



**2021/0106(COD)**

13.6.2022

# **AMENDMENTS 2006 - 2355**

**Draft report**  
**Brando Benifei, Dragoş Tudorache**  
(PE731.563v01-00)

Harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and  
amending certain Union Legislative Acts

Proposal for a regulation  
(COM(2021)0206 – C9-0146/2021 – 2021/0106(COD))



## Amendment 2006

Axel Voss, Deirdre Clune, Eva Maydell

### Proposal for a regulation

#### Article 26 – paragraph 5

*Text proposed by the Commission*

5. Importers shall provide national competent authorities, upon a reasoned request, with all necessary information and documentation to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title in a language which can be easily understood by that national competent authority, ***including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law.*** They shall also ***cooperate with*** those authorities ***on any action national competent authority takes in relation to that system.***

*Amendment*

5. ***Where no authorised representative has been established,*** importers shall provide national competent authorities, upon a reasoned request, with all necessary information and documentation to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title in a language which can be easily understood by that national competent authority. ***To this purpose*** they shall also ***ensure that the technical documentation can be made available to*** those authorities.

Or. en

## Amendment 2007

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H el ene Laporte, Jean-Paul Garraud

### Proposal for a regulation

#### Article 26 – paragraph 5

*Text proposed by the Commission*

5. Importers shall provide national competent authorities, upon a reasoned request, with all necessary information and documentation to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title in ***a language which can be easily understood by*** that national competent authority, including access to the logs automatically generated by the

*Amendment*

5. Importers shall provide national competent authorities, upon a reasoned request, with all necessary information and documentation to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title in ***an official language of*** that national competent authority, including access to the logs automatically generated by the high-risk AI system to the extent

high-risk AI system to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law. They shall also cooperate with those authorities on any action national competent authority takes in relation to that system.

such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law. They shall also cooperate with those authorities on any action national competent authority takes in relation to that system.

Or. fr

**Amendment 2008**  
**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**  
**Article 26 – paragraph 5 a (new)**

*Text proposed by the Commission*

*Amendment*

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

Or. en

**Amendment 2009**  
**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**  
**Article 27 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

1. Before making a high-risk AI system available on the market, distributors shall verify that the high-risk AI system bears the required CE conformity marking, that it is accompanied by the required documentation and instruction of use, and that the provider and the importer of the system, as applicable, have complied with **the** obligations set out in this Regulation.

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

Or. en

## Amendment 2010

Axel Voss, Deirdre Clune, Eva Maydell

### Proposal for a regulation

#### Article 27 – paragraph 2

##### *Text proposed by the Commission*

2. Where a distributor considers or has reason to consider that a high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title, it shall not make the high-risk AI system available on the market until that system has been brought into conformity with those requirements. Furthermore, where the system presents a risk within the meaning of Article 65(1), the distributor shall inform the provider or the importer of the system, as applicable, to that effect.

##### *Amendment*

2. Where a distributor considers or has reason to consider, ***on the basis of the information in its possession***, that a high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title, it shall not make the high-risk AI system available on the market until that system has been brought into conformity with those requirements. Furthermore, where the system presents a risk within the meaning of Article 65(1), the distributor shall inform the provider or the importer of the system, as applicable, to that effect, ***and the market surveillance authorities***.

Or. en

## Amendment 2011

Svenja Hahn, Dragoş Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Moritz Körner, Jan-Christoph Oetjen

### Proposal for a regulation

#### Article 27 – paragraph 2

##### *Text proposed by the Commission*

2. Where a distributor considers or has reason to consider that a high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title, it shall not make the high-risk AI system available on the market until that system has been brought into conformity with those requirements. Furthermore, where the system presents a risk within the meaning of Article 65(1), the distributor shall inform the provider or the importer of the system, as applicable, to that effect.

##### *Amendment*

2. Where a distributor considers or has reason to consider that a high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title, it shall not make the high-risk AI system available on the market until that system has been brought into conformity with those requirements. Furthermore, where the system presents a risk within the meaning of Article 65(1), the distributor shall inform the provider or the importer of the system ***as well as the market***

*surveillance authorities*, as applicable, to that effect.

Or. en

### **Amendment 2012**

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituţa, Michal Šimečka**

#### **Proposal for a regulation Article 27 – paragraph 2**

##### *Text proposed by the Commission*

2. Where a distributor considers or has reason to consider that a high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title, it shall not make the high-risk AI system available on the market until that system has been brought into conformity with those requirements. Furthermore, where the system presents a risk within the meaning of Article 65(1), the distributor shall inform the provider or the importer of the system, as applicable, to that effect.

##### *Amendment*

2. Where a distributor considers or has reason to consider that a high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title, it shall not make the high-risk AI system available on the market until that system has been brought into conformity with those requirements. Furthermore, where the system presents a risk within the meaning of Article 65(1), the distributor shall inform the *market surveillance authority and the* provider or the importer of the system, as applicable, to that effect.

Or. en

### **Amendment 2013**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation Article 27 – paragraph 2**

##### *Text proposed by the Commission*

2. Where a distributor considers or has reason to consider that a high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title, it shall not make the high-risk AI system available on the market until that

##### *Amendment*

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system has been brought into conformity with those requirements. Furthermore, where the system presents a risk within the meaning of Article 65(1), the distributor shall inform the provider or the importer of the system, as applicable, to that effect.

system has been brought into conformity with those requirements. Furthermore, where the system presents a risk within the meaning of Article 65(1), the distributor shall inform the **competent authorities and the** provider or the importer of the system, as applicable, to that effect.

Or. en

#### **Amendment 2014**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation Article 27 – paragraph 4**

##### *Text proposed by the Commission*

4. A distributor that considers or has reason to consider that a high-risk AI system which it has made available on the market is not in conformity with the requirements set out in Chapter 2 of this Title shall take the corrective actions necessary to bring that system into conformity with those requirements, to withdraw it or recall it or shall ensure that the provider, the importer or any relevant operator, as appropriate, takes those corrective actions. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the distributor shall immediately inform the national competent authorities of the Member States in which it has made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective actions taken.

##### *Amendment*

4. A distributor that considers, **on the basis of the information in its possession**, or has reason to consider that a high-risk AI system which it has made available on the market is not in conformity with the requirements set out in Chapter 2 of this Title shall take the corrective actions necessary to bring that system into conformity with those requirements, to withdraw it or recall it or shall ensure that the provider, the importer or any relevant operator, as appropriate, takes those corrective actions. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the distributor shall immediately inform the **provider or importer of the system and the** national competent authorities of the Member States in which it has made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective actions taken.

Or. en

#### **Amendment 2015**

**Svenja Hahn, Dragoş Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Moritz Körner, Jan-Christoph Oetjen**

**Proposal for a regulation**  
**Article 27 – paragraph 4**

*Text proposed by the Commission*

4. A distributor that considers or has reason to consider that a high-risk AI system which it has made available on the market is not in conformity with the requirements set out in Chapter 2 of this Title shall take the corrective actions necessary to bring that system into conformity with those requirements, to withdraw it or recall it or shall ensure that the provider, the importer or any relevant operator, as appropriate, takes those corrective actions. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the distributor shall immediately inform the national competent authorities of the Member States in which it has made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective actions taken.

*Amendment*

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Or. en

**Amendment 2016**

**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud**

**Proposal for a regulation**  
**Article 27 – paragraph 4**

*Text proposed by the Commission*

4. A distributor that considers or has reason to consider that a high-risk AI system which it has made available on the market is not in conformity with the requirements set out in Chapter 2 of this Title shall take the corrective actions necessary to ***bring that system into conformity with those requirements, to withdraw it or recall it*** or shall ensure that

*Amendment*

4. A distributor that considers or has reason to consider that a high-risk AI system which it has made available on the market is not in conformity with the requirements set out in Chapter 2 of this Title shall take the corrective actions necessary to ***to withdraw or recall that system in order to bring it into conformity with those requirements,*** or shall ensure



the provider, the importer or any relevant operator, as appropriate, takes those corrective actions. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the distributor shall immediately inform the national competent authorities of the Member States in which it has made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective actions taken.

that the provider, the importer or any relevant operator, as appropriate, takes those corrective actions. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the distributor shall immediately inform the national competent authorities of the Member States in which it has made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective actions taken.

Or. fr

#### **Amendment 2017**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation** **Article 27 – paragraph 4**

##### *Text proposed by the Commission*

4. A distributor that considers or has reason to consider that a high-risk AI system which it has made available on the market is not in conformity with the requirements set out in Chapter 2 of this Title shall take the corrective actions necessary to bring that system into conformity with those requirements, to withdraw it or recall it or shall ensure that the provider, the importer or any relevant operator, as appropriate, takes those corrective actions. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the distributor shall immediately inform the ***national*** competent authorities of the Member States in which it has made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective actions taken.

##### *Amendment*

4. A distributor that considers or has reason to consider that a high-risk AI system which it has made available on the market is not in conformity with the requirements set out in Chapter 2 of this Title shall take the corrective actions necessary to bring that system into conformity with those requirements, to withdraw it or recall it or shall ensure that the provider, the importer or any relevant operator, as appropriate, takes those corrective actions. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the distributor shall immediately inform the competent authorities of the Member States in which it has made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective actions taken.

Or. en

## Amendment 2018

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

### Proposal for a regulation

#### Article 27 – paragraph 5

##### *Text proposed by the Commission*

5. Upon a reasoned request from a national competent authority, distributors of high-risk AI systems shall provide that authority with all the information and documentation ***necessary to demonstrate the conformity of a high-risk system with the requirements set out in Chapter 2 of this Title. Distributors shall also cooperate with that national competent authority on any action taken by that authority.***

##### *Amendment*

5. Upon a reasoned request from a national competent authority, distributors of high-risk AI systems shall provide that authority with all the information and documentation ***regarding its activities pursuant to paragraphs 1 to 4.***

Or. en

## Amendment 2019

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

### Proposal for a regulation

#### Article 27 – paragraph 5

##### *Text proposed by the Commission*

5. Upon a reasoned request from a national competent authority, distributors of high-risk AI systems shall provide that authority with all the information and documentation necessary to demonstrate the conformity of a high-risk system with the requirements set out in Chapter 2 of this Title. Distributors shall also cooperate with that national competent authority on any action taken by that authority.

##### *Amendment*

5. Upon a reasoned request from a national competent authority, distributors of high-risk AI systems shall provide that authority with all the information and documentation ***in its possession or available to it, in accordance with the obligations of distributors as outlined by this Regulation, that are*** necessary to demonstrate the conformity of a high-risk system with the requirements set out in Chapter 2 of this Title. Distributors shall also cooperate with that national competent authority on any action taken by that authority.

## Amendment 2020

Axel Voss, Deirdre Clune, Eva Maydell

### Proposal for a regulation

#### Article 27 – paragraph 5

*Text proposed by the Commission*

5. Upon a reasoned request from a national competent authority, distributors of high-risk AI systems shall provide that authority with all the information and documentation ***necessary to demonstrate the conformity of a high-risk system with the requirements set out in Chapter 2 of this Title. Distributors shall also cooperate with that national competent authority on any action taken by that authority.***

*Amendment*

5. Upon a reasoned request from a national competent authority ***and where no authorised representative has been appointed***, distributors of high-risk AI systems shall provide that authority with all the information and documentation ***regarding its activities as described in paragraphs 1 to 4.***

## Amendment 2021

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä  
on behalf of the Verts/ALE Group

### Proposal for a regulation

#### Article 27 – paragraph 5

*Text proposed by the Commission*

5. Upon ***a reasoned*** request from a ***national*** competent authority, distributors of high-risk AI systems shall provide that authority with all the information and documentation necessary to demonstrate the conformity of a high-risk system with the requirements set out in Chapter 2 of this Title. Distributors shall also cooperate with that ***national*** competent authority on any action taken by that authority.

*Amendment*

5. Upon request from a competent authority, distributors of high-risk AI systems shall provide that authority with all the information and documentation necessary to demonstrate the conformity of a high-risk system with the requirements set out in Chapter 2 of this Title. Distributors shall also cooperate with that competent authority on any action taken by that authority.

**Amendment 2022**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**

**Article 27 – paragraph 5 a (new)**

*Text proposed by the Commission*

*Amendment*

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

Or. en

**Amendment 2023**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**

**Article 28**

*Text proposed by the Commission*

*Amendment*

**Article 28**

**deleted**

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

***1. Any distributor, importer, user or other third-party shall be considered a provider for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16, in any of the following circumstances:***

***(a) they place on the market or put into service a high-risk AI system under their name or trademark;***

***(b) they modify the intended purpose of a high-risk AI system already placed on the market or put into service;***

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

***2. Where the circumstances referred to in paragraph 1, point (b) or (c), occur, the provider that initially placed the high-risk AI system on the market or put it into***

*service shall no longer be considered a provider for the purposes of this Regulation.*

Or. en

**Amendment 2024**

**Svenja Hahn, Nicola Beer, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen**

**Proposal for a regulation**

**Article 28**

*Text proposed by the Commission*

*Amendment*

**Article 28**

**deleted**

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

***1. Any distributor, importer, user or other third-party shall be considered a provider for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16, in any of the following circumstances:***

***(a) they place on the market or put into service a high-risk AI system under their name or trademark;***

***(b) they modify the intended purpose of a high-risk AI system already placed on the market or put into service;***

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

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

Or. en

*Justification*

*Incorporated in Art. 23a*

## Amendment 2025

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä  
on behalf of the Verts/ALE Group

### Proposal for a regulation

#### Article 28 – title

*Text proposed by the Commission*

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

*Amendment*

Obligations of distributors, importers,  
**deployers** or any other third-party

Or. en

## Amendment 2026

Kosma Zlotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

### Proposal for a regulation

#### Article 28 – paragraph 1 – introductory part

*Text proposed by the Commission*

1. Any distributor, importer, user or other third-party shall be considered a provider for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16, in any of the following circumstances:

*Amendment*

1. Any distributor, importer, user or other third-party shall be considered a provider **of a high-risk AI system** for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16, in any of the following circumstances:

Or. en

## Amendment 2027

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä  
on behalf of the Verts/ALE Group

### Proposal for a regulation

#### Article 28 – paragraph 1 – introductory part

*Text proposed by the Commission*

1. Any distributor, importer, **user** or other third-party shall be considered a provider for the purposes of this Regulation and shall be subject to the

*Amendment*

1. Any distributor, importer, **deployer** or other third-party shall be considered a provider for the purposes of this Regulation and shall be subject to the

obligations of the provider under Article 16, in any of the following circumstances:

obligations of the provider under Article 16, in any of the following circumstances:

Or. en

#### **Amendment 2028**

**Pernando Barrena Arza, Cornelia Ernst**

#### **Proposal for a regulation**

#### **Article 28 – paragraph 1 – point b**

*Text proposed by the Commission*

(b) they modify the intended purpose of a high-risk AI system already placed on the market or put into service;

*Amendment*

(b) they modify the intended purpose ***or reasonably foreseeable use*** of a high-risk AI system already placed on the market or put into service;

Or. en

#### **Amendment 2029**

**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H el ene Laporte, Jean-Paul Garraud**

#### **Proposal for a regulation**

#### **Article 28 – paragraph 1 – point b a (new)**

*Text proposed by the Commission*

*Amendment*

***(ba) they have placed on the market or put into service a high-risk AI system which they have substantially modified by their own means;***

Or. fr

#### **Amendment 2030**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alamets a**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

#### **Article 28 – paragraph 1 – point b a (new)**

*Text proposed by the Commission*

*Amendment*

***(b a) they deploy a high-risk system for a purpose other than the intended purpose;***

Or. en

**Amendment 2031**

**Kosma Zlotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan**

**Proposal for a regulation**

**Article 28 – paragraph 1 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

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

Or. en

**Amendment 2032**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 28 – paragraph 1 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

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

Or. en

**Amendment 2033**

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin**



**Mituța**

**Proposal for a regulation  
Article 28 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2 a. Providers that initially placed the high-risk AI system on the market or put it into service shall cooperate closely with distributors, importers, users, or other third-parties to supply them with the necessary information or documentation in their possession that is required for the fulfilment of the obligations set out in this Regulation, in particular at the moment when such distributors, importers, users or other third-parties become the new providers as determined in paragraph 1 and the initial providers are no longer considered a provider for the purposes of this Regulation as determined in paragraph 2.**

Or. en

**Amendment 2034**

**Pernando Barrena Arza, Cornelia Ernst, Kateřina Konečná**

**Proposal for a regulation  
Article 28 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 28 a**

***Obligations of employers***

**1. Employers shall have the following additional obligations when deploying AI surveillance or monitoring systems in the workplace:**

**(a) consult trade unions on the use of high risk and intrusive forms of AI in the workplace;**

**(b) ensure that workers are aware of the AI systems at the workplace, including their impact on data, digital footprint and**

*work organisation;*

*(c) ensure a human review of decisions made by AI systems that could affect the worker;*

*(d) deliver an annual conformity assessment for workplace-based AI to guard against discrimination by algorithm.*

Or. en

#### **Amendment 2035**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

##### **Article 29 – title**

*Text proposed by the Commission*

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

*Amendment*

29 Obligations of **deployers** of high-risk AI systems

*(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)*

Or. en

#### **Amendment 2036**

**Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Maria Grapini**

#### **Proposal for a regulation**

##### **Article 29 – paragraph -1 (new)**

*Text proposed by the Commission*

*Amendment*

***-1. Users of high-risk AI systems shall ensure that natural persons assigned to ensure or entrusted with human oversight for high-risk AI systems are competent, properly qualified and trained, free from external influence and neither seek nor take instructions from anybody. They shall have the necessary resources in***

*order to ensure the effective supervision of the system in accordance with Article 14.*

Or. en

### **Amendment 2037**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation**

#### **Article 29 – paragraph 1**

*Text proposed by the Commission*

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

*Amendment*

1. Users of high-risk AI systems shall use such systems ***and implement human oversight*** in accordance with the instructions of use accompanying the systems, pursuant to paragraphs 2 and 5 ***of this Article. Users shall bear sole responsibility in case of any use of the AI system that is not in accordance with the instructions of use accompanying the systems.***

Or. en

### **Amendment 2038**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

#### **Article 29 – paragraph 1**

*Text proposed by the Commission*

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

*Amendment*

1. ***Deployers*** of high-risk AI systems shall ***take appropriate technical and organisational measures and ensure that the use of*** such systems ***is*** in accordance with the instructions of use accompanying the systems ***and enables human oversight and decision-making***, pursuant to paragraphs 2 and 5.

Or. en

#### Amendment 2039

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen

#### Proposal for a regulation

#### Article 29 – paragraph 1

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

#### Amendment 2040

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Morten Løkkegaard, Alin Mituța, Michal Šimečka

#### Proposal for a regulation

#### Article 29 – paragraph 1

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

#### Amendment 2041

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

#### Proposal for a regulation

#### Article 29 – paragraph 1

*Text proposed by the Commission*

1. Users **of high-risk AI systems** shall

*Amendment*

1. Users shall **bear sole responsibility**

*use such systems* in accordance with the instructions of use accompanying the systems, *pursuant to paragraphs 2 and 5.*

*in case of any use of the AI system that is not* in accordance with the instructions of use accompanying the systems.

Or. en

**Amendment 2042**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**

**Article 29 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1 a. To the extent the user exercises control over the high-risk AI system, that user shall only assign human oversight to natural persons who have the necessary competence, training and authority as well as ensure that relevant and appropriate robustness and cybersecurity measures are in place and are regularly adjusted or updated.***

Or. en

**Amendment 2043**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 29 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1 a. Deployers shall identify the categories of natural persons and groups likely to be affected by the system before putting it into use.***

Or. en

**Amendment 2044**

**Svenja Hahn, Dragoş Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard,**

**Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen**

**Proposal for a regulation**

**Article 29 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

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

Or. en

**Amendment 2045**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 29 – paragraph 1 b (new)**

*Text proposed by the Commission*

*Amendment*

**1 b. Human oversight following paragraph 1 shall be carried out by natural persons having the necessary competences, training, authority and independence.**

Or. en

**Amendment 2046**

**Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura**

**Proposal for a regulation**

**Article 29 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

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

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

*This regulation does not conflict with the scope of Art. 153 TFEU, which sets minimum requirements for Member States that may be exceeded.*

Or. en

#### **Amendment 2047**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation** **Article 29 – paragraph 2**

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

#### **Amendment 2048**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation** **Article 29 – paragraph 2**

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

#### Amendment 2049

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen

#### Proposal for a regulation

#### Article 29 – paragraph 3

##### *Text proposed by the Commission*

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

##### *Amendment*

3. Without prejudice to paragraph 1, to the extent the user exercises control over the input data, that user shall ensure that input data is relevant in view of the intended purpose of the high-risk AI system. ***To the extent the user exercises control over the high-risk AI system, that user shall also ensure that relevant and appropriate robustness and cybersecurity measures are in place and are regularly adjusted or updated.***

Or. en

#### Amendment 2050

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituța

#### Proposal for a regulation

#### Article 29 – paragraph 3

##### *Text proposed by the Commission*

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

##### *Amendment*

3. Without prejudice to paragraph 1, to the extent the user exercises control over the input data, that user shall ensure that input data is relevant in view of the intended purpose of the high-risk AI system. ***To the extent the user exercises control over the high-risk AI system, that user shall also ensure that relevant and appropriate robustness and cybersecurity measures are in place and are regularly adjusted or updated.***

Or. en



### Amendment 2051

Axel Voss, Deirdre Clune, Eva Maydell

#### Proposal for a regulation

##### Article 29 – paragraph 3

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

### Amendment 2052

Pernando Barrena Arza, Cornelia Ernst

#### Proposal for a regulation

##### Article 29 – paragraph 3

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

### Amendment 2053

Axel Voss, Deirdre Clune, Eva Maydell

#### Proposal for a regulation

##### Article 29 – paragraph 4 – introductory part

*Text proposed by the Commission*

4. Users shall monitor the operation of the high-risk AI system on the basis of the instructions of use. When they have

*Amendment*

4. Users shall monitor the operation of the high-risk AI system on the basis of the instructions of use **and, when relevant,**

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

***inform providers in accordance with Article 61. To the extent the user exercises control over the high-risk AI system, users shall also perform risk assessments in line with Article 9 but limited to the potential adverse effects of using the high-risk AI system and the respective mitigation measures.*** When they have reasons to consider that the use in accordance with the instructions of use may result in the AI system presenting a risk within the meaning of Article 65(1) they shall inform the provider or distributor and ***relevant regulatory authority and*** suspend the use of the system. They shall also inform the provider or distributor ***and relevant regulatory authority*** when they have identified any serious incident and interrupt the use of the AI system. In case the user is not able to reach the provider, ***importer or distributor*** Article 62 shall apply mutatis mutandis.

Or. en

#### **Amendment 2054**

**Svenja Hahn, Nicola Beer, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen**

#### **Proposal for a regulation**

#### **Article 29 – paragraph 4 – introductory part**

##### *Text proposed by the Commission*

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

##### *Amendment*

4. Users shall monitor the operation of the high-risk AI system on the basis of the instructions of use ***and, when relevant, inform providers in accordance with Article 61. To the extent the user exercises control over the high-risk AI system, the user shall also establish a risk management system in line with Article 9 but limited to the potential adverse effects of using the high-risk AI system, the respective mitigation measures.*** When they have reasons to consider that the use in accordance with the instructions of use may result in the AI system presenting a

able to reach the provider, Article 62 shall apply mutatis mutandis.

risk within the meaning of Article 65(1) they shall inform the provider or distributor and suspend the use of the system. They shall also inform the provider or distributor when they have identified any serious incident or any malfunctioning within the meaning of Article 62 and interrupt the use of the AI system. In case the user is not able to reach the provider, Article 62 shall apply mutatis mutandis.

Or. en

#### **Amendment 2055**

**Pernando Barrena Arza, Cornelia Ernst**

#### **Proposal for a regulation**

#### **Article 29 – paragraph 4 – introductory part**

##### *Text proposed by the Commission*

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

##### *Amendment*

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

Or. en

#### **Amendment 2056**

**Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Maria Grapini**

## Proposal for a regulation

### Article 29 – paragraph 4 – introductory part

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## Amendment 2057

**Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura**

## Proposal for a regulation

### Article 29 – paragraph 5 – introductory part

*Text proposed by the Commission*

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

*Amendment*

5. Users of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system, to the extent such logs are under their control. The logs shall be kept for a period that is appropriate in the light of the intended purpose **or reasonably foreseeable use** of the high-risk AI system and applicable legal obligations under Union or national law.

Or. en

## Amendment 2058

Axel Voss, Deirdre Clune, Eva Maydell

### Proposal for a regulation

#### Article 29 – paragraph 5 – introductory part

*Text proposed by the Commission*

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

*Amendment*

5. Users of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system, to the extent such logs are under their control. ***They shall keep them for a period of at least six months, unless provided otherwise in*** applicable Union or national law.

Or. en

## Amendment 2059

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

### Proposal for a regulation

#### Article 29 – paragraph 5 – introductory part

*Text proposed by the Commission*

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

*Amendment*

5. Users of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system, to the extent such logs are under their control. The logs shall be kept for a period that is appropriate in the light of ***industry standards***, the intended purpose of the high-risk AI system and applicable legal obligations under Union or national law.

Or. en

## Amendment 2060

Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

### Proposal for a regulation

**Article 29 – paragraph 5 – subparagraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***Prior to putting into service or use an AI system at the workplace, users shall consult workers representatives, inform the affected employees that they will be subject to the system and obtain their consent.***

Or. en

**Amendment 2061**

**Krzysztof Hetman, Andrzej Halicki, Adam Jarubas, Jerzy Buzek, Janusz Lewandowski, Radosław Sikorski**

**Proposal for a regulation**

**Article 29 – paragraph 5 a (new)**

*Text proposed by the Commission*

*Amendment*

***5 a. Users of high-risk AI systems which affect natural persons, in particular, by evaluating or assessing them, making predictions about them, recommending information, goods or services to them or determining or influencing their access to goods and services, shall inform the natural persons that they are subject to the use of such an high-risk AI system.***

***This information shall include a clear and concise indication of the user and the purpose of the high-risk AI system, information about the rights of the natural person conferred under this Regulation, and a reference to publicly available resource where more information about the high-risk AI system can be found, in particular the relevant entry in the EU database referred to in Article 60, if applicable. This information shall be presented in a concise, intelligible and easily accessible form, including for persons with disabilities.***

***This obligation shall be without prejudice***

*to other Union or Member State laws, in particular Regulation 2016/679 [GDPR], Directive 2016/680 [LED], Regulation 2022/XXX [DSA].*

Or. en

**Amendment 2062**

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Róza Thun und Hohenstein, Alin Mituța**

**Proposal for a regulation**

**Article 29 – paragraph 5 a (new)**

*Text proposed by the Commission*

*Amendment*

**5 a. Users of high-risk AI systems that are public authorities or Union institutions, bodies, offices and agencies shall conduct a fundamental rights impact assessment prior to commencing the use of a high-risk AI system;**

Or. en

**Amendment 2063**

**Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini**

**Proposal for a regulation**

**Article 29 – paragraph 5 a (new)**

*Text proposed by the Commission*

*Amendment*

**5 a. Users of high-risk AI systems shall comply with the registration obligations referred to in Article 51.**

Or. en

**Amendment 2064**

**Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen**

**Proposal for a regulation**  
**Article 29 – paragraph 6**

*Text proposed by the Commission*

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

*Amendment*

6. Users of high-risk AI systems shall use the information provided under Article 13 to comply with their obligation to carry out a data protection impact assessment under Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, **and may revert in part to those data protection impact assessments for fulfilling the obligations set out in this article**.

Or. en

**Amendment 2065**  
**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**  
**Article 29 – paragraph 6**

*Text proposed by the Commission*

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

*Amendment*

6. Users of high-risk AI systems shall use the information provided under Article 13 to comply with their obligation to carry out a data protection impact assessment under Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680 **and may revert in part to those data protection impact assessments for fulfilling the obligations set out in this Article**.

Or. en

**Amendment 2066**  
**Sophia in 't Veld, Michal Šimečka**

**Proposal for a regulation**  
**Article 29 – paragraph 6**



*Text proposed by the Commission*

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

*Amendment*

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

***The data protection impact assessment shall be published.***

Or. en

**Amendment 2067**

**Sophia in 't Veld, Michal Šimečka**

**Proposal for a regulation**

**Article 29 – paragraph 6 a (new)**

*Text proposed by the Commission*

*Amendment*

***6 a. Users of high-risk AI systems shall carry out a human rights impact assessment for the different uses of the system, containing specific information on the context of use of that system, including, the intended purpose or reasonable foreseeably use, geographic and temporal scope, assessment of the legality and fundamental rights impacts of the system, any specific risk of harm likely to impact marginalised persons or those at risk of discrimination, any other negative impact on the public interest; and clear steps as to how the harms identified will be mitigated, and how effective this mitigation is likely to be.***

***The human rights impact assessment shall be published, and be registered by the user in the database referred to under Article 60.***

Or. en

**Amendment 2068**

**Svenja Hahn, Nicola Beer, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen**

**Proposal for a regulation**

**Article 29 – paragraph 6 a (new)**

*Text proposed by the Commission*

*Amendment*

**6 a. Where a user of a high risk AI system is obliged pursuant to Regulation (EU) 2016/679 to provide information regarding the use of automated decision making procedures, the user shall not be obliged to provide information on how the AI system reached a specific result. When fulfilling the information obligations under Regulation (EU) 2016/679, the user shall not be obliged to provide information beyond the information he or she received from the provider under Article 13 of this Regulation.**

Or. en

**Amendment 2069**

**Vincenzo Sofo, Kosma Złotowski**

**Proposal for a regulation**

**Article 29 – paragraph 6 a (new)**

*Text proposed by the Commission*

*Amendment*

**6 a. Users of high risk systems involving an emotion recognition system or a biometric categorisation system in accordance with Article 52 shall implement suitable measures to safeguard the natural person's rights and freedoms and legitimate interests in such a system, including providing the natural person with the ability to express his or her point of view on the resulting categorisation and to contest the decision.**

Or. en

**Amendment 2070**  
**Kosma Zlotowski, Patryk Jaki, Adam Bielan**

**Proposal for a regulation**  
**Article 29 – paragraph 6 a (new)**

*Text proposed by the Commission*

*Amendment*

**6 a. Users shall monitor the performance of high-risk AI systems deployed by end-users and shall ensure that all possible malfunctioning and performance issues are recorded, and when not able to justify or ensure proper performance, communicated to the AI provider. In such cases, the provider and the user shall coordinate to establish the cause of a possible malfunctioning or performance issue.**

Or. en

**Amendment 2071**  
**Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura**

**Proposal for a regulation**  
**Article 29 – paragraph 6 a (new)**

*Text proposed by the Commission*

*Amendment*

**6 a. Users of high-risk AI systems shall refrain from placing on the market or putting into service a high-risk AI system that:**

**(i) is not in conformity with the requirements set out in Chapter 2 of this Title; or**

**(ii) poses a risk of harm to health, safety or fundamental rights despite its conformity with the requirements set out in Chapter 2 of this Title.**

Or. en

**Amendment 2072**

**Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Maria Grapini, Brando Benifei**

**Proposal for a regulation**  
**Article 29 – paragraph 6 a (new)**

*Text proposed by the Commission*

*Amendment*

**6 a. Users of high-risk AI systems referred to in Annex III that make decisions or assist in making decisions related to an affected person, shall inform them that they are subject to the use of the high-risk AI system. This information shall include the type of the AI system used, its intended purpose and the type of decisions it makes.**

Or. en

**Amendment 2073**

**Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura**

**Proposal for a regulation**  
**Article 29 – paragraph 6 a (new)**

*Text proposed by the Commission*

*Amendment*

**6 a. Users of high risk AI systems, who modify or extend the purpose for which the conformity of the AI system was originally assessed, shall establish and document a post-market monitoring system (Art. 61) and must undergo a new conformity assessment (Art. 43) involved by a notified body.**

Or. en

**Amendment 2074**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**  
**Article 29 – paragraph 6 a (new)**

*Text proposed by the Commission*

*Amendment*

**6 a.** *The provider shall be obliged to cooperate closely with the user and in particular provide the user with the necessary information to allow the fulfilment of the obligations set out in this Article.*

Or. en

**Amendment 2075**

**Rob Rooker**

on behalf of the ECR Group

**Proposal for a regulation**

**Article 29 – paragraph 6 a (new)**

*Text proposed by the Commission*

*Amendment*

**6 a.** *Users of high-risk AI systems shall conduct and publish a fundamental rights impact assessment.*

Or. en

**Amendment 2076**

**Svenja Hahn, Nicola Beer, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen**

**Proposal for a regulation**

**Article 29 – paragraph 6 b (new)**

*Text proposed by the Commission*

*Amendment*

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

Or. en

**Amendment 2077**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**  
**Article 29 – paragraph 6 b (new)**

*Text proposed by the Commission*

*Amendment*

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

Or. en

**Amendment 2078**

**Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Maria Grapini**

**Proposal for a regulation**  
**Article 29 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 29 a**

***Fundamental rights impact assessment  
for a high-risk AI system***

***1. Prior to putting a high-risk AI system into use, as defined in Article 6(2), the user shall conduct an assessment of the system's impact in the context of use. This assessment shall consist of, but not limited to, the following elements:***

***(a) a clear outline of the intended purpose for which the system will be used;***

***(b) a clear outline of the intended geographic and temporal scope of the system's use;***

***(c) verification that the use of the system is compliant with Union and national law;***

***(d) categories of natural persons and groups likely to be affected by the use of the system;***

***(e) the foreseeable direct and indirect impact on fundamental rights of putting the high-risk AI system into use;***

***(f) any specific risk of harm likely to impact marginalised persons or vulnerable groups;***

***(g) the foreseeable impact of the use of the system on the environment, including, but not limited to, energy consumption;***

***(h) any other negative impact on the protection of the values enshrined in Article 2 TEU;***

***(i) in the case of public authorities, any other impact on democracy, rule of law and allocation of public funds; and***

***(j) detailed plan on how the risk of harm or the negative direct and indirect impact on fundamental rights identified will be mitigated.***

***2. If a detailed plan to mitigate the risks outlined in the course of the assessment in paragraph 1 cannot be identified, the user shall refrain from putting the high-risk AI system into use and inform the provider, the national supervisory authority and market surveillance authority without undue delay. Market surveillance authorities or, where relevant, national supervisory authorities, pursuant to their capacity under Articles 65, 67 and 67a, shall take this information into account when investigating systems which present a risk at national level.***

***3. The obligations as per paragraph 1 apply for each new deployment of the high-risk AI system.***

***4. In the course of the impact assessment, the user shall notify the national supervisory authority, the market surveillance authority and the relevant stakeholders. and involve representatives of the foreseeable persons or groups of persons affected by the high-risk AI system, as identified in paragraph 1, including but not limited to: equality bodies, consumer protection agencies, social partners and data protection agencies, with a view to receiving input into the impact assessment. The user must allow a period of six weeks for bodies to***

*respond.*

*5. The user shall publish the results of the impact assessment as part of the registration of use pursuant to their obligation under Article 51(2).*

*6. Where the user is already required to carry out a data protection impact assessment pursuant to Article 29(6), the impact assessment outlined in paragraph 1 shall be conducted in conjunction to the data protection impact assessment.*

Or. en

#### **Amendment 2079**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

#### **Proposal for a regulation**

#### **Article 29 a (new)**

*Text proposed by the Commission*

*Amendment*

#### *Article 29 a*

#### *Fundamental rights impact assessment for high-risk AI systems*

*1. Prior to putting a high-risk AI system as defined in Article 6(2) into use, users shall conduct an assessment of the systems' impact in the specific context of use. This assessment shall include, at a minimum, the following elements:*

*(a) a clear outline of the intended purpose for which the system will be used;*

*(b) a clear outline of the intended geographic and temporal scope of the system's use;*

*(ba) categories of natural persons and groups likely to be affected by the use of the system;*

*(c) verification that the use of the system is compliant with relevant Union and national law, and with fundamental rights*



*law;*

*(d) the foreseeable direct or indirect impact on fundamental rights of putting the high-risk AI system into use;*

*(e) any specific risk of harm likely to impact marginalised persons or vulnerable groups;*

*(f) the foreseeable impact of the use of the system on the environment including, but not limited to, energy consumption;*

*(g) any other negative impact on the protection of the values enshrined in Article 2 TEU;*

*(h) in the case of public authorities, any other impact on democracy, rule of law and allocation of public funds; and*

*(i) a detailed plan as to how the harms and the negative direct or indirect impact on fundamental rights identified will be mitigated.*

*2. If a detailed plan to mitigate the risks outlined in the course of the assessment outlined in paragraph 1 cannot be identified, the user shall refrain from putting the high-risk AI system into use and inform the provider and the relevant national competent authorities without undue delay. Market surveillance authorities, pursuant to Articles 65 and 67, shall take this information into account when investigating systems which present a risk at national level.*

*3. The obligation outlined under paragraph 1 applies for each new use of the high-risk AI system.*

*4. In the course of the impact assessment, the user shall notify relevant national competent authorities and relevant stakeholders and involve representatives of the persons or groups of persons that are reasonably foreseeable to be affected by the high-risk AI system, as identified in paragraph 1, including but not limited to: equality bodies, consumer protection agencies, social partners and data protection agencies, with a view to*

*receiving input into the impact assessment. The user must allow a period of six weeks for bodies to respond.*

*5. The user that is a public authority shall publish the results of the impact assessment as part of the registration of use pursuant to their obligation under Article 51(2).*

Or. en

**Amendment 2080**

**Krzysztof Hetman, Andrzej Halicki, Adam Jarubas, Jerzy Buzek, Janusz Lewandowski, Radosław Sikorski**

**Proposal for a regulation  
Article 29 a (new)**

*Text proposed by the Commission*

*Amendment*

*Article 29 a*

*Fundamental rights impact assessments  
for high-risk AI systems*

*1. The user of a high-risk AI system as defined in Article 6 paragraph 2 shall conduct an assessment of the system's impact on fundamental rights and public interest in the context of use before putting the system into use and at least every two years afterwards. The information on clear steps as to how the potential harms identified will be mitigated and how effective this mitigation is likely to be should be included.*

*2. If adequate steps to mitigate the risks outlined in the course of the assessment in paragraph 1 cannot be identified, the system shall not be put into use. Market surveillance authorities, pursuant to their capacity under Articles 65 and 67, shall take this information into account when investigating systems which present a risk at national level.*

*3. In the course of the impact assessment, the user shall notify relevant national*

*authorities and all relevant stakeholders.*

*4. Where, following the impact assessment process, the user decides to put the high-risk AI system into use, the user shall be required to publish the results of the impact assessment as part of the registration of use pursuant to their obligation under Article 51 paragraph 2.*

*5. Users of high-risk AI systems shall use the information provided to them by providers of high-risk AI systems under Article 13 to comply with their obligation under paragraph 1.*

*6. The obligations on users in paragraph 1 is without prejudice to the obligations on users of all high-risk AI systems as outlined in Article 29.*

Or. en

## **Amendment 2081**

**Kosma Zlotowski, Patryk Jaki, Vincenzo Sofò**

### **Proposal for a regulation**

#### **Article 29 a (new)**

*Text proposed by the Commission*

*Amendment*

#### *Article 29 a*

##### *Human rights impact assessment for high-risk AI systems*

*1. The user of a high-risk AI system as defined in Article 6 paragraph 2 may conduct an assessment of the system's impact on fundamental rights and public interest in the context of use before putting the system into use and at least every three years afterwards. This assessment shall include, at minimum, the following:*

*a) a clear outline of the intended purpose for which the system will be used;*

*b) a clear outline of the intended geographic and temporal scope of the*

*system's use;*

*c) categories of natural persons and groups likely to be affected by the use of the system;*

*d) the likely impact on human rights of affected persons identified pursuant to point (c), including any indirect impacts or consequences of the system's use;*

*e) in the case of public authorities, any other impact on the public interest, including democracy and allocation of public funds;*

*2. Where the user of a high-risk AI system is already required to carry out a data protection impact assessment under Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the impact assessment outlined in paragraph 1 may be conducted in conjunction to the data protection impact assessment. The user may publish the results of both assessments, following the obligation under Article 51 paragraph 2.*

Or. en

## **Amendment 2082**

**Rob Rooken**

on behalf of the ECR Group

### **Proposal for a regulation**

#### **Article 29 a (new)**

*Text proposed by the Commission*

*Amendment*

#### *Article 29 a*

##### *Fundamental rights impact assessment for users of high-risk AI*

*Users of high-risk AI systems as defined in Article 6(2) shall conduct an assessment of the systems' impact in the context of use before putting the system into use. This assessment shall include, but is not limited to, the following:*

- a. a clear outline of the intended purpose for which the system will be used;*
- b. a clear outline of the intended geographic and temporal scope of the system's use;*
- c. verification of the legality of the system in accordance with Union and national law, fundamental rights law, Union accessibility legislation, and the extent to which the system is in compliance with this Regulation;*
- d. the likely impact on fundamental rights of the high-risk AI system, including any indirect impacts or consequences of the system's use;*
- e. any specific risk of harm likely to impact persons or groups of persons at risk of discrimination, or increase existing societal inequalities;*
- f. risk to the health of individuals and public health;*
- g. any other negative impact on the public interest; and*
- h. clear steps as to how the harms identified will be mitigated, and how effective this mitigation is likely to be.*

Or. en

## **Amendment 2083**

**Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura**

### **Proposal for a regulation**

#### **Article 29 a (new)**

*Text proposed by the Commission*

*Amendment*

#### *Article 29 a*

##### *Obligation on users to define affected persons*

*1. Before putting into use a high-risk AI system as defined in Article 6(2), the user shall define categories of natural persons and groups likely to be affected by the use*

*of the system.*

Or. en

**Amendment 2084**

**Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura**

**Proposal for a regulation**

**Article 29 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 29 a**

***A fiduciary duty for providers and users  
of high-risk AI systems***

***Providers and users of high-risk AI  
systems have a fiduciary duty to act in the  
interest of the affectees.***

Or. en

**Amendment 2085**

**Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura**

**Proposal for a regulation**

**Article 29 b (new)**

*Text proposed by the Commission*

*Amendment*

**Article 29 b**

***Fundamental rights impact assessments  
for high-risk AI systems***

***1. Users of high-risk AI systems as  
defined in Article 6(2) shall conduct an  
assessment of the systems' impact in the  
context of use before putting the system  
into use. This assessment shall include,  
but is not limited to, the following:***

***a. a clear outline of the intended purpose  
for which the system will be used;***

***b. a clear outline of the intended  
geographic and temporal scope of the  
system's use;***

*c. verification of the legality of the system in accordance with Union and national law, fundamental rights law, Union accessibility legislation, and the extent to which the system is in compliance with this Regulation;*

*d. the likely impact on fundamental rights of the high-risk AI system, including any indirect impacts or consequences of the system's use;*

*e. any specific risk of harm likely to impact marginalised persons or those groups at risk of discrimination, or increase existing societal inequalities;*

*f. the foreseeable impact of the use of the system on the environment, including but not limited to energy consumption;*

*g. any other negative impact on the public interest; and*

*h. clear steps as to how the harms identified will be mitigated, and how effective this mitigation is likely to be.*

*2. If adequate steps to mitigate the risks outlined in the course of the assessment in paragraph 1 cannot be identified, the system shall not be put into use. Market surveillance authorities, pursuant to their capacity under Articles 65 and 67, may take this information into account when investigating systems which present a risk at national level.*

*3. The obligation outlined under paragraph 1 applies for each new deployment of the high-risk AI system.*

*4. In the course of the impact assessment, the user shall notify relevant national authorities and all relevant stakeholders, including but not limited to: equality bodies, consumer protection agencies, social partners and data protection agencies, with a view to receiving input into the impact assessment. The user must allow a period of six weeks for bodies to respond.*

*5. Where, following the impact assessment process, the user decides to put the high-*

*risk AI system into use, the user shall be required to publish the results of the impact assessment as part of the registration of use pursuant to their obligation under Article 51(2).*

*6. Where the user is already required to carry out a data protection impact assessment under Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the impact assessment outlined in paragraph 1 shall be conducted in conjunction to the data protection impact assessment and be published as an addendum.*

*7. Users of high-risk AI systems shall use the information provided under Article 13 to comply with their obligation under paragraph 1.*

*8. Where the user, pursuant to their obligation to define affected categories of persons under Article 29a, finds that use of a high-risk system poses a particular risk to a specific group of natural persons, the user has the obligation to notify established representatives or interest groups acting on behalf of those persons before putting the system into use, with a view to receiving input into the impact assessment.*

*9 The obligations on users in paragraph 1 is without prejudice to the obligations on users of all high risk AI systems as outlined in Article 29.*

Or. en

## **Amendment 2086**

**Jürgen Warborn, Arba Kokalari, Tomas Tobé**

### **Proposal for a regulation**

#### **Article 30 – paragraph 1**

*Text proposed by the Commission*

1. Each Member State shall designate or establish a notifying authority

*Amendment*

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.

responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring. ***These procedures shall be developed in cooperation between the notifying authorities of all Member States and shall result in standard procedures implemented equally in all Member States, with a view to removing administrative border barriers and ensuring that the potential of the internal market is realised.***

Or. en

### **Amendment 2087**

**Barbara Thaler, Lukas Mandl, Axel Voss, Deirdre Clune**

#### **Proposal for a regulation**

#### **Article 30 – paragraph 1**

##### *Text proposed by the Commission*

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.

##### *Amendment*

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. ***To this end, Member States shall ensure a sufficient number of conformity assessment bodies, in order to make the certification feasible in a timely manner.***

Or. en

### **Amendment 2088**

**Pernando Barrena Arza, Cornelia Ernst**

#### **Proposal for a regulation**

#### **Article 30 – paragraph 1**

##### *Text proposed by the Commission*

##### *Amendment*

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.

1. Each Member State shall designate **the national Data Protection Authority (DPA) as the** 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

Or. en

#### **Amendment 2089**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation** **Article 30 – paragraph 7**

*Text proposed by the Commission*

7. Notifying authorities shall have a sufficient number of competent personnel at their disposal for the proper performance of their tasks.

*Amendment*

7. Notifying authorities shall have a sufficient number of competent personnel at their disposal for the proper performance of their tasks. **Where applicable, competent personnel shall have necessary expertise in supervision of fundamental rights.**

Or. en

#### **Amendment 2090**

**Jürgen Warborn, Arba Kokalari, Tomas Tobé**

#### **Proposal for a regulation** **Article 30 – paragraph 8**

*Text proposed by the Commission*

8. Notifying authorities shall make sure that conformity assessments are carried out in a proportionate manner, avoiding unnecessary burdens for providers and that notified bodies perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure and the degree of

*Amendment*

8. Notifying authorities shall make sure that conformity assessments are carried out in a proportionate manner, avoiding unnecessary burdens for providers and that notified bodies perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure and the degree of

complexity of the AI system in question.

complexity of the AI system in question.  
***Particular attention shall be paid to minimising administrative burdens and compliance costs for micro, small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC.***

Or. en

#### **Amendment 2091**

**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H el ene Laporte, Jean-Paul Garraud**

#### **Proposal for a regulation Article 30 – paragraph 8**

##### *Text proposed by the Commission*

8. Notifying authorities shall make sure that conformity assessments are carried out in a proportionate manner, avoiding unnecessary burdens for providers and that notified bodies perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of the AI system in question.

##### *Amendment*

8. Notifying authorities shall make sure that conformity assessments are carried out in a proportionate manner, avoiding unnecessary burdens for providers and that notified bodies perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of ***and risk posed by*** the AI system in question.

Or. fr

#### **Amendment 2092**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Ren e Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado L opez, Maria-Manuel Leit ao-Marques, Marc Angel**

#### **Proposal for a regulation Article 30 – paragraph 8**

##### *Text proposed by the Commission*

8. Notifying authorities shall make sure that conformity assessments are carried out in a proportionate manner, avoiding unnecessary burdens for

##### *Amendment*

8. Notifying authorities shall make sure that conformity assessments are carried out in a proportionate ***and timely*** 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.

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.

Or. en

#### **Amendment 2093**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation**

#### **Article 31 – paragraph 2**

##### *Text proposed by the Commission*

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.

##### *Amendment*

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules 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.

Or. en

#### **Amendment 2094**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

#### **Proposal for a regulation**

#### **Article 31 – paragraph 3**

##### *Text proposed by the Commission*

3. Where the conformity assessment body concerned cannot provide an

##### *Amendment*

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.

accreditation certificate, it shall provide the notifying authority with **all** 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.

Or. en

#### **Amendment 2095**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation**

#### **Article 32 – paragraph 1**

##### *Text proposed by the Commission*

1. Notifying authorities **may** notify only conformity assessment bodies which have satisfied the requirements laid down in Article 33.

##### *Amendment*

1. Notifying authorities **shall** notify only conformity assessment bodies which have satisfied the requirements laid down in Article 33.

Or. en

#### **Amendment 2096**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

#### **Proposal for a regulation**

#### **Article 32 – paragraph 3**

##### *Text proposed by the Commission*

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies concerned.

##### *Amendment*

3. The notification **referred to in paragraph 2** shall include full details of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies concerned, **as well as the relevant**

*attestation of competence.*

Or. en

#### **Amendment 2097**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation Article 32 – paragraph 3**

*Text proposed by the Commission*

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules *and the artificial intelligence technologies* concerned.

*Amendment*

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules concerned.

Or. en

#### **Amendment 2098**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

#### **Proposal for a regulation Article 32 – paragraph 4**

*Text proposed by the Commission*

4. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within *one month of a* notification.

*Amendment*

4. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States. *within two weeks of the validation of the notification where it includes an accreditation certificate referred to in Article 31(2), or within two months of the notification where it includes documentary evidence referred to in Article 31(3).*

Or. en

**Amendment 2099**

**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud**

**Proposal for a regulation**

**Article 32 – paragraph 4**

*Text proposed by the Commission*

4. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within one month of a notification.

*Amendment*

4. The conformity assessment body concerned may ***begin to*** perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within one month of a notification.

Or. fr

**Amendment 2100**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

**Proposal for a regulation**

**Article 32 – paragraph 4 a (new)**

*Text proposed by the Commission*

*Amendment*

***4 a. Where objections are raised, the Commission shall without delay enter into consultation with the relevant Member States and the conformity assessment body. 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 conformity assessment body.***

Or. en

**Amendment 2101**

**Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan**

**Proposal for a regulation**

**Article 33 – paragraph 2**

*Text proposed by the Commission*

2. Notified bodies shall satisfy the ***organisational, quality management, resources and process*** requirements ***that are necessary to fulfil their tasks.***

*Amendment*

2. Notified bodies shall satisfy the ***minimum cybersecurity*** requirements ***set out for public administration entities identified as operators of essential services pursuant to Directive (...) on measures for a high common level of cybersecurity across the Union, repealing Directive (EU) 2016/1148;***

Or. en

**Amendment 2102**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**

**Article 33 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***2 a. Notified bodies shall satisfy the minimum cybersecurity requirements set out for public administration entities identified as operators of essential services pursuant to Directive XXXX/XX on measures for a high common level of cybersecurity across the Union (NIS 2), repealing Directive (EU) 2016/1148.***

Or. en

**Amendment 2103**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 33 – paragraph 4**

*Text proposed by the Commission*

*Amendment*

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

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.

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. ***Notified bodies and their employees should not have provided any service to the provider of a high-risk system for 12 months before the assessment. They should also commit not to work for the provider of a high-risk system assessed or a professional organisation or business association of which the provider of a high-risk system is a member for 12 months after their position in the auditing organisation has ended.***

Or. en

#### **Amendment 2104**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

#### **Proposal for a regulation Article 33 – paragraph 4**

##### *Text proposed by the Commission*

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.

##### *Amendment*

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. ***This shall not preclude the use of assessed AI systems that are necessary for the operations of the conformity assessment body or the use of such systems for personal purposes.***

Or. en

#### **Amendment 2105**

**Proposal for a regulation**  
**Article 33 – paragraph 6**

*Text proposed by the Commission*

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.

*Amendment*

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. ***Any information and documentation obtained by notified bodies pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.***

Or. en

**Amendment 2106**

**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H el ene Laporte, Jean-Paul Garraud**

**Proposal for a regulation**  
**Article 33 – paragraph 7**

*Text proposed by the Commission*

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.

*Amendment*

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 ***and*** the degree of complexity of ***and risk posed by*** the AI system in question.

**Amendment 2107**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**

**Article 33 – paragraph 10**

*Text proposed by the Commission*

10. Notified bodies shall have sufficient internal competences to be able to effectively evaluate the tasks conducted by external parties on their behalf. To that end, at all times and for each conformity assessment procedure and each type of high-risk AI system in relation to which they have been designated, the notified body shall have permanent availability of sufficient administrative, technical 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.

*Amendment*

10. Notified bodies shall have sufficient internal competences to be able to effectively evaluate the tasks conducted by external parties on their behalf. To that end, at all times and for each conformity assessment procedure and each type of high-risk AI system in relation to which they have been designated, the notified body shall have permanent availability of sufficient administrative, technical and scientific personnel who possess experience and knowledge relating to ***AI***, data and data computing and to the requirements set out in Chapter 2 of this Title.

Or. en

**Amendment 2108**

**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H el ene Laporte, Jean-Paul Garraud**

**Proposal for a regulation**

**Article 34 – paragraph 3**

*Text proposed by the Commission*

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the provider.

*Amendment*

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the provider ***and the notifying authority***.

Or. fr

## Amendment 2109

Axel Voss, Deirdre Clune, Eva Maydell

### Proposal for a regulation

#### Article 34 – paragraph 4

*Text proposed by the Commission*

4. Notified bodies shall keep at the disposal of the notifying authority 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.

*Amendment*

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the **verification** of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

Or. en

## Amendment 2110

Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

### Proposal for a regulation

#### Article 36 – paragraph 1

*Text proposed by the Commission*

1. Where a notifying authority has suspicions 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, 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.

*Amendment*

1. Where a notifying authority has suspicions 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, 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 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.

**Amendment 2111**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 37 – paragraph 1**

*Text proposed by the Commission*

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.

*Amendment*

1. The Commission shall investigate all cases where there are reasons to doubt whether a notified body complies with the requirements laid down in Article 33.

Or. en

**Amendment 2112**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

**Proposal for a regulation**  
**Article 37 – paragraph 3**

*Text proposed by the Commission*

3. The Commission shall ensure that all *confidential* information obtained in the course of its investigations pursuant to this Article is treated confidentially.

*Amendment*

3. The Commission shall ensure that all *sensitive* information obtained in the course of its investigations pursuant to this Article is treated confidentially.

Or. en

**Amendment 2113**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 37 – paragraph 4**

*Text proposed by the Commission*

*Amendment*

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 adopt a reasoned decision requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if *necessary*. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(2).

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 adopt a reasoned decision requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if *applicable*. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(2).

Or. en

#### **Amendment 2114**

**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H  l  ne Laporte, Jean-Paul Garraud**

#### **Proposal for a regulation Article 37 – paragraph 4**

##### *Text proposed by the Commission*

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 adopt a reasoned decision requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary. That *implementing act* shall be adopted in accordance with the examination procedure referred to in Article 74(2).

##### *Amendment*

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 adopt a reasoned decision requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary. That *request* shall be adopted in accordance with the examination procedure referred to in Article 74(2).

Or. fr

##### *Justification*

*The terminology used created ambiguity regarding the binding nature of the Commission’s decision, an ambiguity which we resolve in favour of the Member States.*

#### **Amendment 2115**

**Pernando Barrena Arza, Cornelia Ernst**

#### **Proposal for a regulation**

## Article 38 – paragraph 1

*Text proposed by the Commission*

1. The Commission shall ensure that, with regard to the areas covered by this Regulation, appropriate coordination and cooperation between notified bodies active in the conformity assessment procedures of AI systems pursuant to this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.

*Amendment*

1. The Commission shall ensure that, with regard to the areas covered by this Regulation, appropriate coordination and cooperation between notified bodies active in the conformity assessment procedures of AI systems pursuant to this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.  
***The coordination role will be held by the European Data Protection Supervisor.***

Or. en

## Amendment 2116

**Axel Voss, Deirdre Clune, Eva Maydell**

### Proposal for a regulation

#### Article 38 – paragraph 2 a (new)

*Text proposed by the Commission*

*Amendment*

***2 a. The Commission shall provide for the exchange of knowledge and best practices between the Member States' national authorities responsible for notification policy.***

Or. en

## Amendment 2117

**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud**

### Proposal for a regulation

#### Article 39

*Text proposed by the Commission*

*Amendment*

***Article 39***

***deleted***

***39 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.*

*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.*

Or. fr

#### **Amendment 2118**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation Article 39 – paragraph 1**

*Text proposed by the Commission*

*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.*

*Amendment*

*1. In line with EU commitments under the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT), the Commission shall endeavour to maximise the acceptance of test results produced by competent conformity assessment bodies, independent of the territory in which they may be established, where necessary to demonstrate conformity with the applicable requirements of the Regulation.*

Or. en

#### **Amendment 2119**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

#### **Proposal for a regulation Article 39 – paragraph 1**

*Text proposed by the Commission*

*Conformity assessment bodies established under the law of a third country with which*

*Amendment*

*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.

the Union has concluded an agreement *in this respect* may be authorised to carry out the activities of notified Bodies under this Regulation.

Or. en

#### **Amendment 2120**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation**

#### **Article 39 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***2. Conformity assessment bodies established under the law of a third country may carry out the activities of notified bodies under this regulation where they have been accredited as competent by an accreditation body, whether established in the territory of the EU or a third country, that is a signatory of an international accreditation or conformity assessment scheme based on rigorous peer-review processes, such as the International Laboratory Accreditation Collaboration (ILAC) Mutual Recognition Arrangement (MRA) and International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA).***

Or. en

#### **Amendment 2121**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation**

#### **Article 39 – paragraph 1 b (new)**

*Text proposed by the Commission*

*Amendment*

***3. In addition, where conformity assessment bodies established under the law of a third country have not been***

*accredited by signatory bodies of such international accreditation or conformity assessment schemes, third-country conformity assessment bodies may carry out the activities of notified bodies where international mutual recognition arrangements, conformity assessment protocols, or other agreements exist between the EU and the country in which the conformity assessment body is established.*

Or. en

#### **Amendment 2122**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation**

#### **Article 40 – paragraph 1**

*Text proposed by the Commission*

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.

*Amendment*

**1.** High-risk AI systems which are in conformity with harmonised standards ***developed in accordance with Regulation 1025/2021*** 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.

Or. en

#### **Amendment 2123**

**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud**

#### **Proposal for a regulation**

#### **Article 40 – paragraph 1**

*Text proposed by the Commission*

High-risk AI systems ***which are*** in conformity with harmonised standards or

*Amendment*

High-risk AI systems ***shall be*** 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.

parts thereof the references of which have been published in the Official Journal of the European Union, to the extent those standards cover those requirements.

Or. fr

#### *Justification*

*It is dangerous to create a regime of legal presumption allowing a derogation from all the obligations and guarantees under Title III, particularly where high-risk AI systems are concerned, given the specific risks they pose. These systems should be thoroughly and comprehensively checked on a systematic basis.*

#### **Amendment 2124**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation**

#### **Article 40 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***2. When issuing a standardisation request to European standardisation organisations in accordance with Article 10 of Regulation (EU) 1025/2012, the Commission shall specify that standards are coherent, including with sectorial legislation listed in Annex 2, 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 strengthen the Union's digital sovereignty;***

***(b) take into account the concept of trustworthy AI set out in Article 4(a);***

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

***(d) enhance multistakeholder governance, representative of all relevant European***

*stakeholders (e.g. industry, SMEs, civil society, researchers);*

*(e) 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.*

Or. en

#### **Amendment 2125**

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Alin Mituţa**

#### **Proposal for a regulation**

#### **Article 40 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

*The Commission shall issue standardisation requests covering all essential requirements of this Regulation in accordance with Article 10 of Regulation 1025/2012 no later than 6 months after the date of entry into force of this Regulation.*

Or. en

#### **Amendment 2126**

**Pernando Barrena Arza, Cornelia Ernst**

#### **Proposal for a regulation**

#### **Article 40 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

*Harmonised standards shall be limited to technical specifications and procedures. Work organisation and ethical considerations are not applicable.*

**Amendment 2127**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

**Proposal for a regulation**

**Article 40 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***When AI systems are intended to be deployed at the workplace, harmonised standards shall be limited to technical specifications and procedures.***

**Amendment 2128**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**

**Article 40 – paragraph 1 b (new)**

*Text proposed by the Commission*

*Amendment*

***The Commission shall issue standardisation requests covering all essential requirements of the Regulation in accordance with Article 10 of Regulation (EU) No 1025/2012 no later than 6 months after the date of entry into force of the Regulation.***

**Amendment 2129**

**Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan**

**Proposal for a regulation**

**Article 41**

*Text proposed by the Commission*

*Amendment*

**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, 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, when preparing the common specifications referred to in paragraph 1, shall 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 that they have adopted technical solutions that are at least equivalent thereto.**

Or. en

**Amendment 2130**

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation****Article 41 – paragraph 1***Text proposed by the Commission**Amendment*1. **Where harmonised standards**

1. The Commission may, by means of

*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, 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).

implementing acts, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title *for the essential requirements where health and safety, the protection of consumers or of the environment, other aspects of public interest, or clarity and practicability so require after consulting the Board, the Committee referred to in Art 22 of Regulation 1025/2012 as well as the relevant stakeholders and where the following conditions have been fulfilled:*

*(a) the Commission has concluded, that contrary to Article 10(6) of Regulation (EU) No 1025/2012 a harmonised standard does not satisfy the requirements which it aims to cover and which are set out in the corresponding Union harmonisation and has therefore not published a reference of such harmonised standard in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;*

*(b) the Commission has requested one or more European standardization organisations to draft a harmonised standard for the essential health and safety requirements and there are undue delays in the standardisation procedure;*

*(c) the request has, without reason, not been accepted by the European standardization organisations concerned.*

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).

Or. en

#### **Amendment 2131**

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Alin Mituţa**

#### **Proposal for a regulation Article 41 – paragraph 1**

*Text proposed by the Commission*

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, 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).

*Amendment*

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 ***shall issue a standardisation request to one or several of the European standardization organizations in accordance with Article 10 of Regulation 1025/2012 and*** may, by means of implementing acts, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title, ***which shall only be valid until the requested harmonised standards have been elaborated and published in the Official Journal of the European Union.*** Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).

Or. en

**Amendment 2132**

**Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura**

**Proposal for a regulation**

**Article 41 – paragraph 1**

*Text proposed by the Commission*

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, 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

*Amendment*

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, 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).

Article 74(2).

***The Commission shall adopt common specifications setting out how risk management systems should give specific consideration to interaction with or impact on children.***

Or. en

### **Amendment 2133**

**Svenja Hahn, Dragoş Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen**

#### **Proposal for a regulation**

##### **Article 41 – paragraph 1**

*Text proposed by the Commission*

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, 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).

*Amendment*

1. Where harmonised standards referred to in Article 40 do not exist ***and are not expected to be published within a reasonable period*** 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, 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).

Or. en

### **Amendment 2134**

**Andrea Caroppo, Salvatore De Meo**

#### **Proposal for a regulation**

##### **Article 41 – paragraph 1**

*Text proposed by the Commission*

1. Where harmonised standards

*Amendment*

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, 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).

referred to in Article 40 do not exist ***or relevant international standards do not apply*** 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, 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).

Or. en

### **Amendment 2135**

**Alessandra Basso, Marco Campomenosi, Isabella Tovaglieri, Mara Bizzotto, Silvia Sardone, Annalisa Tardino**

#### **Proposal for a regulation Article 41 – paragraph 1**

##### *Text proposed by the Commission*

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, 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).

##### *Amendment*

1. Where harmonised standards referred to in Article 40 ***and international standards*** 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, 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).

Or. en

### **Amendment 2136**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**

on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 41 – paragraph 1**

*Text proposed by the Commission*

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, 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).

*Amendment*

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, **accessibility**, or fundamental right concerns, the Commission may, 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).

Or. en

**Amendment 2137**  
**Marion Walsmann**

**Proposal for a regulation**  
**Article 41 – paragraph 1**

*Text proposed by the Commission*

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, 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).

*Amendment*

1. Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient, **because** there is a need to address specific safety or fundamental right concerns, the Commission may, 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).

**Amendment 2138**

**Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen**

**Proposal for a regulation**

**Article 41 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1 a. When deciding to draft and adopt common specifications, the Commission shall consult the Board, the European standardisation organisations as well as the relevant stakeholders, and duly justify why it decided not to use harmonised standards. The abovementioned organisations shall be regularly consulted while the Commission is in the process of drafting the common specifications.***

Or. en

**Amendment 2139**

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Malik Azmani, Svenja Hahn, Andrus Ansip, Dita Charanzová, Morten Løkkegaard, Alin Mituța**

**Proposal for a regulation**

**Article 41 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

2. The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant bodies or expert groups established under relevant sectorial Union law.

2. The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant ***stakeholders, including industry, start-ups, and SMEs, and of relevant*** bodies or expert groups established under relevant sectorial Union law.

Or. en

#### **Amendment 2140**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation**

#### **Article 41 – paragraph 2**

*Text proposed by the Commission*

2. **The Commission**, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant bodies or expert groups established under relevant sectorial Union law.

*Amendment*

2. When 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.

Or. en

#### **Amendment 2141**

**Svenja Hahn, Dragoş Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Catharina Rinzema, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen**

#### **Proposal for a regulation**

#### **Article 41 – paragraph 2**

*Text proposed by the Commission*

2. The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant bodies or expert groups established under relevant sectorial Union law.

*Amendment*

2. The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of **stakeholders, including SMEs and start-ups**, relevant bodies or expert groups established under relevant sectorial Union law.

Or. en

#### **Amendment 2142**

**Alessandra Basso, Marco Campomenosi, Isabella Tovaglieri, Mara Bizzotto, Silvia Sardone, Annalisa Tardino**

#### **Proposal for a regulation**

#### **Article 41 – paragraph 2**

*Text proposed by the Commission*

2. The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant bodies or expert groups established under relevant sectorial Union law.

*Amendment*

2. The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant bodies, **stakeholders** or expert groups established under relevant sectorial Union law.

Or. en

**Amendment 2143**  
**Marion Walsmann**

**Proposal for a regulation**  
**Article 41 – paragraph 2**

*Text proposed by the Commission*

2. The Commission, **when** preparing the common specifications referred to in paragraph 1, **shall gather the views of** relevant bodies **or** expert groups established under relevant sectorial Union law.

*Amendment*

2. The Commission **shall, before** preparing the common specifications referred to in paragraph 1, **consult** relevant bodies, expert groups **and other relevant stakeholders** established under relevant sectorial Union law.

Or. en

**Amendment 2144**  
**Andrea Caroppo, Salvatore De Meo**

**Proposal for a regulation**  
**Article 41 – paragraph 2**

*Text proposed by the Commission*

2. The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant bodies or expert groups established under relevant sectorial Union law.

*Amendment*

2. The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant bodies, **stakeholders** or expert groups established under relevant sectorial Union law.

Or. en

## Amendment 2145

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H el ene Laporte, Jean-Paul Garraud

### Proposal for a regulation Article 41 – paragraph 3

*Text proposed by the Commission*

*Amendment*

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.***

*deleted*

Or. fr

#### *Justification*

*It is dangerous to create a regime of legal presumption allowing a derogation from the obligations and guarantees under Title III, particularly where high-risk AI systems are concerned, given the specific risks they pose. These systems should be thoroughly and comprehensively checked on a systematic basis.*

## Amendment 2146

Axel Voss, Deirdre Clune, Eva Maydell

### Proposal for a regulation Article 41 – paragraph 3

*Text proposed by the Commission*

*Amendment*

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.

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, ***and as long as those requirements are not covered by harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.***

**Amendment 2147**

**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H el ene Laporte, Jean-Paul Garraud**

**Proposal for a regulation  
Article 41 – paragraph 4**

*Text proposed by the Commission*

*Amendment*

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

Or. fr

*Justification*

*The purpose of this Regulation is to make it possible to securely place AI systems on the market, including high-risk systems, with appropriate obligations and guarantees. It makes no sense to lay down these obligations and then allow providers not to comply with them. This will only create complexities in practice for providers and make the obligations under this Regulation incomprehensible.*

**Amendment 2148**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation  
Article 41 – paragraph 4**

*Text proposed by the Commission*

*Amendment*

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

4. Where providers do not comply with the common specifications referred to in paragraph 1, they shall duly justify that they have adopted technical solutions that **meet the requirements referred to in Chapter 2 to a level** at least equivalent thereto.

Or. en



#### **Amendment 2149**

**Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen**

#### **Proposal for a regulation**

#### **Article 41 – paragraph 4**

*Text proposed by the Commission*

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

*Amendment*

4. Where providers *of high-risk AI systems* do not comply with the common specifications referred to in paragraph 1, they shall duly justify that they have adopted technical solutions that are at least equivalent thereto.

Or. en

#### **Amendment 2150**

**Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen**

#### **Proposal for a regulation**

#### **Article 41 – paragraph 4 a (new)**

*Text proposed by the Commission*

*Amendment*

***4 a. If harmonised standards referred to in Article 40 are developed and the references to them are published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 in the future, the relevant common specifications shall no longer apply.***

Or. en

#### **Amendment 2151**

**Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura**

#### **Proposal for a regulation**

#### **Article 42**

*Text proposed by the Commission*

*Amendment*

***Presumption of conformity with certain requirements***

***1. Taking into account their intended purpose, high-risk AI systems that have been trained and tested on data concerning the specific geographical, behavioural and functional setting within which they are intended to be used shall be presumed to be in compliance with the requirement 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<sup>63</sup> 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.***

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<sup>63</sup> 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).

Or. en

**Amendment 2152**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 42 – paragraph 1**

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 2153**

**Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura**

**Proposal for a regulation**

**Article 42 – paragraph 1**

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 2154**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**

**Article 42 – paragraph 1**

*Text proposed by the Commission*

1. ***Taking into account their intended purpose***, high-risk AI systems that have been trained and tested on data ***concerning*** the specific geographical, behavioural and functional setting within which they are

*Amendment*

1. High-risk AI systems that have been trained and tested on data ***reflecting*** the specific geographical, behavioural and functional setting within which they are intended to be used shall be presumed to be

intended to be used shall be presumed to be in compliance with the **requirement** set out in Article 10(4).

in compliance with the **respective requirements** set out in Article 10(4).

Or. en

## Amendment 2155

Axel Voss, Deirdre Clune, Eva Maydell

### Proposal for a regulation

#### Article 42 – paragraph 2

##### *Text proposed by the Commission*

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<sup>63</sup> 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.

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<sup>63</sup> 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).

##### *Amendment*

2. High-risk AI systems that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme to Regulation (EU) 2019/881 of the European Parliament and of the Council<sup>63</sup> **or pursuant to other harmonization legislation in the field of security of network and information systems and electronic communications networks and services** 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.

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<sup>63</sup> 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).

Or. en

## Amendment 2156

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä  
on behalf of the Verts/ALE Group

### Proposal for a regulation

#### Article 43 – title

*Text proposed by the Commission*

Conformity assessment

*Amendment*

***Third party*** conformity assessment

Or. en

## Amendment 2157

Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

### Proposal for a regulation

#### Article 43 – paragraph 1 – introductory part

*Text proposed by the Commission*

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 ***one*** of the ***following procedures***:

*Amendment*

1. For high-risk AI systems listed in point 1, ***3 and 4*** 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 ***follow 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.***

Or. en

## Amendment 2158

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H el ene Laporte, Jean-Paul Garraud

### Proposal for a regulation

#### Article 43 – paragraph 1 – introductory part

*Text proposed by the Commission*

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 **one** of the **following procedures**:

*Amendment*

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 **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.**

Or. fr

**Amendment 2159**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

**Proposal for a regulation**

**Article 43 – paragraph 1 – introductory part**

*Text proposed by the Commission*

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 **one** of the **following procedures**:

*Amendment*

1. For high-risk AI systems listed in 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 **not** applied harmonised standards referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall follow **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.**

Or. en

### *Justification*

*Use cases listed in Annex III have a major impact on people's lives and therefore it is necessary for AI systems intended to be used in these cases to be assessed by a notified body before they are placed on the market.*

#### **Amendment 2160**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

#### **Article 43 – paragraph 1 – introductory part**

##### *Text proposed by the Commission*

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 one of the following procedures:**

##### *Amendment*

1. For high-risk AI systems listed in Annex III the provider shall **have a conformity assessment carried out by an independent third-party**, following **the conformity assessment procedure set out in Annex VII.**

Or. en

### *Justification*

*integrating with next paragraph*

#### **Amendment 2161**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation**

#### **Article 43 – paragraph 1 – introductory part**

##### *Text proposed by the Commission*

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,

##### *Amendment*

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** one of the following procedures:

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

Or. en

#### **Amendment 2162**

**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H el ene Laporte, Jean-Paul Garraud**

#### **Proposal for a regulation**

**Article 43 – paragraph 1 – point a**

*Text proposed by the Commission*

*Amendment*

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

Or. fr

#### *Justification*

*We propose to abolish the assessment procedure based on internal control.*

#### **Amendment 2163**

**Kateřina Kone n , Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura**

#### **Proposal for a regulation**

**Article 43 – paragraph 1 – point a**

*Text proposed by the Commission*

*Amendment*

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

Or. en

#### **Amendment 2164**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Ren  Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado L pez, Maria-Manuel Leit o-Marques, Marc Angel**



**Proposal for a regulation**  
**Article 43 – paragraph 1 – point a**

*Text proposed by the Commission*

*Amendment*

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

Or. en

**Amendment 2165**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 43 – paragraph 1 – point a**

*Text proposed by the Commission*

*Amendment*

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

Or. en

*Justification*

*integrated into para 1*

**Amendment 2166**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**  
**Article 43 – paragraph 1 – point a**

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

**Amendment 2167**

**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud**

**Proposal for a regulation  
Article 43 – paragraph 1 – point b**

*Text proposed by the Commission*

*Amendment*

**(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.** *deleted*

Or. fr

*Justification*

*Since subparagraph (a) is deleted, the existence of a subparagraph (b) is no longer justified, as its text is directly incorporated into the body of paragraph 1.*

**Amendment 2168**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

**Proposal for a regulation  
Article 43 – paragraph 1 – point b**

*Text proposed by the Commission*

*Amendment*

**(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.** *deleted*

Or. en

**Amendment 2169**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**

## Article 43 – paragraph 1 – point b

*Text proposed by the Commission*

*Amendment*

**(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.**

**deleted**

Or. en

*Justification*

*integrated into para 1*

### Amendment 2170

**Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura**

#### Proposal for a regulation

## Article 43 – paragraph 1 – point b

*Text proposed by the Commission*

*Amendment*

(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.

(b) the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation, ***documentation of analysis and achievement of the tests of strict necessity, proportionality and legality of the system, as well as any associated database or data repository on which it relies***; with the involvement of a notified body, referred to in Annex VII, ***and with the involvement of the relevant national data protection authority***.

Or. en

### Amendment 2171

**Axel Voss, Deirdre Clune, Eva Maydell**

#### Proposal for a regulation

## Article 43 – paragraph 1 – point b

*Text proposed by the Commission*

*Amendment*

(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.

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

Or. en

**Amendment 2172**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 43 – paragraph 1 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

***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.***

***deleted***

Or. en

*Justification*

*integrated into para 1*

**Amendment 2173**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

**Proposal for a regulation**

**Article 43 – paragraph 1 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

***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.***

***deleted***

Or. en

#### **Amendment 2174**

**Alessandra Basso, Marco Campomenosi, Isabella Tovaglieri, Mara Bizzotto, Silvia Sardone, Annalisa Tardino**

#### **Proposal for a regulation**

#### **Article 43 – paragraph 1 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

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.

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. ***Should the provider already have established internal organisation and structures for existing conformity assessments or requirements under other existing rules, the provider may utilise those, or parts of those, existing compliance structures, so long as they also have the capacity and competence needed to fulfil the requirements for the product set out in this Regulation.***

Or. en

**Amendment 2175**  
**Sophia in 't Veld, Michal Šimečka**

**Proposal for a regulation**  
**Article 43 – paragraph 1 – subparagraph 2**

*Text proposed by the Commission*

*Amendment*

*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.*

*deleted*

Or. en

**Amendment 2176**  
**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

**Proposal for a regulation**  
**Article 43 – paragraph 1 – subparagraph 2**

*Text proposed by the Commission*

*Amendment*

*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.*

*deleted*

Or. en

**Amendment 2177**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 43 – paragraph 1 – subparagraph 2**

*Text proposed by the Commission*

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.

*Amendment*

For the purpose of **carrying out** 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.

Or. en

**Amendment 2178**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

**Proposal for a regulation**

**Article 43 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1 a. Without prejudice to paragraph 1, if the provider has applied harmonised standard referred to in Article 40, or where applicable, common specifications referred to in Article 41, it shall follow the conformity assessment procedure based on internal control referred to in Annex VI.***

Or. en

**Amendment 2179**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

**Proposal for a regulation**

**Article 43 – paragraph 1 b (new)**

*Text proposed by the Commission*

*Amendment*

***1 b. In the following cases, the compliance of the high-risk AI system with requirements laid down in Chapter 2 of this Title shall be assessed following the conformity assessment procedure based on the assessment of the quality management system and the assessment of the technical documentation, with the involvement of a notified body, referred to in Annex VII:***

***(a) where harmonised standards, the reference number of which has been published in the Official Journal of the European Union, covering all relevant safety requirements for the AI system, do not exist;***

***(b) where the harmonised standards referred to in point (a) exist but the manufacturer has not applied them or has applied them only in part;***

***(c) where one or more of the harmonised standards referred to in point (a) has been published with a restriction;***

***(d) when the provider considers that the nature, design, construction or purpose of the AI system necessitate third party verification.***

Or. en

**Amendment 2180**

**Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura**

**Proposal for a regulation**

**Article 43 – paragraph 2**



*Text proposed by the Commission*

*Amendment*

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 to 101 of that Directive.

2. 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 to 101 of that Directive.

Or. en

**Amendment 2181**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 43 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

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 to 101 of that Directive.

2. 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 to 101 of that Directive.

Or. en

**Amendment 2182**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

**Proposal for a regulation  
Article 43 – paragraph 2**

*Text proposed by the Commission*

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 to 101 of that Directive.

*Amendment*

2. 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 to 101 of that Directive.

Or. en

**Amendment 2183**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation  
Article 43 – paragraph 2**

*Text proposed by the Commission*

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 to 101 of that Directive.

*Amendment*

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 ***based on internal control shall be verified by means of an ex-post assessment and*** carried out as part of the procedure referred

to in Articles 97 to 101 of that Directive **but only to the extent that prudential risks and related requirements are concerned.**

Or. en

#### **Amendment 2184**

**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H el ene Laporte, Jean-Paul Garraud**

#### **Proposal for a regulation Article 43 – paragraph 2**

##### *Text proposed by the Commission*

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 to 101 of that Directive.

##### *Amendment*

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 **assessment of the quality management system and assessment of the technical documentation, with** the involvement of a notified body, **referred to in Annex VII.** 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 to 101 of that Directive.

Or. fr

#### **Amendment 2185**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation Article 43 – paragraph 3 – introductory part**

##### *Text proposed by the Commission*

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

##### *Amendment*

3. For high-risk AI systems, to which legal acts listed in Annex II, section A, apply, **and which are subject to points 1 and 2 of Article 6** the provider shall follow

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.

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.

Or. en

#### **Amendment 2186**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

#### **Article 43 – paragraph 3 – subparagraph 2**

*Text proposed by the Commission*

*Amendment*

*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.*

*deleted*

Or. en

#### **Amendment 2187**

**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud**

#### **Proposal for a regulation**

#### **Article 43 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

**3a. High-risk AI systems shall**

*periodically be subject to a conformity assessment review procedure.*

Or. fr

#### **Amendment 2188**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation**

#### **Article 43 – paragraph 4 – introductory part**

*Text proposed by the Commission*

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.

*Amendment*

4. High-risk AI systems, ***that have already been subject to a conformity assessment procedure***, shall undergo a new conformity assessment procedure ***in line with the provisions foreseen by the legal acts listed in Annex II, section A***, 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.

Or. en

#### **Amendment 2189**

**Sophia in 't Veld, Michal Šimečka**

#### **Proposal for a regulation**

#### **Article 43 – paragraph 4 – introductory part**

*Text proposed by the Commission*

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.

*Amendment*

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, ***or whenever a change occurs which may affect the compliance with this Regulation.***

Or. en

## Amendment 2190

Jürgen Warborn, Arba Kokalari, Tomas Tobé

### Proposal for a regulation

#### Article 43 – paragraph 4 – introductory part

*Text proposed by the Commission*

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.

*Amendment*

4. High-risk AI systems shall undergo a new conformity assessment procedure whenever they are substantially modified **and the changes could impact performance related to essential requirements**, regardless of whether the modified system is intended to be further distributed or continues to be used by the current user.

Or. en

*Justification*

*Only changes that could impact performance related to essential requirements should be taken into account*

## Amendment 2191

Svenja Hahn, Dragoş Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

### Proposal for a regulation

#### Article 43 – paragraph 4 – introductory part

*Text proposed by the Commission*

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.

*Amendment*

4. High-risk AI systems **that have already been subject to a conformity assessment procedure** shall undergo a new conformity assessment procedure whenever they are substantially modified, **if** the modified system is intended to be further distributed or continues to be used by the current user.

Or. en

## Amendment 2192

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä  
on behalf of the Verts/ALE Group

### Proposal for a regulation

#### Article 43 – paragraph 4 – introductory part

*Text proposed by the Commission*

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**.

*Amendment*

4. High-risk AI systems shall undergo a new **third party** 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 **deployer**.

Or. en

## Amendment 2193

Svenja Hahn, Dragoş Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

### Proposal for a regulation

#### Article 43 – paragraph 4 – subparagraph 1

*Text proposed by the Commission*

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.

*Amendment*

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.  
***The same should apply to updates of the AI system for security reasons in general and to protect against evolving threats of manipulation of the system as long as the update does not include significant changes to the functionality of the system.***

Or. en

## Amendment 2194

Kateřina Konečná, Fernando Barrena Arza, Cornelia Ernst, Elena Kountoura

### Proposal for a regulation

#### Article 43 – paragraph 4 – subparagraph 1

*Text proposed by the Commission*

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.

*Amendment*

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. ***A new conformity assessment is always required whenever safety-related limits of continuing learning high-risk AI systems may be exceeded or have an impact on the health or safety.***

Or. en

## Amendment 2195

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H  l  ne Laporte, Jean-Paul Garraud

### Proposal for a regulation

#### Article 43 – paragraph 4 – subparagraph 1

*Text proposed by the Commission*

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.***

*Amendment*

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 ***shall constitute a substantial modification, including if they*** 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.

Or. fr



**Amendment 2196**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**

**Article 43 – paragraph 4 – subparagraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

*The same should apply to updates of the AI system for security reasons in general and to protect against evolving threats of manipulation of the system. This paragraph only applies if the Member State has established a legal framework, which allows the provider of a high risk AI system, which autonomously make substantial modifications to itself, to regularly perform an automated real-time conformity assessment procedure.*

Or. en

**Amendment 2197**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

**Proposal for a regulation**

**Article 43 – paragraph 4 a (new)**

*Text proposed by the Commission*

*Amendment*

*4 a. The specific interests and needs of the small-scale providers shall be taken into account when setting the fees for third-party conformity assessment under this Article, reducing those fees proportionately to their size and market size.*

Or. en

*Justification*

*If the fees for third-party conformity assessments are reduced for small-scale operators, it will become convenient for them to use this procedure and this will in turn ensure legal*

*certainty for them.*

**Amendment 2198**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**

**Article 43 – paragraph 4 a (new)**

*Text proposed by the Commission*

*Amendment*

**4 a. Any provider may voluntarily apply for a third-party conformity assessment regardless of the risk level of their AI system.**

Or. en

**Amendment 2199**

**Jörgen Warborn, Arba Kokalari, Tomas Tobé**

**Proposal for a regulation**

**Article 43 – paragraph 5**

*Text proposed by the Commission*

*Amendment*

**5. The 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.**

**deleted**

Or. en

**Amendment 2200**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**

**Article 43 – paragraph 5**

*Text proposed by the Commission*

*Amendment*

**5. The Commission is empowered to adopt delegated acts in accordance with**

**5. After consulting the AI Board referred to in Article 56 and after**

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.

***providing substantial evidence, followed by thorough consultation and the involvement of the affected stakeholders,*** the 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 ***amend*** elements of the conformity assessment procedures that become necessary ***or unnecessary*** in light of technical progress.

Or. en

#### **Amendment 2201**

**Svenja Hahn, Dragoş Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen**

#### **Proposal for a regulation Article 43 – paragraph 5**

##### *Text proposed by the Commission*

5. The 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.

##### *Amendment*

5. ***After consulting the AI Board referred to in Article 56 and after providing substantial evidence, followed by thorough consultation and the involvement of the affected stakeholders,*** the 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.

Or. en

#### **Amendment 2202**

**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H  l  ne Laporte, Jean-Paul Garraud**

#### **Proposal for a regulation Article 43 – paragraph 5**

##### *Text proposed by the Commission*

##### *Amendment*

5. The 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.

5. The Commission is empowered to adopt delegated acts in accordance with Article 73 for the purpose of updating Annex VII in order to introduce elements of the conformity assessment procedures that become necessary in light of technical progress.

Or. fr

#### Amendment 2203

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H  l  ne Laporte, Jean-Paul Garraud

#### Proposal for a regulation Article 43 – paragraph 6

*Text proposed by the Commission*

*Amendment*

**6. The 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.**

**deleted**

Or. fr

#### *Justification*

*Since the conformity assessment procedure based on internal control referred to in Article VI has been deleted, as has Annex VI, it is no longer necessary for the Commission to submit exceptionally by delegated act certain high-risk AI systems to the conformity assessment procedure referred to in Annex VII.*

#### **Amendment 2204**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation** **Article 43 – paragraph 6**

*Text proposed by the Commission*

*Amendment*

**6. The 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.** *deleted*

Or. en

#### **Amendment 2205**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

#### **Proposal for a regulation** **Article 43 – paragraph 6**

*Text proposed by the Commission*

*Amendment*

**6. The 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** *deleted*

*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.*

Or. en

**Amendment 2206**

**Jürgen Warborn, Arba Kokalari, Tomas Tobé**

**Proposal for a regulation**

**Article 43 – paragraph 6**

*Text proposed by the Commission*

*Amendment*

**6. The 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.**

*deleted*

Or. en

**Amendment 2207**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**

**Article 43 – paragraph 6**

6. The 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.

6. ***After consulting the AI Board referred to in Article 56 and after providing substantial evidence, followed by thorough consultation and the involvement of the affected stakeholders,*** the 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.

Or. en

#### **Amendment 2208**

**Svenja Hahn, Dragoş Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen**

#### **Proposal for a regulation Article 43 – paragraph 6**

6. The 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

6. ***After consulting the AI Board referred to in Article 56 and after providing substantial evidence, followed by thorough consultation and the involvement of the affected stakeholders,*** the 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

by such systems as well as the availability of adequate capacities and resources among notified bodies.

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.

Or. en

#### Amendment 2209

**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H el ene Laporte, Jean-Paul Garraud**

#### Proposal for a regulation Article 44 – paragraph 1

*Text proposed by the Commission*

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*.

*Amendment*

1. Certificates issued by notified bodies in accordance with Annex VII shall be drawn-up in **the** official Union language **of** the Member State in which the notified body is established.

Or. fr

#### Amendment 2210

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alamets a**  
on behalf of the Verts/ALE Group

#### Proposal for a regulation Article 44 – paragraph 3

*Text proposed by the Commission*

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

*Amendment*

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 suspend or withdraw the certificate issued or impose any restrictions on it, unless compliance with those requirements is ensured by appropriate



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.

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.

Or. en

#### **Amendment 2211**

**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H el ene Laporte, Jean-Paul Garraud**

#### **Proposal for a regulation**

#### **Article 46 – paragraph 2 – introductory part**

*Text proposed by the Commission*

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

*Amendment*

2. Each notified body shall inform the other notified bodies **and the notifying authority** of:

Or. fr

#### **Amendment 2212**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation**

#### **Article 46 – paragraph 3**

*Text proposed by the Commission*

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.

*Amendment*

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

Or. en

#### **Amendment 2213**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alamets a**

on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 46 – paragraph 3**

*Text proposed by the Commission*

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.

*Amendment*

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

Or. en

**Amendment 2214**

**Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura**

**Proposal for a regulation**  
**Article 47**

*Text proposed by the Commission*

[...]

*Amendment*

*deleted*

Or. en

**Amendment 2215**

**Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini**

**Proposal for a regulation**  
**Article 47**

*Text proposed by the Commission*

[...]

*Amendment*

*deleted*

Or. en

**Amendment 2216**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**

on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 47 – paragraph 1**

*Text proposed by the Commission*

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.

*Amendment*

1. By way of derogation from Article 43, any market surveillance authority may ***request a judicial authority to*** 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.

Or. en

**Amendment 2217**  
**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**  
**Article 47 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1 a. 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, and if such authorisation is rejected, its use shall be***

*stopped with immediate effect.*

Or. en

### **Amendment 2218**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation** **Article 47 – paragraph 2**

*Text proposed by the Commission*

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.

*Amendment*

2. The authorisation referred to in paragraph 1 shall be issued only if the market surveillance authority **and judicial authority conclude** 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 **request made and any subsequent** authorisation issued pursuant to paragraph 1.

Or. en

### **Amendment 2219**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation** **Article 47 – paragraph 3**

*Text proposed by the Commission*

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.

*Amendment*

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 **to the request of the market surveillance authority for** an authorisation issued by a market surveillance authority of a Member State in accordance with paragraph 1, that **request** shall be deemed justified.

**Amendment 2220****Axel Voss, Deirdre Clune, Eva Maydell****Proposal for a regulation****Article 47 – paragraph 4***Text proposed by the Commission*

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*.

*Amendment*

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(s).

Or. en

**Amendment 2221****Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group**Proposal for a regulation****Article 47 – paragraph 4***Text proposed by the Commission*

4. Where, within 15 calendar days of receipt of the notification referred to in paragraph 2, objections are raised by a

*Amendment*

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.

Member State against **a request** issued by a market surveillance authority of another Member State, or where the Commission considers the **request** 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 **request** is justified or not. The Commission shall address its decision to the Member State concerned and the relevant operator or operators.

Or. en

#### **Amendment 2222**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation** **Article 47 – paragraph 5**

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

#### **Amendment 2223**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation** **Article 48 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

1. The *provider* shall draw up a written 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 to the relevant national competent authorities upon request.

1. The *notifying authority after third party conformity assessment* shall draw up a written **physical and machine-readable electronic** EU declaration of conformity for each AI system and keep it at the disposal of the national competent authorities for **15** 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 to the relevant national competent authorities upon request.

Or. en

#### **Amendment 2224**

**Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini**

#### **Proposal for a regulation Article 48 – paragraph 1**

##### *Text proposed by the Commission*

1. The provider shall draw up a written 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 to the relevant national competent authorities upon request.

##### *Amendment*

1. The provider shall draw up a written EU declaration of conformity for each **high-risk** AI system and keep it at the disposal of the national **supervisory authority and the national** competent authorities after the **high-risk** AI system has been placed on the market or put into service **for the entire lifecycle of the high-risk** AI system. A copy of the EU declaration of conformity shall be given to the **national supervisory authority and the** relevant national competent authorities upon request.

Or. en

#### **Amendment 2225**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation**

## Article 48 – paragraph 1

*Text proposed by the Commission*

1. The provider shall draw up a written 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** to the relevant national competent authorities upon request.

*Amendment*

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 **submitted** to the relevant national competent authorities upon request.

Or. en

### Amendment 2226

**Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini**

#### Proposal for a regulation Article 48 – paragraph 2

*Text proposed by the Commission*

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.

*Amendment*

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, **including the requirements related to the respect of the Union data protection acquis**. 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 **placed on the market or** made available.

Or. en

### Amendment 2227



Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 48 – paragraph 4**

*Text proposed by the Commission*

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.**

*Amendment*

4. **After receiving** the EU declaration of conformity, the provider shall assume responsibility for **continuous** compliance with the requirements set out in Chapter 2 of this Title **throughout the entire lifecycle.**

Or. en

**Amendment 2228**  
**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**  
**Article 48 – paragraph 5**

*Text proposed by the Commission*

5. The 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.

*Amendment*

5. **After consulting the Board,** the 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.

Or. en

**Amendment 2229**  
**Andrea Caroppo, Salvatore De Meo**

**Proposal for a regulation**  
**Article 49 – paragraph 1**

*Text proposed by the Commission*

1. The CE marking shall be **affixed**

*Amendment*

1. The CE marking shall be **in digital**

*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.*

*format* for high-risk AI systems.

Or. en

#### **Amendment 2230**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

#### **Proposal for a regulation Article 49 – paragraph 1**

##### *Text proposed by the Commission*

1. 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.

##### *Amendment*

1. The CE marking shall be affixed visibly, legibly and indelibly for high-risk AI systems ***before the high-risk AI system is placed on the market.*** 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. ***It may be followed by a pictogram or any other marking indicating a special risk or use.***

Or. en

#### **Amendment 2231**

**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H el ene Laporte, Jean-Paul Garraud**

#### **Proposal for a regulation Article 49 – paragraph 1**

##### *Text proposed by the Commission*

1. 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

##### *Amendment*

1. The CE marking shall be affixed visibly, legibly and indelibly for high-risk AI systems ***before they are placed on the market, made available on the market or***

the high-risk AI system, it shall be affixed to the packaging or to the accompanying documentation, as appropriate.

*put into service*. 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.

Or. fr

#### **Amendment 2232**

**Svenja Hahn, Dragoş Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen**

#### **Proposal for a regulation Article 49 – paragraph 1**

##### *Text proposed by the Commission*

1. 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.

##### *Amendment*

1. The *physical* 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.

Or. en

#### **Amendment 2233**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation Article 49 – paragraph 1**

##### *Text proposed by the Commission*

1. 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.

##### *Amendment*

1. The *physical* 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.

**Amendment 2234**

**Svenja Hahn, Dragoş Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen**

**Proposal for a regulation**

**Article 49 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1 a. A digital CE marking may be used instead of or additionally to the physical marking if it can be accessed via the display of the product or via a machine-readable code or other electronic means.***

Or. en

**Amendment 2235**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**

**Article 49 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1 a. An electronic CE marking may replace the physical marking if it can be accessed via the display of the product or via a machine-readable code.***

Or. en

**Amendment 2236**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

**Proposal for a regulation**

**Article 49 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

**3 a. Where high-risk AI systems are subject to other Union legislation which also provides for the affixing of the CE marking, the CE marking shall indicate that the high-risk AI system also fulfil the requirements of that other legislation.**

Or. en

*Justification*

*Similar provision to the Medical Devices Regulation.*

**Amendment 2237**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**

**Article 50**

*Text proposed by the Commission*

*Amendment*

**Article 50**

**deleted**

**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.***

Or. en

**Amendment 2238**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

**Proposal for a regulation**

**Article 50 – paragraph 1 – introductory part**

*Text proposed by the Commission*

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:

*Amendment*

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

Or. en

**Amendment 2239**

**Jörgen Warborn, Arba Kokalari, Tomas Tobé**

**Proposal for a regulation**

**Article 50 – paragraph 1 – introductory part**

*Text proposed by the Commission*

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:

*Amendment*

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

Or. en

**Amendment 2240**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 50 – paragraph 1 – introductory part**

*Text proposed by the Commission*

The provider shall, for a period ending **10**

*Amendment*

The provider shall, for a period ending **15**

years after the AI system has been placed on the market or put into service, keep at the disposal of the national competent authorities:

years after the AI system has been placed on the market or put into service, keep at the disposal of the national competent authorities:

Or. en

#### **Amendment 2241**

**Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen**

#### **Proposal for a regulation**

#### **Article 50 – paragraph 1 – introductory part**

##### *Text proposed by the Commission*

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:

##### *Amendment*

The provider shall, for a period ending **5** years after the AI system has been placed on the market or put into service, keep at the disposal of the national competent authorities:

Or. en

#### **Amendment 2242**

**Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar**

#### **Proposal for a regulation**

#### **Article 50 – paragraph 1 – introductory part**

##### *Text proposed by the Commission*

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:

##### *Amendment*

The provider shall, for ***the entire lifecycle of the AI system***, keep at the disposal of the national ***supervisory authority and the national*** competent authorities:

Or. en

#### **Amendment 2243**

**Jörgen Warborn, Arba Kokalari, Tomas Tobé**

**Proposal for a regulation**  
**Article 51**

*Text proposed by the Commission*

*Amendment*

*Article 51*

*deleted*

**Registration**

***Before placing on the market or putting into service a high-risk AI system referred to in Article 6(2), the provider or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60.***

Or. en

*Justification*

*This is unnecessarily bureaucratic and creates no added value in terms of safety and trustworthiness of AI systems.*

**Amendment 2244**

**Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen**

**Proposal for a regulation**  
**Article 51 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

Before placing on the market or putting into service a high-risk AI system referred to in Article 6(2), the provider or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60.

Before placing on the market or putting into service a high-risk AI system referred to in Article 6(2) **and Article 6a**, the provider or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60.

Or. en

**Amendment 2245**

**Krzysztof Hetman, Adam Jarubas, Andrzej Halicki, Jerzy Buzek, Janusz Lewandowski, Radosław Sikorski**

**Proposal for a regulation**  
**Article 51 – paragraph 1**



*Text proposed by the Commission*

Before placing on the market or putting into service a high-risk AI system referred to in Article 6(2), the provider or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60.

*Amendment*

**1.** Before placing on the market or putting into service a high-risk AI system referred to in Article 6(2), the provider or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60.

Or. en

**Amendment 2246**

**Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura**

**Proposal for a regulation  
Article 51 – paragraph 1**

*Text proposed by the Commission*

Before placing on the market or putting into service **a high-risk** AI system **referred to in Article 6(2)**, the provider or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60.

*Amendment*

Before placing on the market or putting into service **an** AI system, the provider or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60.

Or. en

**Amendment 2247**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation  
Article 51 – paragraph 1**

*Text proposed by the Commission*

Before placing on the market or putting into service a high-risk AI system referred to in Article **6(2)**, the provider or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60.

*Amendment*

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

Or. en

**Amendment 2248**

**Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar**

**Proposal for a regulation**

**Article 51 – paragraph 1**

*Text proposed by the Commission*

Before placing on the market or putting into service a high-risk AI system referred to in Article 6(2), the provider ***or, where applicable, the authorised representative*** shall register that system in the EU database referred to in Article 60.

*Amendment*

Before placing on the market or putting into service a high-risk AI system referred to in Article 6(2), the provider shall register that system in the EU database referred to in Article 60, ***in accordance with Article 60(2)***.

Or. en

**Amendment 2249**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**

**Article 51 – paragraph 1**

*Text proposed by the Commission*

Before placing on the market or putting into service a high-risk AI system ***referred to in Article 6(2)***, the provider or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60.

*Amendment*

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

Or. en

**Amendment 2250**

**Krzysztof Hetman, Adam Jarubas, Andrzej Halicki, Jerzy Buzek, Janusz Lewandowski, Radosław Sikorski**

**Proposal for a regulation**

**Article 51 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***2. A high-risk AI system designed, developed, trained, validated, tested or approved to be placed on the market or put into service, outside the EU, can be registered in the EU database referred to in Article 60 and placed on the market or put into service in the EU only if it is proven that at all stages of its design, development, training, validation, testing or approval, all the obligations required from such AI systems in EU have been met;***

Or. en

**Amendment 2251**

**Kateřina Konečná, Fernando Barrena Arza, Cornelia Ernst, Elena Kountoura**

**Proposal for a regulation**

**Article 51 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***Before using a high-risk AI system referred to in Article 6(2), the user or, where applicable, the authorised representative, shall register the uses of that system in the EU database referred to in Article 60. A new registration entry must be completed by the user for each new use of a high-risk AI system.***

Or. en

**Amendment 2252**

**Svenja Hahn, Dragoş Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoş, Moritz Körner, Jan-Christoph Oetjen**

**Proposal for a regulation**

**Article 51 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***Before putting into service or using a high-risk AI system in one of the areas listed in Annex III, users who are public***

*authorities or Union institutions, bodies, offices or agencies or users acting on their behalf shall register in the EU database referred to in Article 60.*

Or. en

**Amendment 2253**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 51 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

*Before each deployment of, or substantial modification to, a high-risk AI system referred to in Article 6, the deployer or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60.*

Or. en

**Amendment 2254**

**Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan**

**Proposal for a regulation**

**Article 51 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

*Before using an AI system, public authorities shall register the uses of that system in the EU database referred to in Article 60. A new registration entry must be completed by the user for each use of an AI system.*

Or. en

**Amendment 2255**

**Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López**

**Aguilar, Maria Grapini**

**Proposal for a regulation  
Article 51 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***Before putting into service or using a high-risk AI system in accordance with Article 6(2), the user shall register in the EU database referred to in Article 60.***

Or. en

**Amendment 2256**

**Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura**

**Proposal for a regulation  
Article 51 – paragraph 1 b (new)**

*Text proposed by the Commission*

*Amendment*

***Before using an AI system, public authorities shall register the uses of that system in the EU database referred to in Article 60. A new registration entry must be completed by the user for each new use of an AI system.***

Or. en

**Amendment 2257**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation  
Article 51 – paragraph 1 b (new)**

*Text proposed by the Commission*

*Amendment*

***In case the provider or deployer is a public authority they shall register both high-risk AI systems and all other AI systems.***

Or. en

**Amendment 2258**

**Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini**

**Proposal for a regulation**

**Article 51 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 51 a**

**Legal representative**

- 1. Where an operator pursuant to Article 2 is established outside the Union, they shall designate, in writing, a legal representative in the Union.**
- 2. The legal representative shall reside or be established in one of the Member States where the activities pursuant to Article 2, paragraphs 1 and 1a, are taking place.**
- 3. The operator shall provide its legal representative with the necessary powers and resources to comply with its tasks under this Regulation and to cooperate with the competent authorities.**
- 4. The legal representative shall, where appropriate, also carry out the following compliance tasks:**
  - (a) keep a copy of the EU declaration of conformity and the technical documentation at the disposal of the national supervisory authority and the national competent authorities and national authorities referred to in Article 63(7);**
  - (b) provide a national supervisory authority or a national competent authority, upon a reasoned request, with all the information and documentation necessary to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title, including access to the logs automatically generated by the high-risk AI system to the extent such logs are**

*under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law;*

*(c) cooperate with the national supervisory authority or the national competent authorities, upon a reasoned request, on any action the latter takes in relation to the high-risk AI system;*

*(d) where applicable, comply with the registration obligations as referred into Article 51.*

*5. The legal representative shall be mandated to be addressed, in addition to or instead of the operator, by, in particular, national supervisory authority or the national competent authorities and affected persons, on all issues related to ensuring compliance with this Regulation.*

*6. The legal representative may be held liable for infringements of this Regulation, without prejudice to any liability of or legal actions against the operator, user or provider.*

Or. en

#### *Justification*

*To be included under a new Title IIIA OBLIGATIONS FOR OPERATORS ESTABLISHED OUTSIDE OF THE UNION*

#### **Amendment 2259**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

#### **Title IV**

*Text proposed by the Commission*

*Amendment*

**TRANSPARENCY OBLIGATIONS *FOR CERTAIN AI SYSTEMS***

**TRANSPARENCY OBLIGATIONS**

Or. en

### Amendment 2260

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä  
on behalf of the Verts/ALE Group

#### Proposal for a regulation

##### Article 52 – title

*Text proposed by the Commission*

Transparency obligations *for certain AI systems*

*Amendment*

Transparency obligations

Or. en

### Amendment 2261

Axel Voss, Deirdre Clune, Eva Maydell

#### Proposal for a regulation

##### Article 52 – paragraph 1

*Text proposed by the Commission*

1. Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that natural *persons are informed* that they are interacting with an AI system, unless this is obvious 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.

*Amendment*

1. Providers shall ensure that AI systems intended to *directly* interact with natural persons are designed and developed in such a way that *the AI system, the provider itself or the user can inform the natural person exposed to an AI system* that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. *Where relevant, this information shall also include which functions are AI enabled, if there is human oversight and who is responsible for the decision-making process.* 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.

Or. en

### Amendment 2262

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López



**Aguilar, Maria Grapini**

**Proposal for a regulation  
Article 52 – paragraph 1**

*Text proposed by the Commission*

1. Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that natural persons are informed that they are interacting with an AI system, ***unless this is obvious 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.***

*Amendment*

1. Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that natural persons are informed that they are interacting with an AI system.

Or. en

*Justification*

*This amendment is necessary in order to ensure consistency with the amendments introduced to Article 5.*

**Amendment 2263  
Dragoş Tudorache**

**Proposal for a regulation  
Article 52 – paragraph 1**

*Text proposed by the Commission*

1. Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that natural persons are informed that they are interacting with an AI system, unless this is obvious 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***

*Amendment*

1. Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that natural persons are informed that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use.

*criminal offence.*

Or. en

#### **Amendment 2264**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation** **Article 52 – paragraph 1**

*Text proposed by the Commission*

1. Providers shall ensure that AI systems ***intended to interact with natural persons*** are designed and developed in such a way that natural persons are informed that they are interacting with an AI system, unless this is obvious 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.***

*Amendment*

1. Providers shall ensure that AI systems are designed and developed in such a way that natural persons are informed ***without delay*** that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. This shall ***also include information on which components and functions are supported through AI, information which main parameters the AI system takes into account, and information on human oversight and which person is responsible for decisions made or influenced by the system as well as information on rectification, redress rights and options.***

Or. en

#### **Amendment 2265**

**Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Paul Tang, Maria Grapini**

#### **Proposal for a regulation** **Article 52 – paragraph 2**

*Text proposed by the Commission*

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***

*Amendment*

***deleted***

***AI systems used for biometric categorisation, which are permitted by law to detect, prevent and investigate criminal offences.***

Or. en

*Justification*

*Amendment necessary to ensure consistency with the amended Article 5.*

**Amendment 2266**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 52 – paragraph 2**

*Text proposed by the Commission*

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.***

*Amendment*

2. ***Deployers of a remote biometric*** recognition system or a biometric categorisation system shall inform of the operation of the system the natural persons exposed thereto. This shall ***also include information on which components and functions are supported through AI, information which main parameters the AI system takes into account, and information on human oversight and which person is responsible for decisions made or influenced by the system as well as information on rectification, redress rights and options.***

Or. en

**Amendment 2267**  
**Dragoş Tudorache**

**Proposal for a regulation**  
**Article 52 – paragraph 2**

*Text proposed by the Commission*

2. Users of an emotion recognition

*Amendment*

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.***

system or a biometric categorisation system shall inform of the operation of the system the natural persons exposed thereto.

Or. en

#### **Amendment 2268**

**Svenja Hahn, Dragoş Tudorache, Nicola Beer, Karen Melchior, Vlad-Marius Botoş, Abir Al-Sahlani, Moritz Körner, Jan-Christoph Oetjen**

#### **Proposal for a regulation Article 52 – paragraph 2**

##### *Text proposed by the Commission*

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.***

##### *Amendment*

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.

Or. en

##### *Justification*

*The reliability of emotional recognition systems is highly questionable and may infringe citizens' rights. At very least, suspects must be informed that they are exposed to such a system.*

#### **Amendment 2269**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation Article 52 – paragraph 3 – introductory part**

##### *Text proposed by the Commission*

3. Users of an AI system that generates or manipulates ***image***, audio or

##### *Amendment*

3. Users of an AI system that generates or manipulates audio or ***visual***

*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.

content that would falsely appear to be authentic or truthful **and which features depictions of people appearing to say or do things they did not say or do, without their consent** ('deep fake'), shall disclose that the content has been artificially generated or manipulated. **Disclosure shall mean labelling the content in a way that informs that the content is inauthentic and that is clearly visible for the recipient of that content. To label the content, users shall take into account the generally acknowledged state of the art and relevant harmonised standards and specifications.**

Or. en

## **Amendment 2270** **Geoffroy Didier**

### **Proposal for a regulation** **Article 52 – paragraph 3 – introductory part**

#### *Text proposed by the Commission*

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.

#### *Amendment*

3. Users of an AI system that generates or manipulates image, audio, **text, script** or video content that appreciably resembles existing persons, objects, places, **text, script** 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.

Or. en

#### *Justification*

*To guarantee a transparency over all manipulative AI system and to protect consumers, AI generated text and script should be disclosed.*

## **Amendment 2271** **Svenja Hahn, Dragoş Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen**

## Proposal for a regulation

### Article 52 – paragraph 3 – introductory part

*Text proposed by the Commission*

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.

*Amendment*

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, ***in an appropriate, clear and visible manner***, that the content has been artificially generated or manipulated.

Or. en

## Amendment 2272

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

## Proposal for a regulation

### Article 52 – paragraph 3 – introductory part

*Text proposed by the Commission*

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.

*Amendment*

3. ***Deployers*** of an AI system ***other than those in paragraphs 1 or 2***, 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.

Or. en

## Amendment 2273

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

## Proposal for a regulation

**Article 52 – paragraph 3 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

***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.*** **deleted**

Or. en

*Justification*

*Into para 3a (new)*

**Amendment 2274**

**Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Paul Tang, Maria Grapini**

**Proposal for a regulation**

**Article 52 – paragraph 3 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

***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.*** **deleted**

Or. en

*Justification*

*Amendment necessary to ensure consistency with amended Article 5.*

## Amendment 2275

Axel Voss, Deirdre Clune, Eva Maydell

### Proposal for a regulation

#### Article 52 – paragraph 3 – subparagraph 1

*Text proposed by the Commission*

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.

*Amendment*

However, the first subparagraph shall not apply where the use ***of an AI system that generates or manipulates audio or visual content is authorized*** by law to detect, prevent, investigate and prosecute criminal offences ***or where the content forms part of an evidently creative, satirical, artistic or fictional cinematographic, video game visuals or analogous work*** 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.

Or. en

## Amendment 2276

Dragoş Tudorache

### Proposal for a regulation

#### Article 52 – paragraph 3 – subparagraph 1

*Text proposed by the Commission*

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.

*Amendment*

However, the first subparagraph shall not apply where 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.



**Amendment 2277****Geoffroy Didier****Proposal for a regulation****Article 52 – paragraph 3 – subparagraph 1***Text proposed by the Commission*

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.

*Amendment*

However, the first subparagraph shall not apply where the use is authorised by law to detect, prevent, investigate and prosecute criminal offences ***and shall be without prejudice to*** 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 to appropriate safeguards for the rights and freedoms of third parties.

Or. en

*Justification*

*To guarantee a transparency over all manipulative AI system and to protect consumers, AI generated text and script should be disclosed.*

**Amendment 2278****Svenja Hahn, Dragoş Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Moritz Körner, Jan-Christoph Oetjen****Proposal for a regulation****Article 52 – paragraph 3 – subparagraph 1***Text proposed by the Commission*

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

*Amendment*

However, the first subparagraph shall not apply where the ***content is part of an obviously artistic, creative or fictional cinematographic work*** 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

appropriate safeguards for the rights and freedoms of third parties.

rights and freedoms of third parties.

Or. en

**Amendment 2279**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 52 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

***3 a. Providers shall ensure that recommendation systems used to disseminate and order cultural and creative content are designed in such a way that the personalised suggestion is explainable and non-discriminatory. A clear explanation regarding the parameters determining ranking shall be provided to users and shall be easily accessible. Natural persons shall have the right to opt out of recommended and personalised services. This opt-out possibility shall be easily accessible and not prevent from using the core service.***

Or. en

*Justification*

*Personalised suggestions over cultural and creative content should be explainable to prevent users from being manipulated, to guarantee cultural diversity and to ensure the full implementation of the Article 13-1 AVMS directive. Users should have a right to opt out of recommended and personalised services to respect their rights of free choices.*

**Amendment 2280**  
**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 52 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

**3 a. The obligations in paragraphs 1, 2 and 3 shall be without prejudice to Union law on delaying information of subjects in ongoing criminal investigations, and be without prejudice to 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.**

Or. en

**Amendment 2281**  
**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**  
**Article 52 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

**3 a. 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.**

Or. en

**Amendment 2282**  
**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 52 – paragraph 4**

*Text proposed by the Commission*

*Amendment*

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

4. **The information in paragraphs 1, 2 and 3 shall be provided in an accessible, easy to understand, yet comprehensive manner, at least in one of the languages of the Member State in which the system was made available, and shall not affect the requirements and obligations set out in**

**Amendment 2283**

**Kateřina Konečn, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura**

**Proposal for a regulation**

**Article 52 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 52 a**

***1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list of AI systems subject to transparency obligations under Article 52 by adding AI systems that affect individuals or to which they are subject, where: the AI systems pose a risk of manipulation, harm to the health and safety, or a risk of adverse impact on fundamental rights, that is, in respect of its severity or probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the systems already referred to in Article 52.***

***2. When assessing for the purposes of paragraph 1 whether an AI system poses a risk that is equivalent to or greater than the risk of harm posed by the AI systems already referred to in Article 52, the Commission shall take into account the following non-cumulative criteria:***

***a. the intended purpose of the AI system, or the reasonably foreseeable consequences of its use;***

***b. the extent to which an AI system poses a risk of manipulation, or of adversely impacting one or more fundamental rights in a manner which could be to some degree mitigated by additional transparency measures;***

***c. the extent to which the use of an AI system impairs natural persons' agency, autonomy of choice or may lead to or***

*already has led to developing addictive behaviour;*

*d. the extent to which the use of an AI system may lead to or has already led to price discrimination or other form of economic harm;*

*e. the extent to which the use of an AI system may lead to or has already led to negative societal effects such as increased polarisation of opinions, insufficient exposure to objective sources of information and amplification of illegal online content.*

*f. the extent to which an AI system has been used or is likely to be used;*

*g. the extent to which the use of an AI system has already been shown to pose a risk in the senses of points b) to e) above, has caused harm to health and safety or disproportionate impact on fundamental rights or has given rise to significant concerns in relation to the materialisation of such harm or disproportionate impact, as demonstrated by reports or documented allegations available to national competent authorities;*

*h. the potential extent of such harm or such disproportionate impact, in particular in terms of its intensity and its ability to affect a plurality of persons or to affect a particular group of persons disproportionately;*

*i. the extent to which potentially harmed or adversely impacted persons are dependent on the outcome produced with an AI system, in particular because for practical or legal reasons it is not reasonably possible to opt-out from that outcome or from the functionality of the service which relies on the AI system;*

*j. the extent to which potentially harmed or adversely impacted persons are in a vulnerable position in relation to the user of an AI system, in particular due to an imbalance of power, knowledge, economic or social circumstances, accessibility*

*barriers, or age;*

*k. the extent to which the outcome produced with an AI system is not easily reversible, whereby outcomes having an impact on the health or safety of persons shall not be considered as easily reversible;*

*l. the extent to which existing Union legislation lacks: i. effective measures of redress in relation to the risks posed by an AI system, with the exclusion of claims for damages; ii. effective measures to prevent or substantially minimise those risks.*

Or. en

#### **Amendment 2284**

**Kosma Zlotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan**

#### **Proposal for a regulation**

#### **Article 52 a (new)**

*Text proposed by the Commission*

*Amendment*

#### *Article 52 a*

#### *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.*

Or. en

**Amendment 2285**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 52 a (new)**

*Text proposed by the Commission*

*Amendment*

*Article 52 a*

*Limitations for deep fakes of persons*

*Notwithstanding Article 52 and subject to appropriate safeguards for the rights and freedoms of third parties, the use of AI systems that generate or manipulate image, audio or video content that appreciably resembles existing persons and would falsely appear to a person to be authentic or truthful ('deep fake'), shall be permitted only*

*(a) when used for the exercise of the rights to freedom of expression and to artistic expression, or*

*(b) with the explicit consent of the affected persons.*

Or. en

**Amendment 2286**

**Pernando Barrena Arza, Cornelia Ernst**

**Proposal for a regulation**

**Title IV a (new)**

**Title GENERAL PURPOSE AI SYSTEMS**

**Article 52a (new): Establishment of the Navigator Programme for General purpose AI systems**

**1. A 'Navigator Programme for General purpose AI systems' (the 'Navigator Programme') is established and reports to the European AI Board referred to in Article 56.**

**2. The Navigator Programme shall provide advice and assistance to the Commission in order to:**

**(a) Develop, maintain and enforce a Code of Practice for General purpose AI systems research and development.**

**(b) Coordinate and contribute to the effective cooperation of the Commission and the developers of general purpose AI systems.**

**(c) Assist the Commission in ensuring the enforcement of this Regulation to general purpose AI systems**

**(d) Advise the Commission on the development or alteration of regulatory measures concerning general purpose AI systems to preserve fundamental rights, health and safety of citizens**

**3. The Navigator Programme shall be composed of staff selected for having the competences most appropriate to fulfill the Navigator Programme's**

**functions. External experts from government, civil society and academia may be invited on an ad hoc basis to advise on the issues related to the Navigator Programme's tasks. The Navigator Programme may invite observers to attend its non-confidential meetings and may hold exchanges with interested third parties to an appropriate extent. To that end the Commission may facilitate exchanges between the Navigator Programme and other Union bodies, offices, agencies and advisory groups.**

**4. The modalities and rules of procedure of the Navigator Programme shall be set**



*out in accordance with the internal rules of the Commission. The modalities shall also contain the operational aspects related to the execution of the Navigator Programme's tasks as listed in paragraph 7 of this Article.*

*5. The Navigator Programme shall have a sufficient number of competent personnel for assistance in the proper performance of its tasks.*

*6. The Navigator Programme shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its tasks. The Navigator Programme shall document and implement a structure and procedures to safeguard impartiality and to promote and apply the principles of impartiality throughout its tasks.*

*7. When providing advice and assistance to the Commission in the context of paragraph 2, the Navigator Programme shall in particular:*

*(a) Navigate developers of general purpose AI systems in the legal implications of their work for the health and safety and fundamental rights of EU citizens.*

*(b) Assign a staff member for each identified team of developers of General purpose AI systems to have direct bilateral monthly conversations on relevant advances and implications of the General purpose AI system in question. These conversations shall cover:*

*(i) the latest progress and experimentation in the general purpose AI system team including findings related to unexpected behaviors and upcoming research projects,*

*(ii) design measures taken to identify and mitigate risks prior to development,*

*(iii) demonstrations ('demos') of new versions of the model and of its compliance-by-design features,*

*(iv) steps to take to manage the model's implications for fundamental rights, health and safety in line with this Regulation,*

*(v) measures in place within the*

*developers team for quality assurance and risk management and in the design of upcoming general purpose system for accuracy, robustness and control,*

*(vi) the current usage of the general purpose AI system by other providers, including the estimated number of end-users affected by the general purpose AI system's output monthly, the sectoral, functional, geographic and demographic distribution of applications based on the general purpose AI system, the novel applications, etc.*

*(vii) the adequacy of the self-regulatory measures and of the help provided by the authorities for compliance with the Code of Practice,*

*(viii) the adequacy of the Code of Practice in helping fulfill this Regulation objective of AI adoption and the protection of citizens' fundamental rights, health and safety and societal interest of the Union,*

*(ix) the state of the art of general purpose AI system research and development and the identification of new competing development teams worldwide that would benefit from joining the Navigator Programme.*

*(c) Build and maintain mutual understanding and a common evidence base over the years on general purpose AI systems, their implications, and measures to govern them.*

*(d) Build and maintain trust-based relationships with the developers.*

*(e) Gain expertise on the topic of general purpose AI systems and transfer this expertise as appropriate to all decisions taken by the Commission related to AI systems.*

*(f) Issue opinions, recommendations or written contributions on matters related to the application of the Union's regulations to general purpose AI systems.*

*(g) Develop, maintain and update a database of identified general purpose AI systems with assessment of their influence.*

*(h) Develop, maintain and update a list of upcoming general purpose AI systems*

*research and development projects by developer teams of existing general purpose AI systems,*

*8. The conversations and correspondence generated in the scope of the Navigator Programme shall be covered by a strict confidentiality agreement.*

*9. In particular, the staff members of the Navigator Programme may not share with each other confidential or commercially sensitive information about their assigned general purpose AI system.*

*10. The Navigator Programme shall have documented procedures in place ensuring that its personnel, observers, external experts, 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 its tasks, except when disclosure is required by law. The staff of the Navigator Programme shall be bound to observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation. The staff of the Navigator Programme shall undergo a cooldown period of 5 years after interruption of their contract during which they may not gain from the confidential information they have acquired, neither through entrepreneurial ventures nor contracts nor employments.*

*11. Any information and documentation obtained by the Navigator Programme and its staff during the performance of their duty shall be treated in compliance with the confidentiality obligations set out in Article 70.*

*12. The Code of Practice for general purpose AI systems research and development (the ‘Code of Practice’) shall be drawn following consultation with the developers of identified General purpose AI systems and shall aim to protect fundamental rights, health and safety of EU citizens by considering compliance with proportionate requirements at the design stage (‘compliance-by-design’). The Code of Practice shall be updated yearly*

*in consultation with developers of general purpose AI systems, academics, civil society and national competent authorities in order to be adapted to the evolution of the technology, the progress of the technical safeguards and the maturity and effectiveness of existing institutional safeguards surrounding general purpose AI systems.*

*13. The developers of general purpose AI systems shall comply with the Code of Practice before allowing their general purpose AI systems to be adapted or used or integrated into AI systems or software put into service or made available on the market or to citizens. The Navigator Programme shall assist in their compliance. 14. The Code of Practice and the list of systems whose compliance with it is monitored by the Navigator Programme shall be made public.*

Or. en

**Amendment 2287**

**Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák**

**Proposal for a regulation  
Title IV a (new)**

*Text proposed by the Commission*

*Amendment*

***Rights of affected persons***

***Article 52 a***

***1. Natural persons have the right not to be subject to non-compliant AI systems. The placing on the market, putting into service or use of non-compliant AI system gives rise to the right of the affected natural persons subject to such non-compliant AI systems to seek and receive redress.***

***2. Natural persons have the right to be informed about the use and functioning of AI systems they have been or may be exposed to, particularly in the case of high-risk and other regulated AI systems, according to Article 52.***

***3. Natural persons and public interest***

*organisations have the right to lodge a complaint before the relevant national supervisory authorities against a producer or user of non-compliant AI systems where they consider that their rights or the rights of the natural persons they represent under the present regulation have been violated, and have the right receive effective remedy.*

Or. en

## **Amendment 2288**

**Axel Voss, Deirdre Clune, Eva Maydell**

### **Proposal for a regulation Article 53 – paragraph 1**

*Text proposed by the Commission*

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 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 competent authorities 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.

*Amendment*

1. ***The competent authorities of the Member States shall establish several physical and digital AI regulatory sandboxes six months prior to the entry into application of this Regulation based on well-established criteria that*** provide a controlled environment that facilitates the development, testing and validation of innovative AI systems before their placement on the market or putting into service pursuant to a specific plan. ***SMEs, start-ups, enterprises, innovators or other relevant actors could be included as partners in the regulatory sandboxes.*** This shall take place under the direct supervision and guidance by the ***respective national*** competent 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 ***identify risks to health and safety and fundamental rights, test mitigation measures for identified risks, demonstrate prevention of these risks and otherwise*** ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox. ***The***

*Commission shall play a complementary role, allowing those Member States with demonstrated experience with sandboxing to build on their expertise and, on the other hand, assisting and providing technical understanding and resources to those Member States that seek guidance on the set-up and running of these regulatory sandboxes.*

Or. en

### **Amendment 2289**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

### **Proposal for a regulation** **Article 53 – paragraph 1**

*Text proposed by the Commission*

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 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 competent authorities 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.

*Amendment*

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 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. ***Following a fundamental rights impact assessment, as laid out in Article 9a***, this shall take place under the direct supervision and guidance by the competent authorities with a view to ***identifying risks in particular to the environment, health and safety, and fundamental rights***, ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox. ***Access to the regulatory sandboxes shall require providers to apply for participation. Supervising authorities shall inform applicants of their decision within 3 months of the application, or, in justified cases, of an extension of this deadline by at most another 3 months. The***

*supervising authority shall inform the European Artificial Intelligence Board of the provision of regulatory sandboxes.*

Or. en

## **Amendment 2290**

**Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura**

### **Proposal for a regulation**

#### **Article 53 – paragraph 1**

##### *Text proposed by the Commission*

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 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 competent authorities 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.

##### *Amendment*

1. AI regulatory sandboxes established by ***the Commission in collaboration with*** one or more Member States competent authorities or the European Data Protection Supervisor, ***are considered high risk and*** shall provide a controlled environment that facilitates 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. ***They shall operate in full compliance with the General Data Protection Regulation.*** This shall take place under the direct supervision and guidance by the ***Commission in collaboration with*** competent authorities with a view to ***identifying risks to health and safety and fundamental rights, testing mitigation measures for identified risks, demonstrating prevention of these risks and otherwise*** ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox. ***AI regulatory sandboxes shall remain a technical solution, shall assess potential adverse effects and not be used on the employment context.***

Or. en

## Amendment 2291

Tomislav Sokol

### Proposal for a regulation

#### Article 53 – paragraph 1

*Text proposed by the Commission*

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 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 competent authorities 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.

*Amendment*

1. AI regulatory sandboxes established by ***SMEs, start-ups, enterprises and other innovators***, one or more Member States competent authorities or the European Data Protection Supervisor shall provide a controlled environment that facilitates the ***safe*** 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. ***For Member States competent authorities or the European Data Protection Supervisor***, this shall take place under the direct supervision and guidance by the competent authorities 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. ***For SMEs, start-ups, enterprises and other innovators, this shall take place independently from supervising authorities, while following rules and regulations (e.g. a Code of conduct) established in cooperation with Member State competent authorities.***

Or. en

*Justification*

*The AI Act needs to give more autonomy to SMEs, start-ups, enterprises and other innovators to establish their own AI sandboxes, following rules drawn up in collaboration with Member States. If AI sandboxes can only be established by a state run body, this will create negative effects: on the one hand, a backlog of AI sandbox requests will stifle any form of innovation and overburden governments. On the other, it will create a counter effect by forcing innovators to either test their prototypes in third countries or it will create a grey zone of unregulated and unreported innovation.*

## Amendment 2292



Karlo Ressler

**Proposal for a regulation**  
**Article 53 – paragraph 1**

*Text proposed by the Commission*

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 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 competent authorities 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.

*Amendment*

1. AI regulatory sandboxes established by ***SMEs, start-ups, enterprises and other innovators***, one or more Member States competent authorities or the European Data Protection Supervisor shall provide a controlled environment that facilitates the ***safe*** 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. ***For Member States competent authorities or the European Data Protection Supervisor***, this shall take place under the direct supervision and guidance by the competent authorities 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. ***For SMEs, start-ups, enterprises and other innovators, this shall take place independently from supervising authorities, while following rules and regulations established in close cooperation with Member State competent authorities.***

Or. en

**Amendment 2293**

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Morten Løkkegaard, Alin Mituţa**

**Proposal for a regulation**  
**Article 53 – paragraph 1**

*Text proposed by the Commission*

1. AI regulatory sandboxes ***established by one or more Member States***

*Amendment*

1. ***Member States shall establish*** AI regulatory sandboxes, ***which shall be***

*competent authorities or the European Data Protection Supervisor shall provide a controlled environment that facilitates 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 competent authorities 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.*

*operational by [24 months following the entering into force of this Regulation], and shall ensure that the competent authorities responsible for the regulatory sandboxes have sufficient resources available to fulfil their duties effectively and in a timely manner. Regulatory sandboxes can also be established at local, regional or European level.*

Or. en

#### Amendment 2294

Svenja Hahn, Dragoş Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Botoş, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

#### Proposal for a regulation Article 53 – paragraph 1

##### *Text proposed by the Commission*

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 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 competent authorities *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.

##### *Amendment*

1. AI regulatory sandboxes established by *the European Commission*, one or more Member States, *or other* competent *entities* shall provide a controlled environment that facilitates 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 *in collaboration with* and guidance by *the European Commission or* the competent authorities *in order to identify risks to health and safety and fundamental rights, test mitigation measures for identified risks, demonstrate prevention of these risks and otherwise ensure* compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.

**Amendment 2295**  
**Morten Løkkegaard**

**Proposal for a regulation**  
**Article 53 – paragraph 1**

*Text proposed by the Commission*

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 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 competent authorities 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*.

*Amendment*

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 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 competent authorities with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised. ***Consultation with AI vendors on the technological feasibility of the guidance from the competent authorities should be possible as part of the proces.***

Or. en

**Amendment 2296**  
**Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini**

**Proposal for a regulation**  
**Article 53 – paragraph 1**

*Text proposed by the Commission*

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

*Amendment*

1. ***National supervisory*** authorities or the European Data Protection Supervisor ***may establish AI regulatory sandboxes that*** shall provide a controlled environment ***facilitating*** the development, testing and

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 competent authorities 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*.

validation of innovative AI systems for a limited time before their placement on the market or putting into service. This shall take place under the direct supervision and guidance by the competent authorities with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation.

Or. en

#### **Amendment 2297**

**Kosma Zlotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan**

#### **Proposal for a regulation**

#### **Article 53 – paragraph 1**

##### *Text proposed by the Commission*

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 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 competent authorities 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.

##### *Amendment*

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 development, testing and validation of innovative AI systems 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 competent authorities 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.

Or. en

#### **Amendment 2298**

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Morten Løkkegaard, Alin Mituţa**

**Proposal for a regulation**  
**Article 53 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1 a. AI regulatory sandboxes established by one or more Member States, by local, regional, or national competent authorities, by the Commission or by the European Data Protection Supervisor shall provide a controlled environment that facilitates 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 competent authorities 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.***

Or. en

**Amendment 2299**  
**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**  
**Article 53 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1 a. This article shall also apply to AI systems for which full compliance with the requirements of Title III Chapter 2 requires an initial phase of placing the systems on the market or putting them into service and using the experiences gained in such initial phase to further develop the AI system so as to fully fulfil the requirements of Title III Chapter 2, particularly for the case of general purpose AI Systems.***

Or. en

**Amendment 2300**  
**Morten Løkkegaard**

**Proposal for a regulation**  
**Article 53 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1 a. The AI regulatory sandbox shall allow and facilitate cooperation with the private sector on technical test environments aimed at risk assessment, AI use cases and the involvement of notified bodies, standardisation bodies, and other relevant stakeholders when relevant.***

Or. en

**Amendment 2301**  
**Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini**

**Proposal for a regulation**  
**Article 53 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1 a. National supervisory authorities may establish AI regulatory sandboxes jointly with other national supervisory authorities.***

Or. en

**Amendment 2302**  
**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**  
**Article 53 – paragraph 1 b (new)**

*Text proposed by the Commission*

*Amendment*

***1 b. 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.*

Or. en

**Amendment 2303**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**

**Article 53 – paragraph 1 c (new)**

*Text proposed by the Commission*

*Amendment*

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

***(a) foster innovation and competitiveness 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.*

Or. en

**Amendment 2304**  
**Tomislav Sokol**

**Proposal for a regulation**  
**Article 53 – paragraph 2**

*Text proposed by the Commission*

2. 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.

*Amendment*

2. 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 ***established by one or more Member States competent authorities or the European Data Protection Supervisor. Without prejudice to the Regulation (EU) 2016/679, start-ups, SMEs, enterprises and other innovators may request access to personal data from relevant national authorities to be used in their AI sandbox under the guidelines defined through Member State rules and regulations (e.g. Code of conduct).***

Or. en

*Justification*

*Member States should be encouraged to share personal data with innovators, but under the supervision of relevant competent authorities.*

**Amendment 2305**



Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation**  
**Article 53 – paragraph 2**

*Text proposed by the Commission*

2. 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.

*Amendment*

2. Member States ***in collaboration with the Commission*** 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.***

Or. en

**Amendment 2306**  
**Karlo Ressler**

**Proposal for a regulation**  
**Article 53 – paragraph 2**

*Text proposed by the Commission*

2. 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.

*Amendment*

2. 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 ***personal*** data, the national data protection authorities and those other national authorities are associated to the operation of the AI regulatory sandbox ***established***

*by one or more Member States competent authorities or the European Data Protection Supervisor. Start-ups, SMEs, enterprises and other innovators may request access to personal data from relevant national authorities to be used in their AI sandbox under the guidelines defined through Member State rules and regulations.*

Or. en

#### **Amendment 2307**

**Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini**

#### **Proposal for a regulation Article 53 – paragraph 2**

*Text proposed by the Commission*

2. *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.

*Amendment*

2. *The national supervisory authority* shall ensure that to the extent the innovative AI systems involve the processing of personal data, the national data protection authorities are associated to the operation of the AI regulatory sandbox.

Or. en

#### **Amendment 2308**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation Article 53 – paragraph 2**

*Text proposed by the Commission*

2. Member States shall ensure that to the extent the innovative AI systems involve the processing of personal data or

*Amendment*

2. 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.

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 ***and involved in the control of those aspects of the sandbox it supervises to the full extent of its respective powers.***

Or. en

#### **Amendment 2309**

**Svenja Hahn, Nicola Beer, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen**

#### **Proposal for a regulation Article 53 – paragraph 2**

##### *Text proposed by the Commission*

2. 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.

##### *Amendment*

2. ***The European Commission in collaboration with*** 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.

Or. en

#### **Amendment 2310**

**Pernando Barrena Arza, Cornelia Ernst**

#### **Proposal for a regulation Article 53 – paragraph 2**

##### *Text proposed by the Commission*

2. Member States shall ensure that to the extent the innovative AI systems

##### *Amendment*

2. ***The Commission in collaboration with*** Member States shall ensure that to the

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.

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.

Or. en

**Amendment 2311**  
**Morten Løkkegaard**

**Proposal for a regulation**  
**Article 53 – paragraph 2**

*Text proposed by the Commission*

2. 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.

*Amendment*

2. 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 **personal** data, the national data protection authorities and those other national authorities are associated to the operation of the AI regulatory sandbox.

Or. en

**Amendment 2312**  
**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**  
**Article 53 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2 a. 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 system who fulfils national eligibility and selection criteria and who has been selected by the national competent authorities or by the European Data Protection Supervisor. 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.*

Or. en

#### **Amendment 2313**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation** **Article 53 – paragraph 3**

*Text proposed by the Commission*

3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. 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.

*Amendment*

3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. Any significant risks to **democracy, the environment**, 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, **or, where mitigating measures cannot be identified that stop and remedy such significant risk or harm, Member States shall ensure that the competent authorities have the power to permanently suspend the development and testing process. In the case of abuse, competent authorities shall have the power to ban providers from applying for and participating in the regulatory**

*sandbox for a limited amount of time or indefinitely. Decisions to suspend or ban providers from participating in regulatory sandboxes shall be submitted without delay to the European Artificial Intelligence Board. Applicants shall have access to remedies.*

Or. en

#### **Amendment 2314**

**Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura**

#### **Proposal for a regulation Article 53 – paragraph 3**

##### *Text proposed by the Commission*

3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. **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.

##### *Amendment*

3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. **Regulatory sandboxes involving activities that may impact health, safety and fundamental rights, democracy and rule of law or the environment shall be developed in accordance with redress-by-design principles.** Any significant risks 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.

Or. en

#### **Amendment 2315**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation Article 53 – paragraph 3**

##### *Text proposed by the Commission*

3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. **Any**

##### *Amendment*

3. **The participation in** the AI regulatory sandboxes shall not affect the supervisory and corrective powers of the

*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.*

competent authorities *supervising the sandbox. However, provided that the participant(s) respect the sandbox plan and the terms and conditions for their participation 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.*

Or. en

### **Amendment 2316**

**Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini**

#### **Proposal for a regulation Article 53 – paragraph 3**

##### *Text proposed by the Commission*

3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. 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.*

##### *Amendment*

3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. Any significant risks to fundamental rights, *health, safety or the environment identified during the development and testing of such systems shall result in immediate and adequate mitigation. Where such mitigation proves to be ineffective, the development and testing process shall be suspended without delay until such mitigation takes place.*

Or. en

### **Amendment 2317**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

#### **Proposal for a regulation Article 53 – paragraph 3**

*Text proposed by the Commission*

3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. 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.

*Amendment*

3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. Any significant risks to health and safety, fundamental rights **and the environment** identified during the development and testing of such systems shall result in immediate **and adequate mitigation. Where such** mitigation **proves to be ineffective**, the development and testing process **shall be suspended without delay** until such mitigation takes place.

Or. en

**Amendment 2318**  
**Morten Løkkegaard**

**Proposal for a regulation**  
**Article 53 – paragraph 3**

*Text proposed by the Commission*

3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. 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.

*Amendment*

3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. Any significant risks to health and safety and fundamental rights identified during the development and testing of such systems shall result in immediate **and adequate mitigation. Where such** mitigation **proves to be ineffective**, the development and testing process **shall be suspended without delay** until such mitigation takes place.

Or. en

**Amendment 2319**  
**Tomislav Sokol**

**Proposal for a regulation**  
**Article 53 – paragraph 3**



*Text proposed by the Commission*

3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. 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.

*Amendment*

3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. Any significant risks to health and safety and fundamental rights identified during the development and testing of *AI* systems shall result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place.

Or. en

**Amendment 2320**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**

**Article 53 – paragraph 4**

*Text proposed by the Commission*

4. Participants in the AI regulatory sandbox shall remain liable under applicable Union and Member States liability legislation for any harm inflicted on third parties as a result from the experimentation taking place in the sandbox.

*Amendment*

4. Participants in the AI regulatory sandbox shall remain liable under applicable Union and Member States liability legislation for any harm *intentionally* inflicted on third parties as a result from the experimentation taking place in the sandbox, *which was known or reasonably foreseeable at the time of experimentation and the risk of which the sandbox participants was not made aware of.*

Or. en

**Amendment 2321**

**Morten Løkkegaard**

**Proposal for a regulation**

**Article 53 – paragraph 4**

*Text proposed by the Commission*

4. Participants in the AI regulatory

*Amendment*

4. Participants in the AI regulatory

sandbox shall remain liable under applicable Union and Member States liability legislation for any harm inflicted on third parties as a result **from** the experimentation taking place in the sandbox.

sandbox shall remain liable under applicable Union and Member States liability legislation for any harm inflicted on third parties as a result **of** the experimentation taking place in the sandbox.

Or. en

#### **Amendment 2322**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation**

#### **Article 53 – paragraph 4 a (new)**

*Text proposed by the Commission*

*Amendment*

***4 a. 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.***

Or. en

#### **Amendment 2323**

**Axel Voss, Deirdre Clune, Eva Maydell**

#### **Proposal for a regulation**

#### **Article 53 – paragraph 5**

*Text proposed by the Commission*

*Amendment*

5. Member States' competent authorities ***that have established*** AI regulatory sandboxes ***shall*** coordinate their activities ***and*** cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results from the

5. Member States' competent authorities ***in collaboration with the Commission shall establish*** AI regulatory sandboxes, ***as much as possible through national and regional initiatives, in particular through European digital innovation hubs, and closely*** coordinate their activities ***as well as*** cooperate within

implementation of those *scheme*, 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.

the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results from the implementation of those *schemes*, 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. ***The annual reports or abstracts shall be made available to the public, online, in order to further enable innovation within the Union. Outcomes and learnings of the sandbox should be leveraged when monitoring the effectiveness and enforcement of this Regulation and taken into account when proceeding to amending it. The annual reports shall also be submitted to the AI Board which shall publish on its website a summary of all good practices, lessons learnt and recommendations.***

Or. en

**Amendment 2324**  
**Morten Løkkegaard**

**Proposal for a regulation**  
**Article 53 – paragraph 5**

*Text proposed by the Commission*

5. Member States' competent authorities that have established AI regulatory sandboxes shall coordinate their activities and cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results from the implementation of those scheme, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application of this Regulation and other Union legislation

*Amendment*

5. Member States' competent authorities that have established AI regulatory sandboxes shall coordinate their activities and cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results from the implementation of those scheme, including good practices, ***incidents***, 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***

supervised within the sandbox.

*reports or abstracts thereof shall be made available to the public in order to further enable innovation in the Union, in respect of protecting trade secrets and innovative business and technical ideas.*

Or. en

#### **Amendment 2325**

**Karlo Ressler**

#### **Proposal for a regulation**

#### **Article 53 – paragraph 5**

##### *Text proposed by the Commission*

5. Member States' competent authorities that have established AI regulatory sandboxes shall coordinate their activities and cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results *from* the implementation of those *scheme*, 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.

##### *Amendment*

5. Member States' competent authorities that have established AI regulatory sandboxes shall coordinate their activities and cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results *of* the implementation of those *schemes*, 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. *SMEs, start-ups, enterprises and other innovators shall submit annual reports to Member States' competent authorities and share their good practices, lessons learnt and recommendations on their AI sandboxes.*

Or. en

#### **Amendment 2326**

**Tomislav Sokol**

#### **Proposal for a regulation**

#### **Article 53 – paragraph 5**

##### *Text proposed by the Commission*

##### *Amendment*

5. Member States' competent authorities that have established AI regulatory sandboxes shall coordinate their activities and cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results from the implementation of those scheme, 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.

5. Member States' competent authorities that have established AI regulatory sandboxes shall coordinate their activities and cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results from the implementation of those scheme, 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. ***SMEs, start-ups, enterprises and other innovators are invited to share their good practices, lessons learnt and recommendations on their AI sandboxes with Member State competent authorities.***

Or. en

#### **Amendment 2327**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation** **Article 53 – paragraph 5**

##### *Text proposed by the Commission*

5. Member States' competent authorities that have established AI regulatory sandboxes shall coordinate their activities and cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results from the implementation of those ***scheme***, 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.

##### *Amendment*

5. Member States' competent authorities that have established AI regulatory sandboxes shall coordinate their activities and cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results from the implementation of those ***schemes***, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application ***and possible revision*** of this Regulation and other Union legislation supervised within the sandbox, ***in particular with regards to easing burdens and introducing further regulation where additional risks and***

*potential harms are identified.*

Or. en

#### **Amendment 2328**

**Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini**

#### **Proposal for a regulation Article 53 – paragraph 5**

*Text proposed by the Commission*

5. **Member States' competent authorities that have** established AI regulatory sandboxes shall coordinate their activities and cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results **from** the implementation of those **scheme**, 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.

*Amendment*

5. **The national supervisory authority that has** established **the** AI regulatory sandboxes shall coordinate their activities and cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results **of** the implementation of those **schemes**, including good practices, **incidents**, 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 reports or abstracts thereof shall be made available to the public in order to further enable innovation in the Union.**

Or. en

#### **Amendment 2329**

**Svenja Hahn, Nicola Beer, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen**

#### **Proposal for a regulation Article 53 – paragraph 5**

*Text proposed by the Commission*

5. Member States' competent authorities that have established AI regulatory sandboxes shall coordinate their activities and cooperate within the framework of the European **Artificial**

*Amendment*

5. **The European Commission, Member States' competent authorities and other entities** that have established AI regulatory sandboxes shall coordinate their activities and cooperate within the

**Intelligence Board.** They shall submit annual reports to the Board **and the Commission** on the results from the implementation of those scheme, 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.

framework of the European **Commission's AI Regulatory Sandboxing programme.** **The European Commission** shall submit annual reports to the **European Artificial Intelligence Board** on the results from the implementation of those scheme, 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.

Or. en

#### Amendment 2330

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Morten Løkkegaard, Alin Mituţa**

#### Proposal for a regulation Article 53 – paragraph 5

*Text proposed by the Commission*

5. **Member States'** competent authorities **that have established AI regulatory sandboxes** shall coordinate their activities and cooperate within the framework of the **European Artificial Intelligence Board**. They shall submit annual reports to the **Board** and the Commission on the results **from** the implementation of those scheme, 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.

*Amendment*

5. **National** competent authorities shall coordinate their activities and cooperate within the framework of the **AI Office**. They shall submit annual reports to the **AI Office** and the Commission on the results **of** the implementation of those scheme, including good practices, **incidents**, lessons learnt and recommendations on their setup and, where relevant, on the application of this Regulation **another** Union legislation supervised within the sandbox. **Those reports or abstracts thereof shall be made available to the public in order to further enable innovation in the Union.**

Or. en

#### Amendment 2331

**Pernando Barrena Arza, Cornelia Ernst**

#### Proposal for a regulation

## Article 53 – paragraph 5

*Text proposed by the Commission*

5. Member States' competent authorities that have established AI regulatory sandboxes shall coordinate their activities and cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results from the implementation of those scheme, 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.

*Amendment*

5. **The Commission**, Member States' competent authorities that have established AI regulatory sandboxes shall coordinate their activities and cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results from the implementation of those scheme, 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.

Or. en

### Amendment 2332

**Kosma Zlotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan**

#### Proposal for a regulation

#### Article 53 – paragraph 5

*Text proposed by the Commission*

5. Member States' competent authorities that have established AI regulatory sandboxes shall **coordinate their activities and** cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results from the implementation of those scheme, 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.

*Amendment*

5. Member States' competent authorities that have established AI regulatory sandboxes shall cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results from the implementation of those scheme, 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.

Or. en



## Amendment 2333

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Morten Løkkegaard, Alin Mituța**

### Proposal for a regulation

#### Article 53 – paragraph 5 a (new)

*Text proposed by the Commission*

*Amendment*

**5 a. Regulatory sandboxes shall allow and facilitate the testing of possible adaptations of the regulatory framework governing artificial intelligence in order to enhance innovation or reduce compliance costs, without prejudice to the provisions of this Regulation or to the health, safety, fundamental rights of natural persons or to the values of the Union as enshrined in Article 2 TEU. The results and lessons learned from such tests shall be submitted to the AI Office and the Commission.**

Or. en

## Amendment 2334

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituța**

### Proposal for a regulation

#### Article 53 – paragraph 6

*Text proposed by the Commission*

*Amendment*

6. The modalities and the conditions of the operation of the AI regulatory sandboxes, 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 in accordance with the examination procedure referred to in Article 74(2).

6. The modalities and the conditions of the operation of the AI regulatory sandboxes, 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 in accordance with the examination procedure referred to in Article 74(2) **no later than 12 months following the entry into force of this**

*Regulation and shall ensure, inter alia:*

*(a) that they allow start-ups to use their participation in the sandbox in order to fulfil, in a guided environment with significantly reduced costs, the conformity assessment obligations of this Regulation or the voluntary application of the codes of conduct referred to in Article 69;*

*(b) that adequate resources are dedicated to the establishment and functioning of the regulatory sandboxes so that the regulatory sandboxes can ensure broad access and keep up with demand for participation without creating disincentivising backlogs or delays;*

*(c) that procedures, processes, and bureaucratic requirements for application, selection, participation, and exiting the sandbox are simple, easily intelligible, clearly communicated, and streamlined so as to facilitate the participation of startups with limited legal and bureaucratic capacities;*

*(d) that procedures, processes, and bureaucratic requirements for application, selection, participation, and exiting the sandbox are streamlined across the Union and that participation in a regulatory sandbox established by a Member State by virtue of its obligation in paragraph 1 or by the Commission is uniformly recognised and carries the same legal effects across the Union.*

Or. en

**Amendment 2335**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 53 – paragraph 6**

*Text proposed by the Commission*

*Amendment*

6. The modalities and the conditions

6. The modalities and the conditions

of the operation of the AI regulatory sandboxes, 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 in accordance with the examination procedure referred to in Article 74(2)*.

of the operation of the AI regulatory sandboxes, 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 *by the European Artificial Intelligence Board in close cooperation with the Member States' and competent authorities*. *A list of planned and current sandboxes, including the modalities, conditions, eligibility criteria and application, selection, participation procedure shall be made publicly available by the European Artificial intelligence Board*.

Or. en

#### **Amendment 2336**

**Andrea Caroppo, Salvatore De Meo**

#### **Proposal for a regulation Article 53 – paragraph 6**

##### *Text proposed by the Commission*

6. The modalities and the conditions of the operation of the AI regulatory sandboxes, 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 in accordance with the examination procedure referred to in Article 74(2).

##### *Amendment*

6. The modalities and the conditions of the operation of the AI regulatory sandboxes, 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 *discussed with all the relevant actors of the AI value chain, such as research institutions and businesses, and* set out in implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).

Or. en

#### **Amendment 2337**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**  
**Article 53 – paragraph 6**

*Text proposed by the Commission*

6. The modalities and the conditions of the operation of the AI regulatory sandboxes, 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 in accordance with the examination procedure referred to in Article 74(2).

*Amendment*

6. The modalities and the conditions of the operation of the AI regulatory sandboxes, 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 ***in accordance with the Council's communication(11/2020) and in strong cooperation with relevant stakeholders***. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).

Or. en

**Amendment 2338**

**Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura**

**Proposal for a regulation**  
**Article 53 – paragraph 6 a (new)**

*Text proposed by the Commission*

*Amendment*

***6 a. The modalities referred to in Article 53(6) shall ensure at least the following: (a) participants in the regulatory sandboxing system, in particular small-scale providers, are granted access to pre-deployment services, such as preliminary registration of AI system, insurance, compliance and R&D support services, and to all the other relevant elements of the Union's AI ecosystem and other Digital Single Market initiatives such as testing and experimentation facilities, digital hubs, centers of excellence, testing and experimentation facilities, and EU benchmarking capabilities; and to other value-adding services such as standardization and certification,***

*community social platform and contact databases, tenders and grant making portal and lists of potential investors. (b) foreign providers, in particular small-scale providers, are eligible to take part in the regulatory sandboxes to incubate and refine their products in compliance with this Regulation. (c) individuals such as researchers, entrepreneurs, innovators and other pre-market ideas owners are eligible to take part in the regulatory sandboxes to incubate and refine their products in compliance with this Regulation. (d) there be as little fragmentation as possible of the regulatory sandboxes across Member States, notably through development of a single interface and contact point at the EU level to interact with the regulatory sandbox ecosystem and through the Commission facilitating the creation of transnational and EU-wide regulatory sandboxes*

Or. en

**Amendment 2339**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**

**Article 53 – paragraph 6 a (new)**

*Text proposed by the Commission*

*Amendment*

***6 a. Notwithstanding the modalities and conditions outlined in paragraph 6, Member States shall design regulatory sandboxes to provide access to as many providers as possible. There shall be a particular focus on the use and application of general purpose AI systems. Member States may establish virtual sandboxing environments to ensure that sandboxes can meet the demand.***

Or. en

**Amendment 2340**

**Svenja Hahn, Nicola Beer, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen**

**Proposal for a regulation**

**Article 53 – paragraph 6 a (new)**

*Text proposed by the Commission*

*Amendment*

**6 a. The Commission shall establish an EU AI Regulatory Sandboxing Programme whose modalities referred to in Article 53(6) shall cover the elements set out in Annex IXa. The Commission shall proactively coordinate with national, regional and also local authorities, as relevant.**

Or. en

**Amendment 2341**

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituța, Michal Šimečka**

**Proposal for a regulation**

**Article 53 – paragraph 6 a (new)**

*Text proposed by the Commission*

*Amendment*

**6 a. The Commission shall draw up guidelines for the proper establishment, development, implementation, functioning, and supervision of regulatory sandboxes.**

Or. en

**Amendment 2342**

**Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation**

**Article 53 – paragraph 6 b (new)**

*Text proposed by the Commission*

*Amendment*

**6 b.** *The Commission shall establish an EU AI Regulatory Sandboxing Work Programme whose modalities referred to in Article 53(6) shall cover the elements set out in Annex IXa. The Commission shall proactively coordinate with national and local authorities, where relevant.*

Or. en

**Amendment 2343**

**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel**

**Proposal for a regulation**

**Article 54**

*Text proposed by the Commission*

*Amendment*

**[...]**

***deleted***

Or. en

**Amendment 2344**

**Sophia in 't Veld, Michal Šimečka**

**Proposal for a regulation**

**Article 54**

*Text proposed by the Commission*

*Amendment*

**[...]**

***deleted***

Or. en

*Justification*

*The GDPR already provides the legal basis for further processing and provides for better protection.*

**Amendment 2345**

**Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar**

**Proposal for a regulation  
Article 54**

*Text proposed by the Commission*

*Amendment*

[...]

*deleted*

Or. en

**Amendment 2346**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation  
Article 54 – paragraph 1 – introductory part**

*Text proposed by the Commission*

*Amendment*

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

1. In the AI regulatory sandbox personal data **and data protected by intellectual property rights or trade secrets** lawfully collected for other purposes shall be processed **solely** for the purposes of developing and testing certain AI systems in the sandbox under the following conditions:

Or. en

**Amendment 2347**

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa**

**Proposal for a regulation  
Article 54 – paragraph 1 – introductory part**

*Text proposed by the Commission*

*Amendment*

1. In the AI regulatory sandbox personal data lawfully collected for other purposes shall be processed for the purposes of developing and testing certain

1. In the AI regulatory sandbox personal data lawfully collected for other purposes shall be processed for the purposes of developing and testing certain



innovative AI systems in the sandbox  
*under* the following conditions:

innovative AI systems in the sandbox  
*when all of* the following conditions *are met*:

Or. en

#### **Amendment 2348**

**Axel Voss, Deirdre Clune**

#### **Proposal for a regulation**

#### **Article 54 – paragraph 1 – introductory part**

##### *Text proposed by the Commission*

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

##### *Amendment*

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

Or. en

#### **Amendment 2349**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

#### **Article 54 – paragraph 1 – point a – introductory part**

##### *Text proposed by the Commission*

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

##### *Amendment*

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

Or. en

#### **Amendment 2350**

**Axel Voss, Deirdre Clune**

#### **Proposal for a regulation**

#### **Article 54 – paragraph 1 – point a – introductory part**

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

**Amendment 2351**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 54 – paragraph 1 – point a – point i**

*Text proposed by the Commission*

*Amendment*

(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;***

*deleted*

Or. en

**Amendment 2352**

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Alin Mituţa**

**Proposal for a regulation**

**Article 54 – paragraph 1 – point a – point i**

*Text proposed by the Commission*

*Amendment*

(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

(i) the investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against threats to public security, under the control and

public security, under the control and responsibility of the competent authorities. The processing shall be based on Member State or Union law;

responsibility of the competent authorities. The processing shall be based on Member State or Union law;

Or. en

#### **Amendment 2353**

**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**  
on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

##### **Article 54 – paragraph 1 – point a – point iii**

*Text proposed by the Commission*

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

*Amendment*

(iii) a high level of protection and improvement of the quality of the environment, ***and to counter and remedy the climate crisis;***

Or. en

#### **Amendment 2354**

**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H el ene Laporte, Jean-Paul Garraud**

#### **Proposal for a regulation**

##### **Article 54 – paragraph 1 – point a a (new)**

*Text proposed by the Commission*

*Amendment*

***(aa) natural persons whose personal data are used for the development and testing of certain innovative AI systems in the sandbox shall be informed of the collection and use of their data and shall have given their consent thereto;***

Or. fr

#### **Amendment 2355**

**Axel Voss, Deirdre Clune**

**Proposal for a regulation**  
**Article 54 – paragraph 1 – point c**

*Text proposed by the Commission*

(c) there are effective monitoring mechanisms to identify if any high risks to the ***fundamental*** rights of the data subjects may arise during the sandbox experimentation as well as response mechanism to promptly mitigate those risks and, where necessary, stop the processing;

*Amendment*

(c) there are effective monitoring mechanisms to identify if any high risks to the rights ***and freedoms*** of the data subjects, ***as referred to in Art 35 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;

Or. en