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LIMITE

TELECOM 169 JAI 536 COPEN 142 CYBER 139 DATAPROTECT 113 EJUSTICE 46 COSI 102 IXIM 99 ENFOPOL 213 FREMP 80 RELEX 534 MI 318 COMPET 267 CODEC 556

#### NOTE

la présidence
délégations
8307/22
8115/21
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 70-85

### 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.

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- 2. La présidence slovène a rédigé la première proposition de compromis partiel, qui couvre <u>les articles 1 à 7 et les annexes I à III</u> 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 dans le cadre de la présidence française.
- 3. La présidence française a repris les travaux de rédaction au cours desquels la présidence slovène a achevé ses travaux et a rédigé les parties suivantes de la première proposition de compromis, couvrant <u>les articles 8 à 15 et l'annexe IV</u>, <u>les articles 16 à 29</u>, <u>les articles 30 à 39</u>, <u>les articles 40 à 52</u>, <u>les articles 53 à 55 bis</u> et <u>les articles 59 à 62</u>. En outre, la présidence française a remanié certaines <u>dispositions relatives au domaine de la justice et des affaires intérieures</u> 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 une autre partie de la première proposition de compromis, couvrant <u>les articles 70 à 85</u>, qui figure à l'annexe du présent document.
- 5. <u>La présidence française invite les délégations à examiner les modifications qu'il est</u> proposé d'apporter aux articles 70 à 85 lors de la réunion du groupe TELECOM du 5 <u>mai 2022.</u>
- 6. Les modifications apportées au document par rapport à la proposition de la Commission sont <u>soulignées</u>: les ajouts sont signalés par des **caractères gras**, les suppressions sont <del>barrées</del>.

### II. PRINCIPALES MODIFICATIONS

### 1. Article 70 — Confidentialité

1.1 Les modifications apportées à <u>l'article 70, paragraphe 1</u>, renforcent les exigences en matière de confidentialité et précisent qu'elles s'appliquent également à la Commission, au Comité et à toute autre personne physique ou morale participant à l'application de l'AIA. Elle tient également compte des observations des États membres sur la nécessité de garantir la confidentialité des données par des mesures techniques et organisationnelles.

#### 2. <u>Article 71 - Sanctions</u>

2.1 À <u>l'article 71, paragraphe 1</u>, une modification a été apportée pour indiquer que les sanctions en cas d'infraction à l'AIA devraient être proportionnées à la taille des entreprises.

2.2 Les ajouts à la fin des <u>articles 71 (3) et 71 (4)</u> ont été introduits afin d'adapter les sanctions en cas de non-respect de l'AIA pour les PME, telles que définies par le droit de l'Union, et de clarifier le niveau maximal des sanctions encourues, d'une part, en cas de violation des interdictions (l'article 5) et, d'autre part, en cas de violation d'autres dispositions (y compris l'article 10). Par conséquent, le non-respect de l'article 10 est désormais couvert par <u>l'article 71, paragraphe 4</u>.

2.3 Les modifications apportées à <u>l'article 71, paragraphe 4</u>, précisent que les opérateurs économiques ou les organismes notifiés sont ceux qui peuvent faire l'objet d'amendes administratives.

2.4 L'ajout à <u>l'article 71, paragraphe 6, point b</u>), a été introduit afin d'éviter la double imposition d'amendes pour la même infraction dans un autre État membre (ce qui n'est pas nécessairement interdit en vertu du principe *ne bis in idem*), tandis que l'ajout à <u>l'article 71, paragraphe 6, point c</u>), vise à préciser que le chiffre d'affaires annuel doit également être pris en compte lors de la détermination du montant de l'amende administrative.



2.6 Un nouvel <u>article 71, paragraphe 9</u>, a été ajouté afin de prévoir des garanties procédurales appropriées devant être mises en place par les autorités de surveillance du marché en ce qui concerne les sanctions, et précise que les principes de procédure régulière et de recours juridictionnel effectif devraient être pris en compte lors de l'établissement des règles nationales. Le libellé est fondé sur une disposition similaire du RGPD.

## 4. Articles 72 à 83

4.1. Ces articles n'ont pas été modifiés par la présidence française.

## 4. Article 84 - Évaluation et réexamen

4.1 Des modifications ont été apportées à <u>l'article 84, paragraphe 3, point a)</u>, afin d'assurer
l'alignement sur les modifications correspondantes introduites à <u>l'article 59</u>.

4.2 Les modifications apportées à <u>l'article 84, paragraphe 4</u>, visent à préciser que, compte tenu du caractère volontaire des codes de conduite, leur évaluation doit avoir lieu lorsqu'ils existent. Aucune nouvelle obligation générale n'a été créée pour les États membres, étant donné que ces codes de conduite restent volontaires.

4.3 À <u>l'article 85, paragraphe 2</u>, le délai général d'application du règlement a été porté de 24 à 36 mois après l'entrée en vigueur de l'AIA, afin de donner aux États membres davantage de temps pour se préparer à une mise en œuvre effective et de donner plus de temps aux entreprises pour s'adapter, en suivant l'exemple du RGPD et en tenant compte des conséquences importantes de l'AIA sur les opérateurs. Par conséquent, le délai laissé aux États membres pour la mise en place des autorités notifiantes et des organismes notifiés (titre III, chapitre 4) et de la structure de gouvernance (titre VI) a également été porté à 12 mois, afin de tenir compte des préoccupations exprimées par plusieurs États membres en matière de gouvernance.

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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

# NOTIFIYING 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. <u>Member States may designate a national accreditation body referred to in Regulation (EC)</u> <u>No 765/2008 as a notifying authority.</u> <u>Member States may decide that the assessment</u> <u>and monitoring referred to in paragraph 1 shall be carried out by a national</u> <u>accreditation body within the meaning of and in accordance with Regulation (EC) No</u> <u>765/2008.</u>
- 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 <u>in</u> <u>accordance with Article 70</u>.



- 7. Notifying authorities shall have <u>a sufficient</u> <u>an adequate</u> number of competent personnel at their disposal for the proper performance of their tasks.
- 8. <u>Notifying authorities shall make sure that conformity assessments are carried out in a</u> 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 <u>only</u> conformity assessment bodies which have satisfied the requirements laid down in Article 33.
- 2. Notifying authorities shall notify <u>those bodies to</u> the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.
- 3. The notification <u>referred to in paragraph 2</u> shall include full details of the conformity assessment activities, the conformity assessment module or modules <u>and the artificial</u> <u>intelligence technologies concerned</u> <u>and the relevant attestation of competence. Where</u> <u>a notification is not based on an accreditation certificate as referred to in Article 31</u> (2), the notifying authority shall provide the Commission and the other Member <u>States with documentary evidence which attests to the conformity assessment body's</u> <u>competence and the arrangements in place to ensure that that body will be monitored</u> <u>regularly and will continue to satisfy the requirements laid down in Article 33</u>.

- 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 <u>referred to in this Article</u> <u>without undue</u> <u>delay</u>.

### Article 33 <u>Requirements relating to nN</u>otified bodies

- 1. <u>Notified bodies shall verify the conformity of high-risk AI system in accordance with the</u> <u>conformity assessment procedures referred to in Article 43.</u> <u>A notified body shall be</u> <u>established under national law and have legal personality.</u>
- 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 <u>in which they are</u> <u>located concerned</u> in accordance with national law or that Member State is <u>itself</u> 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. <u>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, tThe 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.</u>
- 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,<br/>including the providers' documentation, to the notifying authority referred to in Article 30<br/>to allow it to conduct its assessment, designation, notification, monitoring and surveillance<br/>activities and to facilitate the assessment outlined in this Chapter.

#### <u>Article 33a</u> <u>Presumption of conformity with requirements relating to notified bodies</u>

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. <u>Notified bodies shall keep at the disposal of the notifying authority t</u>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 <u>shall be kept at the disposal of the notifying authority for a period of 5 years from the termination date of the subcontacting activity</u>.

## <u>Article 34a</u>

### **Operational obligations of notified bodies**

- 1.Notified bodies shall verify the conformity of high-risk AI system in accordance with<br/>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).

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#### *Article 38 Coordination of notified bodies*

- 1. The Commission shall ensure that, with regard to <u>the areas covered by this Regulation</u> <u>high-risk AI systems</u>, appropriate coordination and cooperation between notified bodies active in the conformity assessment procedures <u>of AI systems</u> pursuant to this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.
- 2. <u>Member States</u> <u>The notifying authority</u> 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 <u>establish or</u> designate a national supervisory authority, <u>and at</u> <u>least one notifying authority and at least one market surveillance authority for the</u> <u>purpose of this Regulation as among the</u> national competent authorities. <u>These national</u> <u>competent authorities shall be organised so as to safeguard the principles of</u> <u>objectivity and impartiality of their activities and tasks. Provided that those</u> <u>prinicples are respected, such activities and tasks may be performed by one or several</u> <u>designated authorities, in accordance with the organisational needs of the Member</u> <u>State.</u> <u>The national supervisory authority shall act as notifying authority and market</u> <u>surveillance authority unless a Member State has organisational and administrative reasons</u> <u>to designate more than one authority.</u>
- 3. Member States shall inform the Commission of their designation or designations <u>and</u>, <u>where applicable, the reasons for designating more than one authority</u>.



- 4. Member States shall ensure that national competent authorities are provided with adequate financial <u>resources, technical equipment and well qualified</u> <u>and</u> human resources to <u>effectively</u> fulfil their tasks under this Regulation. <u>In particular, national competent</u> <u>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.</u>
- 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 <u>guidance and</u> advice on the implementation of this Regulation, including **tailored** to <u>small-scale</u> **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 <u>STAND-ALONE</u> HIGH-RISK AI SYSTEMS <u>LISTED IN</u> <u>ANNEX III</u>

#### Article 60 EU database for <u>stand-alone</u> high-risk AI systems <u>listed in Annex III</u>

- 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 <u>listed in Annex III</u> 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, <u>or</u> <u>where applicable by the authorised representative, in accordance with Article 51. The</u> <u>data listed in Annex VIIIa shall be entered into the database by the prospective</u> <u>providers or providers in accordance with Article 54a</u>. <u>The Commission shall provide</u> <u>them with technical and administrative support.</u>

- 3. <u>Information contained in the EU database shall be accessible to the public</u>.
- 4. The EU database shall contain <u>no</u> personal data<u>, except for the information listed in</u> <u>Annex VIII</u> <u>only insofar as necessary for collecting and processing information in</u> <u>accordance with this Regulation. That information shall include the names and contact</u> <u>details of natural persons who are responsible for registering the system and have the legal</u> <u>authority to represent the provider</u>.
- 5. The Commission shall be the controller of the EU database. It shall <u>also</u> <u>ensure make</u> <u>available</u> to providers <u>and prospective providers</u> adequate technical and administrative support.
- 5a.Information contained in the EU database registered in accordance with Article 51shall be accessible to the public. The information registered in accordance with<br/>Article 54a shall be accessible only to market surveillance authorites and the<br/>Commission, unless the prospective provider or provider has given consent for<br/>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 <u>the nature of the artificial intelligence technologies and</u> 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, <u>T</u>the postmarket monitoring system shall <u>actively and systematically</u> 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 postmarket 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 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 <u>credit</u> 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 that constitute a breach of obligations under Union law intended to protect fundamental rights.

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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.