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**LIMITE**

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**NOTE**

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Origine:	la présidence
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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 30-39 et 59-62

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**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 slovène 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 là où la présidence slovène s'est arrêtée et a rédigé les parties suivantes de la première proposition de compromis, couvrant **les articles 8 à 15, l'annexe IV, les articles 16 à 29, les articles 40 à 52 et les articles 53 à 55 bis**. En outre, la présidence française a remanié certaines dispositions relatives au **domaine de la justice et des affaires intérieures** à partir de l'ensemble du projet de règlement, qui ont ensuite été soumises pour examen par les attachés TELECOM et JAI le 7 avril 2022.
4. La présidence française a maintenant rédigé deux autres parties de la première proposition de compromis, couvrant **les articles 30 à 39 et 59 à 62**, qui figurent 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 30 à 39 et aux articles 59 à 62 lors de la réunion du groupe TELECOM du 28 avril 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. PRINCIPALES MODIFICATIONS

### 1. Article 30 - Autorités notifiantes

1.1 Les modifications apportées à l'article 30, paragraphe 2, visent à aligner le texte sur le nouveau cadre législatif (NCL), en particulier sur le règlement (CE) no 765/2008 fixant les prescriptions relatives à l'accréditation et à la surveillance du marché pour la commercialisation des produits.

1.2 Le texte supprimé de l'article 30, paragraphe 8, a été déplacé vers le nouvel article 34 bis, qui précise les obligations opérationnelles des organismes notifiés.

### 2. Article 32 - Procédure de notification

2.1 L'ajout à la fin de l'article 32, paragraphe 3, clarifie la procédure dans les cas où une notification n'est pas fondée sur un certificat d'accréditation visé à l'article 31.

2.2. Le libellé de l'article 32, paragraphe 4, a été modifié pour assurer l'alignement sur les dispositions correspondantes du nouveau cadre législatif (règlement (CE) no 765/2008).

### 3. Article 33 - Exigences relatives aux organismes notifiés

3.1 La première phrase de l'article 33, paragraphe 1, a été supprimée et déplacée vers le nouvel article 34 bis, qui précise les obligations opérationnelles des organismes notifiés. La nouvelle phrase a été ajoutée pour assurer l'alignement sur les dispositions correspondantes du nouveau cadre législatif (règlement (CE) no 765/2008).

3.2. La suppression à l'article 33(10) vise à une meilleure flexibilité quant à la disponibilité dans les organismes notifiés des ressources suffisantes en matière de ressources humaines compétentes dans les domaines administratif, technique, juridique et scientifique en lien avec les technologies de l'IA.

3.3 Le texte de **l'article 33, paragraphe 12**, a été supprimé et déplacé vers le nouvel **article 34 bis**, qui précise les obligations opérationnelles des organismes notifiés.

4. **Article 33 bis - Présomption de conformité aux exigences relatives aux organismes notifiés**

4.1 Le nouvel **article 33 bis** a été ajouté pour clarifier les conditions d'une présomption de conformité aux exigences spécifiées à **l'article 33** en ce qui concerne les organismes notifiés.

5. **Article 34 - Filiales et sous-traitants des organismes notifiés**

5.1 Les modifications apportées à **l'article 34, paragraphe 4**, visent à préciser la durée pendant laquelle les documents concernant l'évaluation des qualifications du sous-traitant ou de la filiale et les travaux effectués par ceux-ci doivent être gardés à la disposition de l'autorité notifiante.

6. **Article 34 bis - Obligations opérationnelles des organismes notifiés**

6.1 Le nouvel **article 34 bis** contient des dispositions déplacées d'autres articles de ce chapitre afin d'assurer l'alignement sur les dispositions correspondantes du nouveau cadre législatif.

7. **Article 36 - Modifications apportées aux notifications**

7.1 Les principales modifications apportées à **l'article 36** ont été introduites pour assurer l'alignement sur les dispositions correspondantes du nouveau cadre législatif (décision no 768/2008/CE).

8. **Article 37 - Contestation de la compétence des organismes notifiés**

8.1 Les principales modifications apportées à **l'article 37** ont été introduites pour assurer l'alignement sur les dispositions correspondantes du nouveau cadre législatif (décision no 768/2008/CE). La phrase ajoutée à la fin confère à la Commission le pouvoir de suspendre, de restreindre ou de retirer la notification dans certains cas, et elle reflète une disposition similaire du règlement relatif aux dispositifs médicaux.

9. **Article 38 - Coordination des organismes notifiés**

9.1 Les modifications apportées à **l'article 38, paragraphe 1**, visent à préciser que ses dispositions ne concernent que les systèmes d'IA à haut risque.

9.2 La modification de **l'article 38, paragraphe 2**, a été introduite pour préciser que l'obligation d'assurer la participation des organismes notifiés aux travaux du groupe sectoriel d'organismes notifiés incombe à l'autorité notifiante.

10. **Article 39 - Organismes d'évaluation de la conformité de pays tiers**

10.1 Les modifications apportées à **l'article 39** visent à préciser que les organismes d'évaluation de la conformité établis en vertu de la législation d'un pays tiers qui peuvent être autorisés à exercer les activités des organismes notifiés doivent satisfaire aux exigences énoncées à **l'article 33**.

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11. **Article 59 - Désignation des autorités nationales compétentes**

11.1 Dans un souci de clarté, le texte de **l'article 59, paragraphe 1**, a été supprimé et fusionné dans **l'article 59, paragraphe 2**.

11.2 Les modifications apportées à **l'article 59, paragraphe 2**, précisent qu'il appartient à chaque État membre de désigner (ou d'établir) les autorités nationales compétentes qui devraient s'entendre comme des autorités de surveillance du marché, des autorités notifiantes et des autorités de surveillance, etelles prévoient une plus grande souplesse pour les États membres en ce qui concerne l'attribution des tâches aux autorités désignées en fonction de leurs besoins organisationnels. Le considérant correspondant a également été adapté en conséquence.

11.3 La suppression de **l'article 59, paragraphe 3**, vise à alléger l'obligation d'information pesant sur les États membres lorsqu'ils informent la Commission de leur désignation ou désignation d'autorités nationales compétentes.

11.4 Les modifications apportées à **l'article 59, paragraphe 4** visent à rendre moins contraignantes les dispositions relatives aux ressources adéquates des autorités nationales compétentes.

11.5 Les modifications apportées à **l'article 59, paragraphe 5**, réduisent la fréquence liée à l'établissement de rapports sur l'état des ressources des autorités nationales compétentes des États membres à l'intention de la Commission, compte tenu également des exigences en matière d'évaluation et de réexamen énoncées à **l'article 84**.

11.6 Le terme «orientations» a été supprimé de **l'article 59, paragraphe 7**, afin d'éviter toute confusion avec les orientations ou lignes directrices que la Commission serait tenue de fournir en vertu du nouvel **article 58 bis**, qui est toujours en cours d'élaboration par la présidence.

## 12. **Article 60 - Base de données de l'UE pour les systèmes d'IA à haut risque de l'annexe III**

12.1 À **l'article 60, paragraphe 1**, une référence à **l'article 54 bis** a été ajoutée pour inclure les essais de systèmes d'IA à haut risque en conditions réelles.

12.2 Les modifications apportées à **l'article 60, paragraphe 2**, clarifient le lien entre cette disposition et **les articles 51 et 54 bis** en ce qui concerne la personne qui doit entrer les données dans la base de données de l'UE. La dernière phrase a été supprimée car la notion de soutien technique et administratif de la Commission est déjà incluse **l'article 60, paragraphe 5**.

12.3 Par souci de clarté, le texte de **l'article 60, paragraphe 3**, a été supprimé et déplacé vers le nouvel **article 60, paragraphe 5 bis**.

12.4 **L'article 60, paragraphe 4**, relatif aux données à caractère personnel dans la base de données de l'UE a été simplifié afin de préciser que la base de données ne devrait inclure aucune donnée à caractère personnel, à l'exception de celles énumérées à **l'annexe VIII**, conformément au principe de minimisation des données prévu par le RGPD.

12.5 Le nouvel **article 60, paragraphe 5 bis**, précise quelles parties de la base de données de l'UE devraient être accessibles au public.

13. **Article 61 - Surveillance après commercialisation par les fournisseurs et plan de surveillance après commercialisation pour les systèmes d'IA à haut risque**

13.1 À **l'article 61, paragraphe 1**, il a été clarifié que le système de surveillance postérieure à la mise sur le marché est uniquement destiné à couvrir les systèmes à haut risque.

13.2 Les modifications apportées à **l'article 61, paragraphe 2**, offrent davantage de souplesse aux fournisseurs en ce qui concerne la collecte, la documentation et l'analyse des données pertinentes nécessaires à l'évaluation de la conformité des systèmes d'IA avec les exigences énoncées dans l'AIA. La dernière phrase a été supprimée et déplacée au début pour préciser en premier lieu l'objet de la disposition.

13.3 Les modifications apportées à **l'article 61, paragraphe 4**, visent à clarifier que, dans certains cas, il devrait suffire que les fournisseurs se conforment à la législation sectorielle qui prévoit déjà des mécanismes bien établis et acceptés de surveillance postérieure à la mise sur le marché.

14. **Article 62 - Notification des incidents graves et des dysfonctionnements**

14.1 Les modifications apportées à **l'article 62, paragraphe 3**, visent à élargir l'éventail des futurs cas d'usage possibles qui nécessiteraient la notification d'incidents graves, si l'annexe III devait être mise à jour dans l'avenir via l'ajout d'autres établissements financiers dans le champ d'application.

14.2 La référence à la notification des incidents graves affectant des systèmes d'IA à haut risque qui sont des composants de sécurité de dispositifs ou sont eux-mêmes des dispositifs, à **l'article 62, paragraphe 4**, a été supprimée et déplacée dans **le nouvel article 62, paragraphe 4 bis**. Il a également été clarifié que la notification devrait être adressée à l'autorité nationale de surveillance.

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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 4**

**NOTIFYING AUTHORITIES AND NOTIFIED BODIES**

*Article 30*

*Notifying authorities*

1. Each Member State shall designate or establish a notifying authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring.
2. ~~Member States may designate a national accreditation body referred to in Regulation (EC) No 765/2008 as a notifying authority.~~ **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.**
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.
4. Notifying authorities shall be organised in such a way that decisions relating to the notification of conformity assessment bodies are taken by competent persons different from those who carried out the assessment of those bodies.
5. Notifying authorities shall not offer or provide any activities that conformity assessment bodies perform or any consultancy services on a commercial or competitive basis.
6. Notifying authorities shall safeguard the confidentiality of the information they obtain **in accordance with Article 70.**

7. Notifying authorities shall have ~~a sufficient~~ **an adequate** number of competent personnel at their disposal for the proper performance of their tasks.
8. ~~Notifying authorities shall make sure that conformity assessments are carried out in a 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.~~

### *Article 31*

#### *Application of a conformity assessment body for notification*

1. Conformity assessment bodies shall submit an application for notification to the notifying authority of the Member State in which they are established.
2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 33. Any valid document related to existing designations of the applicant notified body under any other Union harmonisation legislation shall be added.
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 appropriate.

### *Article 32*

#### *Notification procedure*

1. Notifying authorities may **only** notify ~~only~~ conformity assessment bodies which have satisfied the requirements laid down in Article 33.
2. Notifying authorities shall notify **those bodies to** the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.
3. The notification **referred to in paragraph 2** 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. 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.**

4. The conformity assessment body concerned may perform the activities of a notified body only ~~where~~ **where no objections are raised by the Commission or the other Member States within two weeks of a notification by a notifying authority where it includes an accreditation certificate referred to in Article 31(2), or within two months of a notification by the notifying authority where it includes documentary evidence referred to in Article 31(3)** ~~no objections are raised by the Commission or the other Member States within one month of a notification.~~
5. Notifying authorities shall notify the Commission and the other Member States of any subsequent relevant changes to the notification **referred to in this Article without undue delay.**

### *Article 33*

#### **Requirements relating to notified bodies**

1. ~~Notified bodies shall verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43.~~ **A notified body shall be established under national law and have legal personality.**
2. Notified bodies shall satisfy the organisational, quality management, resources and process requirements that are necessary to fulfil their tasks.
3. The organisational structure, allocation of responsibilities, reporting lines and operation of notified bodies shall be such as to ensure that there is confidence in the performance by and in the results of the conformity assessment activities that the notified bodies conduct.
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.
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.
6. Notified bodies shall have documented procedures in place ensuring that their personnel, committees, subsidiaries, subcontractors and any associated body or personnel of external bodies respect the confidentiality of the information which comes into their possession during the performance of conformity assessment activities, except when disclosure is required by law. The staff of notified bodies shall be bound to observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the notifying authorities of the Member State in which their activities are carried out.
7. Notified bodies shall have procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the AI system in question.

8. Notified bodies shall take out appropriate liability insurance for their conformity assessment activities, unless liability is assumed by the Member State **in which they are located** ~~concerned~~ in accordance with national law or that Member State is **itself** directly responsible for the conformity assessment.
9. Notified bodies shall be capable of carrying out all the tasks falling to them under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by notified bodies themselves or on their behalf and under their responsibility.
10. Notified bodies shall have sufficient internal competences to be able to effectively evaluate the tasks conducted by external parties on their behalf. ~~To that end, at all times and for each conformity assessment procedure and each type of high risk AI system in relation to which they have been designated,~~ The notified body shall have permanent availability of sufficient administrative, technical, **legal** 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.
11. Notified bodies shall participate in coordination activities as referred to in Article 38. They shall also take part directly or be represented in European standardisation organisations, or ensure that they are aware and up to date in respect of relevant standards.
- ~~12. Notified bodies shall make available and submit upon request all relevant documentation, including the providers' documentation, to the notifying authority referred to in Article 30 to allow it to conduct its assessment, designation, notification, monitoring and surveillance activities and to facilitate the assessment outlined in this Chapter.~~

#### **Article 33a**

#### **Presumption of conformity with requirements relating to notified bodies**

**Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union it shall be presumed to comply with the requirements set out in Article 33 in so far as the applicable harmonised standards cover those requirements.**

#### *Article 34*

#### *Subsidiaries of and subcontracting by notified bodies*

1. Where a notified body subcontracts specific tasks connected with the conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements laid down in Article 33 and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.
3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the provider.
4. ~~Notified bodies shall keep at the disposal of the notifying authority t~~The relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation **shall be kept at the disposal of the notifying authority for a period of 5 years from the termination date of the subcontracting activity.**

#### Article 34a

##### Operational obligations of notified bodies

1. **Notified bodies shall verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43.**
2. **Notified bodies shall perform their activities while avoiding unnecessary burdens for providers, and taking due account of the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of the high risk AI system in question. In so doing, the notified body shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the high risk AI system with the requirements of this Regulation.**
3. **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 that authority to conduct its assessment, designation, notification, monitoring activities and to facilitate the assessment outlined in this Chapter.**

#### *Article 35*

##### *Identification numbers and lists of notified bodies designated under this Regulation*

1. The Commission shall assign an identification number to notified bodies. It shall assign a single number, even where a body is notified under several Union acts.
2. The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified. The Commission shall ensure that the list is kept up to date.

*Article 36*  
*Changes to notifications*

1. Where a notifying authority has ~~suspicions~~ **sufficient reasons to consider** ~~or has been informed~~ that a notified body no longer meets the requirements laid down in Article 33, or that it is failing to fulfil its obligations, **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. It shall immediately inform the Commission and the other Member States accordingly** ~~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.~~
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 **and market surveillance authorities** at their request.

*Article 37*  
*Challenge to the competence of notified bodies*

1. The Commission shall, where necessary, investigate all cases where there are reasons to doubt whether a notified body complies with the requirements laid down in Article 33.
2. The notifying authority shall provide the Commission, on request, with all relevant information relating to the notification of the notified body concerned.
3. The Commission shall ensure that all confidential information obtained in the course of its investigations pursuant to this Article is treated confidentially.
4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements laid down in Article 33, it shall **inform the notifying authority accordingly and request it** ~~adopt a reasoned decision requesting the notifying Member State~~ to take the necessary corrective measures, including ~~withdrawal of de-notification~~ if necessary. **That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(2). Where the notifying authority fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the notification. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(2).**

*Article 38*  
*Coordination of notified bodies*

1. The Commission shall ensure that, with regard to ~~the areas covered by this Regulation~~ **high-risk AI systems**, appropriate coordination and cooperation between notified bodies active in the conformity assessment procedures ~~of AI systems~~ pursuant to this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.
2. ~~Member States~~ **The notifying authority** shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.

*Article 39*  
*Conformity assessment bodies of third countries*

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.**

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## CHAPTER 2

### NATIONAL COMPETENT AUTHORITIES

*Article 59*  
*Designation of national competent authorities*

- ~~1. National competent authorities shall be established or designated by each Member State for the purpose of ensuring the application and implementation of this Regulation. National competent authorities shall be organised so as to safeguard the objectivity and impartiality of their activities and tasks.~~
2. Each Member State shall **establish or** designate a national supervisory authority, **and at least one notifying authority and at least one market surveillance authority for the purpose of this Regulation as among the national competent authorities. These national competent authorities shall be organised so as to safeguard the principles of objectivity and impartiality of their activities and tasks. Provided that those principles are respected, such activities and tasks may be performed by one or several designated authorities, in accordance with the organisational needs of the Member State. 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.**
3. Member States shall inform the Commission of their designation or designations ~~and, where applicable, the reasons for designating more than one authority.~~

4. Member States shall ensure that national competent authorities are provided with adequate financial **resources, technical equipment and well qualified** ~~and~~ human resources to **effectively** 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.~~
5. **By [one year after entry into force of this Regulation] and afterwards six months before the deadline referred to in Article 84(2)** Member States shall ~~report to~~ **inform** the Commission ~~on an annual basis~~ on the status of the financial **resources, technical equipment and** ~~and~~ human resources of the national competent authorities with an assessment of their adequacy. The Commission shall transmit that information to the Board for discussion and possible recommendations.
6. The Commission shall facilitate the exchange of experience between national competent authorities.
7. National competent authorities may provide ~~guidance and~~ advice on the implementation of this Regulation, including **tailored** to ~~small-scale~~ **SME** providers. Whenever national competent authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the competent national authorities under that Union legislation shall be consulted, as appropriate. Member States may also establish one central contact point for communication with operators.
8. When Union institutions, agencies and bodies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as the competent authority for their supervision.

## TITLE VII

### EU DATABASE FOR ~~STAND-ALONE~~ HIGH-RISK AI SYSTEMS LISTED IN ANNEX III

#### *Article 60*

#### *EU database for ~~stand-alone~~ high-risk AI systems **listed in Annex III***

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 **listed in Annex III** ~~referred to in Article 6(2)~~ which are registered in accordance with Articles ~~51~~ **and 54a**.
2. The data listed in Annex VIII shall be entered into the EU database by the providers, **or where applicable by the authorised representative, in accordance with Article 51. The data listed in Annex VIIIa shall be entered into the database by the prospective providers or providers in accordance with Article 54a.** ~~The Commission shall provide them with technical and administrative support.~~



3. ~~Information contained in the EU database shall be accessible to the public.~~
4. The EU database shall contain **no** personal data, **except for the information 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.~~
5. The Commission shall be the controller of the EU database. It shall ~~also~~ **ensure** **make available** to providers **and prospective providers** adequate technical and administrative support.
- 5a. Information contained in the EU database registered in accordance with Article 51 shall be accessible to the public. The information registered in accordance with Article 54a shall be accessible only to market surveillance authorities and the Commission, unless the prospective provider or provider has given consent for making this information also accessible the public.**

## TITLE VIII

### POST-MARKET MONITORING, INFORMATION SHARING, MARKET SURVEILLANCE

#### CHAPTER 1

#### POST-MARKET MONITORING

##### *Article 61*

##### *Post-market monitoring by providers and post-market monitoring plan for high-risk AI systems*

1. Providers shall establish and document a post-market monitoring system in a manner that is proportionate to ~~the nature of the artificial intelligence technologies and~~ the risks of the high-risk AI system.
2. **In order to allow the provider to evaluate the compliance of AI systems with the requirements set out in Title III, Chapter 2 throughout their life cycle, ~~the~~ post-market monitoring system shall actively and systematically collect, document and analyse relevant data, which may be provided by users or which may be collected through other sources on the performance of high-risk AI systems, throughout their life time and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.**
3. The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt an implementing act laying down detailed provisions establishing a template for the post-market monitoring plan and the list of elements to be included in the plan.

4. For high-risk AI systems covered by the legal acts referred to in Annex II, where a post-market monitoring system and plan is already established under that legislation, ~~the elements described in paragraphs 1, 2 and 3 shall be integrated into that system and plan as appropriate~~ **the post-market monitoring documentation as prepared under that legislation shall be deemed sufficient, provided that the template referred to in paragraph 3 is used.**

The first subparagraph shall also apply to high-risk AI systems referred to in point 5(b) of Annex III placed on the market or put into service by credit institutions regulated by Directive 2013/36/EU.

## CHAPTER 2

### SHARING OF INFORMATION ON SERIOUS INCIDENTS ~~AND MALFUNCTIONING~~

#### *Article 62*

#### *Reporting of serious incidents ~~and of malfunctioning~~*

1. Providers of high-risk AI systems placed on the Union market shall report any serious incident ~~or any malfunctioning of those systems which constitutes a breach of obligations under Union law intended to protect fundamental rights~~ to the market surveillance authorities of the Member States where that incident ~~or breach~~ occurred.

Such notification shall be made immediately after the provider has established a causal link between the AI system and the **serious incident** ~~or malfunctioning~~ or the reasonable likelihood of such a link, and, in any event, not later than 15 days after the providers becomes aware of the serious incident ~~or of the malfunctioning~~.

2. Upon receiving a notification related to a **serious incident referred to in Article 3(44)(c)** ~~a breach of obligations under Union law intended to protect fundamental rights~~, the **relevant** market surveillance authority shall inform the national public authorities or bodies referred to in Article 64(3). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1. That guidance shall be issued 12 months after the entry into force of this Regulation, at the latest.
3. For high-risk AI systems referred to in point 5(~~b~~) of Annex III which are placed on the market or put into service by providers that are ~~credit~~ **financial** institutions **that are subject to requirements regarding their internal governance, arrangements or processes under Union financial services legislation** ~~regulated by Directive 2013/36/EU and for high risk AI systems which are safety components of devices, or are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746~~, the notification of serious incidents ~~or malfunctioning~~ shall be limited to those **referred to in Article 3(44)(c)** ~~that constitute a breach of obligations under Union law intended to protect fundamental rights~~.

4. **For high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746 the notification of serious incidents shall be limited to those referred to in Article 3(44)(c) and be made to the national supervisory authority of the Member States where that incident occurred.**
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