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NOTE

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Objet:	Proposition de Règlement du Parlement européen et du Conseil établissant des règles harmonisées concernant l'intelligence artificielle (législation sur l'intelligence artificielle) et modifiant certains actes législatifs de l'Union - Texte de compromis de la présidence - Articles 40-52

I. INTRODUCTION

1. La Commission a adopté la proposition de règlement établissant des règles harmonisées concernant l'intelligence artificielle (loi sur l'intelligence artificielle, AIA) le 21 avril 2021.

2. La présidence slovène a rédigé la première proposition de compromis partiel, qui couvre **les articles 1 à 7 et les annexes I à III** de l'AIA proposée. Cette proposition de compromis partiel a été présentée au groupe TELECOM le 30 novembre 2021 par la présidence SI et a fait l'objet d'un examen approfondi lors de la réunion du groupe TELECOM du 11 janvier 2022 sous la présidence française.

3. La présidence française a repris les travaux de rédaction, dans le cadre desquels la présidence slovène s'est retirée, et a rédigé les parties suivantes de la première proposition de compromis, couvrant **les articles 8 à 15 et l'annexe IV**, ainsi que **les articles 16 à 29**.

4. La présidence française a maintenant rédigé **une autre partie de la première proposition de compromis, couvrant les articles 40 à 52**, qui figure à l'annexe du présent document.

5. **La présidence française invite les délégations à examiner les modifications qu'il est proposé d'apporter aux articles 40 à 52 lors de la réunion du groupe TELECOM du 22 février 2022.**

6. Les modifications apportées au document par rapport à la proposition de la Commission sont soulignées: les ajouts sont signalés par des caractères **gras**, les suppressions sont ~~barrées~~.

II. PRINCIPAUX CHANGEMENTS

1. Article 40 — Normes harmonisées

1.1 Un nouvel **article 40, paragraphe 2**, précisant les objectifs généraux que devront atteindre les normes élaborées par les organismes de normalisation à la demande de la Commission, a été ajouté. Le nouveau texte prévoit également l'obligation pour la Commission de demander à ces organismes de fournir des preuves de leurs meilleurs efforts pour atteindre ces objectifs.

2. **Article 41 — Spécifications communes**

2.1 Afin de garantir une plus grande participation des États membres à l'élaboration de spécifications communes en ce qui concerne les exigences applicables aux systèmes d'IA à haut risque au moyen d'actes d'exécution, les modifications apportées à **l'article 41, paragraphe 1**, visent à obliger la Commission à consulter le comité d'IA.

2.2. Les modifications apportées à **l'article 41, paragraphe 2**, ont été introduites pour encadrer l'habilitation de la Commission à adopter des spécifications communes au moyen d'une référence aux objectifs énumérés à **l'article 40, paragraphe 2**, récemment ajouté.

3. **Article 42 — Présomption de conformité avec certaines exigences**

3.1 Le mot «et» a été remplacé par «ou» à **l'article 42, paragraphe 1**, afin d'indiquer que les conditions concernant les données sur la base desquelles les systèmes d'IA à haut risque ont été entrainés et testés ne sont pas cumulables.

4. **Article 43 — Évaluation de la conformité**

4.1 **L'article 43, paragraphe 2**, est toujours en cours de révision afin d'intégrer les retours d'information reçus de la Banque centrale européenne.

4.2 **Le premier alinéa de l'article 43, paragraphe 4**, a été supprimé afin d'assurer la cohérence avec le nouvel **article 23 bis**.

4.3 Le texte du **second paragraphe de l'article 43, paragraphe 4,** a été déplacé vers la définition de la «modification substantielle» à **l'article 3(23).**

4.4 Les modifications apportées aux **articles 43 (4) et (5)** visent à garantir une plus grande participation des États membres au processus des actes délégués par l'intermédiaire du comité IA.

5. **Article 45 — Recours contre les décisions des organismes notifiés**

5.1 La référence à l'intérêt légitime dans la décision contre laquelle une procédure de recours devrait être ouverte a été supprimée pour tenir compte du fait que ces lois procédurales sont généralement la prérogative des législateurs nationaux.

6. **Article 47 — Dérogation à la procédure d'évaluation de la conformité**

6.1 Le nouvel **article 47, paragraphe 1 bis**, a été ajouté afin de donner aux autorités répressives la possibilité de demander une autorisation ex post pour mettre sur le marché ou mettre en service un système d'IA à haut risque spécifique, conformément à **l'article 5, paragraphe 3**.

7. **Article 48 — Déclaration UE de conformité**

7.1 Les modifications apportées à **l'article 48, paragraphe 5**, ont été apportées pour garantir une plus grande participation des États membres au processus des actes délégués par l'intermédiaire du comité de l'IA.

8. **Article 49 — Marquage de conformité CE**

8.1 L'ordre des **articles 49 (1) et (2)** a été modifié afin d'assurer une séquence plus logique des exigences.

9. **Article 50 — Conservation des documents**

9.1 Le texte de **l'article 50** a été déplacé à **l'article 18**.

10. **Article 51 — Enregistrement**

10.1 Les modifications apportées à **l'article 51** sont liées à la suppression des références au terme «autonome» dans **les titres du titre VII et de l'article 60**, qui sont considérées comme peu claires.

11. **Article 52 — Obligations de transparence pour certains systèmes d'IA**

11.1 Le nouveau texte ajouté à la fin de **l'article 52, paragraphe 2**, concernant des garanties appropriées pour les droits et libertés des tiers est destiné à assurer l'alignement sur la dernière phrase de **l'article 52, paragraphe 3.**

11.2 La suppression, à **l'article 52, paragraphe 3**, de la référence à «l'exercice du droit à la liberté d'expression et du droit à la liberté des arts et des sciences» a été faite parce que cette notion est déjà implicite dans la formulation «autorisée par la loi», utilisée à **l'article 52, paragraphe 3**, deuxième alinéa.

11.3 Le nouvel **article 53, paragraphe 3 bis**, a été ajouté pour préciser comment et quand les informations visées aux paragraphes précédents doivent être fournies aux personnes physiques qui ont été exposées à des systèmes d'IA relevant du **titre IV**.

12. Le nouvel **article 52 bis** a été déplacé à **l'article 4 bis** et est toujours en cours de réexamen.

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

Chapter 5 (Articles 40-52)

CHAPTER 5

STANDARDS, CONFORMITY ASSESSMENT, CERTIFICATES, REGISTRATION

Article 40
Harmonised standards

1. High-risk AI systems which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title, to the extent those standards cover those requirements.

2. When issuing a standardisation request to European standardisation organisations in accordance with Article 10 of Regulation 1025/2012, the Commission shall specify that standards are coherent, easy to implement and drafted in such a way that they aim to fulfil in particular the following objectives:

a) ensure that AI systems placed on the market or put into service in the Union are safe and respect Union values and strenghten the Union's digital sovereignty;

b) promote investment and innovation in AI, as well as competitiveness and growth of the Union market;

c) enhance multistakeholder governance, representative of all relevant European stakeholders (e.g. industry, SMEs, civil society, researchers).

d) contribute to strengthening global cooperation on standardisation in the field of AI that is consistent with Union values and interests.

The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the above objectives.

Article 41
Common specifications

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, **after consulting the AI Board referred to in Article 56**, by means of implementing acts, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).

2. ~~The Commission,~~ **Ww**~~w~~hen preparing the common specifications referred to in paragraph 1, **the Commission** shall **fulfil the objectives referred of Article 40(2) and** gather the views of relevant bodies or expert groups established under relevant sectorial Union law.

3. High-risk AI systems which are in conformity with the common specifications referred to in paragraph 1 shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title, to the extent those common specifications cover those requirements.

4. Where providers do not comply with the common specifications referred to in paragraph 1, they shall duly justify **in the technical documentation referred to in Article 11** that they have adopted technical solutions that are at least equivalent thereto.

Article 42
Presumption of conformity with certain requirements

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

2. High-risk AI systems that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 of the European Parliament and of the Council[1] and the references of which have been published in the Official Journal of the European Union shall be presumed to be in compliance with the cybersecurity requirements set out in Article 15 of this Regulation in so far as the cybersecurity certificate or statement of conformity or parts thereof cover those requirements.

Article 43
Conformity assessment

1. For high-risk AI systems listed in point 1 of Annex III, where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider has applied harmonised standards referred to in Article 40, or, where

[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).

applicable, common specifications referred to in Article 41, the provider shall ~~follow~~ **opt for** one of the following procedures:

(a) the conformity assessment procedure based on internal control referred to in Annex VI; **or**

(b) the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation, with the involvement of a notified body, referred to in Annex VII.

Where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider has not applied or has applied only in part harmonised standards referred to in Article 40, or where such harmonised standards do not exist and common specifications referred to in Article 41 are not available, the provider shall follow the conformity assessment procedure set out in Annex VII.

For the purpose of the conformity assessment procedure referred to in Annex VII, the provider may choose any of the notified bodies. However, when the system is intended to be put into service by law enforcement, immigration or asylum authorities as well as EU institutions, bodies or agencies, the market surveillance authority referred to in Article 63(5) or (6), as applicable, shall act as a notified body.

2. For high-risk AI systems referred to in points 2 to 8 of Annex III, providers shall follow the conformity assessment procedure based on internal control as referred to in Annex VI, which does not provide for the involvement of a notified body. For high-risk AI systems referred to in point 5(b) of Annex III, placed on the market or put into service by credit institutions regulated by Directive 2013/36/EU, the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to101 of that Directive.

3. For high-risk AI systems, to which legal acts listed in Annex II, section A, apply, the provider shall follow the relevant conformity assessment as required under those legal acts. The requirements set out in Chapter 2 of this Title shall apply to those high-risk AI systems and shall be part of that assessment. Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII shall also apply.

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.

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.

4. ~~High-risk AI systems shall undergo a new conformity assessment procedure whenever they are substantially modified, regardless of whether the modified system is intended to be further distributed or continues to be used by the current user.~~

~~For high-risk AI systems that continue to learn after being placed on the market or put into service, changes to the high-risk AI system and its performance that have been pre-determined by the provider at the moment of the initial conformity assessment and are part of the information contained in the technical documentation referred to in point 2(f) of Annex IV, shall not constitute a substantial modification.~~

5. **After consulting the AI Board referred to in Article 56, t**~~T~~he Commission is empowered to adopt delegated acts in accordance with Article 73 for the purpose of updating Annexes VI and Annex VII ~~in order to introduce elements of the conformity assessment procedures that become necessary~~ in light of technical progress.

6. **After consulting the AI Board referred to in Article 56, t**~~T~~he Commission is empowered to adopt delegated acts to amend paragraphs 1 and 2 in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex VII or parts thereof. The Commission shall adopt such delegated acts taking into account the effectiveness of the conformity assessment procedure based on internal control referred to in Annex VI in preventing or minimizing the risks to health and safety and protection of fundamental rights posed by such systems as well as the availability of adequate capacities and resources among notified bodies.

Article 44
Certificates

1. Certificates issued by notified bodies in accordance with Annex VII shall be drawn-up in an official Union language determined by the Member State in which the notified body is established or in an official Union language otherwise acceptable to the notified body.

2. Certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the provider, the validity of a certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures.

3. Where a notified body finds that an AI system no longer meets the requirements set out in Chapter 2 of this Title, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it, unless compliance with those requirements is ensured by appropriate corrective action taken by the provider of the system within an appropriate deadline set by the notified body. The notified body shall give reasons for its decision.

Article 45
Appeal against decisions of notified bodies

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~~.

Article 46
Information obligations of notified bodies

1. Notified bodies shall inform the notifying authority of the following:

(a) any Union technical documentation assessment certificates, any supplements to those certificates, quality management system approvals issued in accordance with the requirements of Annex VII;

(b) any refusal, restriction, suspension or withdrawal of a Union technical documentation assessment certificate or a quality management system approval issued in accordance with the requirements of Annex VII;

(c) any circumstances affecting the scope of or conditions for notification;

(d) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(e) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

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

(a) quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued;

(b) EU technical documentation assessment certificates or any supplements thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or supplements thereto which it has issued.

3. Each notified body shall provide the other notified bodies carrying out similar conformity assessment activities covering the same artificial intelligence technologies with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 47
Derogation from conformity assessment procedure

1. By way of derogation from Article 43, any market surveillance authority may authorise the placing on the market or putting into service of specific high-risk AI systems within the territory of the Member State concerned, for exceptional reasons of public security or the protection of life and health of persons, environmental protection and the protection of key industrial and infrastructural assets. That authorisation shall be for a limited period of time, while the necessary conformity assessment procedures are being carried out, and shall terminate once those procedures have been completed. The completion of those procedures shall be undertaken without undue delay.

1a. In a duly justified situation of urgency for exceptional reasons of public security or in case of specific, substantial and imminent threat to the life or physical safety of natural persons , law enforcement authorities may put a specific high-risk AI system into service without the authorisation referred to in paragraph 1 provided that such authorisation is requested during or after the use without undue delay.

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.

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.

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

5. If the authorisation is considered unjustified, this shall be withdrawn by the market surveillance authority of the Member State concerned.

6. By way of derogation from paragraphs 1 to 5, for high-risk AI systems intended to be used as safety components of devices, or which are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746, Article 59 of Regulation (EU) 2017/745 and Article 54 of Regulation (EU) 2017/746 shall apply also with regard to the derogation from the conformity assessment of the compliance with the requirements set out in Chapter 2 of this Title.

Article 48
EU declaration of conformity

1. The provider shall draw up a written **or electronically signed** EU declaration of conformity for each AI system and keep it at the disposal of the national competent authorities for 10 years after the AI system has been placed on the market or put into service. The EU declaration of conformity shall identify the AI system for which it has been drawn up. A copy of the EU declaration of conformity shall be ~~given~~ **submitted** to the relevant national competent authorities upon request.

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

3. Where high-risk AI systems are subject to other Union harmonisation legislation which also requires an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all Union legislations applicable to the high-risk AI system. The declaration shall contain all the information required for identification of the Union harmonisation legislation to which the declaration relates.

4. By drawing up the EU declaration of conformity, the provider shall assume responsibility for compliance with the requirements set out in Chapter 2 of this Title. The provider shall keep the EU declaration of conformity up-to-date as appropriate.

5. **After consulting the AI Board referred to in Article 56, t**~~T~~he 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.

Article 49
CE marking of conformity

1. **The CE marking of conformity** ~~referred to in paragraph 1 of this Article~~ **shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.** ~~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.~~

2. ~~The CE marking referred to in paragraph 1 of this Article shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.~~ **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.**

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.

~~*Article 50*~~
~~*Document retention*~~

~~The provider shall, for a period ending 10 years after the AI system has been placed on the market or put into service, keep at the disposal of the national competent authorities:~~

~~(a) the technical documentation referred to in Article 11;~~

~~(b) the documentation concerning the quality management system referred to Article 17;~~

~~(c) the documentation concerning the changes approved by notified bodies where applicable;~~

~~(d) the decisions and other documents issued by the notified bodies where applicable;~~

~~(e) the EU declaration of conformity referred to in Article 48.~~

Article 51
Registration

Before placing on the market or putting into service a high-risk AI system **listed in Annex III** ~~referred to in Article 6(23)~~, the provider or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60.

TITLE IV

TRANSPARENCY OBLIGATIONS FOR CERTAIN AI SYSTEMS

Article 52
Transparency obligations for certain AI systems

1. Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way **that those systems inform** ~~*that*~~ natural persons ~~are informed~~ that they are interacting with an AI system, unless this is obvious **from the point view of a reasonable person** 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.

2. Users of an emotion recognition system or a biometric categorisation system shall inform of the operation of the system the natural persons exposed thereto. This obligation shall not apply to AI systems used for biometric categorisation, which are permitted by law to detect, prevent and investigate criminal offences**, subject to appropriate safeguards for the rights and freedoms of third parties**.

3. Users of an AI system that generates or manipulates image, audio or video content that appreciably resembles existing persons, objects, places or other entities or events and would falsely appear to a person to be authentic or truthful ('deep fake'), shall disclose that the content has been artificially generated or manipulated.

   However, the first subparagraph shall not apply where the use is authorised by law to detect, prevent, investigate and prosecute criminal offences ~~or it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, and~~ subject to appropriate safeguards for the rights and freedoms of third parties.

3a. The information referred to in paragraphs 1 to 3 shall be provided to natural persons in a clear and visible manner at the latest at the time of the first interaction or exposure.

4. Paragraphs 1, 2 and 3 shall not affect the requirements and obligations set out in Title III of this Regulation.

TITLE IVA

GENERAL PURPOSE AI SYSTEMS

Article 52a

General purpose AI systems

1. The placing on the market, putting into service or use of general purpose AI systems shall not, by themselves only, make those systems subject to the provisions of this Regulation.

2. Any person who places on the market or puts into service under its own name or trademark or uses a general purpose AI system made available on the market or put into service for an intended purpose that makes it subject to the provisions of this Regulation shall be considered the provider of the AI system subject to the provisions of this Regulation.

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

4. The provisions of this Article shall apply irrespective of whether the general purpose AI system is open source software or not.
