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**LIMITE**

**TELECOM 29  
JAI 105  
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**NOTE**

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Origine:	la présidence
Destinataire:	délégations
N° doc. préc.:	5293/22
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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 16-29

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**I. INTRODUCTION**

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

2. Le 12 octobre 2021, la présidence slovène a demandé aux délégations du groupe « Télécommunications et société de l'information » (WP TELECOM) de soumettre avant le 26 octobre leurs observations écrites et suggestions d'ordre rédactionnel sur les **articles 1 à 29** et sur les **annexes I à III** de la proposition de règlement, en vue de commencer à travailler sur le premier texte de compromis partiel de la proposition. Sur le fondement des réponses des délégations ainsi que du résultat des débats qui se sont tenus au sein du Conseil, la présidence slovène a rédigé une première proposition de compromis partiel, portant sur les articles 1 à 7 et sur les annexes I à III de la proposition de règlement. Cette proposition de compromis partiel a été présentée au WP TELECOM le 30 novembre 2021 par la présidence slovène et a été débattue en détail lors de la réunion du WP TELECOM du 11 janvier 2022, sous présidence française.
3. La présidence française a repris le travail de rédaction là où l'avait laissé la présidence slovène, et elle a rédigé la deuxième partie de la première proposition de compromis, portant sur les articles 8 à 15 et sur l'annexe IV, qui a été débattue lors de la réunion du WP TELECOM du 18 janvier 2022.
4. La présidence française a maintenant achevé la rédaction de **la troisième partie de la première proposition de compromis, portant sur les articles 16 à 29**, qui figure en annexe du présent document.
5. **La présidence française invite les délégations à débattre des modifications qu'il est proposé d'apporter aux articles 16 à 29 lors de la réunion du WP TELECOM du 10 février 2022.**
6. Les modifications apportées par rapport à la proposition de la Commission sont signalées comme suit dans le document : les ajouts sont en **gras** et les suppressions sont ~~barrées~~.

## II. PRINCIPAUX CHANGEMENTS

### 1. Article 16 – Obligations incombant aux fournisseurs de systèmes d'IA à haut risque

1.1. Un **point a bis**) a été ajouté pour mieux clarifier l'étendue des obligations des fournisseurs.

1.2. Des références à certains articles ont été insérées aux **points c), d), e) et g)** pour clarifier les liens entre les dispositions en question.

### 2. Article 17 – Système de gestion de la qualité

2.1. Les modifications apportées à l'**article 17, paragraphe 3**, sont destinées à préciser que, s'agissant des éléments mentionnés au **paragraphe 1, points g), h) et i)**, les fournisseurs qui sont des établissements de crédit régis par la directive 2013/36/UE restent soumis à des obligations au titre de la LIA.

### 3. Article 18 – Conservation de la documentation

3.1. Le titre de l'**article 18** a été modifié, car l'obligation pour les fournisseurs de systèmes d'IA à haut risque d'établir une documentation technique est déjà inscrite à l'**article 11**.

3.2. Le nouveau texte à l'**article 18, paragraphe 1**, est issu de l'**article 50**, qui est désormais supprimé.

3.3. Un **paragraphe 1 bis** a été ajouté à l'**article 18** pour préciser ce qui doit advenir de la documentation requise en cas de faillite du fournisseur ou de son mandataire.

#### 4. **Article 20 – Journaux générés automatiquement**

4.1. Les modifications apportées à l'**article 20, paragraphe 1**, précisent que les fournisseurs doivent conserver les journaux générés automatiquement pendant une période d'au moins six mois, conformément aux usages actuels du secteur.

#### 5. **Article 21 – Mesures correctives**

5.1. Les modifications apportées à l'**article 21** introduisent l'obligation pour les fournisseurs de systèmes d'IA à haut risque de coopérer avec les utilisateurs en cas de non-conformité d'un système d'IA à haut risque qu'ils ont mis sur le marché ou mis en service, afin d'en déterminer les causes.

#### 6. **Article 23 bis – Conditions auxquelles d'autres personnes sont soumises aux obligations du fournisseur**

6.1. Le **paragraphe 1** du nouvel **article 23 bis** contient du texte issu de l'ancien **article 28**, qui est désormais supprimé. Le texte a été légèrement modifié pour mieux préciser dans quelles situations d'autres participants à la chaîne de valeur sont tenus d'assumer les responsabilités du fournisseur.

6.2. Le **paragraphe 3** du nouvel **article 23 bis** contient du texte issu de l'ancien **article 24** concernant les situations dans lesquelles les fabricants sont tenus d'assumer les obligations des fournisseurs. Le texte a été légèrement modifié pour l'harmoniser avec le paragraphe 1 du même article et pour indiquer les différents scénarios dans lesquels de telles situations peuvent se présenter tout au long de la chaîne de valeur.

## 7. Article 25 – Mandataires

7.1. L'ajout du mot « seulement » à l'**article 25, paragraphe 2**, est destiné à garantir que les fournisseurs ne confieront pas la responsabilité d'autres tâches à leurs mandataires.

7.2. Les modifications apportées aux **points -a), a), b), c) et d)** de l'**article 25, paragraphe 2**, sont destinées à faire concorder le texte sur les obligations des mandataires avec les dispositions sur les obligations des importateurs et à rééquilibrer la répartition des responsabilités tout au long de la chaîne de valeur.

7.3. Les deux alinéas ajoutés à la fin de l'**article 25, paragraphe 2, point d)**, donnent la possibilité de résilier le mandat du mandataire dans certaines situations et prévoient que la responsabilité puisse être partagée entre les mandataires et les fournisseurs en cas de systèmes d'IA défectueux.

## 8. Article 26 – Obligations des importateurs

8.1. Les modifications apportées à l'**article 26, paragraphes 1 et 2**, sont destinées à clarifier certaines obligations des importateurs, et notamment à préciser ce que désigne la documentation requise que les importateurs doivent vérifier.

8.2. Un **paragraphe 4 bis** a été ajouté à l'**article 26** pour indiquer que les importateurs doivent conserver certains documents requis en vertu de la LIA pendant une période de dix ans à compter de la mise sur le marché ou de la mise en service du système d'IA.

8.3. Le nouveau **paragraphe 5 bis** de l'**article 26** contient du texte provenant de la fin du **paragraphe 5** sur l'obligation pour les importateurs de coopérer avec les autorités nationales compétentes.

## 9. Article 27 – Obligations des distributeurs

9.1. Les modifications apportées à l'**article 27, paragraphes 1 et 5**, sont destinées à clarifier certaines obligations des distributeurs, et notamment à préciser ce que désigne la documentation requise que les distributeurs doivent vérifier.

9.2. Le nouveau **paragraphe 5 bis** de l'**article 27** contient du texte provenant de la fin du **paragraphe 5** sur l'obligation pour les distributeurs de coopérer avec les autorités nationales compétentes.

## 10. Article 29 – Obligations des utilisateurs de systèmes d'IA à haut risque

10.1. Les modifications apportées à l'**article 29, paragraphe 1**, sont destinées à préciser que les utilisateurs sont dans l'obligation de procéder à un contrôle humain conformément à la notice d'utilisation, et le nouveau **paragraphe 1 bis** crée une obligation supplémentaire selon laquelle les utilisateurs doivent confier le contrôle humain à des personnes physiques répondant à certaines caractéristiques.

10.2. Les modifications apportées à l'**article 29, paragraphe 5**, concernant l'obligation pour les utilisateurs de conserver les journaux générés automatiquement par les systèmes d'IA à haut risque pendant une période d'au moins six mois, ont été introduites pour faire le pendant avec les modifications apportées à l'**article 20, paragraphe 1**, s'agissant des fournisseurs.

10.3. Le nouveau **paragraphe 6 bis** de l'**article 29** porte sur l'obligation pour les utilisateurs de coopérer avec les autorités nationales compétentes, sur le modèle des obligations équivalentes auxquelles sont soumis les autres participants à la chaîne de valeur.

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 3 (Articles 16-29)**

**CHAPTER 3**

**OBLIGATIONS OF PROVIDERS AND USERS OF HIGH-RISK AI SYSTEMS AND**  
**OTHER PARTIES**

*Article 16*

*Obligations of providers of high-risk AI systems*

Providers of high-risk AI systems shall:

- (a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title;
- (aa) **indicate their name, registered trade name or registered trade mark, the address at which they can be contacted on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as applicable;**
- (b) have a quality management system in place which complies with Article 17;
- (c) ~~draw up~~ **keep** the ~~technical~~ documentation **referred to in Article 18** ~~of the high-risk AI system;~~
- (d) when under their control, keep the logs automatically generated by their high-risk AI systems **as referred to in Article 20;**
- (e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure **as referred to in Article 43,** prior to its placing on the market or putting into service;

- (f) comply with the registration obligations referred to in Article 51;
- (g) take the necessary corrective actions **as referred to in Article 21**, if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title;
- (h) inform the national competent authorities of the Member States in which they made the AI system available or put it into service and, where applicable, the notified body of the non-compliance and of any corrective actions taken;
- (i) to affix the CE marking to their high-risk AI systems to indicate the conformity with this Regulation in accordance with Article 49;
- (j) upon request of a national competent authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title.

#### *Article 17*

#### *Quality management system*

1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:
  - (a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the high-risk AI system;
  - (b) techniques, procedures and systematic actions to be used for the design, design control and design verification of the high-risk AI system;
  - (c) techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the high-risk AI system;
  - (d) examination, test and validation procedures to be carried out before, during and after the development of the high-risk AI system, and the frequency with which they have to be carried out;
  - (e) technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, the means to be used to ensure that the high-risk AI system complies with the requirements set out in Chapter 2 of this Title;



- (f) systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market or putting into service of high-risk AI systems;
  - (g) the risk management system referred to in Article 9;
  - (h) the setting-up, implementation and maintenance of a post-market monitoring system, in accordance with Article 61;
  - (i) procedures related to the reporting of serious incidents ~~and of malfunctioning~~ in accordance with Article 62;
  - (j) the handling of communication with national competent authorities, competent authorities, including sectoral ones, providing or supporting the access to data, notified bodies, other operators, customers or other interested parties;
  - (k) systems and procedures for record keeping of all relevant documentation and information;
  - (l) resource management, including security of supply related measures;
  - (m) an accountability framework setting out the responsibilities of the management and other staff with regard to all aspects listed in this paragraph.
2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation.
  3. For providers that are credit institutions regulated by Directive 2013/36/ EU, the obligation to put **in place** a quality management system **in place with the exception of paragraph 1, letter g), h) and i)** shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to Article 74 of that Directive. In that context, any harmonised standards referred to in Article 40 of this Regulation shall be taken into account.

#### *Article 18*

##### *Obligation to draw up technical documentation-Documentation keeping*

1. ~~Providers of high risk AI systems shall draw up the technical documentation referred to in Article 11 in accordance with Annex IV. 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 in 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.**

- 1a. Each Member State shall determine conditions under which the documentation referred to in paragraph 1 remains at the disposal of the national competent authorities for the period indicated in that paragraph for the cases when a provider or its authorised representative established on its territory goes bankrupt or ceases its activity prior to the end of that period.**
- 2. Providers that are credit institutions regulated by Directive 2013/36/EU shall maintain the technical documentation as part of the documentation concerning internal governance, arrangements, processes and mechanisms pursuant to Article 74 of that Directive.

*Article 19*  
*Conformity assessment*

- 1. Providers of high-risk AI systems shall ensure that their systems undergo the relevant conformity assessment procedure in accordance with Article 43, prior to their placing on the market or putting into service. Where the compliance of the AI systems with the requirements set out in Chapter 2 of this Title has been demonstrated following that conformity assessment, the providers shall draw up an EU declaration of conformity in accordance with Article 48 and affix the CE marking of conformity in accordance with Article 49.
- 2. For high-risk AI systems referred to in point 5(b) of Annex III that are placed on the market or put into service by providers that are 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.

*Article 20*  
*Automatically generated logs*

1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. ~~The logs shall be kept~~ **They shall keep them** for a period **of at least six months, unless provided otherwise in that is appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under** Union or national law.
2. Providers that are credit institutions regulated by Directive 2013/36/EU shall maintain the logs automatically generated by their high-risk AI systems as part of the documentation under Articles 74 of that Directive.

*Article 21*  
*Corrective actions*

Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system which they have placed on the market or put into service is not in conformity with this Regulation shall **immediately investigate, where applicable, the causes in collaboration with the reporting user and immediately** take the necessary corrective actions to bring that system into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the high-risk AI system in question and, where applicable, the authorised representative and importers accordingly.

*Article 22*  
*Duty of information*

Where the high-risk AI system presents a risk within the meaning of Article 65(1) and that risk is known to the provider of the system, that provider shall immediately inform the national competent authorities of the Member States in which it made the system available and, where applicable, the notified body that issued a certificate for the high-risk AI system, in particular of the non-compliance and of any corrective actions taken.

*Article 23*  
*Cooperation with competent authorities*

Providers of high-risk AI systems shall, upon request by a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member State concerned. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.

*Article 23a*  
**Conditions for other persons to be subject to the obligations of a provider** ~~*Obligations of distributors, importers, users or any other third-party*~~

- 1. Any natural or legal person ~~distributor, importer, user or other third-party~~ shall be considered a provider of a new high-risk AI system for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16, in any of the following circumstances:**
  - (a) they put their name or trademark on a high-risk AI system already placed on the market or put into service, without prejudice to contractual arrangements stipulating that the obligations are allocated otherwise;**
  - (b) ~~they modify the intended purpose of a high-risk AI system already placed on the market or put into service;~~**
  - (c) they make a substantial modification to a high-risk AI system already placed on the market or put into service;**
  - (d) they modify the intended purpose of an AI system which is not high-risk and is already placed on the market or put into service, in a way which makes the modified system a high-risk AI system;**
  - (e) they fulfil the conditions referred in Article 52a(2).**
- 2. Where the circumstances referred to in paragraph 1, point (a) ~~(b)~~ or (c), occur, the provider that initially placed the high-risk AI system on the market or put it into service shall no longer be considered a provider for the purposes of this Regulation.**

**3. For high-risk AI systems that are safety components of products to which the legal acts listed in Annex II, section A apply, the manufacturer of those products shall be considered the provider of the high-risk AI system and shall be subject to the obligations under Article 16 under either of the following scenarios:**

**(i) the high-risk AI system is placed on the market together with the product under the name or trademark of the product manufacturer;**

**(ii) the high-risk AI system is put into service under the name or trademark of the product manufacturer after the product has been placed on the market.**

#### *Article 24*

#### *Obligations of product manufacturers*

~~Where a high risk AI system related to products to which the legal acts listed in Annex II, section A, apply, is placed on the market or put into service together with the product manufactured in accordance with those legal acts and under the name of the product manufacturer, the manufacturer of the product shall take the responsibility of the compliance of the AI system with this Regulation and, as far as the AI system is concerned, have the same obligations imposed by the present Regulation on the provider.~~

#### *Article 25*

#### *Authorised representatives*

1. Prior to making their systems available on the Union market, ~~where an importer cannot be identified,~~ providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.
2. The authorised representative shall perform the tasks specified in the mandate received from the provider. **For the purpose of this Regulation,** ~~the~~ mandate shall empower the authorised representative to carry out **only** the following tasks:

**(-a) verify that the EU declaration of conformity and the technical documentation have been drawn up and that an appropriate conformity assessment procedure has been carried out by the provider;**

**(a) keep at the disposal of the national competent authorities and national authorities referred to in Article 63(7), for a period ending 10 years after the high-risk AI system has been placed on the market or put into service, a copy of the EU declaration of conformity, the technical documentation and, if applicable, the certificate issued by the notified body** ~~keep a copy of the EU declaration of conformity and the technical documentation at the disposal of the national competent authorities and national authorities referred to in Article 63(7);~~

- (b) provide a national competent authority, upon a reasoned request, with all the information and documentation, **including that kept according to point (b)**, necessary to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law;
- (c) cooperate with ~~competent~~ national **competent** authorities, upon a reasoned request, on any action the latter takes in relation to the high-risk AI system.
- (d) comply with the registration obligations referred to in Article 51 or, if the registration is carried out by the provider itself, verify that the information referred to in point 3 of Annex VIII is correct.**

**The authorised representative shall terminate the mandate if it considers or has reason to consider that the provider acts contrary to its obligations under this Regulation. In such a case, it shall also immediately inform the market surveillance authority of the Member State in which it is established, as well as, where applicable, the relevant notified body, about the termination of the mandate and the reasons thereof.**

**The authorised representative shall be legally liable for defective AI systems on the same basis as, and jointly and severally with, the provider in respect of its potential liability under Council Directive 85/374/EEC.**

*Article 26*  
*Obligations of importers*

1. Before placing a high-risk AI system on the market, importers of such system shall ensure **that such a system is in conformity with this Regulation by verifying** that:
  - (a) the ~~appropriate~~ **relevant** conformity assessment procedure **referred to in Article 43** has been carried out by the provider of that AI system;
  - (b) the provider has drawn up the technical documentation in accordance with Annex IV;
  - (c) the system bears the required **CE** conformity marking and is accompanied by **the EU declaration of conformity** and ~~the required documentation and~~ instructions of use;
  - (d) the authorised representative referred to in Article 25 has been established by the provider.**

2. Where an importer considers or has reason to consider that a high-risk AI system is not in conformity with this Regulation, **or is falsified, or accompanied by falsified documentation**, it shall not place that system on the market until that AI system has been brought into conformity. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the importer shall inform the provider of the AI system and the market surveillance authorities to that effect.
3. Importers shall indicate their name, registered trade name or registered trade mark, and the address at which they can be contacted on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as applicable.
4. Importers shall ensure that, while a high-risk AI system is under their responsibility, where applicable, storage or transport conditions do not jeopardise its compliance with the requirements set out in Chapter 2 of this Title.
- 4a. Importers shall keep, for a period ending 10 years after the AI system has been placed on the market or put into service, a copy of the certificate issued by the notified body, where applicable, of the instructions for use and of the EU declaration of conformity.**
5. Importers shall provide national competent authorities, upon a reasoned request, with all necessary information and documentation, **including that kept in accordance with paragraph 5**, to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title in a language which can be easily understood by that national competent authority. **To this purpose they shall also ensure that the technical documentation can be made available to those authorities.** ~~including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law. They shall also cooperate with those authorities on any action national competent authority takes in relation to that system.~~
- 5a. Importers shall cooperate with national competent authorities on any action those authorities take in relation to an AI system.**

*Article 27*  
*Obligations of distributors*

1. Before making a high-risk AI system available on the market, distributors shall verify that the high-risk AI system bears the required CE conformity marking, that it is accompanied by ~~the required documentation and~~ **EU declaration of conformity and** instruction of use, and that the provider and the importer of the system, as applicable, have complied with their obligations **set out Article 16, point (b) and 26(3) respectively** ~~in this Regulation.~~

2. Where a distributor considers or has reason to consider that a high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title, it shall not make the high-risk AI system available on the market until that system has been brought into conformity with those requirements. Furthermore, where the system presents a risk within the meaning of Article 65(1), the distributor shall inform the provider or the importer of the system, as applicable, to that effect.
3. Distributors shall ensure that, while a high-risk AI system is under their responsibility, where applicable, storage or transport conditions do not jeopardise the compliance of the system with the requirements set out in Chapter 2 of this Title.
4. A distributor that considers or has reason to consider that a high-risk AI system which it has made available on the market is not in conformity with the requirements set out in Chapter 2 of this Title shall take the corrective actions necessary to bring that system into conformity with those requirements, to withdraw it or recall it or shall ensure that the provider, the importer or any relevant operator, as appropriate, takes those corrective actions. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the distributor shall immediately inform the national competent authorities of the Member States in which it has made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective actions taken.
5. Upon a reasoned request from a national competent authority, distributors of high-risk AI systems shall provide that authority with all the information and documentation **regarding its activities as described in paragraph 1 to 4** ~~necessary to demonstrate the conformity of a high-risk system with the requirements set out in Chapter 2 of this Title. Distributors shall also cooperate with that national competent authority on any action taken by that authority.~~

**5a. Importers shall cooperate with national competent authorities on any action those authorities take in relation to an AI system.**

*Article 28*

*Obligations of distributors, importers, users or any other third party*

- ~~1. Any distributor, importer, user or other third party shall be considered a provider of high-risk AI system for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16, in any of the following circumstances:~~
  - ~~(a) they place on the market or put into service a high-risk AI system under their name or trademark;~~
  - ~~(b) they modify the intended purpose of a high-risk AI system already placed on the market or put into service;~~



~~(c) they make a substantial modification to the high-risk AI system.;~~

~~**(d) they modify the intended purpose of an AI system which is not high-risk and is already placed on the market or put into service, in a way which makes the modified system a high-risk AI system.**~~

~~2. Where the circumstances referred to in paragraph 1, point (b) or (c), occur, the provider that initially placed the high-risk AI system on the market or put it into service shall no longer be considered a provider for the purposes of this Regulation.~~

#### *Article 29*

#### *Obligations of users of high-risk AI systems*

1. Users of high-risk AI systems shall use such systems **and implement human oversight** in accordance with the instructions of use accompanying the systems, pursuant to paragraphs 2 and 5 **of this Article**.

**1a. Users shall assign human oversight to natural persons who have the necessary competence, training and authority.**

2. The obligations in paragraph 1 **and 1a** are without prejudice to other user obligations under Union or national law and to the user's discretion in organising its own resources and activities for the purpose of implementing the human oversight measures indicated by the provider.

3. Without prejudice to paragraph 1, to the extent the user exercises control over the input data, that user shall ensure that input data is relevant in view of the intended purpose of the high-risk AI system.

4. Users shall monitor the operation of the high-risk AI system on the basis of the instructions of use. When they have reasons to consider that the use in accordance with the instructions of use may result in the AI system presenting a risk within the meaning of Article 65(1) they shall inform the provider or distributor and suspend the use of the system. They shall also inform the provider or distributor when they have identified any serious incident ~~or any malfunctioning within the meaning of Article 62~~ and interrupt the use of the AI system. In case the user is not able to reach the provider, Article 62 shall apply mutatis mutandis.

For users that are credit institutions regulated by Directive 2013/36/EU, the monitoring obligation set out in the first subparagraph shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to Article 74 of that Directive.

5. Users of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system, to the extent such logs are under their control ~~and. The logs shall be kept~~ **They shall keep them** for a period **of at least six months, unless provided otherwise** ~~that is appropriate in the light of the intended purpose of the high-risk AI system and in applicable legal obligations under~~ Union or national law.

Users that are credit institutions regulated by Directive 2013/36/EU shall maintain the logs as part of the documentation concerning internal governance arrangements, processes and mechanisms pursuant to Article 74 of that Directive.

6. Users of high-risk AI systems shall use the information provided under Article 13 to comply with their obligation to carry out a data protection impact assessment under Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, where applicable.

**6a. Users shall cooperate with national competent authorities on any action those authorities take in relation to an AI system.**

7. **The obligations established by this Article shall not apply to users who use the AI system in the course of a personal non-professional activity.**

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