), 19 (2), 20 (2), 29 (4) und (5), 43 (2), 61 (4), 62 (3) – only refer to “credit institutions” and Directive 2013/36/EU (the EU Directive which regulates credit institutions). As Art. 63 para. 4 obviously is part of an EU-Regulation, i.e. directly applicable by concerned authorities, it must be unambiguous to ensure a flawless implementation. Thus, a legal definition should be added (e.g. in Art. 3 of this Regulation) to clarify which financial institutions regulated under which</p>

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	<p>concrete sectoral EU-legislative act (CRD? Solvency II Directive? IFD/MIFID? etc.) would/should be comprised by Art. 63 para. 4 (and subsequently, other Articles of this Regulation).</p> <p>- It should be clarified that the function of “the relevant authority responsible for the financial supervision of those institutions under that legislation” as “market surveillance authority” is restricted only to AI systems which are placed on the market, put into service or used by financial institutions in direct connection with the provision of financial services which are subject to prudential supervision by financial supervisors due to Union</p>

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	<p>legislation on financial services (i.e. regulated services/activities).</p> <p>- A specific issue arises in the context of the Single Supervisory Mechanism (SSM). Within the SSM framework, the supervision of banks is split between ECB and national competent (banking supervisory) authorities ("NCAs"). This specific feature should be taken into account as well in this Regulation, i.e. Art. 63 para. 4 should clearly differentiate and determine how the interaction between ECB and NCAs is envisioned to avoid any complex conflicts regarding competences of authorities.</p> <p>Requests for further information:</p> <p>- It is still currently unclear what the</p>

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	<p>envisioned empowerment for “relevant authorities responsible for the financial supervision” as “market surveillance authority” would effectively mean. It would therefore be important to further specify and explain what the envisioned “surveillance” of the market surveillance authority would entail (specific level of supervision) and what resources would be needed to perform these tasks.</p> <p>- As “relevant authorities responsible for the financial supervision of those institutions under that legislation” are not yet acting as “market surveillance authorities”, would Regulation (EU) 2019/1020 apply to them in future as a result of Art. 63 para. 4 in the context of Art. 63 para. 1 of this proposal?</p>

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	<p>If this was the case, how and from which starting date Regulation (EU) 2019/1020 would apply to these authorities? In this context, it must be mentioned that Regulation (EU) 2019/1020 comprises as well provisions which are subject to national transposition, e.g. Art. 14 of Regulation (EU) 2019/1020 (“Powers of market surveillance authorities”) – these provisions of Regulation (EU) 2019/1020 are currently clearly not transposed in relation to financial supervisory authorities as they have not yet been in the scope of Regulation (EU) 2019/1020.</p>
<p>5. For AI systems listed in point 1(a) in so far as the systems are used for law</p>	<p>ES:</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>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>	<p>(Comments):</p> <p>Proper coordination with National Supervisory Authority must be ensured somehow.</p> <p>SK:</p> <p>(Comments):</p> <p>It should be clarified whether the national competent authorities supervising the activities of the law enforcement, immigration or asylum authorities need to be institutionally independent (as it is required for institutions under directive 2016/680 and regulation 2016/679). See also request for CLS opinion contained in general remarks to the proposal in the previous round of comments.</p>

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

Presidency compromise text	Drafting Suggestions Comments
	<p>activities of law enforcement, immigration or asylum authorities putting into service or using those systems.</p> <p>NL:</p> <p>(Comments):</p> <p>NL proposes here to use a similar formulation as for par. 4</p>
<p>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.</p>	<p>IT:</p> <p>(Comments):</p> <p>An ad hoc European Authority shall be set up instead.</p> <p>NL:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Drafting):</p> <p>6. For AI systems placed on the market, put into service or used by judicial authorities, the market surveillance authorities for the purpose of this Regulation shall be the national competent authority supervising the activities of the judicial authorities</p> <p>NL:</p> <p>(Comments):</p> <p>We suggest to add extra paragraph to protect the independency of the judiciary</p>
7. Member States shall facilitate the	ES:

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<p>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.</p>	<p>(Drafting):</p> <p>7. Member States shall facilitate the coordination through the national supervisory authority, 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.</p> <p>ES:</p> <p>(Comments):</p> <p>Allocating the responsibility to the national supervisory authority will provide with</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>more certainty.</p> <p>IT:</p> <p>(Comments):</p> <p>A list of facilitating acts or guidelines could help identifying the relevant facilitating acts to be implemented at National and Cross border level.</p>
<p><i>Article 64</i> <i>Access to data and documentation</i></p>	<p>DK:</p> <p>(Comments):</p> <p>In general, we are supportive of this article, but foresee that some kind of coordination would be needed in order not to subject providers to 27 different requests concerning documentation, access to source</p>

Presidency compromise text	Drafting Suggestions Comments
	code as well as testing.
	<p>ES:</p> <p>(Drafting):</p> <p>1. In the context of their activities and for the purpose of assessing the compliance of a high-risk AI system with the requirements set out in this Regulation, the market surveillance authorities may use input/output auditing systems.</p>
<p>1. Access to data and documentation in the context of their activities, the market surveillance authorities shall be granted full access to the training, validation and testing datasets used by the provider, including through application programming interfaces ('API') or other appropriate technical means</p>	<p>ES:</p> <p>(Drafting):</p> <p>2. Access to data and documentation in Additionally, in the context of their activities and when necessary, the market surveillance authorities shall be granted full</p>

Presidency compromise text	Drafting Suggestions Comments
and tools enabling remote access.	<p>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.</p> <p>BG:</p> <p>(Comments):</p> <p>Who should grant the access? Is the provider only? Is data always under the control of providers only?</p> <p>PL:</p> <p>(Comments):</p> <p><i>1. The provision requiring the disclosure and sharing of data and documentation requires explicit clarification in terms of the</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p><i>relationship with the trade secret. This information may be of a confidential nature, and often constitute the main, if not the only, factor of the competitive advantage of a given solution. The rights granted to national allowance market surveillance authorities, such as requesting access to datasets, APIs and source code, seem to go too far. In particular, the lack of precise definitions of key risks (such as discrimination, bias) does not increase the objectivity of supervisory assessment;</i></p> <p><i>2. Additionally, real procedural guarantees should be introduced to protect business secrets against both unauthorized access and access</i></p> <p><i>and redundant or unjustified access by persons or entities to this type of</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p><i>information;</i></p> <p><i>3. A proportionality approach should be embedded in the compliance systems of high-risk AI applications.</i></p> <p><i>4. Key to the application of Art. 64 with regard to high-risk systems in the area of law enforcement and the management of migration, asylum and border control shall respect the principle of confidentiality referred to in Art. 70.</i></p> <p>SE:</p> <p>(Drafting):</p> <p>Access to data and documentation in the context of their activities, the market surveillance authorities shall be granted full access to the documentation as well as the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>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. If remote access is deemed inappropriate due to data protection or security reasons access should be given on premise.</p> <p>SE:</p> <p>(Comments):</p> <p>Full access to data may pose a problem. How can companies be sure that no data leaks occur? Must be enough to provide this if there is a reason to question the compliance?</p> <p>EE:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>This can be problematic when a user turns into provider under article 28, for example in case of general purpose AI systems. The end-provider may not have access to all the data and the API.</p> <p>DK:</p> <p>(Comments):</p> <p>It is unclear whether the access to datasets is limited to high-risk systems or apply for any system.</p> <p>Furthermore, we are wondering how the provider can grant full access to the different datasets, when these might not be stored by the provider. Based on the high-</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>risk requirements and the annex concerning technical documentation, the provider will need to describe in detail the data sets used and that notified bodies shall be granted full access to the datasets, but the providers will not directly be required to store such data.</p> <p>NL:</p> <p>(Drafting):</p> <p>Access to data and documentation in the context of their activities, where strictly necessary for their task the market surveillance authorities shall be granted full access to the training, validation and testing datasets used by the provider, including through application programming interfaces ('API') or other appropriate technical means</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>and tools enabling remote access.</p> <p>Additional safeguards or restrictions may be in place in case these datasets are used to detect, prevent, investigate and prosecute criminal offences insofar and as long as necessary for these purposes.</p> <p>NL:</p> <p>(Comments):</p> <p>The AI Act should not provide for an unlimited legal basis for sharing personal data with surveillance authorities. This should be limited to their respective tasks. Additional safeguards should be in place in case of personal data used by LEA's.</p> <p>The access to data in article 64(1) and 64(2)</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>seems rather restricted, in practice access to other information than the data sources highlighted here might be necessary. The wording needs to provide room for authorities to access all information necessary for their tasks, while at the same time acknowledging that unnecessary sharing of operational data should be avoided. It would be good to stress that the amount of information requested should be proportionate to the risks involved and take account of the size of the organisation.</p>
<p>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</p>	<p>ES:</p> <p>(Drafting):</p> <p>3. Where necessary If the activities</p>

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<p>surveillance authorities shall be granted access to the source code of the AI system.</p>	<p>described in paragraph (1) and (2) are not deemed sufficient by the market surveillance authorities to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the market surveillance authorities shall be granted access to the source code of the AI system, where necessary, upon a reasoned request.</p> <p>IE:</p> <p>(Comments):</p> <p>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</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>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</p> <p>PT:</p> <p>(Drafting):</p> <p>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.</p> <p>PT:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>In our view, this article is not clear. What is the source code of an AI system? Should all the integrated components of a final product be considered? If yes, how can a provider grant access to the the source code of a third party component, or a service deployed as PaaS. On the other hand, it is not clear what will the market surveillance authorities do with the source code? Can we consider the assembly code embeded in a GPU part of the high-risk AI system just because the system is to be deployed using GPUs?</p> <p>BG:</p> <p>(Drafting):</p> <p>“2. Where necessary to assess the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2, and upon a reasoned request and after all other ways for access are exhausted or proved insufficient, the market surveillance authorities shall be granted access to the source code of the AI system.”</p> <p>BG:</p> <p>(Comments):</p> <p><u>Justification:</u> Like other Member States, we would be interested in a more gradual approach</p> <p>LT:</p> <p>(Comments):</p> <p>Having in mind ongoing e-commerce</p>

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	<p>negotiation at the WTO and proposal on the protection of source code and algorithms, scrutiny and explanation on this paragraph is necessary in order to clarify that granting access to the course code to the market surveillance authorities do not contradict with EU proposal tabled at the WTO or will not cause any negative turns from EU side on the negotiations.</p> <p>HU:</p> <p>(Drafting):</p> <p>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</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>access to the source code of the AI system.</p> <p>AI operators shall support and equip market surveillance authorities with the necessary means to facilitate robust testing, including granting access to the source code of the AI system, taking into account the principles of necessity and proportionality</p> <p>DK:</p> <p>(Comments):</p> <p>Access to source code is sensitive for companies. It would be necessary to discuss this issue further, in particular to reach agreement on what would constitute a reasoned request, and when and how such a request would be justified.</p>

Presidency compromise text	Drafting Suggestions Comments
	NL: (Comments): See above, in practice access to other types of information might be needed just as well. This seems very limitative.
3. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights in relation to the use of high-risk AI systems referred to in Annex III shall have the power to request and access any documentation created or maintained under this Regulation when access to that documentation is necessary for the fulfilment of the competences under	ES: (Drafting): 4 BE: (Comments): Link with uncertainty about which general rules apply or do not apply to law enforcement - Regarding "... the power to

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<p>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>request and access any documentation . . .”, exceptions and/or limitations should be possible for some law enforcement AI systems.</p> <p>PT:</p> <p>(Drafting):</p> <p>3. The Board, national public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights in relation to the use of high-risk AI systems referred to in Annex III shall have the power to request and access any documentation created or maintained under this Regulation when access to that documentation is necessary</p>

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	<p>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>PT:</p> <p>(Comments):</p> <p>Suggestion based upon the SK non-paper on revamping the governance model of the Regulation</p> <p>HR:</p> <p>(Comments):</p> <p>NHRIs, ombudsmen and equality bodies as competent authorities for protecting</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>fundamental rights in member states should have the power to request and access any documentation in relation to all AI systems, not only high-risk, to adequately respond to AI-related risks and potentially rights violation.</p> <p>DK:</p> <p>(Comments):</p> <p>We are still assessing this paragraph, where national public authorities or bodies which enforce Union law protecting fundamental rights can request and access <i>any</i> documentation. As the Commission explained, this is an invention in terms of legislation.</p>

Presidency compromise text	Drafting Suggestions Comments
<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>	<p>IT: (Comments):</p> <p>We suggest extending the timeline from 3 months to 12 months after the entering into force of this Regulation to give sufficient time for Member States to update compliance schemes and help as well Market Surveillance authorities to integrate the new requirements. The proposal has an exponentially larger scope and mandate respect other previous sectorial provision that demonstrated practically the impossibility to comply with short time of implementation and application and</p>

Presidency compromise text	Drafting Suggestions Comments
	we've to consider a realistic time to do it.
<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>IT:</p> <p>(Comments):</p> <p>Could the Commission give some more details on the process relating to the foreseen testing?</p> <p>What/Which kind of “technical means” are intended in this respect?</p> <p>How much time is considered “reasonable time” following the -we imagine - the date of the request? We would prefer to have a definite time (i.e. 3 months).</p>

Presidency compromise text	Drafting Suggestions Comments
	DK: (Comments):
<p>6. Any information and documentation obtained by the national public authorities or bodies referred to in paragraph 3 pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.</p>	
	<p>NL: (Drafting): NEW Article 64A Right to Complain</p>

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	<p>1. Without prejudice to any other administrative or judicial remedy, every natural person exposed to an AI system shall have the right to lodge a complaint with a supervisory authority, in particular in the Member State of his or her habitual residence, place of work or place of the alleged infringement if the data subject considers that the use of AI systems affecting him or her infringes this Regulation or poses a serious risk to his or her fundamental rights.</p> <p>2. The supervisory authority with which the complaint has been lodged shall inform the complainant on the progress and the outcome of the complaint including the possibility of a judicial remedy.</p> <p>NL:</p> <p>(Comments):</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>The current proposal currently lacks any inclusion of end/natural persons in its provisions, as redress is left to pending proposals and domain specific regulation. However, to increase legal protection and strengthen governance, a right to complain is necessary and inspired by the GDPR.</p>
<p><i>Article 65</i> <i>Procedure for dealing with AI systems presenting a risk at national level</i></p>	<p>NL:</p> <p>(Comments):</p> <p>We presume a high risk AI-system will be evaluated against Title II, chapter 2 and 3. But what would the evaluation criteria be for a) prohibited systems (b) AI-systems meant in art. 52 (c) any other low/no risk systems AI-system?</p>

Presidency compromise text	Drafting Suggestions Comments
<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>BG:</p> <p>(Drafting):</p> <p>AI systems presenting a risk shall be understood as a product presenting a risk defined in Article 3, point 19 of Regulation (EU) 2019/1020 insofar as risks to the health or safety or to the protection of fundamental rights of persons, and especially, children are concerned.</p> <p>BG:</p> <p>(Comments):</p> <p><u>Justification:</u> Children are among the vulnerable groups and their rights and interests need special protection</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>NL:</p> <p>(Drafting):</p> <p>AI systems presenting a risk shall be understood as a product presenting a risk defined in Article 3, point 19 of Regulation (EU) 2019/1020 insofar as risks to the health or safety and as product presenting a risk to the protection of fundamental rights of persons are concerned in article 3. [...].</p> <p>NL:</p> <p>(Comments):</p> <p>This is the first time the notion of risk is explained a bit more. Article 3.19 of Reg 2019/1020 does not mention fundamental rights, so it seems to be insufficient for the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>purposes of this regulation. We propose to include a more fitting description of product presenting a risk in the definitions part of the regulation, which gives the appropriate attention to fundamental rights risks, as well as risks for harms at a societal level, rather than an individual level.</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</p>	<p>ES:</p> <p>(Comments):</p> <p>There is an important question to be solved here:</p> <p>The AI system presenting the risk may not be an AI system included in annex III or II.</p> <p>But in the case a risk is detected, the provider will be obliged to comply with Requirements. And this could lead, for example, to an update of annex III. But annex III can't be updated out of the 8 areas.</p> <p>We deem necessary to bring coherence in this</p>

Presidency compromise text	Drafting Suggestions Comments
<p>rights are present, the market surveillance authority shall also inform the relevant national public authorities or bodies referred to in Article 64(3). The relevant operators shall cooperate as necessary with the market surveillance authorities and the other national public authorities or bodies referred to in Article 64(3).</p>	<p>regard:</p> <ul style="list-style-type: none"> - Allowing updates of annex III out of the 8 areas. <p>SE:</p> <p>(Drafting):</p> <p>Without prejudice to Article 19 of the Regulation (EU) 2019/1020, wWhere 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.</p> <p>When risks to the protection of fundamental</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>rights and non-discrimination are present, SE:</p> <p>(Comments):</p> <p>This amendment has been made in the battery regulation in order to ensure alignment with the provisions of the recently adopted market surveillance regulation 2019/1020.</p> <p>Must be more important to evaluate the real effects of the AI-system than compliance with AIA?</p> <p>In terms of AI, non-discrimination is essential if the providers and users of AI want the public to trust in the use of AI. It is all the more pertinent as several cases of discrimination already have been exposed.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Therefore, non-discrimination should be particularly prominent in the regulation.</p> <p>DK:</p> <p>(Drafting):</p> <p>[...] they shall carry out an evaluation of the AI system concerned in respect of its compliance with all the relevant requirements and obligations laid down in this Regulation.</p> <p>DK:</p> <p>(Comments):</p> <p>The market surveillance authorities are required to evaluate all requirements and obligations. In our view, it would be sufficient with the relevant requirements</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>and obligations in terms of the risk.</p> <p>NL:</p> <p>(Drafting):</p> <p>When risks to the protection of fundamental rights are present,</p>
<p>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</p>	<p>HR:</p> <p>(Comments):</p> <p>Regarding the obligation of the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, it is important to emphasize that it is not enough to take only appropriate corrective actions but also protection</p>

Presidency compromise text	Drafting Suggestions Comments
<p>with the nature of the risk, as it may prescribe.</p>	<p>measures. It should be adjusted to place greater emphasis on those potentially affected by AI-enabled products and services and more specifically, on enhancing their ability to identify and seeks redress against breaches of equality and other fundamental rights.</p> <p>DK:</p> <p>(Drafting):</p> <p>[...] to withdraw the AI system from the market, or to recall it within a reasonable period, which is commensurate with the nature of the risk, as it may prescribe, and which is in any case no longer than five working days.</p> <p>DK:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>We suggest a clear maximum timeframe for reacting to AI systems that do not comply with the requirements in this regulation. Too much flexibility risks uncertainty for the different actors and disproportional risks for consumers and citizens.</p> <p>NL:</p> <p>(Drafting):</p> <p>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</p>

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	<p>appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a reasonable period or withdraw it, commensurate with the nature of the risk, as it may prescribe.</p> <p>NL:</p> <p>(Comments):</p> <p>If the AI system cannot be corrected it should be able to withdraw it.</p>
<p>The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph.</p>	<p>DK:</p> <p>(Drafting):</p> <p>The market surveillance authority shall inform the relevant notified body</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph. However, the time frame mentioned in article 18(3) shall be not less than 10 working days.</p> <p>DK:</p> <p>(Comments):</p> <p>We would suggest adding a specific timeframe, also as article 18(3) in regulation 1020/2019 states that “the economic operator concerned shall be given the opportunity to be heard within an appropriate period of not less than 10 working days.”</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>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.</p>	<p>IT:</p> <p>(Comments):</p> <p>Cooperation mechanisms and procedures shall be set up in order to make the exchange of information system effective.</p> <p>SE:</p> <p>(Drafting):</p> <p>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 national supervisory authorities of other Member States and the European Artificial Intelligence Board of the results of the evaluation and of the</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>actions which it has required the operator to take.</p> <p>NL:</p> <p>(Drafting):</p> <p>Where the market surveillance authority considers that non-compliance is not restricted to its national territory, it shall inform the Commission and the other Member States within a reasonable time of the results of the evaluation and of the actions which it has required the operator to take.</p> <p>NL:</p> <p>(Comments):</p> <p>To prevent long delays/ lack of information</p>

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	or doubling of evaluations.
<p>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.</p>	<p>IT: (Comments):</p>
<p>5. Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market, to withdraw the product from that market or to</p>	<p>SE: (Drafting): That authority shall inform the Commission and the other Member States and the European Artificial Intelligence Board, without delay, of those measures.</p>

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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:	<p>ES:</p> <p>(Comments):</p> <p>In the line of the previous comment, it seems that there is an assumption that the AI system is a high-risk AI system, and therefore it is automatically supposed to comply with requirements and to have passed a conformity assessment. But the article talks about AI systems, so the prior situation will not always be the case. It seems to be some contradiction here.</p> <p>IT:</p> <p>(Comments):</p> <p>EU guidelines could be appropriate.</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>(a) a failure of the AI system to meet requirements set out in Title III, Chapter 2;</p>	<p>ES:</p> <p>(Comments):</p> <p>In the line of the previous comment, it seems that there is an assumption that the AI system is a high-risk AI system, and therefore it is automatically supposed to comply with requirements and to have passed a conformity assessment. But the article talks about AI systems, so the prior situation will not always be the case. It seems to be some contradiction here.</p>
<p>(b) shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 conferring a presumption of conformity.</p>	<p>ES:</p> <p>(Comments):</p> <p>In the line of the previous comment, it seems that there is an assumption that the AI system is a high-risk AI system, and therefore it is automatically supposed to comply with requirements and to have passed a conformity assessment. But the article talks about AI systems, so the prior situation will not always be the case. It seems to be some contradiction here.</p>

Presidency compromise text	Drafting Suggestions Comments
<p>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.</p>	<p>SE:</p> <p>(Drafting):</p> <p>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 national supervisory authorities of other Member States and the European Artificial Intelligence Board 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</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>measure, of their objections.</p> <p>SE:</p> <p>(Comments):</p> <p>Some other modifications will be needed if the proposed change is accepted.</p>
<p>8. Where, within three months of receipt of the information referred to in paragraph 5, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified. This is without prejudice to the procedural rights of the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020.</p>	<p>DK:</p> <p>(Comments):</p> <p>To protect the future endeavour of the different actors, we believe that a three-month time frame for objections is too long and could potentially hurt the operator by prolonging the matter without a finalized resolution.</p>

Presidency compromise text	Drafting Suggestions Comments
<p>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.</p>	<p>IT:</p> <p>(Comments):</p> <p>Explicit reference to Member States rules and procedures shall be introduced.</p>
<p><i>Article 66</i> <i>Union safeguard procedure</i></p>	<p>HU:</p> <p>(Drafting):</p> <p>Article 66 Union safeguard procedure</p> <p>HU:</p> <p>(Comments):</p> <p>The current wording of Article 66 of the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Proposal establishes a broad right to the Commission to rebut decisions of the competent national authorities. This gives the right to the Commission to de facto decide a dispute between two Member States.</p> <p>The power of a Member State to dispute a decision of a national authority of another Member State, as well as the power of overruling national authorities, in our view, an excessive interference with the powers of national authorities, therefore, we recommend omitting this provision.</p>
<p>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</p>	<p>IT:</p> <p>(Drafting):</p>

Presidency compromise text	Drafting Suggestions Comments
<p>Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall without delay enter into consultation with the relevant Member State and operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not within 9 months from the notification referred to in Article 65(5) and notify such decision to the Member State concerned.</p>	<p>IT:</p> <p>(Comments):</p> <p>The procedure and parameters to be taken into account in order to evaluate the national measure shall be provided.</p> <p>Terms included shall be substituted with “without delay”.</p> <p>SE:</p> <p>(Drafting):</p> <p>Where, within three months of receipt of the notification referred to in Article 65(5), objections are raised by a Member State</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall without delay enter into consultation with the market surveillance authority of the relevant Member State and operator or operators and shall evaluate the national measure.</p> <p>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 the market surveillance authority of another Member State, the European Artificial Intelligence Board shall without delay enter into consultation with the market surveillance authority of the relevant Member State and</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>operator or operators and shall evaluate the national measure.</p> <p>On the basis of the results of that evaluation, the Commission European Artificial Intelligence Board shall decide whether the national measure is justified or not within 9 months from the notification referred to in Article 65(5) and notify such decision to the Member State concerned.</p> <p>SE:</p> <p>(Comments):</p> <p>The article should be directed to the relevant authority, i.e. the market surveillance authority. The Swedish constitution prohibits the Government to intervene in</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>how an administrative authority decides in a particular case.</p> <p>HU:</p> <p>(Drafting):</p> <p>1. Where, within three months of receipt of the notification referred to in Article 65(5), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall without delay enter into consultation with the relevant Member State and operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>whether the national measure is justified or not within 9 months from the notification referred to in Article 65(5) and notify such decision to the Member State concerned.</p> <p>DK:</p> <p>(Drafting):</p> <p>[...] On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not within 5 9 months from the notification referred to in Article 65(5) and notify such decision to the Member State concerned.</p> <p>DK:</p> <p>(Comments):</p> <p>It is unclear which kind of procedure will be</p>

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	<p>used when the Commission will decide on the national measure. In existing legislation, it states that the Commission shall adopt an implementing act in the form of a decision determining whether the national measure is justified or not. When a decision will have an effect in all member states, we would underline the need to have a procedure which outlines a proper involvement of the member states.</p> <p>Furthermore, it is positive with a clear timeframe for the Union safeguard procedure. However, as the regulation sets strict requirements for actors to comply with, the Commission and member states should also work within an ambitious timeframe, also with respect to providing</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>legal certainty. Therefore, we suggest a shorter timeframe.</p> <p>NL:</p> <p>(Comments):</p> <p>What happens with the system during this time of talks and investigations?</p> <p>Regarding: “objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall without delay enter into consultation with the relevant Member State and operator or operators and shall evaluate the national measure.”</p> <p>There can be two situations: another</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>member state does not agree with the decision of the member state to approve the AI system, or to disapprove the AI system. However, Article 66 (2) and (3) only covers the latter situation. What if other member states object to an admission of an AI system to the internal market by another member state? Is this situation deliberately left out? Is there a remedy against the decision of the Commission?</p>
<p>2. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant AI system is withdrawn from</p>	<p>ES:</p> <p>(Comments):</p> <p>What if the National measure was a concrete restriction on the AI system and not its withdrawal?</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.</p>	<p>It seems that the writing is not complete, as it only mentions withdrawal.</p> <p>IT:</p> <p>(Comments):</p> <p>paragraph 2: Is there a term provided for Member States to withdraw the AI system from the market?</p> <p>SE:</p> <p>(Drafting):</p> <p>If the national measure is considered unjustified, the market surveillance authority of the relevant Member State concerned shall withdraw the measure.</p> <p>HU:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Drafting):</p> <p>2. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant AI system is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.</p>
<p>3. Where the national measure is considered justified and the non-compliance of the AI system is attributed to shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 of this Regulation, the</p>	<p>HU:</p> <p>(Drafting):</p> <p>3. — Where the national measure is considered justified and the non-compliance of the AI system is attributed to</p>

Presidency compromise text	Drafting Suggestions Comments
<p>Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.</p>	<p>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.</p>
<p><i>Article 67</i> <i>Compliant AI systems which present a risk</i></p>	<p>DK: (Comments): In terms of procedure, we would have the same request as set out in article 66. Also, the involvement of the European Artificial Intelligence Board could be relevant in terms of the procedure set out in article 67, as it could call for greater coordination Furthermore, the use of the term risk in this</p>

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	<p>article might be too broad in order to distinguish between different risks. To take an example, there will always be a risk to the health or safety of people when it comes to medical devices, but it is the manufacturer's responsibility to minimize these risks in order to ensure that the effect and performance are in line with the given risk. However, this seems to be in contrast with the specific wording of this article, where a system can be withdrawn from the market, if any given risk is not completely eliminated. This should be clarified as well as considered whether there should be a distinction between any risks and unacceptable or undocumented risks.</p>

Presidency compromise text	Drafting Suggestions Comments
<p>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 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>SK:</p> <p>(Comments):</p> <p>It should be clearly stated and guaranteed that the MSs have a possibility to intervene under this article also in relation to systems which are prohibited under article 5, and also in relation to systems which are not high-risk. This is necessary also because the proposed act is a full-harmonisation measure.</p> <p>BG:</p> <p>(Drafting):</p> <p>1. Where, having performed an evaluation under Article 65 and there is enough evidence, the market surveillance</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a serious risk to the health or safety of persons.....</p> <p>BG:</p> <p>(Comments):</p> <p><u>Justification</u>: it should be underlined that this provision addresses very rare and exceptional situations for the sake of avoiding excessive burden.</p> <p>IT:</p> <p>(Comments):</p> <p>In order to avoid uncertainty and contradictory applications, a formal procedure shall be defined and the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>principle of due process shall be included.</p> <p>SE:</p> <p>(Drafting):</p> <p>or national law intended to protect fundamental rights, non-discrimination or to other aspects of public interest protection,</p> <p>SE:</p> <p>(Comments):</p> <p>In terms of AI, non-discrimination is</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>essential if the providers and users of AI want the public to trust in the use of AI. It is all the more pertinent as several cases of discrimination already have been exposed. Therefore, non-discrimination should be particularly prominent in the regulation.</p> <p>This is one of the elements which constitutes a risk which creates uncertainty for the companies concerned.</p> <p>HU:</p> <p>(Drafting):</p> <p>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</p>

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

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>mentioned here as in other parts of the text.</p> <p>NL:</p> <p>(Drafting):</p> <p>to the compliance with obligations under Union or national law intended to protect fundamental rights</p> <p>NL:</p> <p>(Comments):</p> <p>It is unclear what is meant with 'obligations under Union or national law intended to protect fundamental rights'. Does this for instance cover the Charter of Fundamental Rights? Also, there may be (unacceptable) risks to fundamental rights which are not yet</p>

Presidency compromise text	Drafting Suggestions Comments
	covered by national or Union law.
<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</p>	<p>SE: (Drafting): The market surveillance authority shall immediately inform the European Artificial Intelligence Board and the other Member</p>

Presidency compromise text	Drafting Suggestions Comments
supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.	States. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.
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.	SE: (Drafting): The European Artificial Intelligence Board shall without delay enter into consultation with the market surveillance authority and the relevant operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the European

Presidency compromise text	Drafting Suggestions Comments
	<p>Artificial Intelligence Board shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.</p> <p>DK:</p> <p>(Drafting):</p> <p>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, within 5 months.</p> <p>DK:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>The regulation sets strict requirements for actors to comply with, therefore, the Commission and member states should also work within an ambitious timeframe, also in order to provide legal certainty. Therefore, we suggest a shorter timeframe.</p>
<p>5. The Commission shall address its decision to the Member States.</p>	<p>SE:</p> <p>(Drafting):</p> <p>The European Artificial Intelligence Board</p>
<p><i>Article 68</i></p> <p><i>Formal non-compliance</i></p>	
<p>1. Where the market surveillance</p>	

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>authority of a Member State makes one of the following findings, it shall require the relevant provider to put an end to the non-compliance concerned:</p>	
<p>(a) the conformity marking has been affixed in violation of Article 49;</p>	
<p>(b) the conformity marking has not been affixed;</p>	
<p>(c) the EU declaration of conformity has not been drawn up;</p>	
<p>(d) the EU declaration of conformity has not been drawn up correctly;</p>	

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(e) the identification number of the notified body, which is involved in the conformity assessment procedure, where applicable, has not been affixed;	
2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the high-risk AI system being made available on the market or ensure that it is recalled or withdrawn from the market.	<p>IT:</p> <p>(Comments):</p> <p>Reference to Member States rules and procedures shall be included.</p>
	<p>ES:</p> <p>(Drafting):</p> <p>CHAPTER 4</p> <p>DIRECT</p>

Presidency compromise text	Drafting Suggestions Comments
	<p data-bbox="840 440 1232 469">COMPLAINT PROCEDURE</p> <p data-bbox="757 493 1312 580"><i>Article 69: Right to lodge a complaint with a supervisory authority</i></p> <p data-bbox="745 604 1321 1137">1. Without prejudice to any other administrative or judicial remedy, every citizen shall have the right to lodge a complaint with a supervisory authority, in particular in the Member State of his or her habitual residence, place of work or place of the alleged infringement if the citizen considers that he or she has been subjected to an AI system that infringes this Regulation.</p> <p data-bbox="745 1161 1290 1305">2. The supervisory authority will examine the complaint and issue a report with the decision taken as regards of the complaint.</p> <p data-bbox="745 1342 801 1370">ES:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>Citizens should have the right to inform about situations where an AI system that may affect health, safety or fundamental rights.</p>
TITLE IX	
CODES OF CONDUCT	<p>BE:</p> <p>(Comments):</p> <p>We support the Commission's will to facilitate a framework for the creation of codes of conduct, which aim to encourage providers of non-high-risk AI systems to apply voluntarily the mandatory requirements for high-risk AI systems as</p>

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	<p>laid out in Title III. Providers of non-high-risk AI systems, or the organizations that represent them, may agree on and implement the codes of conduct themselves. In this regard, we would like to stress that the Commission should always make sure that there is enough scope and flexibility for the Member States and the sectors to organize themselves. A coordination at EU level will of course always be necessary to incentivize implementation and ensure a level playing field.</p>
<p><i>Article 69</i> <i>Codes of conduct</i></p>	<p>DK:</p> <p>(Comments):</p> <p>As the general objective should be to</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>enhance trustworthy AI – not only for the AI which poses serious risks - we are supportive of voluntary tools to create incentives to develop and use trustworthy AI. In our view, this can become a competitive advantage for our companies. In this respect, we find that a voluntary labelling scheme would be a practical tool to achieve this objective – with a national scheme already launched. At the same time, we find that code of conducts could be a first, initial step in this direction.</p> <p>However, it is very directly stated in this article that the goal is to foster the voluntary application of the high-risk requirements – as well as the voluntary application of further requirements. In our view, there should be a clear difference between the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>requirements imposed on high-risk AI and the requirements in the code of conducts, bearing in mind that the code of conducts concerns AI with no or minimal risk.</p> <p>Otherwise all AI will de facto be subject to the stricter high-risk requirements. The impact assessment estimates that the aggregated cost for high-risk AI when looking at both compliance as well as verification could amount to up to 10% of the total investment in high-risk AI. It would therefore not be proportionate to set such a threshold for being trustworthy for systems which represents only minimal or no risks for citizen's rights or safety.</p>
<p>I. The Commission and the Member States shall encourage and facilitate the</p>	<p>ES:</p>

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<p>drawing up of codes of conduct intended to foster the voluntary application to AI systems other than high-risk AI systems of the requirements set out in Title III, Chapter 2 on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems.</p>	<p>(Drafting):</p> <ol style="list-style-type: none"> 1. The Commission and the Member States shall encourage and facilitate the drawing up of codes of conduct intended to foster trustworthy AI systems. This may be done through different sets of recommendations, such as the voluntary application to AI systems other than high-risk AI systems of the requirements set out in Title III, Chapter 2 on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems. <p>ES:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Taking into account the variety of AI systems, it could be appropriate not to necessarily drive codes of conduct to the application of the requirements of Chapter II, Tit III (as some of them may be exaggerated or useless for certain AI systems and their use). Leave it as a recommendation concerning the way of developing such codes instead could be useful.</p> <p>IE:</p> <p>(Comments):</p> <p>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?</p> <p>BG:</p> <p>(Comments):</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>Codes of conduct are an instrument of self-regulation and therefore, they are voluntary. In this regard, it is not clear how exactly the Commission and the Member States in paragraph 1 or the Board in paragraph 2 will encourage and facilitate drawing up of voluntary codes as long as Member States should not have a leading role in the self-regulatory process. The Board could exchange best practices about any existing codes of conduct and disseminate the information about their presence at national level so that companies could draw on the already existing experience, if they wish so</p> <p>HR:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Regarding AI systems that are not high risk, for ensuring compliance with human rights legal standards, requirements shouldn't be on voluntary basis but mandatory.</p> <p>HU:</p> <p>(Drafting):</p> <p>1. The Commission, the Board and the Member States shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to</p> <p>a) AI systems other than high-risk AI systems of the requirements set out in Title III, Chapter 2 on the basis of technical specifications and solutions that are appropriate means</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>of ensuring compliance with such requirements in light of the intended purpose of the systems, and 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.</p> <p>HU:</p> <p>(Comments):</p> <p>We recommend simplifying the text. We did not make a new sub-paragraph. Paragraphs</p>

Presidency compromise text	Drafting Suggestions Comments
	1 and 2 of the original text (in column 1) have been merged into paragraph 1 (a) and (b)).
<p>2. The Commission and the Board shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to AI systems of requirements related for example to environmental sustainability, accessibility for persons with a disability, stakeholders participation in the design and development of the AI systems and diversity of development teams on the basis of clear objectives and key performance indicators to measure the achievement of those objectives.</p>	<p>ES: (Drafting):</p> <p>2. The Commission and the Board shall encourage and facilitate the drawing up of codes of conduct, like those 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</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>objectives and key performance indicators to measure the achievement of those objectives.</p> <p>BG:</p> <p>(Comments):</p> <p>We don't see the reason for having two separate paragraphs one for the requirements set out in Title III, Chapter 2 in the previous paragraph and another for requirements related to environmental sustainability etc. as this would imply that there would be two different types of codes of conduct while this should not be the intention. Therefore, we would propose to merge the two paragraphs</p> <p>SE:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Drafting):</p> <p>The Commission, European Artificial Intelligence Board and the Member States 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, gender equality and accessibility for persons with a disability</p> <p>SE:</p> <p>(Comments):</p> <p>Gender equality should be an integral part of all codes of conduct, all the more as both the Commission and the Member states</p>

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	<p>have been called upon to “design, implement and monitor targeted measures to overcome gender stereotypes in the context of AI, with the aim of ensuring gender equality in this area.” (CCs on the Impact of AI on Gender equality in the Labour Market)</p> <p>HU:</p> <p>(Drafting):</p> <p>2. — The Commission and the Board shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to AI systems of requirements related for example to environmental sustainability, accessibility for persons with a disability, stakeholders</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>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.</p>
<p>3. Codes of conduct may be drawn up by individual providers of AI systems or by organisations representing them or by both, including with the involvement of users and any interested stakeholders and their representative organisations. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems.</p>	<p>BG: (Drafting):</p> <p>2. 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 or by the users, and including with the involvement of any interested stakeholders and their representative organisations.</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>BG:</p> <p>(Comments):</p> <p>It is not very clear whose responsibility is to draw up the codes of conduct i.e. providers, organisations representing them or both, or the Commission and the Board/Member States as the latter ones will have the role of facilitators. Users should also have the right to draw up codes of conduct, as their needs and responsibilities are not always the same as those of the providers. It is not enough to merely involve them although all involved actors should co-operate with each other</p> <p>SE:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	Codes of conduct procedures are not defined or illustrated. Who shall comply to the demands?
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.	
	<p>PT:</p> <p>(Drafting):</p> <p>5 – The Commission and the Board shall recommend including in these codes of conduct concepts such as: privacy; accountability; safety and security;</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>transparency, explainability and interpretability; fairness and non-discrimination; human control of technology; professional responsibility; and promotion of human values.</p> <p>PT:</p> <p>(Comments):</p> <p>In order to ensure such important matters are covered</p>
TITLE X	
CONFIDENTIALITY AND PENALTIES	
<i>Article 70</i> <i>Confidentiality</i>	ES:

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>LEAs should have a more particular treatment in this article.</p> <p>SK:</p> <p>(Comments):</p> <p>Implementing acts should stipulate in detail what measures need to be taken in order to meet the confidentiality requirements contained in article 70.</p> <p>SE:</p> <p>(Comments):</p> <p>Under Section 3.5 Fundamental Rights it is stated that the increased transparency requirements will not disproportionately affect the right to protection of intellectual property and that all disclosure of</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>information will take place in accordance with relevant legislation in this area, including Directive 2016/943 on protection against undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure. However it is not entirely clear, as it on the one hand it could be interpreted as if there will be a certain restriction on intellectual property rights even if it is judged to be in proportion, on the other hand disclosure of information will take place in accordance with relevant legislation. Would it be possible to get an example or further description of the extent to which the AIA may or may not affect intellectual property rights.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>FI:</p> <p>(Comments):</p> <p>National competent authorities and notified bodies may be subject to legislation on access to official documents in the Member States.</p> <p>This article is very general and hence problematic from a constitutional point of view</p> <p>FI has a constitutional requirement that only necessary derogations from the principle of public access to official records are allowed; this prohibits vague, blanket rules on confidentiality.</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>DK:</p> <p>(Comments):</p> <p>As set out in our written comments covering article 1-29, we underlined the necessity of directly reflecting in article 2 that the regulation should not oblige member states or entities to supply information where such supply would be contrary to national security or defence interest. Similar wording can be found in the scope of the NIS2. We find that this would also affect this article.</p>
<p>1. National competent authorities and notified bodies involved in the application of this Regulation shall respect the confidentiality of information and data</p>	<p>SE:</p> <p>(Drafting):</p> <p>National competent authorities and notified</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
<p>obtained in carrying out their tasks and activities in such a manner as to protect, in particular:</p>	<p>bodies involved in the application of this Regulation shall, according to Union and national law respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:</p> <p>SE:</p> <p>(Comments):</p> <p>Should there not be a general clause for confidentiality aimed at the Commission and the European Artificial Intelligence Board?</p> <p>FI:</p> <p>(Drafting):</p> <p>National competent authorities and notified</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>bodies involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks and activities <i>according to Member State law</i> in such a manner as to protect, in particular:</p> <p>FI:</p> <p>(Comments):</p> <p>Intellectual property rights are by nature public; reference to them should be removed or it should be clarified - what is the actual object of confidentiality intended here?</p> <p>Confidentiality should be protected <i>according to MS law</i> (domestic rules on</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>administrative proceedings etc.)</p> <p>HU:</p> <p>(Drafting):</p> <p>National competent authorities, and notified bodies, public authorities or private entities involved in the regulatory sandboxes set out in Title V, and any other authority, body or private entity 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:</p> <p>HU:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>We propose to extend the confidentiality obligation in Article 70 (1) to national market surveillance authorities, and in general to all authority and body that may receive information about the functioning of the AI system during the course of its tasks under the AI Regulation Proposal, including during the regulatory sandboxes.</p>
<p>(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.</p>	<p>FI:</p> <p>(Comments):</p> <p>Art 70(1)(a) should be defined by reference to Art 2 Directive 2016/943; the definition is clear and unambiguous, and this directive has already been implemented in MS law.</p>

Presidency compromise text	Drafting Suggestions Comments
<p>(b) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits;(c) public and national security interests;</p>	<p>CZ:</p> <p>(Drafting):</p> <p>(b) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits;(e) public and national security interests;</p> <p>CZ:</p> <p>(Comments):</p> <p>Typo.</p>
<p>(c) integrity of criminal or administrative proceedings.</p>	<p>CZ:</p> <p>(Drafting):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(c) integrity of criminal or administrative proceedings-;</p> <p>NL:</p> <p>(Drafting):</p> <p>integrity of criminal investigations and or administrative proceedings.</p>
	<p>CZ:</p> <p>(Drafting):</p> <p>(d) public and national security interests.</p> <p>CZ:</p> <p>(Comments):</p> <p>See above Art. 70(1)(b).</p>

Presidency compromise text	Drafting Suggestions Comments
<p>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.</p>	<p>NL:</p> <p>(Drafting):</p> <p>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 or national security interests or jeopardise the detection, prevention, investigation and prosecution of</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>criminal offences, including the safeguarding against and the prevention of threats to public security.</p> <p>NL:</p> <p>(Comments):</p> <p>Supervision might go further than only the category of high risk AI systems. We propose to delete the reference to Annex III, the exception for law enforcement would then still be intact.</p>
<p>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</p>	<p>SE:</p> <p>(Drafting):</p> <p>Only staff of the market surveillance authority holding the appropriate level of</p>

Presidency compromise text	Drafting Suggestions Comments
<p>the premises of those authorities. Those authorities shall ensure that the market surveillance authorities referred to in Article 63(5) and (6), as applicable, can, upon request, immediately access the documentation or obtain a copy thereof. Only staff of the market surveillance authority holding the appropriate level of security clearance shall be allowed to access that documentation or any copy thereof.</p>	<p>security clearance shall be allowed to access that documentation or any copy thereof.</p> <p>SE:</p> <p>(Comments):</p> <p>The proposed text should be adjusted to clarify that it is only concerning how the documentation should be made available.</p> <p>CZ:</p> <p>(Drafting):</p> <p>When the law enforcement, immigration or asylum authorities are providers or sole users of high-risk AI systems referred to in points 1, 6 and 7 of Annex III, the technical documentation referred to in Annex IV shall remain within the premises of those</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>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>CZ:</p> <p>(Comments):</p> <p>The protection of documentation according to Article 70(2) should also apply in cases where the law enforcement, immigration or asylum authorities are not providers but sole</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>users of such AI systems.</p> <p>DK:</p> <p>(Comments):</p> <p>We are questioning why it is only within areas such as law enforcement, immigration or asylum that information exchanged on a confidential basis shall not be disclosed without the prior consultation of the originating national competent authority and the user. In legislation such as medical devices or machinery product, similar provisions cover the entire scope of these acts, not just certain areas of it. We would like to have a similar provision in the AI Act, also with respect to consistency with existing legislation.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>NL:</p> <p>(Comments):</p> <p>A definition of <i>'premises'</i> would be helpful. This could either be a physical location (e.g. offices) or could be digitally stored in a private cloud environment (e. g. a data center) which can be located off-premise.</p> <p>Should there not be a distinction between law enforcement and immigration and asylum authorities in this context?</p>
	<p>SE:</p> <p>(Drafting):</p> <p>Only staff of the market surveillance authority holding the appropriate level of</p>

Presidency compromise text	Drafting Suggestions Comments
	security clearance shall be allowed to access that documentation or any copy thereof.
<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 countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of confidentiality.</p>	<p>BE:</p> <p>(Comments):</p> <p>Link with uncertainty about which general rules apply or do not apply to law enforcement - More information is needed</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>about which confidential information could be shared with third countries, and if also restrictions apply, especially in the domain of law enforcement.</p> <p>NL:</p> <p>(Drafting):</p> <p>The Commission and Member States may, notwithstanding paragraphs 1 and 2, exchange, where necessary, confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of confidentiality</p>
	<p>LV:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Drafting):</p> <p>5. Persons who have suffered from AI activities may go to court and claim compensation.</p> <p>HU:</p> <p>(Drafting):</p> <p>5. The provisions of this Regulation shall not affect the right of access to information and documents of national authorities based on Member State or Union law.</p> <p>HU:</p> <p>(Comments):</p> <p>In order to avoid any doubt and conflict</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>with laws regulating certain authorities, we suggest this provision for clarification.</p> <p>AT:</p> <p>(Drafting):</p> <p>NEW</p> <p>Article 70a</p> <p>Exceptions for AI systems with enhanced confidentiality requirements</p> <p>1. A provider of a high-risk AI system that is confronted with a request by a competent national authority for information, documentation, access to data, disclosure of the source code or a similar measure under this Regulation may refuse to comply with the request if that provider can demonstrate that the relevant materials would, if</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>disclosed to unauthorised parties, jeopardise public and national security interests.</p> <p>2. A provider relying on paragraph 1 shall immediately notify the Commission of the refusal to comply with the request and the reasons of the refusal. The Commission shall, upon having investigated the matter, issue a decision addressed at the relevant national authority and the provider. In that decision, the Commission may provide that only Commission staff holding the appropriate level of security clearance shall be allowed to access the relevant materials, and impose further restrictions and safeguards as appropriate.</p> <p>AT:</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>(Comments):</p> <p>In addition to a new enforcement mechanism for systemic risks it is suggested to insert a provision that avoids threats to public and national security interests which could result if national authorities in all 27 Member States had full access to all relevant data and the source code of, e.g., AI systems that are safety components in critical infrastructure (such as AI systems used to detect attacks on power grids within the Union).</p>
<p><i>Article 71</i></p> <p><i>Penalties</i></p>	<p>ES:</p> <p>(Comments):</p> <p>We would like to understand two questions in this regard:</p> <p>1.- How the maximum amount for fines has been</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>decided, under which criteria?</p> <p>2.- The reasons for the big differences between the fines to be established for companies or other entities and the EU institutions/agencies/bodies.</p> <p>SK:</p> <p>(Comments):</p> <p>Proportionality of the proposed sanctions needs to be considered as they may be challenged in courts to their strictness and the complexity/vagueness of obligations.</p> <p>Powers of exhortation, persuasion and guidance need to complement and balance the sanctioning powers – see general comments to Title VI above .</p> <p>PL:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p><i>1. Penalties should be imposed on the basis of a clear list of conditions and the specifically mentioned violations. The envisaged sanctions are too severe (especially for low-margin companies) and will disproportionately increase the business risk associated with with the use and development of artificial intelligence. This may have a negative impact on the development of artificial intelligence in the European Union. There is a risk that the authorities will act arbitrarily without any specific administrative order. It is suggested to introduce clear premises and mitigating and aggravating circumstances, similar to the solutions introduced in the</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p><i>GDPR.</i></p> <p><i>2. The suggested solution of extending the criteria for determining the amount, analogically to the solution adopted in Art. 83 sec. 2 GDPR.</i></p> <p><i>3. Authorities should be encouraged to make available tools to estimate penalties and the risk of incurring them.</i></p> <p><i>4. points out that it seems that for the same breach of Article 10 of the draft and for the breach of the provisions of the General Data Protection Regulation (GDPR), a second penalty may be imposed (double penalty: Article 71 (6) (b) of the draft). This matter requires a precise explanation at</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p><i>least in the preamble. There is a risk of systemic contradiction in determining the double card in the same case.</i></p> <p>SE:</p> <p>(Comments):</p> <p>Important that both the requirements and the penalties are proportionate and not unnecessarily high. Some requirements are very difficult to comply with, for an example see comment below.</p> <p>FI:</p> <p>(Comments):</p> <p>We support broad national discretion in terms of penalties, which includes e.g. the following aspects:</p>

Presidency compromise text	Drafting Suggestions Comments
	<ul style="list-style-type: none"> • The national body, which decides on the penalties, should be multimember. • Slight failures to comply with the requirements of AI Act could not be sanctioned. <p>Due process and legal remedies, regulated by national law, must be taken into account when imposing sanctions under AI Act.</p> <p>EE:</p> <p>(Comments):</p> <p>Article 71 should refrain from using the term “<i>administrative fine</i>” as it is not harmonized in the EU, while in some Member States administrative fines may be formally classified as criminal sanctions. If the intention of Article 71 is to enable administrative agencies to issue the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>respective fines, then this should be explicitly stated, as opposed to classifying the fine as administrative. Additionally, Member States should retain discretion in choosing the specific form of the sanction to ensure compatibility of Article 71 with national rules.</p> <p>Furthermore, the maximum fines for natural persons should be reassessed and possibly lowered. It is arguable that such high fines for natural persons may essentially be considered as criminal punishment, which would require Article 83 of the TFEU as a legal basis of the AIA. It would be helpful if the Council Legal Service could provide their opinion on this issue.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Additionally, it should be considered that such a high margin for the fines in Article 71 does not provide a sufficiently clear understanding on the part of the natural person as regards the potential severity of a potential penalty in the case of any specific infringement – such ambiguity regarding the punishment may thereby infringe the <i>nullum crimen nulla poena sine lege certa</i> principle.</p> <p>DK:</p> <p>(Comments):</p> <p>In general, we are supportive of the introduction of effective and proportionate sanctions, including fines, as part of securing an effective enforcement.</p>

Presidency compromise text	Drafting Suggestions Comments
	However, in terms of proportionality, we are questioning the level of fines, as this seems to differ from existing legislation such as the GDPR.
<p>1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests of small-scale SME providers, including and start-up, and their economic viability.</p>	<p>BG: (Drafting): “.....They shall take into particular account the size and the interests of small-scale SME providers, including and start-up, and their economic viability.”</p> <p>BG: (Comments): <u>Justification</u>: the penalties need to be proportionate to the size of the enterprises.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>HR:</p> <p>(Comments):</p> <p>Existing equality and fundamental rights legal protections should be strengthened to adequately respond to AI-related risks. Evidence requirements for assessing harmfulness in that context should be especially strict, and the burden of proof should be on the developer/deployer and not on those affected.</p> <p>SE:</p> <p>(Drafting):</p> <p>The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>interests of small-scale SME providers, including and start-ups, and their economic viability.</p> <p>FI:</p> <p>(Comments):</p> <p>It should be ensured that the penalties, laid down by this Regulation or national law, do not result in double jeopardy especially in terms of the penalties imposed by the GDPR. The relation of the penalties to those of the GDPR should be clarified.</p> <p>Penalties should be proportionate and accurately regulated. In this Act, the penalties do not appear to be proportionate. It should be clarified what penalty applies to whom.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>EE:</p> <p>(Comments):</p> <p>We support taking into account the interests of the SMEs and the size of the enterprise while imposing penalties. To ensure effective implementation of the Act, it should be further explained, how should the interests of the SMEs be taken into account while imposing fines.</p> <p>How to guarantee the uniform application of this obligation and equal treatment of SMEs across the internal market?</p> <p>AT:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>The wording of the provision is too vague, as it does not state exactly to what extent the penalties will actually be reduced. A separate paragraph, comparable to paragraphs 3-6, should be included in Art 71, in which the maximum amount and percentage to be finally applied to SMEs and start-ups are stated.</p> <p>Art. 85 para. 3 letter b of the Regulation on AI currently foresees that Art. 71 should apply from twelve months following the entry into force of this Regulation.</p> <p>However, Art. 71 shall sanction non-compliance with Articles which will only be applicable from 24 months following the</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>entering into force of the Regulation (e.g. Art. 5, 10, etc.). We do not understand why the provision which shall sanction non-compliance with specific provisions should be (transposed) and applicable before the specific provisions themselves will be applicable.</p> <p>We would therefore advocate that Art. 71 should be applicable from 24 months following the entering into force of the Regulation as it is the case for the rest of this Regulation and to delete Art. 85 para. 3 letter b of this Regulation accordingly.</p>
<p>2. The Member States shall notify the Commission of those rules and of those measures and shall notify it, without delay,</p>	<p>IT:</p>

Presidency compromise text	Drafting Suggestions Comments
of any subsequent amendment affecting them.	(Comments): A term for notification to the Commission shall be fixed.
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:	<p>IE:</p> <p>(Comments):</p> <p>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.</p> <p>FI:</p> <p>(Comments):</p> <p>Paragraph 3 is too open. It should be</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>clarified what actions can lead to a fine referred to in that paragraph.</p> <p>EE:</p> <p>(Comments):</p> <p>Is this high fine rate justified and proportionate considering that the obligations stemming from articles 5 and 10 are unclear and article 5(1)(b) now also includes vague legal concepts, such as “social and economic situation”? It should also be considered that as a result of the changes to art 5(1)(a) and (b), they can also be infringed regardless of the aim and the will of the offender, since they no longer only take into account the will of the operator, but also the effect to the persons.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>HU:</p> <p>(Drafting):</p> <p>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, in case of SME and start-up, up to 3 % of its worldwide annual turnover for the preceding financial year, whichever is higher:</p> <p>HU:</p> <p>(Comments):</p> <p>We strongly recommend that the fines for</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>non-compliance in Article 71 (3) b) are proportionate and limited for SMEs, a blanket reference of Article 71 (1) is not sufficient for this; it should be defined, either in a specific amount or percentage.</p>
	<p>EE:</p> <p>(Comments):</p> <p>A lower and proportionate sum should be applied if the offender is a natural person. Please also see comments above to Art 71.</p>
<p>(a) non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;</p>	<p>FI:</p> <p>(Comments):</p> <p>Article 5 does not absolutely prohibit certain artificial intelligence practices. It should be clarified whether this paragraph</p>

Presidency compromise text	Drafting Suggestions Comments
	concerns non-compliance with national legislation in terms of Article 5(4).
(b) non-compliance of the AI system with the requirements laid down in Article 10.	<p>SE:</p> <p>(Comments):</p> <p>Article 10 contains stipulations which we deem difficult to comply with such as “free of error”.</p> <p>FI:</p> <p>(Comments):</p> <p>We would like to ask why the non-compliance of Article 10 is subject to higher fines than the non-compliance of the other requirements on high-risk AI systems. Why does this paragraph concern Article 10 as a</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>whole? Should it only concern Article 10(5)?</p> <p>DK:</p> <p>(Drafting):</p> <p>(b) — non-compliance of the AI system with the requirements laid down in Article 10.</p> <p>DK:</p> <p>(Comments):</p> <p>With respect to proportionality, we are sceptical of putting non-compliance with article 10 in terms of data on the same footing as infringement of article 5 in terms of prohibition of AI practices. It would be more appropriate to include it in paragraph 4.</p>

Presidency compromise text	Drafting Suggestions Comments
<p>4. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to 20 000 000 EUR or, if the offender is a company, up to 4 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.</p>	<p>LV: (Comments): It should be noted that it is necessary to clarify Article 71 of the Regulation by ensuring that it is clear and predictable what type of action is to be declared punishable and what punishment is applicable to it, subject to the principle that the more severe the possible sanction, the clearer and more precise the prerequisites for sanctions are.</p> <p>FI: (Comments): Paragraph 4 is too open. It should be clarified what actions can lead to a fine</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>referred to in that paragraph.</p> <p>EE:</p> <p>(Comments):</p> <p>A lower and proportionate sum should be applied if the offender is a natural person. Please also see comments above to Art 71.</p> <p>HU:</p> <p>(Drafting):</p> <p>The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to 20 000 000 EUR or, if the offender is a company, up to</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>4 % of its total worldwide annual turnover for the preceding financial year, whichever is higher, in case of SME and start-up, up to 3 % of its worldwide annual turnover for the preceding financial year, whichever is higher.</p> <p>DK:</p> <p>(Drafting):</p> <p>4. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to 20 000 000 EUR or, if the offender is a company, up to 4 % of its total worldwide annual turnover for the preceding financial year, whichever</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>is higher.</p> <p>DK:</p> <p>(Comments):</p> <p>With respect to proportionality, we are sceptical of putting non-compliance with article 10 in terms of data on the same footing as infringement of article 5 in terms of prohibition of AI practices. It would be more appropriate to include it in paragraph 4.</p>
<p>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</p>	<p>LV:</p> <p>(Drafting):</p> <p>5. The supply of incorrect, incomplete or misleading information to notified bodies</p>

Presidency compromise text	Drafting Suggestions Comments
<p>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.</p>	<p>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. In cases where the regulatory framework of the Member States provides criminal liability for activities mentioned above, administrative liability to natural personas may not be applied.</p> <p>LV:</p> <p>(Comments):</p> <p>For provision of deliberately false information, if information to be provided by law, criminal liability is provided for</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>natural persons in Latvia. Given that Regulation is directly applicable, there will be a situation in which there are two regulations providing liability for the same infringement. Regulation of Latvia does not provide double punishment for the same violation. Clarification is necessary to clarify which regulatory act is to be applied in the case where a higher level of legal liability is already provided in a Member State for an identical infringement.</p> <p>FI:</p> <p>(Comments):</p> <p>Point 5 is too drastic considering that other administrative measures should be used first.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Possibility for national derogations is absolutely needed.</p> <p>EE:</p> <p>(Drafting):</p> <p>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 1 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.</p> <p>EE:</p>

Presidency compromise text	Drafting Suggestions Comments
	(Comments): Same rate as in the DMA and DSA.
	EE: (Comments): A lower and proportionate sum should be applied if the offender is a natural person. Please also see comments above to art 71.
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:	HU: (Comments): We recommend regulating clearly, whether the fine may be imposed repeatedly or not, and if so, how often.
(a) the nature, gravity and duration of the infringement and of its consequences;	IT:

Presidency compromise text	Drafting Suggestions Comments
	(Comments): The effects of the infringement shall be included as well.
(b) whether administrative fines have been already applied by other market surveillance authorities to the same operator for the same infringement.	LV: (Drafting): (b) whether administrative fines have been already applied by other market surveillance authorities to the same operator for the same infringement. LV: (Comments): With the development of legal doctrine, repetition as a special feature of the imposition of a sentence can no longer be taken into account, as it violates the

Presidency compromise text	Drafting Suggestions Comments
	<p>principle of the prohibition of double punishment. The fact that an infringement is repeated does not change the nature of the infringement and there are no grounds for punishing the person more severely for this infringement. We draw your attention to the fact that the national legislation of Latvia - neither the Law on Administrative Liability nor the Criminal Law - does not provide for recurrence to be taken into account when determining the applicable penalty.</p> <p>SE:</p> <p>(Comments):</p> <p>There needs to be further analysis on whether double punishment is probable, to what extent and by what regulation in order</p>

Presidency compromise text	Drafting Suggestions Comments
	to avoid it to the greatest extent possible.
(c) the size and market share of the operator committing the infringement;	<p>BG:</p> <p>(Drafting):</p> <p>“(c) the size, the annual turnover and or market share of the operator committing the infringement;</p> <p>PL:</p> <p>(Drafting):</p> <p>“(c) the size, the annual turnover and or market share of the operator committing the infringement;</p>
	<p>FI:</p> <p>(Drafting):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>d) Insignificance of the infringement</p> <p>FI:</p> <p>(Comments):</p> <p>Insignificant of the infringement or partial non-compliance of the requirements of AI Act should be taken into account when imposing fines.</p>
<p>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.</p>	<p>LV:</p> <p>(Drafting):</p> <p>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 or officials.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>LV:</p> <p>(Comments):</p> <p>We draw attention to the fact that in Latvia, in accordance with the administrative liability law, the penalty may be applied only to specific officials and not to public authorities.</p> <p>SI:</p> <p>(Drafting):</p> <p>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 and responsible persons within these public authorities and bodies.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>SI:</p> <p>(Comments):</p> <p>Need to mention also responsible persons.</p> <p>FI:</p> <p>(Comments):</p> <p>We support national discretion on penalties imposed on public authorities.</p>
<p>8. Depending on the legal system of the Member States, the rules on administrative fines may be applied in such a manner that the fines are imposed by competent national courts of other bodies as applicable in those Member States. The application of such rules in those Member States shall have an</p>	<p>DK:</p> <p>(Drafting):</p> <p>[...] by competent national courts or other bodies as applicable in those Member States.</p> <p>DK:</p>

Presidency compromise text	Drafting Suggestions Comments
equivalent effect.	<p>(Comments):</p> <p>As our constitution does not provide for administrative fines, article 71(8) is key for us to maintain in its current form.</p> <p>In this context, we would just like to highlight what seems to be a misspelling, as the paragraph 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” which rather should be “or other bodies”.</p>
<p><i>Article 72</i></p> <p><i>Administrative fines on Union institutions, agencies and bodies</i></p>	

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>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:</p>	<p>IT:</p> <p>(Comments):</p> <p>Italy expresses reservations on this provision.</p>
<p>(a) the nature, gravity and duration of the infringement and of its consequences;</p>	
<p>(b) the cooperation with the European Data Protection Supervisor in order to remedy the infringement and mitigate the</p>	

Presidency compromise text	Drafting Suggestions Comments
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:	SI: (Drafting): 2. The following infringements shall be subject to administrative fines of up to 500 2 000 000 EUR:

Presidency compromise text	Drafting Suggestions Comments
	SI: (Comments): To better align the fines of Union institutions, agencies and bodies with others we suggest to raise the fine from 500K to 2 mio EUR.
(a) non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;	
(b) non-compliance of the AI system with the requirements laid down in Article 10.	
3. The non-compliance of the AI system with any requirements or obligations under	

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

Presidency compromise text	Drafting Suggestions Comments
<p>5. The rights of defense of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the European Data Protection Supervisor's file, subject to the legitimate interest of individuals or undertakings in the protection of their personal data or business secrets.</p>	
<p>6. Funds collected by imposition of fines in this Article shall be the income of the general budget of the Union.</p>	
	<p>EE:</p> <p>(Comments):</p> <p>To facilitate access to justice, EE suggests</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>that the regulation should establish a direct complaint procedure with a national competent authority. This would provide a swift procedure to identify cases where individuals are subjected to AI practices prohibited under Art 5, high-risk AI systems that do not meet the conformity requirements of AIA or other incidents where fundamental rights of individuals are infringed.</p> <p>It would also aid national competent authorities in fulfilling their tasks concerning supervision over the implementation of the AIA, since the complaints by individuals could lead to more effective monitoring and evaluation of problematic AI practices.</p>

Presidency compromise text	Drafting Suggestions Comments
TITLE XI	
DELEGATION OF POWER AND COMMITTEE PROCEDURE	
<p><i>Article 73</i></p> <p><i>Exercise of the delegation</i></p>	<p><i>CZ:</i></p> <p><i>(Comments):</i></p> <p>Amending parts of the regulation through delegated acts is a sensitive point for numerous MS and its added value and related risks should be carefully considered before establishing this possibility.</p> <p>Incorporating some crucial parts of the text, such as Annex I or III, into the normative part of the proposal, should be further</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>discussed.</p> <p>See also our comments in relation to AI Board.</p> <p>EE:</p> <p>(Comments):</p> <p>Article 73 should establish a procedure, whereby the Commission must consult with stakeholders and their representative organisations prior to adopting delegated acts, especially when updating the list of AI techniques and approaches in Annex I or the list of high-risk AI systems in Annex III.</p> <p>DK:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>As mentioned in our written comments covering article 1 to 29, we are skeptical of for example defining an AI system in an annex which can be updated through delegated acts or updating the list of high-risk system through delegated acts. We are still assessing whether such an approach is the right way forward. As a preliminary view, at least the scope of the different delegated acts must be further delimited, especially to achieve legal certainty.</p> <p>Furthermore, we are still interested in hearing the opinion of the Council Legal Service in terms of whether the definition of AI as well as annex 3 would constitute non-essential elements according to article 290 TFEU.</p>

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</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>BG:</p> <p>(Comments):</p> <p style="text-align: center;">We will submit our comments to this article at a later stage</p> <p>PL:</p> <p>(Comments):</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</p>	<p>DK:</p> <p>(Comments):</p> <p>We are still assessing this adjustment. In our view, it is part of the wider discussion on</p>

Presidency compromise text	Drafting Suggestions Comments
<p>from <i>[entering into force of the Regulation]</i>.</p>	<p>the usage of delegated acts in order to find the right approach.</p> <p>NL:</p> <p>(Drafting):</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>NL:</p> <p>(Comments):</p> <p>The Netherlands is of the opinion that articles 4, 7(1) and 43(6) should contain references to implementing acts rather than</p>

Presidency compromise text	Drafting Suggestions Comments
	delegated acts as the nature of Annexes I, III and the decision about the conformity assessment procedures are of <i>essential</i> nature and require involvement of co-legislators.
<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 the Council opposes such extension not later than three months before the end of each period.</p>	<p>HU: (Drafting): The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.</p> <p>HU:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>Since the AI technology is expected to change very rapidly in the near future, the conditions of the AI Regulation itself should be revised explicitly by the European Parliament and the Council whether it poses any threats to the fundamental rights. Consequently, the re-delegation of power to the Commission should not be based on a tacit process, but an explicit decision.</p> <p>DK:</p> <p>(Comments):</p> <p>We are still assessing this adjustment. In our view, it is part of the wider discussion on the usage of delegated acts in order to find the right approach.</p>

Presidency compromise text	Drafting Suggestions Comments
<p>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.</p>	<p>NL: (Drafting):</p> <p>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</p> <p>NL: (Comments):</p> <p>See 73.1</p>
<p>4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament</p>	

Presidency compromise text	Drafting Suggestions Comments
and to the Council.	
<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>NL:</p> <p>(Drafting):</p> <p>Any delegated act adopted pursuant to Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall</p> <p>NL:</p> <p>(Comments):</p> <p>See 73.1</p>
<i>Article 74</i>	

Presidency compromise text	Drafting Suggestions Comments
<i>Committee procedure</i>	
<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>	<p>ES: (Comments): We deem necessary to clarify whether this Committee will be actually made from the European AI Board.</p> <p>IT: (Comments): The Committee shall be granted reinforced advisory powers.</p>
<p>2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.</p>	

Presidency compromise text	Drafting Suggestions Comments
TITLE XII	
FINAL PROVISIONS	
<i>Article 75</i> <i>Amendment to Regulation (EC) No</i> <i>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	SK: (Comments): “Shall be taken into account” – a more

Presidency compromise text	Drafting Suggestions Comments
<p>the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Chapter 2, Title III of that Regulation shall be taken into account.”</p>	<p>narrow and concrete language should be used to prevent fragmentation of legal framework in relevant sectors.</p>
<p>_____</p>	
<p>* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...).”</p>	
<p><i>Article 76</i> <i>Amendment to Regulation (EU) No 167/2013</i></p>	<p>DK: (Comments): Article 2 should be reworded, to clarify how the AI-regulation will affect the Regulations</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>and Directives on vehicles referred to in the Article, Article 2 states that only Article 84 applies to the vehicle Regulations and Directives as listed in Annex II section B. However, when taking a closer look at the Articles 76, 77, 80 and 82 of the AI-regulation it is clear that these Articles do also apply to Regulations and Directives on vehicles, despite the wording of Article 2. The consequence of the proposed Articles 76, 77, 80 and 82 in the AI-regulation is that future delegated acts pursuant to the respective vehicle Regulations and Directives related to the use of AI in safety components, shall take into account the requirements set out in Title III, Chapter 2.</p> <p>There are thus discrepancies between</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Article 2 and Articles 76, 77, 80 and 82.</p> <p>It should be stated more clearly in Article 2 that the vehicle Regulations and Directives listed in Annex II section B, are also subject to Articles 76, 77, 80 and 82. The AI-regulation should in other words be clear and consistent that the requirements in this Regulation also applies to the mentioned vehicle Regulations and Directives.</p>
<p>In Article 17(5) of Regulation (EU) No 167/2013, the following subparagraph is added:</p>	
<p>“When adopting delegated acts pursuant to the first subparagraph concerning artificial</p>	<p>SK:</p>

Presidency compromise text	Drafting Suggestions Comments
<p>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.</p>	<p>(Comments): See comment to article 75 above.</p>
<p>_____</p>	
<p>* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...).”</p>	
<p><i>Article 77</i> <i>Amendment to Regulation (EU) No 168/2013</i></p>	<p>DK: (Comments): Article 2 should be reworded, to clarify how</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>the AI-regulation will affect the Regulations and Directives on vehicles referred to in the Article. Article 2 states that only Article 84 applies to the vehicle Regulations and Directives as listed in Annex II section B. However, when taking a closer look at the Articles 76, 77, 80 and 82 of the AI-regulation it is clear that these Articles do also apply to Regulations and Directives on vehicles, despite the wording of Article 2.</p> <p>The consequence of the proposed Articles 76, 77, 80 and 82 in the AI-regulation is that future delegated acts pursuant to the respective vehicle Regulations and Directives related to the use of AI in safety components, shall take into account the requirements set out in Title III, Chapter 2.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>There are thus discrepancies between Article 2 and Articles 76, 77, 80 and 82.</p> <p>It should be stated more clearly in Article 2 that the vehicle Regulations and Directives listed in Annex II section B, are also subject to Articles 76, 77, 80 and 82. The AI-regulation should in other words be clear and consistent that the requirements in this Regulation also applies to the mentioned vehicle Regulations and Directives.</p>
<p>In Article 22(5) of Regulation (EU) No 168/2013, the following subparagraph is added:</p>	

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>“When adopting delegated acts pursuant to the first subparagraph concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX on [Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.</p>	<p>SK:</p> <p>(Comments):</p> <p>See comment to article 75 above.</p>
<p>_____</p>	
<p>* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...).”</p>	
<p><i>Article 78</i></p> <p><i>Amendment to Directive 2014/90/EU</i></p>	

Presidency compromise text	Drafting Suggestions Comments
In Article 8 of Directive 2014/90/EU, the following paragraph is added:	
<p>“4. For Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, when carrying out its activities pursuant to paragraph 1 and when adopting technical specifications and testing standards in accordance with paragraphs 2 and 3, the Commission shall take into account the requirements set out in Title III, Chapter 2 of that Regulation.</p>	<p>SK: (Comments): See comment to article 75 above.</p>

Presidency compromise text	Drafting Suggestions Comments
* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...).”.	
<i>Article 79</i> <i>Amendment to Directive (EU) 2016/797</i>	
In Article 5 of Directive (EU) 2016/797, the following paragraph is added:	
“12. When adopting delegated acts pursuant to paragraph 1 and implementing acts pursuant to paragraph 11 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament	SK: (Comments): See comment to article 75 above.

Presidency compromise text	Drafting Suggestions Comments
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 ...).”.	
<p><i>Article 80</i> <i>Amendment to Regulation (EU) 2018/858</i></p>	<p>DK:</p> <p>(Comments):</p> <p>Article 2 should be reworded, to clarify how the AI-regulation will affect the Regulations and Directives on vehicles referred to in the Article. Article 2 states that only Article 84 applies to the vehicle Regulations and</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Directives as listed in Annex II section B. However, when taking a closer look at the Articles 76, 77, 80 and 82 of the AI-regulation it is clear that these Articles do also apply to Regulations and Directives on vehicles, despite the wording of Article 2. The consequence of the proposed Articles 76, 77, 80 and 82 in the AI-regulation is that future delegated acts pursuant to the respective vehicle Regulations and Directives related to the use of AI in safety components, shall take into account the requirements set out in Title III, Chapter 2.</p> <p>There are thus discrepancies between Article 2 and Articles 76, 77, 80 and 82.</p> <p>It should be stated more clearly in Article 2</p>

Presidency compromise text	Drafting Suggestions Comments
	that the vehicle Regulations and Directives listed in Annex II section B, are also subject to Articles 76, 77, 80 and 82. The AI-regulation should in other words be clear and consistent that the requirements in this Regulation also applies to the mentioned vehicle Regulations and Directives.
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]	SK: (Comments): See comment to article 75 above.

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

Presidency compromise text	Drafting Suggestions Comments
added:	
<p>“3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [<i>on Artificial Intelligence</i>] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.</p>	<p>SK:</p> <p>(Comments):</p> <p>See comment to article 75 above.</p>

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

Presidency compromise text	Drafting Suggestions Comments
(2) In Article 19, the following paragraph is added:	
<p>“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.”</p>	<p>SK: (Comments): See comment to article 75 above.</p>
(3) In Article 43, the following paragraph is added:	
“4. When adopting implementing acts	SK:

Presidency compromise text	Drafting Suggestions Comments
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.”	(Comments): See comment to article 75 above.
(4) In Article 47, the following paragraph is added:	
“3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into	SK: (Comments): See comment to article 75 above.

Presidency compromise text	Drafting Suggestions Comments
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.”	SK: (Comments): See comment to article 75 above.
(6) In Article 58, the following paragraph is added:	
“3. When adopting delegated acts pursuant	SK:

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>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.”.</p>	<p>(Comments):</p> <p>See comment to article 75 above.</p>
<p><i>Article 82</i> <i>Amendment to Regulation (EU) 2019/2144</i></p>	<p>DK:</p> <p>(Comments):</p> <p>Article 2 should be reworded, to clarify how the AI-regulation will affect the Regulations and Directives on vehicles referred to in the Article. Article 2 states that only Article 84 applies to the vehicle Regulations and Directives as listed in Annex II section B.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>However, when taking a closer look at the Articles 76, 77, 80 and 82 of the AI-regulation it is clear that these Articles does also apply to Regulations and Directives on vehicles, despite the wording of Article 2.</p> <p>The consequence of the proposed Articles 76, 77, 80 and 82 in the AI-regulation is that future delegated acts pursuant to the respective vehicle Regulations and Directives related to the use of AI in safety components, shall take into account the requirements set out in Title III, Chapter 2.</p> <p>There are thus discrepancies between Article 2 and Articles 76, 77, 80 and 82.</p> <p>It should be stated more clearly in Article 2 that the vehicle Regulations and Directives</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>listed in Annex II section B, are also subject to Articles 76, 77, 80 and 82. The AI-regulation should in other words be clear and consistent that the requirements in this Regulation also applies to the mentioned vehicle Regulations and Directives.</p>
<p>In Article 11 of Regulation (EU) 2019/2144, the following paragraph is added:</p>	
<p>“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</p>	<p>SK: (Comments): See comment to article 75 above.</p>

Presidency compromise text	Drafting Suggestions Comments
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 ...).”.	
	<p>CZ:</p> <p>(Drafting):</p> <p>Article 82(a)</p> <p><i>Amendment to Regulation (EU) 2019/1020</i></p> <p>In Annex I of Regulation (EU) 2019/1020, the following paragraph is added:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>“(70) Regulation of the European Parliament and of the Council of [date] laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts No [number].”</p> <p>CZ:</p> <p>(Comments):</p> <p>Amendment to Regulation (EU) 2019/1020 adding a future Artificial Intelligence Act to Annex I should be added to this Proposal.</p>
<p><i>Article 83</i> <i>AI systems already placed on the market or</i></p>	<p>SK:</p>

Presidency compromise text	Drafting Suggestions Comments
<i>put into service</i>	<p>(Comments):</p> <p>Slovakia sees no adequate justification for this exemptions (derogations) contained in subsections (1) and (2) of this article.</p> <p>Possible concerns related to prohibition of retroactivity can be solved via period for adaptation. The exemption incentivizes “race to the bottom” in the period before entry of the act into force.</p> <p>In any case, “significant change” should be defined in article 3.</p> <p>SE:</p> <p>(Comments):</p> <p>The provisions of the AI Regulation do not apply to high-risk systems that have been placed on the market or commenced use</p>

Presidency compromise text	Drafting Suggestions Comments
	before a certain date, unless they undergo "substantial modification". Clarification is needed on what should be considered such a change, see comment on Article 43.4.
<p>1. This Regulation shall not apply to the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before <i>[12 months after the date of application of this Regulation referred to in Article 85(2)]</i>, unless the replacement or amendment of those legal acts leads to a significant change in the design or intended purpose of the AI system or AI systems concerned.</p>	<p>SK: (Comments):</p> <p>BE: (Comments):</p> <p>The articulation between the notion of « substantial modification » under Art. 3(23) and the notion of "significant change" under Art. 83 should be clarified. The notion of significant change should be</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>defined in a precise and comprehensive way.</p> <p>PT:</p> <p>(Drafting):</p> <p>1. This Regulation shall not apply to the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before <i>[12 months after the date of application of this Regulation referred to in Article 85(2)]</i>, unless the replacement or amendment of those legal acts leads to a significant change in the design or intended purpose of the AI system or AI systems concerned. These AI systems shall be</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>certified in accordance with this regulation within [24 months after the date of application of this Regulation referred to in Article 85(2)]</p> <p>PT:</p> <p>(Comments):</p> <p>We do not understand these exceptions.</p> <p>We consider that (1) a period of 12 months should be given for these systems to be certified under this regulation.</p> <p>PL:</p> <p>(Comments):</p> <p><i>Position on the relationship between the draft regulation e-codex (https://eur-lex.europa.eu/legal-</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p><i>content/PL/TXT/?uri=CELEX%3A52020PC0712) and the act on artificial intelligence and in particular art. 83 and Annex IX.</i></p> <p><input type="checkbox"/> <i>There is no need to include e-codex in Annex IX, even if artificial intelligence systems would be used to improve its performance (e.g. optimizing network traffic or protecting the system from attack). E-codex, unlike large-scale systems for home affairs, is a decentralized communication system in which there is no processing at EU level of data subject to judicial cooperation. This data is processed at pc.z. This may change after the launch of the JIT platform and the modernization of the Eurojust anti-terrorist register (proposals of 1 December this year);</i></p> <p><input type="checkbox"/> <i>e-codex, as a communication system, is</i></p>

Presidency compromise text	Drafting Suggestions Comments
	<p><i>not a high-risk system from a fundamental rights perspective;</i></p> <p><input type="checkbox"/> <i>all decisions of the Presidency in this matter should be preceded by an exchange of views within the E.31 group (e-justice).</i></p> <p>IT:</p> <p>(Comments):</p> <p>Could the Commission provide some clarification on AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX?</p> <p>CZ:</p> <p>(Drafting):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>CZ:</p> <p>(Comments):</p> <p>For the sake of legal clarity, the definition of “significant change” should be provided. Alternatively, the term “significant change” should be replaced by “substantial modification” and as such, it should be better clarified to make sure it is well understood by everyone. The definition of “substantial modification” (as proposed in Article 3(23)) might benefit from updating so as to make it clear that the modification of the AI system based on a standard software update following up-to-date market development within the scope of the intended purpose of the original AI system</p>

Presidency compromise text	Drafting Suggestions Comments
	does not constitute a substantial modification. This is also how we understood the recitals but it is such an important aspect that it should be established clearly within the definition itself. This should be incorporated directly into the text.
The requirements laid down in this Regulation shall be taken into account, where applicable, in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX 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	ES:

Presidency compromise text	Drafting Suggestions Comments
<p>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.</p>	<p>(Drafting):</p> <p>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 substantial modifications in their design or intended purpose.</p> <p>ES:</p> <p>(Comments):</p> <p>In order to align language.</p> <p>PT:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Drafting):</p> <p>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>as of [6 months after the date of application of this Regulation referred to in Article 85(2)]</i></p> <p>PT:</p> <p>(Comments):</p> <p>Finally, we believe a period of 6 months should be given for the high-risk AI systems</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>to be certified under this regulation, in order to avoid high-risk AI systems previously placed on the market or put into service with negative impacts to fall outside of scope of this Regulation just because they were placed on the market or put into service before the date of application of this Regulation referred to in Article 85(2).</p> <p>SE:</p> <p>(Comments):</p> <p>“Significant changes” compared to “substantial changes” and “modifications” in article 28 and article 43. Reason to the difference in wording?</p> <p>CZ:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>For the sake of legal clarity, the definition of “significant change” should be provided. Alternatively, the term “significant change” should be replaced by “substantial modification” and as such, it should be better clarified to make sure it is well understood by everyone. The definition of “substantial modification” (as proposed in Article 3(23)) might benefit from updating so as to make it clear that the modification of the AI system based on a standard software update following up-to-date market development within the scope of the intended purpose of the original AI system does not constitute a substantial modification. This is also how we</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>understood the recitals but it is such an important aspect that it should be established clearly within the definition itself. This should be incorporated directly into the text.</p> <p>DK:</p> <p>(Comments):</p> <p>It would be necessary to clarify whether a significant change equals a substantial modification as defined in article 3.</p> <p>Furthermore, we still find it necessary to further clarify the concept of substantial modification in order not to capture minor changes.</p> <p>Also, if we foresee a procedure where a high-risk system is added to the scope, it</p>

Presidency compromise text	Drafting Suggestions Comments
	would be relevant to discuss whether a transition period would be needed for such a system.
<i>Article 84</i> <i>Evaluation and review</i>	
1.—The Commission shall assess the need for amendment of the list in Annex III once a year following the entry into force of this Regulation.	
1a. The Commission shall assess the need for amendment of the list in Annex I every 24 months following the entry into force of this Regulation and until the end of the period of the delegation of power.	BE: (Comments): The addition of this possibility might create some legal uncertainty for systems in place

Presidency compromise text	Drafting Suggestions Comments
<p>The findings of that assessment shall be presented to the European Parliament and the Council.</p>	<p>or under development, that become AI due to changes in Annex I. Linked with the comment that the definition of 'AI system', together with the list of (AI) techniques and approaches in Annex I, are already too broad,</p> <p>CZ:</p> <p>(Drafting):</p> <p>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 Artificial Intelligence Board, the European</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>Parliament and the Council.</p> <p><i>CZ:</i></p> <p>(Comments):</p> <p>CZ welcomes the effort to make changes in the Annex I more predictable. However, CZ is still of the opinion that substantial parts of the text should be incorporated directly into the text.</p> <p><i>DK:</i></p> <p>(Comments):</p> <p>We are still assessing this adjustment. In our view, it is part of the wider discussion on the definition and the usage of delegated acts in order to find the right approach.</p>

Presidency compromise text	Drafting Suggestions Comments
<p>1b. The Commission shall assess the need for amendment of the list in Annex III every 24 months following the entry into force of this Regulation and until the end of the period of the delegation of power. The findings of that assessment shall be presented to the European Parliament and the Council.</p>	<p>BE:</p> <p>(Drafting):</p> <p>1b. The Commission shall assess the need for amendment of the list in Annex III every 24-12 months following the entry into force of this Regulation and until the end of the period of the delegation of power. The findings of that assessment shall be presented to the European Parliament and the Council.</p> <p>BE:</p> <p>(Comments):</p> <p>Given the rapid development of AI systems, the period of 24 months seems far too long. In addition to the proposed review, the EU</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>AI Board should be able to table review proposals in the interim where new use cases of AI systems become a pressing concern.</p> <p>CZ:</p> <p>(Drafting):</p> <p>1b. The Commission shall assess the need for amendment of the list in Annex III every 24 months following the entry into force of this Regulation and until the end of the period of the delegation of power. The findings of that assessment shall be presented to the European Artificial Intelligence Board, the European Parliament and the Council.</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>CZ:</p> <p>(Comments):</p> <p>CZ welcomes the effort to make changes in the Annex III more predictable. However, CZ is still of the opinion that substantial parts of the text should be incorporated directly into the text.</p> <p>DK:</p> <p>(Comments):</p> <p>We are still assessing this adjustment. In our view, it is part of the wider discussion on the high-risk and the usage of delegated acts in order to find the right approach.</p>
	<p>NL:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Drafting):</p> <p>1c The Commission will establish a multistakeholder expert group to assist with the evaluation of Annexes I and III.</p> <p>NL:</p> <p>(Comments):</p> <p>The amendments of annexes I and III need consultation of all relevant stakeholders to ensure that the regulation reflects the latest insights by a wide range of actors and remains effective. The High Level Expert Group could serve as example.</p>
<p>2. By [three years after the date of application of this Regulation referred to in Article 85(2)] and every four years</p>	<p>IE:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
<p>thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The reports shall be made public.</p>	<p>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 reduced or an interim review be conducted to capture any weaknesses in the system at as early a stage as possible.</p> <p>PT:</p> <p>(Drafting):</p> <p>2. Yearly until By <i>[three years after the date of application of this Regulation referred to in Article 85(2)]</i> and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>Parliament and to the Council. The reports shall be made public.</p> <p>PT:</p> <p>(Comments):</p> <p>It is referred in this paragraph that "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". In our opinion, during the first three years an annual report should be submitted.</p> <p>IT:</p> <p>(Comments):</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>Could the Commission provide some clarification on the evaluation procedure in order to Annex III? Is there the participation of expert groups?</p>
<p>3. The reports referred to in paragraph 2 shall devote specific attention to the following:</p>	<p>DK:</p> <p>(Comments):</p> <p>As this is a ground-breaking regulation, it could be necessary to devote attention to other parts of the regulation in order to assess the effectiveness and proportionality of the regulation.</p>

Presidency compromise text	Drafting Suggestions Comments
<p>(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;</p>	<p>CZ:</p> <p>(Comments):</p> <p>Oversight over financial and human resources should be done internally under the sole competence of MS.</p>
<p>(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.</p>	
<p>4. Within [<i>three years after the date of application of this Regulation referred to in Article 85(2)</i>] and every four years</p>	<p>PT:</p> <p>(Drafting):</p>

Presidency compromise text	Drafting Suggestions Comments
<p>thereafter, the Commission shall evaluate the impact and effectiveness of codes of conduct to foster the application of the requirements set out in Title III, Chapter 2 and possibly other additional requirements for AI systems other than high-risk AI systems.</p>	<p>4. Yearly until Within [<i>three years after the date of application of this Regulation referred to in Article 85(2)</i>] and every four years thereafter, the Commission shall evaluate the impact and effectiveness of codes of conduct to foster the application of the requirements set out in Title III, Chapter 2 and possibly other additional requirements for AI systems other than high-risk AI systems.</p> <p>PT:</p> <p>(Comments):</p> <p>It is referred “within [<i>three years after the date of application of this Regulation referred to in Article 85(2)</i>] and every four years thereafter, the Commission shall</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>evaluate the impact and effectiveness of codes of conduct". We believe that during the first three years this evaluation should be done and made public annually.</p> <p>DK:</p> <p>(Comments):</p> <p>As in article 69, it states directly that the goal is to foster the voluntary application of the high-risk requirements. In our view, there should be a difference between the requirements imposed on high-risk AI and the requirements in the code of conducts.</p>
<p>5. For the purpose of paragraphs 1 to 43 the Board, the Member States and national competent authorities shall provide the</p>	<p>CZ:</p> <p>(Drafting):</p>

Presidency compromise text	Drafting Suggestions Comments
Commission with information on its request.	<p>5. For the purpose of paragraphs 1 to 43 the Board, the Member States and national competent authorities shall provide the Commission with information on its request.</p> <p>CZ:</p> <p>(Comments):</p> <p>Typo.</p>
	<p>CZ:</p> <p>(Drafting):</p> <p>(5a.) In carrying out the evaluations and reviews referred to in paragraphs 1 to 4, the Commission shall actively seek opinions from all relevant stakeholders across</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>economy and society.</p> <p>CZ:</p> <p>(Comments):</p> <p>Due to the impact of regulation on economy and society, the Commission should listen to the opinions of all relevant stakeholders across business and society, in carrying out evaluations and revisions.</p>
<p>6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 43 the Commission shall take into account the positions and findings of the Board, of the European Parliament, of the Council, and of other relevant bodies or sources.</p>	<p>CZ:</p> <p>(Drafting):</p> <p>6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 43 the Commission shall take into account the positions and findings of the Board, of the European Parliament, of the Council, and of</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>other relevant bodies or sources, in particular stakeholders, industry representatives and AI specialists.</p> <p>CZ:</p> <p>(Comments):</p> <p>Typo.</p> <p>Due to the impact of regulation on economy and society, the Commission should listen to the opinions of all relevant stakeholders across business and society, in carrying out evaluations and revisions.</p>
<p>7. The Commission shall, if necessary, submit appropriate proposals to amend this</p>	

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].	BG: (Drafting): 2. This Regulation shall apply from [24

Presidency compromise text	Drafting Suggestions Comments
	<p>36 months following the entering into force of the Regulation].</p> <p>BG:</p> <p>(Comments):</p> <p><u>Justification</u>: the complexity of requirements and the costs, skills development, training etc., but also the need for adoption of harmonized standards which are crucial for its application justify a longer transition period</p> <p>IT:</p> <p>(Comments):</p> <p>Could the Commission evaluate a reduction of the term of application?</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>CZ:</p> <p>(Comments):</p> <p>Given the complexity and robustness of the proposed regulation, longer period for entry into force should be introduced, e.g. 30 months instead of 24.</p> <p>DK:</p> <p>(Comments):</p> <p>It is essential that there is sufficient time to establish the foundation for an effective implementation as well as prepare the much-needed guidance. Therefore, it cannot be stressed enough that sufficient time from the entry into force to application must be maintained. We see 24 months as a</p>

Presidency compromise text	Drafting Suggestions Comments
	minimum.
<p>3. By way of derogation from paragraph 2:</p>	<p>SK:</p> <p>(Comments):</p> <p>The periods contained in (a) and (b) are too short and need to be prolonged. The institutional build-up will require a lot of efforts, resources and precision.</p>
<p>(a) Title III, Chapter 4 and Title VI shall apply from [three months following the entry into force of this Regulation];</p>	<p>IE:</p> <p>(Comments):</p> <p>Why do the provision on notified bodies and governance structures apply from three months but the provisions for penalties apply from 12 months? We would propose</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>that 12 months for the development of both structures would be more coherent.</p> <p>BG:</p> <p>(Drafting):</p> <p>(a) Title III, Chapter 4 and Title VI shall apply from three twenty four months following the entry into force of this Regulation];</p> <p>BG:</p> <p>(Comments):</p> <p><u>Justification:</u> for notifying authorities and notified bodies 3 months will not be sufficient; moreover, the date of application under letter a) should be consistent with the one under letter b)</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>CZ:</p> <p>(Comments):</p> <p>Given the complexity and robustness of the proposed regulation, longer period for entry into force should be introduced, e.g. 18 months instead of 3. It would also be worth clarifying what is exactly expected from the authorities in relation to this deadline.</p>
<p>(b) Article 71 shall apply from [twelve months following the entry into force of this Regulation].</p>	<p>BG:</p> <p>(Drafting):</p> <p>(b) Article 71 shall apply from [twelve twenty four months following the entry into force of this Regulation].</p> <p>CZ:</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>(Comments):</p> <p>Given the complexity and robustness of the proposed regulation, longer period for entry into force should be introduced, e.g. 18 months instead of 3.</p> <p>AT:</p> <p>(Comments):</p> <p>This provision stipulates that Art. 71 should apply from twelve months following the entry into force of this Regulation.</p> <p>However, Art. 71 shall sanction non-compliance with Articles which will only be applicable from 24 months following the entering into force of the Regulation (e.g. Art. 5, 10, etc.). We do not understand why</p>

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>the provision which shall sanction non-compliance with specific provisions should be (transposed) and applicable before the specific provisions (e.g. Art. 5 or 10 of the Regulation) themselves will be applicable.</p> <p>We would therefore advocate that Art. 71 should be applicable from 24 months following the entering into force of the Regulation as it is the case for the rest of this Regulation.</p>
<p>This Regulation shall be binding in its entirety and directly applicable in all Member States.</p>	
<p>Done at Brussels,</p>	

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
<p><i>For the European Parliament</i> <i>For the Council</i></p>	
<p><i>The President</i> <i>The President</i></p>	
<p>ANNEX IV TECHNICAL DOCUMENTATION referred to in Article 11(1)</p>	<p>BE:</p> <p>(Comments):</p> <p>The technical documentation, detailed in Annex IV, should make a reference to the open source nature of the AI system to be used. It is an EU priority to promote open source and in that particular case, it generally presents limited risks of failure due to the fact that it is auditable by the entire community that uses it.</p>

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;	

Presidency compromise text	Drafting Suggestions Comments
(c) the versions of relevant software or firmware and any requirement related to version update;	
(d) the description of all forms in which the AI system is placed on the market or put into service;	
(e) the description of hardware on which the AI system is intended to run;	BE: (Comments): To what extent is this relevant information for the description of a high-risk system?
(f) where the AI system is a component of products, photographs or illustrations showing external features, marking and	

Presidency compromise text	Drafting Suggestions Comments
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:	
(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	CZ:

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
<p>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;</p>	<p>(Comments):</p> <p>The term “general logic” should be defined.</p> <p>AT:</p> <p>(Comments):</p> <p>Suggestion to also include the extent to which an AI application is based on assumptions about gender differences.</p>
<p>(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</p>	<p>BE:</p> <p>(Comments):</p>

Presidency compromise text	Drafting Suggestions Comments
computational resources used to develop, train, test and validate the AI system;	“The computational resources used to develop, train, test and validate the AI system”, to what extent are these ‘computational resources’ relevant?
(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);	SE: (Drafting): (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

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
	<p>methodologies (e.g. outliers detection);</p> <p>SE;</p> <p>(Comments);</p> <p>The stage of collecting, labeling and cleaning data is often outsourced by the provider as a first step before internal processing. Outsourcing can prove to be necessary from a standpoint of innovation and competitiveness.</p>
<p>(e) assessment of the human oversight measures needed in accordance with Article 14, including an assessment of the technical measures needed to facilitate the interpretation of the outputs of AI systems by the users, in accordance with Articles</p>	

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>13(3)(d):</p>	
<p>(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:</p>	
<p>(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.</p>	<p>BE:</p> <p>(Comments):</p> <p>To make a distinction with R&D, test logs and test reports in this Article should be limited to the versions of the AI system</p>

Presidency compromise text	Drafting Suggestions Comments
<p>as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point (f).</p>	<p>placed on the market or put into service.</p>
<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</p>	<p>SE: (Drafting): risks to health and safety, fundamental rights and non-discrimination in view of the intended purpose of the AI system; SE: (Comments): A correction. The sources of risks are not to</p>

Presidency compromise text	Drafting Suggestions Comments
<p>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>	<p>discrimination, but to non-discrimination.</p>
<p>4. A detailed description of the risk management system in accordance with Article 9;</p>	
<p>5. A description of any change made to the system through its lifecycle;</p>	
<p>6. A list of the harmonised standards applied in full or in part the references of</p>	

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>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;</p>	
<p>7. A copy of the EU declaration of conformity;</p>	
<p>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).</p>	

Presidency compromise text	Drafting Suggestions Comments
	<p>ES:</p> <p>(Drafting):</p> <p>9A description of potential risks for health, and in particular mental health, safety and fundamental rights arising from the hypothetical widespread usage of the AI system or of similar systems in society, taking into account similar past incidents and how mitigating measures may compensate these risks.</p> <p>ES:</p> <p>(Comments):</p> <p>This is a provision that focus on how the spread of the system may affect society and helps providers to ask themselves if the</p>

Presidency compromise text	Drafting Suggestions Comments
	safeguards they establish may bring protection in the AI system use.
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	

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

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>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;</p>	
<p>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.</p>	
<p>ANNEX VI CONFORMITY ASSESSMENT PROCEDURE BASED ON INTERNAL CONTROL</p>	

Presidency compromise text	Drafting Suggestions Comments
<p>1. The conformity assessment procedure based on internal control is the conformity assessment procedure based on points 2 to 4.</p>	
<p>2. The provider verifies that the established quality management system is in compliance with the requirements of Article 17.</p>	
<p>3. The provider examines the information contained in the technical documentation in order to assess the compliance of the AI system with the relevant essential requirements set out in Title III, Chapter 2.</p>	

Presidency compromise text	Drafting Suggestions Comments
<p>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.</p>	
<p>ANNEX VII CONFORMITY BASED ON ASSESSMENT OF QUALITY MANAGEMENT SYSTEM AND ASSESSMENT OF TECHNICAL DOCUMENTATION</p>	
<p>1. Introduction</p>	
<p>Conformity based on assessment of quality</p>	

<p style="text-align: center;">Presidency compromise text</p>	<p style="text-align: center;">Drafting Suggestions</p> <p style="text-align: center;">Comments</p>
<p>management system and assessment of the technical documentation is the conformity assessment procedure based on points 2 to 5.</p>	
<p>2. Overview</p>	
<p>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.</p>	
<p>3. Quality management system</p>	

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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;	
(b) the list of AI systems covered under the same quality management system;	BG: (Drafting): (b) the list of AI systems covered under the same quality management system which could be the existing one certified under ISO 9001:2015 on quality management and ISO 27001 or TISAX for ISMS;

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	<p>BG:</p> <p>(Comments):</p> <p><u>Justification</u>: see our first set of comments on Art 17, in our view, there should be a reference to existing certifications for quality management in order to avoid excessive costs for new quality management systems</p>
<p>(c) the technical documentation for each AI system covered under the same quality management system;</p>	<p>BG:</p> <p>(Drafting):</p> <p>(c) the technical documentation for each AI system covered under the same quality management system which could be the existing one certified under ISO 9001:2015 on quality management and ISO 27001 or</p>

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	TISAX for ISMS;
(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 determine whether it satisfies the	

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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	HU:

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<p>systems covered by the latter shall be brought to the attention of the notified body by the provider.</p>	<p>(Drafting):</p> <p>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 prior to the implementation of such change.</p> <p>HU:</p> <p>(Comments):</p> <p>We recommend turning this into a proactive obligation, so that the change can be evaluated before it is put into use.</p>
<p>The proposed changes shall be examined by the notified body, which shall decide whether the modified quality management</p>	

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<p>system continues to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.</p>	
<p>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.</p>	<p>HU: (Drafting): The notified body shall notify the provider of its decision within a month from the receipt of the notification referred to in point 3.4.</p> <p>HU: (Comments): We recommend setting a deadline here, in order to assure that providers get an approval within a reasonable time period.</p>

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<p>4. Control of the technical documentation.</p>	<p>BE:</p> <p>(Comments):</p> <p>It is currently difficult to assess the concrete impact of the requirements and assessment procedure on the development time and it is not clear if some requirements are proportionate to the scope/scale of an AI system.</p>
<p>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</p>	

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

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<p>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.</p>	<p>(Comments):</p> <p>See our comments on Art 64</p> <p>Who grants the access to training and testing datasets? Are both under the sole control of the provider?</p> <p>HU:</p> <p>(Drafting):</p> <p>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 AI providers shall support the notified body with necessary and appropriate means and documentation. This may include the</p>

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	<p>possibility of granting 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.</p> <p>HU:</p> <p>(Comments):</p> <p>We recommend amending the current wording of point 4.3 of the Proposal, as in the current form it might unduly endanger trade secrets, know-how and intellectual property rights.</p>
4.4. In examining the technical documentation, the notified body may	

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<p>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. 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>PT: (Drafting): 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</p>

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	<p>body shall also be granted access to the source code of the AI system.</p> <p>PT:</p> <p>(Comments):</p> <p>In our view, this article is not clear. What is the source code of an AI system? Should all the integrated components of a final product be considered? If yes, how can a provider grant access to the the source code of a third party component, or a service deployed as PaaS. On the other hand, it is not clear what will the market surveillance authorities do with the source code? Can we consider the assembly code embeded in a GPU part of the high-risk AI system just because the system is to be deployed using</p>

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	GPUs?
<p>4.6. The decision shall be notified to the provider or its authorised representative. The notification shall contain the conclusions of the assessment of the technical documentation and the reasoned assessment decision.</p>	
<p>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</p>	

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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, 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	

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<p>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.</p>	
<p>4.7. Any change to the AI system that could affect the compliance of the AI system with the requirements or its intended purpose shall be approved by the notified body which issued the EU technical documentation assessment certificate. The provider shall inform such notified body of</p>	

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<p>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</p>	

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management system.	
<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</p>	

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<p>provider maintains and applies the quality management system and shall provide the provider with an audit report. In the context of those audits, the notified body may carry out additional tests of the AI systems for which an EU technical documentation assessment certificate was issued.</p>	
<p>ANNEX VIII INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF HIGH-RISK AI SYSTEMS IN ACCORDANCE WITH ARTICLE 51</p>	
<p>The following information shall be provided and thereafter kept up to date with regard to high-risk AI systems to be registered in accordance with Article 51.</p>	<p>CZ: (Drafting):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>1. The following information shall be provided and thereafter kept up to date with regard to high-risk AI systems to be registered in accordance with Article 51.</p> <p>CZ:</p> <p>(Comments):</p> <p>Please see above (under Art. 60(1)). There are substantial operational reasons for restricting information on precise technical capabilities of law enforcement.</p>
1. Name, address and contact details of the provider;	<p>CZ:</p> <p>(Drafting):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>4-a) Name, address and contact details of the provider;</p> <p>NL:</p> <p>(Drafting):</p> <p>1. Title position Name, address and contact details of the provider;</p> <p>NL:</p> <p>(Comments):</p> <p>People often change jobs, and the name used in the database may not be up to date anymore. Referring to the position/job of someone is more resistant to changes.</p>
2. Where submission of information is	CZ:

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<p>carried out by another person on behalf of the provider, the name, address and contact details of that person;</p>	<p>(Drafting):</p> <p>2-b Where submission of information is carried out by another person on behalf of the provider, the name, address and contact details of that person;</p> <p>NL:</p> <p>(Drafting):</p> <p>2. Where submission of information is carried out by another person on behalf of the provider, the title position name, address and contact details of that person;</p> <p>NL:</p> <p>(Comments):</p> <p>People often change jobs, and the name</p>

Presidency compromise text	Drafting Suggestions Comments
	used in the database may not be up to date anymore. Referring to the position/job of someone is more resistant to changes.
3. Name, address and contact details of the authorised representative, where applicable;	<p>CZ:</p> <p>(Drafting):</p> <p>3-c) Name, address and contact details of the authorised representative, where applicable;</p> <p>NL:</p> <p>(Drafting):</p> <p>3. Title position Name, address and contact details of the authorised representative, where applicable;</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>NL:</p> <p>(Comments):</p> <p>People often change jobs, and the name used in the database may not be up to date anymore. Referring to the position/job of someone is more resistant to changes.</p>
	<p>NL:</p> <p>(Drafting):</p> <p>3a. Title position Name, address and contact details of the user, where applicable;</p> <p>NL:</p> <p>(Comments):</p> <p>Besides the provider, it should be clear also</p>

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	which organisations are using these systems.
4. AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system;	CZ: (Drafting): 4-d) 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;	CZ: (Drafting): 5-e) Description of the intended purpose of the AI system;

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	<p>NL:</p> <p>(Drafting):</p> <p>Description of the intended purpose of the AI system, the context and actual purpose of deployment (if different from intended purpose), and the designation of impacted persons;</p> <p>NL:</p> <p>(Comments):</p> <p>Intended purpose could differ from actual use</p>
<p>6. Status of the AI system (on the market, or in service; no longer placed on the market/in service, recalled);</p>	<p>CZ:</p> <p>(Drafting):</p>

Presidency compromise text	Drafting Suggestions Comments
	<p>6.f) Status of the AI system (on the market, or in service; no longer placed on the market/in service, recalled);</p>
<p>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;</p>	<p>CZ: (Drafting): 7.g) 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;</p>
<p>8. A scanned copy of the certificate referred to in point 7, when applicable;</p>	<p>ES: (Drafting): 8) A scanned copy or electronic copy of the certificate referred to in point 7, when</p>

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	<p>applicable;</p> <p>CZ:</p> <p>(Drafting):</p> <p>8-h A scanned copy of the certificate referred to in point 7, when applicable;</p>
<p>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;</p>	<p>CZ:</p> <p>(Drafting):</p> <p>9-i Member States in which the AI system is or has been placed on the market, put into service or made available in the Union;</p>
<p>10. A copy of the EU declaration of conformity referred to in Article 48;</p>	<p>CZ:</p> <p>(Drafting):</p>

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	40.j) A copy of the EU declaration of conformity referred to in Article 48;
<p>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.</p>	<p>CZ:</p> <p>(Drafting):</p> <p>44.k) 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.</p> <p>NL:</p> <p>(Comments):</p> <p>How does the exemption 'this information</p>

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	shall not be provided for high-risk AI systems in the areas of law enforcement (...)’ relate to the exception regarding tax and customs authorities, laid down in preamble no. 38?
12. URL for additional information (optional).	CZ: (Drafting): 12.1 URL for additional information (optional).
	ES: (Drafting): 13. Post market monitoring plan CZ:

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	<p>(Drafting):</p> <p>2. The information under point 1. e), i) and k) shall not be provided for high-risk AI systems in the areas of law enforcement, migration, asylum and border control management and AI systems used to manage and operate critical infrastructure referred to in Annex III, points 1, 2 a) and aa) and points 6 and 7.</p> <p>CZ:</p> <p>(Comments):</p> <p>Alternatively, registration of such AI systems should not be mandatory.</p> <p>Furthermore, it should be further clarified that as regards point 1 of Annex III</p>

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	(biometric identification systems), such systems are excluded from the requirement only if used by law enforcement and/or for migration, asylum and border control management.
ANNEX IX UNION LEGISLATION ON LARGE-SCALE IT SYSTEMS IN THE AREA OF FREEDOM, SECURITY AND JUSTICE	
1. Schengen Information System	
(a) Regulation (EU) 2018/1860 of the European Parliament and of the Council of 28 November 2018 on the use of the Schengen Information System for the return of illegally staying third-country nationals	

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(OJ L 312, 7.12.2018, p. 1).	
(b) Regulation (EU) 2018/1861 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of border checks, and amending the Convention implementing the Schengen Agreement, and amending and repealing Regulation (EC) No 1987/2006 (OJ L 312, 7.12.2018, p. 14)	
(c) Regulation (EU) 2018/1862 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of	

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<p>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 repealing</p>	

Presidency compromise text	Drafting Suggestions Comments
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	
<p>(a) Amended proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the establishment of 'Eurodac' for the comparison of biometric data for the effective application of Regulation (EU) XXX/XXX [Regulation on Asylum and Migration Management] and of Regulation (EU) XXX/XXX [Resettlement Regulation], for identifying an illegally staying third-country national or stateless</p>	

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<p>person and on requests for the comparison with Eurodac data by Member States' law enforcement authorities and Europol for law enforcement purposes and amending Regulations (EU) 2018/1240 and (EU) 2019/818 – COM(2020) 614 final.</p>	
<p>4. Entry/Exit System</p>	
<p>(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</p>	

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<p>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).</p>	
<p>5. European Travel Information and Authorisation System</p>	
<p>(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).</p>	

<p>Presidency compromise text</p>	<p>Drafting Suggestions</p> <p>Comments</p>
<p>(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).</p>	
<p>6. European Criminal Records Information System on third-country nationals and stateless persons</p>	
<p>(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</p>	

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<p>(ECRIS-TCN) to supplement the European Criminal Records Information System and amending Regulation (EU) 2018/1726 (OJ L 135, 22.5.2019, p. 1).</p>	
<p>7. Interoperability</p>	
<p>(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).</p>	
<p>(b) Regulation (EU) 2019/818 of the European Parliament and of the Council of 20 May 2019 on establishing a framework</p>	

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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