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NOTE

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Objet:	Proposition de Règlement du Parlement européen et du Conseil établissant des règles harmonisées concernant l'intelligence artificielle (législation sur l'intelligence artificielle) et modifiant certains actes législatifs de l'Union - Texte de compromis de la présidence - Articles 53-55a

I. INTRODUCTION

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

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

3. La présidence française a repris les travaux de rédaction, dans le cadre desquels la présidence slovène s'est retirée, et a rédigé les parties suivantes de la première proposition de compromis, couvrant **les articles 8 à 15 et l'annexe IV, les articles 16 à 29 et les articles 40 à 52**.

4. La présidence française a maintenant rédigé une autre partie de la première proposition de compromis, couvrant **les articles 53 à 55 bis (Mesures de soutien à l'innovation)**, qui figure à l'annexe du présent document. En ce qui concerne ces articles, la présidence a également révisé **les considérants 72, 73 et 74, ainsi que les articles 3 et 9**, et elle a également ajouté **une nouvelle annexe VIII bis**, ainsi que **le nouvel article 63 bis et les considérants 73 bis et 74 bis**. Ces parties du texte figurent également à l'annexe du présent document afin de mieux comprendre les modifications apportées aux articles 53 à 55 bis.

5. **La présidence française invite les délégations à examiner les modifications qu'il est proposé d'apporter aux articles 53 à 55 bis, ainsi que les modifications apportées aux dispositions connexes lors de la réunion du groupe TELECOM du 10 mars 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 53 — Bacs à sable réglementaires de l'IA**

1.1 Les modifications apportées à **l'article 53, paragraphe 1**, précisent les conditions communes dans lesquelles des bacs à sable réglementaires peuvent être établis dans les États membres et, le cas échéant, les conditions dans lesquelles une coopération peut avoir lieu.

1.2 Le nouvel **article 53, paragraphe 1 ter**, contient une liste d'objectifs que les bacs à sable réglementaires sont censés atteindre.

1.3 Les ajouts à **l'article 53, paragraphe 2**, précisent qui a le droit de demander la mise en place de bacs à sable réglementaires et quels autres acteurs de l'écosystème de l'IA peuvent également être impliqués.

1.4 Le nouvel **article 53, paragraphe 2 bis**, contient des dispositions supplémentaires précisant les aspects opérationnels d'un bac à sable réglementaire, tels que les droits d'accès, l'éligibilité, les coûts, la durée maximale et les éléments d'un plan spécifique de bac à sable devant être élaboré par les participants et les autorités compétentes.

1.5 Les ajouts apportés à **l'article 53, paragraphe 3**, précisent les conditions dans lesquelles les participants au bac à sable ne devraient pas faire l'objet de sanctions administratives de la part des autorités en cas de violation de la législation applicable de l'Union ou d'un État membre.

1.6 Le nouvel **article 53, paragraphe 4 bis**, précise que les bacs à sable réglementaires devraient faciliter la coopération transfrontalière, transsectorielle et internationale ou les synergies en ce qui concerne les bacs à sable réglementaires.

1.7 Les modifications apportées à **l'article 53, paragraphe 5**, précisent les procédures de diffusion des rapports annuels sur la mise en œuvre des bacs à sable réglementaires, ainsi que les éléments à inclure dans ces rapports.

1.8 Le nouvel **article 53, paragraphe 5 ter**, prévoit l'obligation pour la Commission de mettre à disposition des informations sur les bacs à sable réglementaires de l'IA par l'intermédiaire d'une plateforme d'information unique visée à **l'article 55**.

1.9 L'objectif des modifications apportées à **l'article 53, paragraphe 6**, est de fournir de plus amples précisions pour les actes d'exécution que la Commission sera en mesure d'adopter à l'avenir pour définir plus en détail le processus de mise en place et le fonctionnement des bacs à sable réglementaires de l'IA.

2. **Article 54 - Traitement de données à caractère personnel en vue du développement de certains systèmes d'IA dans l'intérêt public dans le cadre du bac à sable réglementaire de l'IA**

2.1 Les modifications apportées au titre et au **premier alinéa de l'article 54, paragraphe 1**, créent une nouvelle base juridique pour le traitement des données à caractère personnel aux fins du développement de certains systèmes d'IA dans l'intérêt public dans le cadre du bac à sable réglementaire de l'IA, comme le permet le RGPD et conformément à celui-ci. Certaines des conditions de ce traitement énumérées aux **points a) à g)** ont été clarifiées en conséquence.

2.2. La référence au domaine répressif, précédemment incluse à **l'article 54, paragraphe 1, point a) i)**, a été déplacée à un point distinct et clarifiée à **l'article 54, paragraphe 1 bis**, étant donné qu'elle ne relève pas de la nouvelle base juridique créée à **l'article 54, paragraphe 1**. L'objectif est de préciser que ce domaine n'est pas affecté par cette nouvelle base juridique mais doit toujours respecter les exigences énumérées dans cet article.

2.3 **L'article 54, paragraphe 2**, a été supprimé à la lumière des modifications apportées à **l'article 54, paragraphe 1**, qui crée une nouvelle base juridique pour le traitement des données à caractère personnel, et parce que le considérant 72 a été modifié afin de clarifier la relation avec d'autres actes législatifs relatifs à la protection des données à caractère personnel.

3. **Article 54a - Tests de systèmes d'IA à haut risque en conditions réelles**

3.1 Le nouvel **article 54 bis** établit des règles prévoyant la possibilité de tester des systèmes d'IA en conditions réelles par les fournisseurs ou les fournisseurs potentiels de systèmes d'IA à haut risque énumérés à l'annexe III, et précise comment cet article doit être articulé avec d'autres actes législatifs sectoriels existants.

3.2 En outre, le nouveau texte de **l'article 54 bis, paragraphe 2**, clarifie l'interaction possible entre les tests de systèmes d'IA à haut risque dans des conditions réelles et les bacs à sable réglementaires de l'IA, étant donné que les tests en conditions réelles peuvent se produire en dehors d'un bac à sable réglementaire ou dans le cadre du bac à sable réglementaire.

4. **Article 54b - Consentement éclairé pour participer à des tests en conditions réelles**

4.1 Le nouvel **article 54 ter** est étroitement lié au nouvel **article 54 bis** décrit ci-dessus et prévoit l'obligation d'obtenir le consentement éclairé des participants aux tests en conditions réelles avant leur participation à ces tests. Le nouveau texte comprend également une liste d'exigences en matière d'information qui devraient être remplies avant de solliciter le consentement éclairé des participants aux tests en conditions réelles.

5. **Article 55 - Mesures de soutien aux opérateurs, en particulier les PME, y compris les jeunes pousses (start-ups)**

5.1 Les modifications apportées au titre de **l'article 55** et aux **articles 55, paragraphe 1, et 55, paragraphe 2,** visent à préciser que les mesures de soutien couvrent tous les acteurs de la chaîne de valeur de l'IA, et pas seulement les fournisseurs et les utilisateurs, et qu'elles se concentrent en particulier sur les PME, y compris les jeunes pousses (start-ups)

5.2 Le nouvel **article 55, paragraphe 3**, contient une liste de mesures spécifiques que la Commission sera tenue de prendre pour apporter un soutien ciblé à tous les acteurs couverts par l'AIA, parallèlement aux mesures prévues pour les États membres, en vue d'une meilleure application de l'AIA.

6. **Article 55a - Dérogations pour des opérateurs spécifiques**

6.1 Le nouvel **article 55 bis** prévoit une dérogation spéciale, en vertu de laquelle les microentreprises (selon la définition de l'UE) seront exemptées de l'obligation de mettre en place un système de gestion de la qualité, identifié comme l'un des principaux coûts pour les plus petites entreprises innovantes.

7. **Annexe VIII bis**

7.1 La nouvelle **annexe VIII bis** précise les informations relatives aux tests en conditions réelles qui devraient être enregistrées par le fournisseur d'un système d'IA à haut risque dans la base de données de l'Union visée à l'article 60, paragraphe 6.

En ce qui concerne les modifications décrites ci-dessus, les parties suivantes du texte ont également été modifiées:

8. À **l'article 3 (Définitions)**, quatre nouvelles définitions relatives aux tests en conditions réelles ont été ajoutées: «tests en conditions réelles», «plan de test en conditions réelles», «participant» et «consentement éclairé».

9. À **l'article 9 (Système de gestion des risques)**, il a été précisé au point (6) que les procédures de test peuvent inclure des essais en conditions réelles.

10. Au **titre VIII**, un nouvel **article 63 bis** a été ajouté, qui contient des dispositions détaillées sur la surveillance des tests en conditions réelles par les autorités de surveillance du marché.

11. **Le considérant 72** a été modifié pour apporter des précisions supplémentaires sur les modifications apportées aux **articles 53 et 54** concernant les bacs réglementaires à sable de l'IA.

12. **Les considérants 73 et 74** ont été modifiés et **le nouveau considérant 73 bis** a été ajouté afin de tenir compte des modifications apportées à **l'article 55**.

13. **Le nouveau considérant 74 bis** a été ajouté pour expliquer la nouvelle dérogation introduite à **l'article 55 bis**.

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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

Title V (Articles 53-55a and Annex VIIIa)

TITLE V

MEASURES IN SUPPORT OF INNOVATION

Article 53
AI regulatory sandboxes

1. 1. AI regulatory sandboxes ~~established by one or more Member States competent authorities or the European Data Protection Supervisor~~ shall provide a controlled environment ~~that facilitates the~~**for the** development, testing and validation of innovative AI systems, ~~for a limited time~~ before their placement on the market or putting into service ~~pursuant to a specific plan. This shall take place~~ under the direct supervision and guidance by the **national** competent authorities **and, where appropriate, in cooperation with other relevant national authorities, or by the European Data Protection Supervisor in relation to AI systems provided by the EU institutions, bodies and agencies.** ~~with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.~~

1a. The national competent authority or the European Data Protection Supervisor, as appropriate, may also supervise testing in real world conditions upon the request of participants in the sandbox.

1b. The establishment of AI regulatory sandboxes as defined in paragraph 1 shall aim to contribute to the following objectives:

a) foster innovation and competiveness and facilitate the development of an AI ecosystem;

b) facilitate and accelerate access to the Union market for AI systems, including provided by small and medium enterprises (SMEs) and start-ups;

c) improve legal certainty through cooperation with the authorities involved in the AI regulatory sandbox with a view to ensuring compliance with this Regulation and, where appropriate, with other Union and Member States legislation;

d) enhance authorities' understanding of the opportunities and risks of AI systems as well as of the suitability and effectiveness of the measures for preventing and mitigating those risks;

e) contribute to the uniform and effective implementation of this Regulation and, where appropriate, its swift adaptation, notably as regards the techniques in Annex I, the high-risk AI systems in Annex III, the technical documentation in Annex IV;

f) contribute to the development or update of harmonised standards and common specifications referred to in Articles 40 and 41 and their uptake by providers.

2. **The AI regulatory sandboxes may be established upon the decision of the national competent authorities, including jointly with those from other Member States, or by the European Data Protection Supervisor. They may be established upon request of any provider or prospective provider having an interest in participating in the sandbox, or at the sole initiative of the national competent authorities or the European Data Protection Supervisor.**

Member States shall ensure that to the extent the innovative AI systems involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the national data protection authorities and those other national authorities are associated to ~~the operation of~~ the AI regulatory sandbox.

As appropriate, national competent authorities may allow for the involvement in the AI regulatory sandbox of other actors within the AI ecosystem such as national or European standardisation organisations, notified bodies, testing and experimentation facilities, research and experimentation labs and innovation hubs.

2a. Access to the AI regulatory sandboxes and supervision and guidance by the relevant authorities shall be free of charge, without prejudice to exceptional costs that national competent authorities may recover in a fair and proportionate manner. It shall be open to any provider or prospective provider of an AI systemwho fulfils the eligibility and selection criteria referred to in paragraph 6(a) and who has been selected by the national competent authorities or by the European Data Protection Supervisor following the selection procedure referred to in paragraph 6(b). Providers or prospective providers may also submit applications in partnership with users or any other relevant third parties.

Participation in the AI regulatory sandbox shall be limited to a period that is appropriate to the complexity and scale of the project in any case not longer than a maximum period of 2 years, starting upon the notification of the selection decision. The participation may be extended for up to 1 more year.

Participation in the AI regulatory sandbox shall be based on a specific plan agreed between the participant(s) and the national competent authoritie(s) or the European Data Protection Supervisor, as applicable. The plan shall contain as a minimum the following:

a) description of the participant(s) involved and their roles, the envisaged AI system and its intended purpose, and relevant development, testing and validation process;
b) the specific regulatory issues at stake and the guidance that is expected from the authorities supervising the AI regulatory sandbox;
c) the specific modalities of the collaboration between the participant(s) and the authoritie(s), as well as any other actor involved in the AI regulatory sandbox;
d) a risk management and monitoring mechanism to identify, prevent and mitigate any risk referred to in Article 9(2)(a);
e) the key milestones to be completed by the participant(s) for the AI system to be considered ready to exit from the regulatory sandbox.

3. The **participation in the** AI regulatory sandboxes shall not affect the supervisory and corrective powers of the ~~competent~~ authorities **supervising the sandbox**. ~~Any significant risks to health and safety and fundamental rights identified during the development and testing of such systems shall result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place.~~ **However, provided that the participant(s) respect the sandbox plan and the terms and conditions for their participation as referred to in paragraph 6(c) and follow in good faith the guidance given by the authorities, no administrative enforcement action shall be taken by the authorities for infringement of applicable Union or Member State legislation.**

4. **The p**~~P~~Participants ~~in the AI regulatory sandbox~~ remain liable under applicable Union and Member States liability legislation for any ~~harm~~ **damage caused** ~~inflicted~~ ~~on third parties~~ **in the course of their participation** ~~as a result from the experimentation taking place~~ in ~~the~~ **an AI-regulatory** sandbox.

4a. The AI regulatory sandboxes shall be designed and implemented in such a way that, where relevant, they facilitate cross-border cooperation between national competent authorities and synergies with relevant sectoral regulatory sandboxes. Cooperation may also be envisaged with third countries outside the Union establishing mechanisms to support AI innovation.

5. ~~Member States'~~ **National** competent authorities that have established AI regulatory sandboxes **and the European Data Protection Supervisor** shall coordinate their activities and cooperate within the framework of the European Artificial Intelligence Board.

They shall **publish on their websites** ~~submit~~ annual reports ~~to the Board and the Commission~~ on ~~the results from~~ the implementation of those **sandboxes**, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application of this Regulation and other Union legislation supervised within the sandbox. **Those annual reports shall be submitted to the AI Board which shall publish on its website a summary of all good practices, lessons learnt and recommendations**.

5b. The Commission shall ensure that information about AI regulatory sandboxes, including about those established under this Article, is available through a single information platform as referred to in Article 55(3)(b).

6. The **detailed** modalities and the conditions **for the establishment and** ~~of the~~ operation of the AI regulatory sandboxes **under this Regulation**~~, including the eligibility criteria and the procedure for the application, selection, participation and exiting from the sandbox, and the rights and obligations of the participants shall be set out in implementing acts. Those implementing acts~~ shall be adopted **through implementing acts** in accordance with the examination procedure referred to in Article 74(2).

Those implementing acts shall include general common rules on the following issues:

a) the eligibility and selection criteria for participation in the regulatory sandbox;
b) the procedure for the application, selection, participation, monitoring and exiting from the sandbox, including templates of all relevant documents;
c) the terms and conditions applicable to the participants, including in relation to their collaboration with the authorities supervising the sandbox, as well as the conditions for suspension and termination of the participation in the sandbox;
d) the modalities for the involvement in the AI regulatory sandbox of other national authorities and other actors within the AI ecosystem;
e) the modalities and procedures for cross-border cooperation, including the establishment and operation by two or more Member States of cross-border AI regulatory sandboxes.

Article 54

*~~Further~~ ~~p~~**P**rocessing of personal data for developing certain AI systems in the public interest in the AI regulatory sandbox*

1. In the AI regulatory sandbox personal data ~~lawfully collected for other purposes~~ ~~shall~~ **may** be processed for the purposes of developing and testing certain innovative AI systems in the sandbox under the following **cumulative** conditions:

   (a) the innovative AI systems shall be developed for safeguarding substantial public interest in one or more of the following areas:

   ~~(i) the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security, under the control and responsibility of the competent authorities. The processing shall be based on Member State or Union law;~~

   (ii) public safety and public health, including ~~disease~~ prevention, control and treatment **of disease and improvement of health care systems**;

   (iii) a high level of protection and improvement of the quality of the environment;

   (iv) a high level of efficiency and quality of public administration and public services.

   (b) the data processed are necessary for complying with one or more of the requirements referred to in Title III, Chapter 2 where those requirements cannot be effectively fulfilled by processing anonymised, synthetic or other non-personal data;

   (c) there are effective monitoring mechanisms to identify if any high risks to the ~~fundamental~~ **rights and freedoms** of the data subjects**, as referred to in Article 35 of Regulation (EU) 2016/679 and in Article 35 of Regulation (EU) 2018/1725,** may arise during the sandbox experimentation as well as response mechanism to promptly mitigate those risks and, where necessary, stop the processing;

   (d) any personal data to be processed in the context of the sandbox are in a functionally separate, isolated and protected data processing environment under the control of the participants and only authorised persons have access to that data;

   (e) any personal data processed are not **to** be transmitted, transferred or otherwise accessed by other parties **that are not participants in the sandbox nor transferred to a third country outside the Union or an international organisation**;

(f) any processing of personal data in the context of the sandbox ~~do not lead to measures or decisions affecting the data subjects~~; **shall not affect the application of the rights of the data subjects as provided for under Union law on the protection of personal data, in particular in Article 22 of Regulation (EU) 2016/679 and Article 24 of Regulation (EU) 2018/1725;**

(g) any personal data processed in the context of the sandbox are **protected by means of appropriate technical and organisational measures and** deleted once the participation in the sandbox has terminated or the personal data has reached the end of its retention period;

(h) the logs of the processing of personal data in the context of the sandbox are kept for the duration of the participation in the sandbox ~~and 1 year after its termination, solely for the purpose of and only as long as necessary for fulfilling accountability and documentation obligations under this Article or other application Union or Member States legislation~~;

(i) complete and detailed description of the process and rationale behind the training, testing and validation of the AI system is kept together with the testing results as part of the technical documentation in Annex IV;

(j) a short summary of the AI project developed in the sandbox, its objectives and expected results published on the website of the competent authorities.

1a. For the purpose of prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security, under the control and responsibility of law enforcement authorities, the processing of personal data in AI regulatory sandboxes shall be based on a specific Member State or Union law and subject to the same cumulative conditions as referred to in paragraph 1.

~~2. Paragraph 1 is without prejudice to Union or Member States legislation excluding processing for other purposes than those explicitly mentioned in that legislation.~~

Article 54a

Testing of high-risk AI systems in real world conditions

1. Testing of AI systems in real world conditions may be conducted by providers or prospective providers of high-risk AI systems listed in Annex III, in accordance with the provisions of this Article and the real-world testing plan referred to in this Article.

The detailed elements of the real-world testing plan shall be specified in implementing acts adopted by the Commission in accordance with the examination procedure referred to in Article 74(2).

This provision shall be without prejudice to Union or Member State legislation for the testing in real world conditions of high-risk AI systems related to products covered by legislation listed in Annex II.

2. Providers or prospective providers may conduct testing of high-risk AI systems referred to in Annex III in real world conditions at any time before the placing on the market or putting into service of the AI system on their own or in partnership with one or more prospective users.

The testing in real world conditions under this Article may occur in the course of the participation in a AI regulatory sandbox under the conditions specified in Article 53(1a). In such a case, supervision and guidance by the national competent authorities or, where applicable, the European Data Protection Supervisor, may be extended to the testing in real world conditions.

3. The testing of high-risk AI systems in real world conditions under this Article shall be without prejudice to ethical review that may be required by national or Union law.

4. Providers or prospective providers may conduct the testing in real world conditions only where all of the following conditions are met:

(a) the provider or prospective provider has drawn up a real-world testing plan and submitted it to the market surveillance authority in the Member State(s) where the testing in real world conditions is to be conducted or the European Data Protection Supervisor, as applicable;

(b) the market surveillance authority in the Member State(s) where the testing in real world conditions is to be conducted or to the European Data Protection Supervisor, as applicable, have not objected to the testing within 30 days after its submission;

(c) the provider or prospective provider or has registered the testing in real world conditions in the EU database referred to in Article 60(6) with a Union-wide unique single identification number and the information specified in Annex VIIIa;

(d) the provider or prospective provider conducting the testing in real world conditions is established in the Union or it has appointed a legal representative for the purpose of the testing in real world conditions who is established in the Union;

(e) data collected and processed for the purpose of the testing in real world conditions shall not be transferred to countries outside the Union, unless the transfer and the processing provides equivalent safeguards to those provided under Union law;

(f) the testing in real world conditions does not last longer than necessary to achieve its objectives and in any case not longer than 12 months;

(g) the testing in real world conditions does not involve persons belonging to vulnerable groups, unless that testing is essential with respect to those vulnerable groups insofar as data of comparable validity cannot be obtained through testing in real conditions on other persons or by other methods;

(h) the testing in real world conditions is designed to involve as little inconvenience as possible for the subjects of that testing; such possible inconvenience shall be specifically anticipated and defined by the provider or prospective provider in the real-world testing plan, monitored and possibly mitigated in the course of the testing;

(i) where a provider or prospective provider organises the testing in real world conditions in cooperation with one or more prospective users, the latter have been informed of all aspects of the testing that are relevant to their decision to participate, including the instructions of use of the AI system referred to in Article 13; the provider or prospective provider and the user(s) shall conclude an agreement specifying their roles and responsibilities with a view to ensuring compliance with the provisions for testing in real world conditions under this Regulation and other applicable Union and Member States legislation;

(j) the subjects of the testing in real world conditions have given informed consent in accordance with Article 64b;

(k) the testing in real world conditions is effectively overseen by the provider or prospective provider and user(s) with persons who are suitably qualified in the relevant field and have the necessary capacity, training and authority to perform their tasks;

(l) the predictions, recommendations or decisions of the AI system can be effectively reversed or disregarded.

5. Any subject of the testing in real world conditions, or his or her legally designated representative, as appropriate, may, without any resulting detriment and without having to provide any justification, withdraw from the testing at any time by revoking his or her informed consent. The withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on the informed consent before its withdrawal.

6. Any serious incident or malfunctioning identified in the course of the testing in real world conditions shall be reported to the national market surveillance authority in accordance with Article 62 of this Regulation. The provider or prospective provider or shall adopt immediate mitigation measures or, failing that, suspend the testing in real world conditions until such mitigation takes place or otherwise terminate it. The provider or prospective provider shall establish a procedure for the prompt recall of the AI system upon such termination of the testing in real world conditions.

7. Providers or prospective providers shall notify the national market surveillance authority in the Member State(s) where the testing in real world conditions is to be conducted or to the European Data Protection Supervisor, as applicable, of the suspension or termination of the testing in real world conditions and the final outcomes.

8. The provider and prospective provider shall be liable under applicable Union and Member States liability legislation for any damage caused to the subjects by reason of their participation in the testing in real world conditions.

Article 54b

Informed consent to participate in testing in real world conditions

1. For the purpose of testing in real world conditions under Article 54a, informed consent shall be freely given by the subject of testing prior to his or her participation in such testing and after having been duly informed with concise, clear, relevant, and understandable information regarding:

(i) the nature and objectives of the testing in real world conditions and the possible inconvenience that may be linked to his or her participation;

(ii) the conditions under which the testing in real world conditions is to be conducted, including the expected duration of the subject's participation;

(iii) the subject's rights and guarantees regarding participation, in particular his or her right to refuse to participate in and the right to withdraw from the field testing at any time without any resulting detriment and without having to provide any justification;

(iv) the modalities for requesting the reversal or the disregard of the predictions, recommendations or decisions of the AI system;

(v) the Union-wide unique single identification number of the testing in real world conditions in accordance with Article 54a(c) and the contact details of the provider or its legal representative from whom further information can be obtained.

2. The informed consent shall be dated and documented and a copy shall be given to the subject or his or her legal representative.

Article 55

Support m~~M~~easures for operators, in particular SMEs, including start-ups ~~small-scale providers and users~~

1. Member States shall undertake the following actions:

   (a) provide ~~small-scale~~ SME**s** ~~providers~~**, including** ~~and~~ start-ups**,** with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility ~~conditions~~ **and selection criteria**;

   (b) organise specific awareness raising **and training** activities about the application of this Regulation tailored to the needs of the ~~small-scale~~ **SMEs** ~~providers and users~~**, including start-ups**;

   (c) where appropriate, establish a dedicated channel for communication with ~~small-scale~~ **SMEs** ~~providers and user~~**, including start-ups,** ~~and other innovators~~ to provide ~~guidance~~ **advice** and respond to queries about the implementation of this Regulation.

2. The specific interests and needs of the ~~small-scale~~ **SME** providers**, including start-ups,** shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size**,** ~~and~~ market size **and other relevant indicators**.

3. The Commission shall undertake the following actions:

   (a) **upon request of the AI Board, provide standardised documents for the areas covered by this Regulation;**

   (b) **develop and maintain a single information platform providing easy to use information in relation to this Regulation for all operators across the Union;**

   (c) **organise appropriate communication campaigns to raise awareness about the obligations arising from this Regulation;**

   (d) evaluate and promote the convergence of best practices in public procurement procedures in relation to AI systems.

Article 55a

Derogations for specific operators

The obligations laid down in Article 17 of this Regulation shall not apply to microenterprises as defined in Article 2(3) of Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises.

ANNEX VIIIa

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF HIGH-RISK AI SYSTEMS LISTED IN ANNEX III IN RELATION TO TESTING IN REAL WORLD CONDITIONS IN ACCORDANCE WITH ARTICLE 54a

The following information shall be provided and thereafter kept up to date with regard to testing in real world conditions to be registered in accordance with Article 54a:

1. Union-wide unique single identification number of the testing in real world conditions;

2. Name and contact details of the provider or prospective provider and users involved in the testing in real world conditions;

3. A brief description of the AI system, its intended purpose and other information necessary for the identification of the system;

4. A summary of the main characteristics of the plan for testing in real world conditions;

5. Information on the suspension or termination of the testing in real world conditions.

***

OTHER CHANGES RELATES TO THE ABOVE MODIFICATIONS

ARTICLES:

Article 3
Definitions

(48) 'testing in real world conditions' means the temporary testing of an AI system for its intended purpose in real world conditions outside of a laboratory or otherwise simulated environment with a view to gathering reliable and robust data and to assessing and verifying the conformity of the AI system with the requirements of this Regulation; testing in real world conditions shall not be considered as placing the AI system on the market or putting it into service within the meaning of this Regulation, provided that all conditions under Article 54a are fulfilled;

(49) 'real world testing plan' means a document that describes the objectives, methodology, geographical, population and temporal scope, monitoring, organisation and conduct of testing in real world conditions;

(50) 'subject' for the purpose of real world testing means a natural person who participates in a real world testing;

(51) 'informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular testing in real world conditions, after having been informed of all aspects of the testing that are relevant to the subject's decision to participate; in the case of minors and of incapacitated subjects, the informed consent shall be given by their legally designated representative;

Article 9
Risk management system

6. Testing procedures shall be suitable to achieve the intended purpose of the AI system ~~and do not need to go beyond what is necessary to achieve that purpose~~. **Testing procedures may include testing in real world conditions in accordance with Article 54a.**

Article 63a

Supervision of testing in real world conditions by market surveillance authorities

1. Market surveillance authorities shall have the competence and powers to ensure that testing in real world conditions is in accordance with this Regulation.

2. Where testing in real world conditions is conducted for AI systems that are supervised within an AI regulatory sandbox under Article 54, the market surveillance authorities or the European Data protection Supervisor, as appropriate, shall verify the compliance with the provisions of Article 54a as part of their supervisory role for the AI regulatory sandbox. Those authorities may, as appropriate, allow the testing in real world conditions to be conducted by the provider or prospective provider in derogation to the conditions set out in Article 54a(4) (f) and (g).

3. Where a market surveillance authority has been informed by the prospective provider, the provider or any third party of a serious incident or has other grounds for considering that the conditions set out in Articles 54a and 54b are not met, it may take any of the following decisions on its territory, as appropriate:

(a) suspend or terminate the testing in real world conditions;

(b) require the provider or prospective provider and user(s) to modify any aspect of the testing in real world conditions.

4. Where a market surveillance authority has taken a decision referred to in paragraph 3 of this Article or has issued an objection within the meaning of Article 54a(4)(b), the decision or the objection shall indicate the grounds thereof and the modalities and conditions for the provider or prospective provider to challenge the decision or objection.

5. Where applicable, where a market surveillance authority has taken a decision referred to in paragraph 3 of this Article, it shall communicate the grounds therefor to the market surveillance authorities of the other Member States in which the AI system has been tested in accordance with the testing plan.

RECITALS:

(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs)**, including** ~~and~~ start-ups. **The participation in the sandbox should focus on issues that raise legal uncertainty for providers and prospective providers to innovate and experiment with AI in the Union. The supervision of the AI systems in the regulatory sandbox should therefore cover their development, testing and validation before the systems are placed on the market or put into service, including testing in real life conditions, as well as the notion and occurrence of substantial modification that may require a new conformity assessment procedure. Access to the AI regulatory sandbox and regulatory supervision should be in principle free of charge without prejudice to exceptional costs that may be recovered by national authorities in a fair and proportionate manner, in particular in cases where the authorities have provided additional services for the actual development, testing and validation of the AI system such as technical or physical environment and tools for the testing, access to data, etc.** To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. This Regulation should provide the legal basis for the use of personal data collected ~~for other purposes~~ for developing certain AI systems in the public interest within the AI regulatory sandbox, in line with Article 6~~(4)~~**(1)(e) and 9(2)(g)** of Regulation (EU) 2016/679, and Article 5 **and 10** of Regulation (EU) 2018/1725, and without prejudice to Article**s** ~~4(2)~~ **8 and 10** of Directive (EU) 2016/680. **This new legal basis under this Regulation is without prejudice to the possibility for participants to rely on other legal bases for processing of personal data under Articles 6(1) and 9(2) of Regulation (EU) 2016/679 and Articles 5 and 10(2) of Regulation (EU) 2018/1725. All other obligations of data controllers and rights of data subjects under Regulation (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU) 2016/680 remain applicable. In particular, this Regulation should not provide a legal basis in the meaning of Article 22(2)(b) of Regulation (EU) 2016/679 and Article 24(2)(b) of Regulation (EU) 2018/1725.** Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

(73) In order to promote and protect innovation, it is important that the interests of ~~small-scale~~**SME** providers and users of AI systems are taken into particular account. To this objective, Member States should develop initiatives, which are targeted at those operators, including on awareness raising and information communication. Moreover, the specific interests and needs of ~~small-scale~~**SME** providers shall be taken into account when ~~N~~**n**otified **b**~~B~~odies set conformity assessment fees. Translation costs related to mandatory documentation and communication with authorities may constitute a significant cost for providers and other operators, notably those of a smaller scale. Member States should possibly ensure that one of the languages determined and accepted by them for relevant providers' documentation and for communication with operators is one which is broadly understood by the largest possible number of cross-border users.

(73a) In order to promote and protect innovation, the AI-on demand platform, all relevant EU funding programmes and projects, such as Digital Europe Programme, Horizon Europe, implemented by the Commission and the Member States at national or EU level should contribute to the achievement of the objectives of this Regulation.

(74) **In particular, i**~~I~~n order to minimise the risks to implementation resulting from lack of knowledge and expertise in the market as well as to facilitate compliance of providers, **notably SMEs,** and notified bodies with their obligations under this Regulation, the AI-on demand platform, the European Digital Innovation Hubs and the Testing and Experimentation Facilities established by the Commission and the Member States at national or EU level should possibly contribute to the implementation of this Regulation. Within their respective mission and fields of competence, they may provide in particular technical and scientific support to providers and notified bodies.

(74a) Moreover, in order to ensure proportionality considering the very small size of some operators regarding costs of innovation, it is appropriate to exempt microenterprises from the obligation to establish a quality management system which would reduce the administrative burden and the costs for those enterprises without affecting the level of protection and the need for compliance with the requirements for high-risk AI systems.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS

Chapter 5 (Articles 40-52)

CHAPTER 5

STANDARDS, CONFORMITY ASSESSMENT, CERTIFICATES, REGISTRATION

Article 40
Harmonised standards

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

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

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

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

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

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

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

Article 41
Common specifications

1. Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns, the Commission may, **after consulting the AI Board referred to in Article 56**, by means of implementing acts, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).

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

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

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

Article 42
Presumption of conformity with certain requirements

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

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

Article 43
Conformity assessment

1. For high-risk AI systems listed in point 1 of Annex III, where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider has applied harmonised standards referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall ~~follow~~ **opt for** one of the following procedures:

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

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

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

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

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

[1] Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 1).

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

For the purpose of that assessment, notified bodies which have been notified under those legal acts shall be entitled to control the conformity of the high-risk AI systems with the requirements set out in Chapter 2 of this Title, provided that the compliance of those notified bodies with requirements laid down in Article 33(4), (9) and (10) has been assessed in the context of the notification procedure under those legal acts.

Where the legal acts listed in Annex II, section A, enable the manufacturer of the product to opt out from a third-party conformity assessment, provided that that manufacturer has applied all harmonised standards covering all the relevant requirements, that manufacturer may make use of that option only if he has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering the requirements set out in Chapter 2 of this Title.

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

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

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

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

Article 44
Certificates

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

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

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

Article 45
Appeal against decisions of notified bodies

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available to parties ~~having a legitimate interest in that decision~~.

Article 46
Information obligations of notified bodies

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

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

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

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

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

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

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

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

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

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

Article 47
Derogation from conformity assessment procedure

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

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

2. The authorisation referred to in paragraph 1 shall be issued only if the market surveillance authority concludes that the high-risk AI system complies with the requirements of Chapter 2 of this Title. The market surveillance authority shall inform the Commission and the other Member States of any authorisation issued pursuant to paragraph 1.

3. Where, within 15 calendar days of receipt of the information referred to in paragraph 2, no objection has been raised by either a Member State or the Commission in respect of an authorisation issued by a market surveillance authority of a Member State in accordance with paragraph 1, that authorisation shall be deemed justified.

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

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

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

Article 48
EU declaration of conformity

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

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

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

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

5. **After consulting the AI Board referred to in Article 56, t**~~T~~he Commission shall be empowered to adopt delegated acts in accordance with Article 73 for the purpose of updating the content of the EU declaration of conformity set out in Annex V in order to introduce elements that become necessary in light of technical progress.

Article 49
CE marking of conformity

1. **The CE marking of conformity** ~~**referred to in paragraph 1 of this Article**~~ **shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.** ~~The CE marking shall be affixed visibly, legibly and indelibly for high-risk AI systems. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it shall be affixed to the packaging or to the accompanying documentation, as appropriate.~~

2. ~~The CE marking referred to in paragraph 1 of this Article shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.~~ **The CE marking shall be affixed visibly, legibly and indelibly for high-risk AI systems. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it shall be affixed to the packaging or to the accompanying documentation, as appropriate.**

3. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 43. The identification number shall also be indicated in any promotional material which mentions that the high-risk AI system fulfils the requirements for CE marking.

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

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

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

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

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

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

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

Article 51
Registration

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

TITLE IV

TRANSPARENCY OBLIGATIONS FOR CERTAIN AI SYSTEMS

Article 52
Transparency obligations for certain AI systems

1. Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way **that those systems inform** ~~*that*~~ natural persons ~~are informed~~ that they are interacting with an AI system, unless this is obvious **from the point view of a reasonable person** from the circumstances and the context of use. This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences, unless those systems are available for the public to report a criminal offence.

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

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

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

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

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

~~TITLE IVA~~

~~GENERAL PURPOSE AI SYSTEMS~~

~~*Article 52a*~~

~~*General purpose AI systems*~~

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

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

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

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