



*Committee on the Internal Market and Consumer Protection
Committee on Civil Liberties, Justice and Home Affairs*

2021/0106(COD)

13.6.2022

AMENDMENTS

310 - 538

Draft report
Brando Benifei, Drago 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 310

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Citation 5 a (new)

Text proposed by the Commission

Amendment

*Having regard to the opinion of the
European Central Bank,*

Or. en

Amendment 311

Svenja Hahn, Drago Tudorache, Nicola Beer, Dita Charanzová, Andrus Ansip, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Citation 5 a (new)

Text proposed by the Commission

Amendment

*Having regard to the opinion of the
European Central Bank,*

Or. en

Amendment 312

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Citation 5 b (new)

Text proposed by the Commission

Amendment

*Having regard to the joint opinion of the
European Data Protection Board and the
European Data Protection Supervisor,*

Or. en

Amendment 313

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

on behalf of the Verts/ALE Group

Proposal for a regulation

Recital 1

Text proposed by the Commission

(1) The purpose of this Regulation is to improve the functioning of the internal market by laying down a uniform legal framework in particular for the development, marketing and use of artificial intelligence in conformity with Union values. This Regulation pursues a number of overriding reasons of public interest, such as a high level of protection of health, safety and fundamental rights, ***and it*** ensures the free movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the development, marketing and use of AI systems, unless explicitly authorised by this Regulation.

Amendment

(1) The purpose of this Regulation is to improve the functioning of the internal market by laying down a uniform ***minimum*** legal framework in particular for the development, marketing and use of artificial intelligence in conformity with Union values. This Regulation pursues a number of overriding reasons of public interest, such as a high level of protection of health, safety and fundamental rights, ***as well as the environment, society, rule of law and democracy, economic interests and consumer protection. It also*** ensures the free movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the development, marketing and use of AI systems, unless explicitly authorised by this Regulation, ***or justified by the need to ensure the protection of the rights and freedoms of natural persons, or the ethical principles advocated by this Regulation***

Or. en

Amendment 314

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

Proposal for a regulation

Recital 1

Text proposed by the Commission

(1) The purpose of this Regulation is to ***improve*** the functioning of the internal market ***by laying*** down a uniform legal framework in particular for the development, ***marketing and*** use of artificial intelligence in conformity with

Amendment

(1) The purpose of this Regulation is to ***ensure a high level of protection of fundamental rights, health, safety and the environment, as well as the Union values enshrined in Article 2 of the Treaty on European Union (TEU), from harmful***

Union values. ***This Regulation pursues a number of overriding reasons of public interest, such as a high level of protection of health, safety and fundamental rights,*** and it ensures the free movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the development, marketing and use of AI systems, unless explicitly authorised by this Regulation.

effects of the use of artificial intelligence systems in the Union while enhancing innovation and improving the functioning of the internal market. ***This Regulation lays down a uniform legal framework in particular for the development, the placing on the market, the putting into service and the*** use of artificial intelligence in conformity with Union values and it ensures the free movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the development, marketing and use of AI systems, unless explicitly authorised by this Regulation.

Or. en

Amendment 315

Vincenzo Sofo, Kosma Złotowski

Proposal for a regulation

Recital 1

Text proposed by the Commission

(1) The purpose of this Regulation is to improve the functioning of the internal market by laying down a uniform legal framework in particular for the development, marketing and use of artificial intelligence in conformity with Union values. This Regulation pursues a number of overriding reasons of public interest, such as a high level of protection of health, safety and fundamental rights, and it ensures the free movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the development, marketing and use of AI systems, unless explicitly authorised by this Regulation.

Amendment

(1) The purpose of this Regulation is to improve the functioning of the internal market by laying down a uniform legal framework in particular for the development, marketing and use of artificial intelligence in conformity with Union values, ***the Universal Declaration of Human Rights, the European Convention on Human Rights and the Charter of Fundamental Rights of the EU.*** This Regulation pursues a number of overriding reasons of public interest, such as a high level of protection of health, safety and fundamental rights, and it ensures the free movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the development, marketing and use of AI systems, unless explicitly authorised by this Regulation.

Or. en

Amendment 316

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

Recital 1

Text proposed by the Commission

(1) The purpose of this Regulation is to improve the functioning of the internal market by laying down a uniform legal framework in particular for the development, marketing and use of artificial intelligence in conformity with Union values. This Regulation pursues a number of overriding reasons of public interest, such as a high level of protection of health, safety **and** fundamental rights, and it ensures the free movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the development, marketing and use of AI systems, unless explicitly authorised by this Regulation.

Amendment

(1) The purpose of this Regulation is to improve the functioning of the internal market by laying down a uniform legal framework in particular for the development, ***the placing on the market, the putting into service and the*** marketing and use of artificial intelligence in conformity with Union values. This Regulation pursues a number of overriding reasons of public interest, such as a high level of protection of health, safety, fundamental rights, ***the environment and the Union values enshrined in Article 2 of the Treaty on European Union (TEU),*** and it ensures the free movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the development, marketing and use of AI systems, unless explicitly authorised by this Regulation.

Or. en

Amendment 317

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

Proposal for a regulation

Recital 1

Text proposed by the Commission

(1) L'objectif du présent règlement est d'améliorer le fonctionnement du marché intérieur en établissant un cadre juridique uniforme, en particulier pour le

Amendment

(1) L'objectif du présent règlement est d'améliorer le fonctionnement du marché intérieur en établissant un cadre juridique uniforme, en particulier pour le

développement, la commercialisation et l'utilisation de l'intelligence artificielle dans le respect des valeurs de l'Union. Le présent règlement poursuit un objectif justifié par un certain nombre de raisons impérieuses d'intérêt général, telles que la nécessité d'un niveau élevé de protection de la santé, de la sécurité et des droits fondamentaux, et il garantit la libre circulation transfrontière des biens et services fondés sur l'IA, empêchant ainsi les États membres d'imposer des restrictions concernant le développement, la commercialisation et l'utilisation de systèmes d'IA, sauf autorisation expresse du présent règlement.

développement, la commercialisation et l'utilisation de l'intelligence artificielle dans le respect des valeurs de l'Union. Le présent règlement poursuit un objectif justifié par un certain nombre de raisons impérieuses d'intérêt général, telles que la nécessité d'un niveau élevé de protection de la santé, de la sécurité et des droits fondamentaux, et il garantit la libre circulation transfrontière des biens et services fondés sur l'IA, empêchant ainsi les États membres d'imposer des restrictions concernant le développement, la commercialisation et l'utilisation de systèmes d'IA, sauf autorisation expresse du présent règlement *et sans préjudice d'une législation nationale plus stricte à l'égard de la protection des droits fondamentaux.*

Or. fr

Amendment 318

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation Recital 1

Text proposed by the Commission

(1) The purpose of this Regulation is to improve the functioning of the internal market by laying down a uniform legal framework in particular for the development, marketing and use of artificial intelligence in conformity with Union values. This Regulation pursues a number of overriding reasons of public interest, such as a high level of protection of health, safety and fundamental rights, and it ensures the free movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the development, marketing and use of AI systems, unless explicitly authorised by this Regulation.

Amendment

(1) The purpose of this Regulation is to improve the functioning of the internal market by laying down a uniform legal framework in particular for the development, marketing and use of artificial intelligence in conformity with Union values. This Regulation pursues a number of overriding reasons of public interest, such as a high level of protection of health, safety, **environment** and fundamental rights, **as well as consumer protection** and it ensures the free movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the development, marketing and use of AI systems, unless explicitly authorised by

this Regulation.

Or. en

Amendment 319

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

Proposal for a regulation

Recital 1 a (new)

Text proposed by the Commission

Amendment

(1 a) The term “artificial intelligence” (AI) refers to systems developed by humans that can, using different techniques and approaches, generate outputs such as content, predictions, recommendations and decisions. The context they are used in is decisive for how much and what kind of influence they can have, and whether they are perceived by an observer as “intelligent”. The term “automated decision-making” (ADM) has been proposed as it could avoid the possible ambiguity of the term AI. ADM involves a user delegating initially a decision, partly or completely, to an entity by way of using a system or a service. That entity then uses automatically executed decision-making models to perform an action on behalf of a user, or to inform the user’s decisions in performing an action

Or. en

Amendment 320

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

Proposal for a regulation

Recital 2

Text proposed by the Commission

Amendment

(2) Artificial intelligence systems (AI systems) can be easily deployed in multiple sectors of the economy and society, including cross border, and circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that artificial intelligence is safe and is developed and used in compliance with fundamental rights obligations. ***Differing national rules may lead to fragmentation of the internal market and decrease legal certainty for operators that develop or use AI systems.*** A consistent and high level of protection throughout the Union should therefore be ensured, while divergences hampering the free circulation of AI systems and related products and services within the internal market should be prevented, by laying down uniform obligations for operators and guaranteeing the uniform protection of overriding reasons of public interest and of rights of persons throughout the internal market based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). To the extent that this Regulation contains specific rules on the protection of individuals with regard to the processing of personal data concerning restrictions of the use of AI systems ***for 'real-time' remote biometric identification in publicly accessible spaces for the purpose of law enforcement,*** it is appropriate to base this Regulation, in as far as those specific rules are concerned, on Article 16 of the TFEU. In light of those specific rules and the recourse to Article 16 TFEU, it is appropriate to consult the European Data Protection Board.

(2) Artificial intelligence systems (AI systems) can be easily deployed in multiple sectors of the economy and society, including cross border, and circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that artificial intelligence is safe and is developed and used in compliance with fundamental rights obligations. A consistent and high level of protection throughout the Union should therefore be ensured, while divergences hampering the free circulation of AI systems and related products and services within the internal market should be prevented, by laying down uniform obligations for operators and guaranteeing the uniform protection of overriding reasons of public interest and of rights of persons throughout the internal market based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). To the extent that this Regulation contains specific rules on the protection of individuals with regard to the processing of personal data concerning restrictions of the use of AI systems biometric identification in publicly accessible spaces, it is appropriate to base this Regulation, in as far as those specific rules are concerned, on Article 16 of the TFEU. In light of those specific rules and the recourse to Article 16 TFEU, it is appropriate to consult the European Data Protection Board.

Or. en

Amendment 321
Vincenzo Sofo, Kosma Złotowski

Proposal for a regulation
Recital 2

Text proposed by the Commission

(2) Artificial intelligence systems (AI systems) can be easily deployed in multiple sectors of the economy and society, including cross border, and circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that artificial intelligence is safe and is developed and used in compliance with fundamental rights obligations. Differing national rules may lead to fragmentation of the internal market and decrease legal certainty for operators that develop or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured, while divergences hampering the free circulation of AI systems and related products and services within the internal market should be prevented, by laying down uniform obligations for operators and guaranteeing the uniform protection of overriding reasons of public interest and of rights of persons throughout the internal market based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). To the extent that this Regulation contains specific rules on the protection of individuals with regard to the processing of personal data concerning restrictions of the use of AI systems for ‘real-time’ remote biometric identification in publicly accessible spaces for the purpose of law enforcement, it is appropriate to base this Regulation, in as far as those specific rules are concerned, on Article 16 of the TFEU. In light of those specific rules and the recourse to Article 16 TFEU, it is appropriate to consult the European Data Protection Board.

Amendment

(2) Artificial intelligence systems (AI systems) can be easily deployed in multiple sectors of the economy and society, including cross border, and circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that artificial intelligence is safe and is developed and used in compliance with fundamental rights obligations. Differing national rules may lead to fragmentation of the internal market and decrease legal certainty for operators that develop or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured, while divergences hampering the free circulation of AI systems and related products and services within the internal market should be prevented, by laying down uniform obligations for operators and guaranteeing the uniform protection of overriding reasons of public interest and of rights of persons throughout the internal market based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). To the extent that this Regulation contains specific rules on the protection of individuals with regard to the processing of personal data concerning restrictions of the use of AI systems for ‘real-time’ remote biometric identification in publicly accessible spaces for the purpose of law enforcement, it is appropriate to base this Regulation, in as far as those specific rules are concerned, on Article 16 of the TFEU **and to align it with relevant EU legislation such as the GDPR and the EUDPR**. In light of those specific rules and the recourse to Article 16 TFEU, it is appropriate to consult the European Data Protection Board **and to take into consideration the EDPB-EDPS Joint Opinion 5/2021**.

Or. en

Amendment 322**Fernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura****Proposal for a regulation****Recital 2***Text proposed by the Commission*

(2) Artificial intelligence systems (AI systems) can be easily deployed in multiple sectors of the economy and society, including cross border, and circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that artificial intelligence is safe and is developed and used in compliance with fundamental rights obligations. Differing national rules may lead to fragmentation of the internal market and decrease legal certainty for operators that develop or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured, while divergences hampering the free circulation of AI systems and related products and services within the internal market should be prevented, by laying down uniform obligations for operators and guaranteeing the uniform protection of overriding reasons of public interest and of rights of persons throughout the internal market based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). To the extent that this Regulation contains specific rules on the protection of individuals with regard to the processing of personal data concerning restrictions of the use of AI systems for ‘real-time’ remote biometric identification in publicly accessible spaces for the purpose of law enforcement, it is appropriate to base this Regulation, in as far as those specific rules are concerned, on Article 16 of the TFEU. In light of those specific rules and the recourse to Article 16 TFEU, it is appropriate to consult the European Data Protection Board.

Amendment

(2) Artificial intelligence systems (AI systems) can be easily deployed in multiple sectors of the economy and society, including cross border, and circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that artificial intelligence is safe and is developed and used in compliance with fundamental rights obligations. Differing national rules may lead to fragmentation of the internal market and decrease legal certainty for operators that develop or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured, while divergences hampering the free circulation of AI systems and related products and services within the internal market should be prevented, by laying down uniform obligations for operators and guaranteeing the uniform protection of overriding reasons of public interest and of rights of persons throughout the internal market based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). To the extent that this Regulation contains specific rules on the protection of individuals with regard to the processing of personal data concerning restrictions of the use of AI systems for ‘real-time’ remote biometric identification in publicly accessible **and online** spaces for the purpose of law enforcement, it is appropriate to base this Regulation, in as far as those specific rules are concerned, on Article 16 of the TFEU. In light of those specific rules and the recourse to Article 16 TFEU, it is appropriate to consult the European Data Protection Board.

Or. en

Amendment 323

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

Proposal for a regulation

Recital 2

Text proposed by the Commission

(2) Les systèmes d'intelligence artificielle (ci-après les «systèmes d'IA») peuvent être facilement déployés dans plusieurs secteurs de l'économie et de la société, y compris transfrontières, et circuler dans toute l'Union. Certains États membres ont déjà envisagé l'adoption de règles nationales destinées à faire en sorte que l'intelligence artificielle soit sûre et à ce qu'elle soit développée et utilisée dans le respect des obligations en matière de droits fondamentaux. La disparité des règles nationales peut entraîner une fragmentation du marché intérieur et réduire la sécurité juridique pour les opérateurs qui développent ou utilisent des systèmes d'IA. Il convient donc de garantir un niveau de protection cohérent et élevé dans toute l'Union, tandis que les divergences qui entravent la libre circulation des systèmes d'IA et des produits et services connexes au sein du marché intérieur devraient être évitées, en établissant des obligations uniformes pour les opérateurs et en garantissant la protection uniforme des raisons impérieuses d'intérêt général et des droits des citoyens dans l'ensemble du marché intérieur conformément à l'article 114 du traité sur le fonctionnement de l'Union européenne (TFUE). Dans la mesure où le présent règlement contient des règles spécifiques sur la protection des personnes physiques en ce qui concerne le traitement des données à caractère personnel, à savoir notamment des restrictions portant sur l'utilisation de systèmes d'IA pour l'identification biométrique à distance «en temps réel» dans des espaces accessibles

Amendment

(2) Les systèmes d'intelligence artificielle (ci-après les «systèmes d'IA») peuvent être facilement déployés dans plusieurs secteurs de l'économie et de la société, y compris transfrontières, et circuler dans toute l'Union. Certains États membres ont déjà envisagé l'adoption de règles nationales destinées à faire en sorte que l'intelligence artificielle soit sûre et à ce qu'elle soit développée et utilisée dans le respect des obligations en matière de droits fondamentaux. La disparité des règles nationales peut entraîner une fragmentation du marché intérieur et réduire la sécurité juridique pour les opérateurs qui développent ou utilisent des systèmes d'IA. Il convient donc de garantir un niveau de protection **minimal**, cohérent et élevé dans toute l'Union, tandis que les divergences qui entravent la libre circulation des systèmes d'IA et des produits et services connexes au sein du marché intérieur devraient être évitées, en établissant des obligations uniformes pour les opérateurs et en garantissant la protection uniforme des raisons impérieuses d'intérêt général et des droits des citoyens dans l'ensemble du marché intérieur conformément à l'article 114 du traité sur le fonctionnement de l'Union européenne (TFUE). Dans la mesure où le présent règlement contient des règles spécifiques sur la protection des personnes physiques en ce qui concerne le traitement des données à caractère personnel, à savoir notamment des restrictions portant sur l'utilisation de systèmes d'IA pour l'identification biométrique à distance «en temps réel» dans des espaces accessibles

au public à des fins répressives, il convient de fonder le présent règlement, dès lors que ces règles spécifiques sont concernées, sur l'article 16 du TFUE. Compte tenu de ces règles spécifiques et du recours à l'article 16 du TFUE, il convient de consulter le comité européen de la protection des données.

au public à des fins répressives, il convient de fonder le présent règlement, dès lors que ces règles spécifiques sont concernées, sur l'article 16 du TFUE. Compte tenu de ces règles spécifiques et du recours à l'article 16 du TFUE, il convient de consulter le comité européen de la protection des données.

Or. fr

Amendment 324

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

Proposal for a regulation

Recital 2

Text proposed by the Commission

(2) Artificial intelligence systems (AI systems) can be easily deployed in multiple sectors of the economy and society, including cross border, and circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that artificial intelligence is safe and is developed and used in compliance with fundamental rights obligations. Differing national rules may lead to fragmentation of the internal market and decrease legal certainty for operators that develop or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured, while divergences hampering the free circulation of AI systems and related products and services within the internal market should be prevented, by laying down uniform obligations for operators and guaranteeing the uniform protection of overriding reasons of public interest and of rights of persons throughout the internal market based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). **To the extent that** this Regulation **contains specific** rules on the protection of individuals with regard to the processing of

Amendment

(2) Artificial intelligence systems (AI systems) can be easily deployed in multiple sectors of the economy and society, including cross border, and circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that artificial intelligence is safe and is developed and used in compliance with fundamental rights obligations. Differing national rules may lead to fragmentation of the internal market and decrease legal certainty for operators that develop or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured, while divergences hampering the free circulation of AI systems and related products and services within the internal market should be prevented, by laying down uniform obligations for operators and guaranteeing the uniform protection of overriding reasons of public interest and of rights of persons throughout the internal market based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). **As AI systems rely on the processing of large volumes of data, including personal data, it is appropriate**

personal data *concerning restrictions of the use of AI systems for ‘real-time’ remote biometric identification in publicly accessible spaces for the purpose of law enforcement, it is appropriate to base this Regulation, in as far as those specific rules are concerned, on Article 16 of the TFEU.* In light of *those specific rules and* the recourse to Article 16 TFEU, it is appropriate to consult the European Data Protection Board.

to base this Regulation on Article 16 of the TFEU, which enshrines the right of everyone to the protection of personal data concerning them and provides for the adoption of rules on the protection of individuals with regard to the processing of personal data. In light of the recourse to Article 16 TFEU, it is appropriate to consult the European Data Protection Board.

Or. en

Amendment 325

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

Proposal for a regulation Recital 2 a (new)

Text proposed by the Commission

Amendment

(2 a) However, in line with Article 114(2) TFEU, this Regulation does not affect the rights and interests of employed persons. This Regulation should therefore not affect Community law on social policy and national labour law and practice, that is any legal and contractual provision concerning employment conditions, working conditions, including health and safety at work and the relationship between employers and workers, including information, consultation and participation. This Regulation should not affect the exercise of fundamental rights as recognized in the Member States and at Union level, including the right or freedom to strike or to take other action covered by the specific industrial relations systems in Member States, in accordance with national law and/or practice. Nor should it affect concertation practices, the right to negotiate, to conclude and enforce collective agreement or to take collective action in accordance with national law

and/or practice. It should in any case not prevent the Commission from proposing specific legislation on the rights and freedoms of workers affected by AI systems.

Or. en

Amendment 326

Maria-Manuel Leitão-Marques, Eva Kaili

Proposal for a regulation

Recital 2 a (new)

Text proposed by the Commission

Amendment

(2 a) The deployment of artificial intelligence applications across sectors will only accelerate in the years to come. The European Union should therefore consider, in separate legislation, the creation of an Artificial Intelligence Adjustment Fund, which could be beneficial for Member States to cover the accustoming of their labour markets to the new conditions arising from the rapid mass introduction of artificial intelligence systems that could affect specific job sectors.

Or. en

Amendment 327

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Brando Benifei

Proposal for a regulation

Recital 2 a (new)

Text proposed by the Commission

Amendment

(2 a) This Regulation should not affect the restrictions, prohibitions or enforcement that apply where an artificial intelligence practice infringes another EU law, including EU acquis on data

protection, privacy, or the confidentiality of communications, on non discrimination, consumer protection or on competition.

Or. en

Amendment 328

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

Proposal for a regulation

Recital 3 a (new)

Text proposed by the Commission

Amendment

(3 a) The development of AI applications might bring down the costs and increase the volume of services available, e.g. health services, public transport, Farming 4.0, making them more affordable to a wider spectrum of society; that AI applications may also result in the rise of unemployment, pressure on social care systems, and an increase of poverty; in accordance with the values enshrined in Article 3 of the Treaty on European Union, there might be a need to adapt the Union AI transformation to socioeconomic capacities, to create adequate social shielding, support education and incentives to create alternative jobs; the establishment of a Union AI Adjustment Fund building upon the experience of The European Globalisation Adjustment Fund (EGF) or the currently developed Just Transition Fund should be considered;

Or. en

Amendment 329

Jörgen Warborn, Tomas Tobé, Arba Kokalari

Proposal for a regulation

Recital 3 a (new)

Text proposed by the Commission

Amendment

(3 a) The deployment of artificial intelligence is critical for European competitiveness and in particular for the success of small and medium-sized enterprises in industrial sectors. AI solutions can support European companies to optimise production processes, predict machinery failures and develop more efficient and smart services. The potential of AI can however only fully materialise if European industry, and in particular SMEs, are provided with a permissive legislative framework which avoids any overregulation that would funnel resources away from R&D towards unnecessary compliance costs.

Or. en

Amendment 330

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 3 a (new)

Text proposed by the Commission

Amendment

(3 a) To ensure that Artificial Intelligence leads to socially and environmentally beneficial outcomes, Member States should support such measures through allocating sufficient resources, including public funding, and giving priority access to regulatory sandboxes to projects led by civil society and social stakeholders. Such projects should be based on the principle of interdisciplinary cooperation between AI developers, experts in equality and non-discrimination, accessibility, and consumer, environmental, and digital rights, and the academic community.

Or. en

Amendment 331

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 3 a (new)

Text proposed by the Commission

Amendment

(3 a) In order for Member States to reach the carbon neutrality targets, European companies should seek to utilise all available technological advancements that can assist in realising this goal. AI is a well-developed and ready-to-use technology that can be used to process the ever-growing amount of data created during industrial, environmental, health and other processes. To facilitate investments in AI-based analysis and optimisation solutions, this Regulation should provide a predictable and proportionate environment for low-risk industrial solutions.

Or. en

Amendment 332

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 3 a (new)

Text proposed by the Commission

Amendment

(3 a) To ensure that Artificial Intelligence leads to socially and environmentally beneficial outcomes, Member States should support such measures through allocating sufficient resources, including public funding, and giving priority access to regulatory sandboxes to projects led by civil society and social stakeholders. Such projects should be based on the principle of interdisciplinary cooperation between AI

developers, experts in equality and non-discrimination, accessibility, and consumer, environmental, and digital rights, and the academic community.

Or. en

Amendment 333

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 3 b (new)

Text proposed by the Commission

Amendment

(3 b) Furthermore, in order for Member States to fight against climate change, to achieve climate-neutrality and to meet the Sustainable Development Goals (SDGs), the European companies should ensure the sustainable design of AI systems to reduce resource usage and energy consumption, thereby limiting the risks to the environment; AI systems have the potential to automatically provide businesses with detailed insight into their emissions, including value chains, and forecast future emissions, thus helping to adjust and achieve the Union's emission targets.

Or. en

Amendment 334

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

Proposal for a regulation

Recital 4

Text proposed by the Commission

Amendment

(4) At the same time, depending on the circumstances regarding its specific application and use, artificial intelligence may generate risks and cause harm to

(4) At the same time, depending on the circumstances regarding its specific application and use, artificial intelligence may generate risks and cause harm to

public interests and rights that are protected by Union law. Such harm might be material or immaterial.

public interests and rights that are protected by Union law, *whether individual, societal, environmental, economic, or to the rule of law and democracy*. Such harm might be material or immaterial. *Harm should be understood as injury or damage to the life, health, physical integrity and the property of a natural or legal person, economic harm to individuals, damage to their environment, security and other aspects defined in the scope of New Approach directives, complemented by collective harms such as harm to society, the democratic process and the environment, or going against core ethical principles. Immaterial harms should be understood as meaning harm as a result of which the affected person suffers considerable detriment, an objective and demonstrable impairment of his or her personal interests and an economic loss calculated having regard, for example, to annual average figures of past revenues and other relevant circumstances. Such immaterial harm can therefore consist of psychological harm, reputational harm or change in legal status. Harm can be caused (i) by single events and (ii) through exposure over time to harmful algorithmic practices, as well as (iii) through action distributed among a number of actors where the entity causing the harm is not necessarily that which uses the AI or (iv) through uses of AI which are different than intended for the given system.*

Or. en

Amendment 335

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

Proposal for a regulation Recital 4

Text proposed by the Commission

Amendment

(4) At the same time, depending on the circumstances regarding its specific application and use, artificial intelligence may generate risks and cause harm to public interests and rights that are protected by Union law. Such harm might be material or immaterial.

(4) At the same time, depending on the circumstances regarding its specific application and use, *as well as the level of technological development*, artificial intelligence may generate risks and cause harm to public interests and rights that are protected by Union law. Such harm might be material or immaterial, *including physical, psychological, societal or economic harm*.

Or. en

Amendment 336

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 4

Text proposed by the Commission

(4) At the same time, depending on the circumstances regarding its specific application and use, artificial intelligence may generate risks and cause harm to public interests and rights that are protected by Union law. Such harm might be material or immaterial.

Amendment

(4) At the same time, depending on the circumstances regarding its specific application and use, artificial intelligence may generate risks and cause harm to public interests and rights that are protected by Union law. Such harm might be material or immaterial *and might affect one or more persons, a groups of persons or society as a whole, as well as the environment*.

Or. en

Amendment 337

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Recital 4

Text proposed by the Commission

(4) At the same time, depending on the circumstances regarding its specific application and use, artificial intelligence may generate risks and cause harm to

Amendment

(4) At the same time, depending on the circumstances regarding its specific application and use, artificial intelligence may generate risks and cause harm to

public interests and rights that are protected by Union law. Such harm might be material or immaterial.

public **and private** interests and rights that are protected by Union law. Such harm might be material or immaterial.

Or. en

Amendment 338

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

Recital 4 a (new)

Text proposed by the Commission

Amendment

(4 a) In order to ensure the dual green and digital transition, and secure the technological resilience of the EU, to reduce the carbon footprint of artificial intelligence and achieve the objectives of the new European Green Deal, this Regulation should contribute to the promotion of a green and sustainable artificial intelligence and to the consideration of the environmental impact of AI systems throughout their lifecycle. Sustainability should be at the core at the European artificial intelligence framework to guarantee that the development of artificial intelligence is compatible with sustainable development of environmental resources for current and future generations, at all stages of the lifecycle of artificial intelligence products; sustainability of artificial intelligence should encompass sustainable data sources, data centres, resource use, power supplies and infrastructure;

Or. en

Justification

As adopted in the ENVI opinion.

Amendment 339

Bettina Vollath

Proposal for a regulation

Recital 4 a (new)

Text proposed by the Commission

Amendment

(4 a) AI available in the Union market or otherwise affecting people in the Union should be designed human centered, so that people can trust that the technology is used in a way that is safe and compliant with the law, including the respect of fundamental rights what requires a shift towards a Human Centered AI Engineering, also in research and education.

Or. en

Amendment 340

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 4 a (new)

Text proposed by the Commission

Amendment

(4 a) The concept of decision autonomy for machines is at its core in conflict with fundamental notions of our societies, such as human dignity, autonomy, and the rights to private life and the protection of personal data. This Regulation should reconcile the potential benefits to society offered by AI with the primacy of humans over machines;

Or. en

Amendment 341

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

Proposal for a regulation

Recital 4 a (new)

Text proposed by the Commission

Amendment

(4 a) Given the major impact that artificial intelligence can have on society and the need to build trust, it is vital for artificial intelligence systems to respect the principles of fairness, accountability, transparency and accountability, privacy and security, and social benefit.

Or. en

Amendment 342

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

Recital 4 b (new)

Text proposed by the Commission

Amendment

(4 b) Despite the high potential of solutions to the environmental and climate crisis offered by artificial intelligence, the design, training and execution of algorithms imply a high energy consumption and, consequently, high levels of carbon emissions. Artificial intelligence technologies and data centres have a high carbon footprint due to increased computational energy consumption, and high energy costs due to the volume of data stored and the amount of heat, electric and electronic waste generated, thus resulting in increased pollution. These environmental and carbon footprints are expected to increase overtime as the volume of data transferred and stored and the increasing development of artificial intelligence applications will continue to grow exponentially in the years to come. It is therefore important to minimise the climate and environmental footprint of artificial intelligence and related

technologies and that AI systems and associated machinery are designed sustainably to reduce resource usage and energy consumption, thereby limiting the risks to the environment.

Or. en

Justification

From the ENVI adopted opinion.

Amendment 343

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

Recital 4 c (new)

Text proposed by the Commission

Amendment

(4 c) To promote the sustainable development of AI systems and in particular to prioritise the need for sustainable, energy efficient data centres, requirements for efficient heating and cooling of data centres should be consistent with the long-term climate and environmental standards and priorities of the Union and comply with the principle of 'do no significant harm' within the meaning of Article 17 of Regulation (EU) 2020/852 on the establishment of a framework to facilitate sustainable investment, and should be fully decarbonised by January 2050. In this regard, Member States and telecommunications providers should collect and publish information relating to the energy performance and environmental footprint for artificial intelligence technologies and data centres including information on the energy efficiency of algorithms to establish a sustainability indicator for artificial intelligence technologies. A European code of conduct for datacentre energy

efficiency can establish key sustainability indicators to measure four basic dimensions of a sustainable data centre, namely, how efficiently it uses energy, the proportion of energy generated from renewable energy sources, the reuse of any waste and heat, and the usage of fresh water.

Or. en

Justification

From the ENVI adopted opinion.

Amendment 344

Karlo Ressler

Proposal for a regulation

Recital 5

Text proposed by the Commission

(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and safety and the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council³³, and it ensures the protection of ethical principles, as specifically requested by the European Parliament³⁴.

Amendment

(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and safety and the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. ***These rules should be supportive to new innovative solutions and robust in protecting fundamental rights of all the actors.*** By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by

the European Council, and it ensures the protection of ethical principles, as specifically requested. *One of the fundamental principles of this legislative framework is that there is no doubt between the protection of fundamental rights or the support of innovation, since this Regulation provides rules that adequately address both of mentioned priorities.*

³³ European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6.

³⁴ European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

Or. en

Amendment 345

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 Recital 5

Text proposed by the Commission

(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and safety **and** the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market **and** putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the

Amendment

(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and safety, the protection of fundamental rights, as recognised and protected by Union law, **the environment and the Union values enshrined in Article 2 TEU**. To achieve that objective, rules regulating the **development, the** placing on the market, **and the** putting into service

internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council³³, and it ensures the protection of ethical principles, as specifically requested by the European Parliament³⁴.

and the use of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council³³, and it ensures the protection of ethical principles, as specifically requested by the European Parliament³⁴.

³³ European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6.

³⁴ European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

³³ European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6.

³⁴ European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

Or. en

Amendment 346 **Axel Voss, Deirdre Clune, Eva Maydell**

Proposal for a regulation **Recital 5**

Text proposed by the Commission

(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and safety and the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market and putting into service of

Amendment

(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and safety and the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market and putting into service of

certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council³³, and it ensures the protection of ethical principles, as specifically requested by the European Parliament³⁴.

certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services.

Furthermore, clear rules supporting the application and design of AI systems should be laid down, thus enabling a European ecosystem of public and private actors creating AI systems in line with European values. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council³³, and it ensures the protection of ethical principles, as specifically requested by the European Parliament³⁴.

³³ European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6.

³⁴ European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

³³ European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6.

³⁴ European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

Or. en

Amendment 347

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

Proposal for a regulation Recital 5

Text proposed by the Commission

(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time *meets* a high level of

Amendment

(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time *guarantees* a high

protection of public interests, such as health and safety and the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council³³, and it ensures the protection of ethical principles, as specifically requested by the European Parliament³⁴.

level of protection of public interests, such as health and safety and the protection of fundamental rights, as recognised and protected by Union law *as well as the environment, society, rule of law and democracy, economic interests and consumer protection*. To achieve that objective, rules regulating the placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council³³, and it ensures the protection of ethical principles, as specifically requested by the European Parliament³⁴.

³³ European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6.

³⁴ European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

³³ European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6.

³⁴ European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

Or. en

Amendment 348

Svenja Hahn, Drago Tudorache, Nicola Beer, Dita Charanzová, Andrus Ansip, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Ondej Kovač, Jan-Christoph Oetjen

Proposal for a regulation Recital 5

Text proposed by the Commission

(5) A Union legal framework laying down harmonised rules on artificial

Amendment

(5) A Union legal framework laying down harmonised rules on artificial

intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and safety and the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council³³, and it ensures the protection of ethical principles, as specifically requested by the European Parliament³⁴.

intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and safety and the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules *as well as measures in support of innovation with a particular focus on SMEs and start-ups*, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council³³, and it ensures the protection of ethical principles, as specifically requested by the European Parliament³⁴.

³³ European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6.

³⁴ European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

³³ European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6.

³⁴ European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

Or. en

Amendment 349

Marion Walsmann

Proposal for a regulation

Recital 5

Text proposed by the Commission

Amendment

(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and safety and the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council³³, and it ensures the protection of ethical principles, as specifically requested by the European Parliament³⁴.

³³ European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6.

³⁴ European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and safety and the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of ***promoting the "AI made in Europe" and*** being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council³³, and it ensures the protection of ethical principles, as specifically requested by the European Parliament³⁴.

³³ European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6.

³⁴ European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

Or. en

Amendment 350

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

Proposal for a regulation Recital 5

Text proposed by the Commission

(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as **health and safety and** the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market **and** putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council³³, and it ensures the protection of ethical principles, as specifically requested by the European Parliament³⁴.

³³ European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6.

³⁴ European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

Amendment

(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as the protection of fundamental rights, **health and safety**, as recognised and protected by Union law. To achieve that objective, rules regulating the **development, the** placing on the market, putting into service **and the use** of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council³³, and it ensures the protection of ethical principles, as specifically requested by the European Parliament³⁴.

³³ European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6.

³⁴ European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

Or. en

Amendment 351

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 5

Text proposed by the Commission

(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and **safety** and the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council³³, and it ensures the protection of ethical principles, as specifically requested by the European Parliament³⁴.

Amendment

(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and **the environment** and the protection of fundamental rights **and values**, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council³³, and it ensures the protection of ethical principles, as specifically requested by the European Parliament³⁴.

³³ European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6.

³⁴ European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

³³ European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6.

³⁴ European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

Or. en

Amendment 352

Jörgen Warborn, Arba Kokalari, Tomas Tobé

**Proposal for a regulation
Recital 5**

Text proposed by the Commission

(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and safety and the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council³³, and it ensures the protection of ethical principles, as specifically requested by the European Parliament³⁴.

³³ European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6.

³⁴ European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

Amendment

(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public **and private** interests, such as health and safety and the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council³³, and it ensures the protection of ethical principles, as specifically requested by the European Parliament³⁴.

³³ European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6.

³⁴ European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

Or. en

Amendment 353

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 5 a (new)

Text proposed by the Commission

Amendment

(5 a) Furthermore, in order to foster the development of artificial intelligence in line with Union values, the Union needs to address the main gaps and barriers blocking the potential of the digital transformation including the shortage of digitally skilled workers, cybersecurity concerns, lack of investment and access to investment, and existing and potential gaps between large companies, SME's and start-ups. Special attention should be paid to ensuring that the benefits of AI and innovation in new technologies are felt across all regions of the Union and that sufficient investment and resources are provided especially to those regions that may be lagging behind in some digital indicators.

Or. en

Amendment 354

Vincenzo Sofo, Kosma Złotowski

Proposal for a regulation

Recital 5 a (new)

Text proposed by the Commission

Amendment

(5 a) The regulatory framework addressing artificial intelligence should be without prejudice to existing and future Union laws concerning data protection, privacy, and protection of fundamental rights. In this regard, requirements of this Regulation should be consistent with the aims and objectives of, among others, the GDPR and the EUDPR. Where this Regulation addresses automated processing within the context of article 22 of the GDPR, the requirements contained in that article should continue to apply, ensuring the highest levels of protection for European citizens over the use of their personal data.

Amendment 355
Marion Walsmann

Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission

Amendment

(5 a) The Union legal framework for AI should respect existing sector specific legislations and create legal certainty by avoiding duplication and additional administrative burden;

Amendment 356
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 5 b (new)

Text proposed by the Commission

Amendment

(5 b) To ensure the development of secure, trustworthy and ethical AI, the European Commission established the High-Level Expert Group on Artificial Intelligence. In formulating both Ethics guidelines for Trustworthy AI and a corresponding Assessment List for Trustworthy Artificial Intelligence, this independent group solidified the foundational ambition for 'Trustworthy AI'. As noted by the group, Trustworthiness is a prerequisite for people, societies and companies to develop, deploy and use AI systems. Without AI systems – and the human beings behind them – being demonstrably worthy of trust, serious and unwanted consequences may ensue and the uptake of AI might be hindered, preventing the realisation of the potentially vast social

and economic benefits that trustworthy AI systems can bring. This approach should be seen as the basis of a European approach to both ensure and scale AI that is innovative and ethical.

Or. en

Amendment 357

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 6

Text proposed by the Commission

(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be based on the key functional characteristics of the *software*, in particular *the* ability, for a given set of human-defined objectives, to *generate outputs such as content, predictions, recommendations, or decisions which influence the environment with which the system interacts, be it in a physical or digital dimension*. AI systems *can be* designed to operate with varying levels of autonomy and be used on a stand-alone *basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded)*. *The definition of AI system should be complemented by a list of specific techniques and approaches used for its development, which should be kept up-to-date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list.*

Amendment

(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. *This definition should be in line with definitions that have found international acceptance. Moreover, it should be based on the key functional characteristics of artificial intelligence distinguishing it from more classic software systems and modelling approaches such as logistic regression and other techniques that are similarly transparent, explainable and interpretable. For the purposes of this Regulation, the definition should be based on the key functional characteristics of the AI system, in particular its ability, for a given set of human-defined objectives, to make predictions, recommendations, or decisions that influence real or virtual environments, whereby it uses machine and/or human-based data and inputs to (i) perceive real and/or virtual environments; (ii) abstract these perceptions into models through analysis in an automated manner (e.g. with machine learning), or manually; and (iii) use model inference to formulate options for outcomes.* AI systems *are* designed to operate with varying levels of autonomy and *can* be used on a stand-alone *software* system,

integrated into *a physical* product (embedded), *used to* serve the functionality of *a physical* product without being integrated therein (non-embedded) *or used as a subsystem of a software/physical/hybrid system of systems. If an AI system is used as a subsystem of a system of systems, then all parts including their interfaces to other parts of the system of systems that would be obsolete if the AI functionality were turned off or removed are essential parts of the AI system thus fall directly under this regulation. Any parts of the system of systems to which this does not hold true are not covered by this regulation and the obligations listed in this regulation do not apply to them. This is to ensure that the integration of AI systems into existing systems is not blocked by this regulation.*

Or. en

Amendment 358

Svenja Hahn, Nicola Beer, Dita Charanzová, Andrus Ansip, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Recital 6

Text proposed by the Commission

(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be based on the key functional characteristics of *the software*, in particular the ability, for a given set of human-defined objectives, to generate outputs such as content, predictions, recommendations, or decisions which influence *the environment with which the system interacts, be it in a physical or digital dimension*. AI systems can be designed to operate with varying levels of autonomy and be used on a stand-alone basis or as a component of a product,

Amendment

(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. *Therefore, the term AI system should be defined in line with internationally accepted definitions.* The definition should be based on the key functional characteristics of *AI systems*, in particular the ability, for a given set of human-defined objectives, to generate outputs such as content, predictions, recommendations, or decisions which influence *their physical or digital environment*. AI systems can be designed to operate with varying levels of autonomy

irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded). The definition of AI system should be complemented by a list of specific techniques and approaches used for its development, which should be kept up-to-date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list.

and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded). The definition of AI system should be complemented by a list of specific techniques and approaches used for its development, which should be kept up-to-date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list. ***In order to ensure alignment of definitions on an international level, the European Commission should engage in a dialogue with international organisations such as the Organisation for Economic Cooperation and Development (OECD), should their definitions of the term 'AI system' be adjusted.***

Or. en

Amendment 359

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

Proposal for a regulation Recital 6

Text proposed by the Commission

(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be based on the key functional characteristics of the software, in particular the ability, ***for a given set of human-defined objectives***, to generate outputs such as content, predictions, recommendations, or decisions which influence the environment with which the system interacts, be it in a physical or digital dimension. AI systems can be designed to operate with varying

Amendment

(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be based on the key functional characteristics of the software, in particular the ability ***to perceive, reason and act on machine and/or human-based inputs***, to generate outputs such as content, ***hypotheses***, predictions, recommendations, or decisions which influence the environment with which the system interacts, be it in a physical or digital dimension. AI systems

levels of autonomy and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded). *The definition of AI system should be complemented by a list of specific techniques and approaches used for its development, which should be kept up-to-date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list.*

can be designed to operate with varying levels of autonomy and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded).

Or. en

Amendment 360

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

Recital 6

Text proposed by the Commission

(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be based on the key functional characteristics of the software, in particular the ability, *for a given set of human-defined objectives*, to generate outputs such as content, predictions, recommendations, or decisions which influence the environment with which the system interacts, be it in a physical or digital dimension. AI systems can be designed to operate with varying levels of autonomy and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded). *The definition of*

Amendment

(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be based on the key functional characteristics of the software, in particular the ability to generate outputs such as content, predictions, recommendations, or decisions which influence the environment with which the system interacts, be it in a physical or digital dimension. AI systems can be designed to operate with varying levels of autonomy and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded). *AI systems can be developed through various techniques*

AI system should be complemented by a list of specific techniques and approaches used for its development, which should be kept up-to-date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list.

using learning, reasoning or modelling, such as: machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning; logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems; statistical approaches, Bayesian estimation, search and optimization methods.

Or. en

Justification

To ensure a future-proof Regulation and legal certainty, it is more appropriate to list the techniques in this recital and delete Annex I, to remove the need for updates and the risk of loopholes.

Amendment 361

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

**Proposal for a regulation
Recital 6**

Text proposed by the Commission

(6) Il convient de définir clairement la notion de système d'IA afin de garantir une sécurité juridique, tout en offrant la flexibilité nécessaire pour s'adapter aux progrès technologiques à venir. La définition devrait être *basée* sur les caractéristiques fonctionnelles clés du logiciel, en particulier la capacité, pour un ensemble donné d'objectifs *définis par l'homme*, à générer des résultats tels que du contenu, des prédictions, des recommandations ou des décisions qui influencent l'environnement avec lequel le système interagit, que ce soit dans une dimension physique ou numérique. Les systèmes d'IA peuvent être conçus pour fonctionner à différents niveaux

Amendment

(6) Il convient de définir clairement la notion de système d'IA afin de garantir une sécurité juridique, tout en offrant la flexibilité nécessaire pour s'adapter aux progrès technologiques à venir. La définition devrait être *fondée* sur les caractéristiques fonctionnelles clés du logiciel, en particulier la capacité, pour un ensemble donné d'objectifs *ou de paramètres ayant pour origine la commande humaine*, à générer des résultats tels que du contenu, des prédictions, des recommandations ou des décisions qui influencent l'environnement avec lequel le système interagit, que ce soit dans une dimension physique ou numérique. Les systèmes d'IA peuvent être

d'autonomie et être utilisés seuls ou en tant que composant d'un produit, que le système soit physiquement incorporé dans le produit (intégré) ou qu'il serve la fonctionnalité du produit sans être incorporé dans celui-ci (non intégré). La définition des systèmes d'IA devrait être complétée par une liste de techniques et d'approches spécifiques utilisées pour le développement de ces systèmes, laquelle devrait être mise à jour, pour tenir compte de l'évolution du marché et de la technologie, par l'adoption d'actes délégués de la Commission modifiant ladite liste.

conçus pour fonctionner à différents niveaux d'autonomie et être utilisés seuls ou en tant que composant d'un produit, que le système soit physiquement incorporé dans le produit (intégré) ou qu'il serve la fonctionnalité du produit sans être incorporé dans celui-ci (non intégré). La définition des systèmes d'IA devrait être complétée par une liste de techniques et d'approches spécifiques utilisées pour le développement de ces systèmes, laquelle devrait être mise à jour, pour tenir compte de l'évolution du marché et de la technologie, par l'adoption d'actes délégués de la Commission modifiant ladite liste. *Ces actes délégués ne devraient consister qu'en des ajouts à la liste des techniques utilisées.*

Or. fr

Amendment 362

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

Proposal for a regulation Recital 6

Text proposed by the Commission

(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be based on the key functional characteristics of the *software*, in particular the ability, for a given set of *human-defined* objectives, to generate outputs such as content, predictions, recommendations, or decisions *which influence the environment with which the system interacts, be it in a physical or digital dimension*. AI systems can be designed to operate with varying levels of autonomy and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product

Amendment

(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be based on the key functional characteristics of the *system*, in particular the ability, for a given set of objectives, to generate outputs such as content, predictions, recommendations, or decisions. AI systems can be designed to operate with varying levels of autonomy and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded). The definition of

(embedded) or serve the functionality of the product without being integrated therein (non-embedded). The definition of AI system should be complemented by a list of specific techniques and approaches used for its development, which should be kept up-to-date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list.

AI system should be complemented by a list of specific techniques and approaches used for its development, which should be kept up-to-date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list.

Or. en

Justification

AI systems are neither necessarily software or hardware, the distinction of which may be less relevant in the light of more current technological developments.

Amendment 363

Marion Walsmann

Proposal for a regulation

Recital 6

Text proposed by the Commission

(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be based on the key functional characteristics of the software, in particular the ability, for a given set of human-defined objectives, to generate outputs such as content, predictions, recommendations, or decisions which influence the environment with which the system interacts, be it in a physical or digital dimension. AI systems can be designed to operate with varying levels of autonomy and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded). The definition of AI system should be complemented by a

Amendment

(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate *existing harmless applications and* future technological developments. The definition should be based on the key functional characteristics of the software, in particular the ability, for a given set of human-defined objectives, to generate outputs such as content, predictions, recommendations, or decisions which influence the environment with which the system interacts, be it in a physical or digital dimension. AI systems can be designed to operate with varying levels of autonomy and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded). The definition of

list of specific techniques and approaches used for its development, which should be kept up-to-date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list.

AI system should be complemented by a list of specific techniques and approaches used for its development, which should be kept up-to-date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list.

Or. en

Amendment 364

Karlo Ressler

Proposal for a regulation Recital 6

Text proposed by the Commission

(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be ***based on the key functional characteristics of the software, in particular the ability, for a given set of human-defined objectives, to generate outputs such as content, predictions, recommendations, or decisions which influence the environment with which the system interacts, be it in a physical or digital dimension.*** AI systems can be designed to operate with varying levels of autonomy and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded). The definition of AI system should be complemented by a list of specific techniques and approaches used for its development, which should be kept up-to-date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list.

Amendment

(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be ***aligned with internationally accepted approach.*** AI systems can be designed to operate with varying levels of autonomy and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded). The definition of AI system should be complemented by a list of specific techniques and approaches used for its development, which should be kept up-to-date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list. ***The Commission should engage in dialogue with key international organizations, so that the common international standards could be achieved to the highest possible extent.***

Amendment 365

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 6 a (new)

Text proposed by the Commission

Amendment

(6 a) Defining AI systems is an ongoing process that should take into account the context in which AI operates, keep pace with societal developments in this field and not lose sight of the link between the ecosystem of excellence and the ecosystem of trust. The definition of AI system should be complemented by a list of specific techniques and approaches used for its development, which should be kept up-to-date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list. In the drafting process of these delegated acts, the Commission shall insure the input of all relevant stakeholders including the technical experts and developers of AI systems. This consultation can take place through existing bodies such as the High Level Expert Group on AI or a newly established similar advisory body that is closely included in the work of the European Artificial Intelligence Board. Should the definition of 'AI system' from the OECD be adjusted in the coming years, the European Commission should engage in dialogue with these organisations to ensure alignment between the two definitions. Should the AI Act still be undergoing legislative procedure, the co-legislators should consider these latest developments during the legislative process, so as to ensure alignment, legal clarity and broad international acceptance of the AI Act Definition of 'AI Systems'.

Amendment 366

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 6 b (new)

Text proposed by the Commission

Amendment

(6 b) Taking into account the work of International Standardisation Organisations, it is important to highlight the differences as well as the connection between Automation, Heteronomy and Autonomy. Experts speak of an automated system with different levels of automation instead of levels of autonomy. Autonomy is understood as the highest level of automation. An autonomous AI system would be capable to change its scope or its goals independently. However, today's AI technologies do not allow full autonomy yet and are not self-governing. Instead, they operate based on algorithms and otherwise obey the commands of operators. A fully autonomous AI system would be a genuine General or Super AI. Despite these restrictions, this Regulation will use the term "autonomy" as it is a key element of international accepted definitions.

Amendment 367

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 7

Text proposed by the Commission

Amendment

(7) The notion of biometric data used in this Regulation is in line with and should be interpreted consistently with the notion

(7) The notion of biometric data used in this Regulation is in line with and should be interpreted consistently with the notion

of biometric data as defined in Article 4(14) of Regulation (EU) 2016/679 of the European Parliament and of the Council³⁵, Article 3(18) of Regulation (EU) 2018/1725 of the European Parliament and of the Council³⁶ and Article 3(13) of Directive (EU) 2016/680 of the European Parliament and of the Council³⁷.

of biometric data as defined in Article 4(14) of Regulation (EU) 2016/679 of the European Parliament and of the Council³⁵, Article 3(18) of Regulation (EU) 2018/1725 of the European Parliament and of the Council³⁶ and Article 3(13) of Directive (EU) 2016/680 of the European Parliament and of the Council³⁷. *An additional definition has been added for ‘biometrics-based data’ to cover physical, physiological or behavioural data that may not meet the criteria to be defined as biometric data (i.e. would not allow or confirm the unique identification of a natural person) but which may be used for purposes such as emotion recognition or biometric categorisation. The addition of this definition does not narrow the scope of, nor exclude anything from, the definition of biometric data, but rather provides for a comprehensive scope for additional forms of data which may be used for purposes such as biometric categorisation but which would not allow or confirm unique identification.*

³⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

³⁶ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39)

³⁷ Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of

³⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

³⁶ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39)

³⁷ Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of

personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (Law Enforcement Directive) (OJ L 119, 4.5.2016, p. 89).

personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (Law Enforcement Directive) (OJ L 119, 4.5.2016, p. 89).

Or. en

Amendment 368

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 7

Text proposed by the Commission

(7) The notion of biometric data used in this Regulation is in line with and should be interpreted consistently with the notion of biometric data as defined in Article 4(14) of Regulation (EU) 2016/679 of the European Parliament and of the Council³⁵, Article 3(18) of Regulation (EU) 2018/1725 of the European Parliament and of the Council³⁶ and Article 3(13) of Directive (EU) 2016/680 of the European Parliament and of the Council³⁷.

Amendment

(7) The notion of biometric data used in this Regulation is in line with and should be interpreted consistently with the notion of biometric data as defined in Article 4(14) of Regulation (EU) 2016/679 of the European Parliament and of the Council³⁵, Article 3(18) of Regulation (EU) 2018/1725 of the European Parliament and of the Council³⁶ and Article 3(13) of Directive (EU) 2016/680 of the European Parliament and of the Council³⁷. *An additional definition has been added for ‘biometrics-based data’ to cover physical, physiological or behavioural data that may not meet the criteria to be defined as biometric data (i.e. would not allow or confirm the unique identification of a natural person) but which may be used for purposes such as emotion recognition or biometric categorisation. The addition of this definition does not narrow the scope of, nor exclude anything from, the definition of biometric data, but rather provides for a comprehensive scope for additional forms of data which may be used for purposes such as biometric categorisation but which would not allow*

or confirm unique identification.

³⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

³⁶ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39)

³⁷ Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (Law Enforcement Directive) (OJ L 119, 4.5.2016, p. 89).

³⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

³⁶ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39)

³⁷ Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (Law Enforcement Directive) (OJ L 119, 4.5.2016, p. 89).

Or. en

Amendment 369

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

Proposal for a regulation Recital 7

Text proposed by the Commission

(7) The notion of biometric data used

Amendment

(7) The notion of biometric data used

in this Regulation is ***in line with and should be interpreted consistently with the notion of biometric data as*** defined in Article 4(14) of Regulation (EU) 2016/679 of the European Parliament and of the Council³⁵, ***Article 3(18) of Regulation (EU) 2018/1725 of the European Parliament and of the Council³⁶ and Article 3(13) of Directive (EU) 2016/680 of the European Parliament and of the Council³⁷.***

³⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

³⁶ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39)

³⁷ Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (Law Enforcement Directive) (OJ L 119, 4.5.2016, p. 89).

in this Regulation is ***the same as that*** defined in Article 4(14) of Regulation (EU) 2016/679 of the European Parliament and of the Council³⁵.

³⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

Or. en

Amendment 370

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

Proposal for a regulation

Recital 7

Text proposed by the Commission

(7) The notion of biometric data used in this Regulation is in line with and should be interpreted consistently with the notion of biometric data as defined in Article 4(14) of Regulation (EU) 2016/679 of the European Parliament and of the Council³⁵, Article 3(18) of Regulation (EU) 2018/1725 of the European Parliament and of the Council³⁶ and Article 3(13) of Directive (EU) 2016/680 of the European Parliament and of the Council³⁷.

Amendment

(7) The notion of biometric data used in this Regulation is in line with and should be interpreted consistently with the notion of biometric data as defined in Article 4(14) of Regulation (EU) 2016/679 of the European Parliament and of the Council³⁵, Article 3(18) of Regulation (EU) 2018/1725 of the European Parliament and of the Council³⁶ and Article 3(13) of Directive (EU) 2016/680 of the European Parliament and of the Council³⁷. *The notion of “biometrics-based data” is broader, covering situations where the data in question may not, of itself, confirm the unique identification of an individual.*

³⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

³⁶ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39)

³⁷ Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of

³⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

³⁶ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39)

³⁷ Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of

personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (Law Enforcement Directive) (OJ L 119, 4.5.2016, p. 89).

personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (Law Enforcement Directive) (OJ L 119, 4.5.2016, p. 89).

Or. en

Amendment 371

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

Proposal for a regulation

Recital 8

Text proposed by the Commission

(8) The notion of **remote** biometric identification system as used in this Regulation should be defined functionally, as an AI system **intended** for the identification of natural persons **at a distance** through the comparison of a person's biometric data with the biometric data contained in a reference database, **and without prior knowledge whether the targeted person will be present and can be identified**, irrespectively of the particular technology, processes or types of biometric data used. **Considering their different characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between 'real-time' and 'post' remote biometric identification systems. In the case of 'real-time' systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the 'real-time' use of the AI systems in question by providing for**

Amendment

(8) The notion of biometric identification system as used in this Regulation should be defined functionally, as an AI system **performing automated recognition of physical, physiological, behavioural, and psychological human features**, for the **purpose of** identification of natural persons through the comparison of a person's biometric data with the biometric data contained in a reference database, irrespectively of the particular technology, processes or types of biometric data used.

minor delays. ‘Real-time’ systems involve the use of ‘live’ or ‘near-‘live’ material, such as video footage, generated by a camera or other device with similar functionality. In the case of ‘post’ systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.

Or. en

Amendment 372

Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Marc Angel

Proposal for a regulation Recital 8

Text proposed by the Commission

(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a person’s biometric data with the biometric data contained in a reference database, and without prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used. *Considering their different characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between ‘real-time’ and ‘post’ remote biometric identification systems. In the case of ‘real-time’ systems, the capturing of the biometric data, the comparison and*

Amendment

(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a person’s biometric data with the biometric data contained in a reference database, and without prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used.

the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the ‘real-time’ use of the AI systems in question by providing for minor delays. ‘Real-time’ systems involve the use of ‘live’ or ‘near-‘live’ material, such as video footage, generated by a camera or other device with similar functionality. In the case of ‘post’ systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.

Or. en

Amendment 373
Patrick Breyer

Proposal for a regulation
Recital 8

Text proposed by the Commission

(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a person’s biometric data with the biometric data contained in a reference database, and without prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used. ***Considering their different characteristics and manners in which they are used, as well as the different risks***

Amendment

(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a person’s biometric data with the biometric data contained in a reference database, and without prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used. ***Because remote biometric identification relates to how a system is designed and installed, and not solely to***

involved, a distinction should be made between ‘real-time’ and ‘post’ remote biometric identification systems. In the case of ‘real-time’ systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the ‘real-time’ use of the AI systems in question by providing for minor delays. ‘Real-time’ systems involve the use of ‘live’ or ‘near-‘live’ material, such as video footage, generated by a camera or other device with similar functionality. In the case of ‘post’ systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.

whether or not data subjects have consented, this definition applies even when warning notices are placed in the location that is under the surveillance of the remote biometric identification system, and is not de facto annulled by pre-enrolment.

Or. en

Amendment 374

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard, Vlad-Marius Boto , Abir Al-Sahlani, Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation Recital 8

Text proposed by the Commission

(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a person’s biometric data with the biometric data contained in a reference database, and

Amendment

(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a person’s biometric data with the biometric data contained in a reference database, and

without prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used. Considering their different characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between ‘real-time’ and ‘post’ remote biometric identification systems. In the case of ‘real-time’ systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the ‘real-time’ use of the AI systems in question by providing for minor delays. ‘Real-time’ systems involve the use of ‘live’ or ‘near-‘live’ material, such as video footage, generated by a camera or other device with similar functionality. In the case of ‘post’ systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.

without prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used. Considering their different characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between ‘real-time’ and ‘post’ remote biometric identification systems. In the case of ‘real-time’ systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the ‘real-time’ use of the AI systems in question by providing for minor delays. ‘Real-time’ systems involve the use of ‘live’ or ‘near-‘live’ material, such as video footage, generated by a camera or other device with similar functionality. In the case of ‘post’ systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.

The notion of remote biometric identification system shall not include verification or authentication systems whose sole purpose is to confirm that a specific natural person is the person he or she claims to be, and systems that are used to confirm the identity of a natural person for the sole purpose of having access to a service, a device or premises.

Or. en

Amendment 375

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Andrus Ansip, Dita Charanzová, Morten Løkkegaard,

**Proposal for a regulation
Recital 8**

Text proposed by the Commission

(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database, and without prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used. Considering their different characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between 'real-time' and 'post' remote biometric identification systems. In the case of 'real-time' systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the 'real-time' use of the AI systems in question by providing for minor delays. 'Real-time' systems involve the use of 'live' or 'near-'live' material, such as video footage, generated by a camera or other device with similar functionality. In the case of 'post' systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.

Amendment

(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database, and without prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used. Considering their different characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between 'real-time' and 'post' remote biometric identification systems. In the case of 'real-time' systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the 'real-time' use of the AI systems in question by providing for minor delays. 'Real-time' systems involve the use of 'live' or 'near-'live' material, such as video footage, generated by a camera or other device with similar functionality. In the case of 'post' systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.

The notion of remote biometric identification system shall not include authentication and verification systems

whose purpose is to confirm, based on prior consent, that a specific natural person is the person he or she claims to be or to confirm the identity of a natural person for the purpose of having access to a service, a device or premises.

Or. en

Amendment 376

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

Proposal for a regulation Recital 8

Text proposed by the Commission

(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference **database**, and without prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used. Considering their different characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between 'real-time' and 'post' **remote** biometric identification systems. In the case of 'real-time' systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the 'real-time' use of the AI systems in question by providing for minor delays. 'Real-time' systems involve the use of 'live' or 'near-'live' material, such as video footage, generated by a camera or other device with

Amendment

(8) The notion of **biometric identification system, including** remote biometric identification system as used in this Regulation, should be defined functionally, as an AI system intended for the identification of natural persons **including** at a distance through the comparison of a person's biometric data with the biometric data contained in a reference **data repository, excluding verification/ authentication systems whose sole purpose is to confirm that a specific natural person is the person he or she claims to be, and systems that are used to confirm the identity of a natural person for the sole purpose of having access to a service, a device or premises**, and without prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used. Considering their different characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between 'real-time' and 'post' biometric identification systems. In the case of 'real-time' systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously,

similar functionality. In the case of ‘post’ systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.

near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the ‘real-time’ use of the AI systems in question by providing for minor delays. ‘Real-time’ systems involve the use of ‘live’ or ‘near-live’ material, such as video footage, generated by a camera or other device with similar functionality. In the case of ‘post’ systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.

Or. en

Amendment 377

Kosma Złotowski, Patryk Jaki, Eugen Jurzyca, Adam Bielan

Proposal for a regulation Recital 8

Text proposed by the Commission

(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a person’s biometric data with the biometric data contained in a *reference* database, and without prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used. Considering their different characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between ‘real-time’ and ‘post’ remote biometric identification systems. In the

Amendment

(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a person’s biometric data with the biometric data contained in a database *data repository, excluding verification/authentication systems whose sole purpose is to confirm that a specific natural person is the person he or she claims to be, and systems that are used to confirm the identity of a natural person for the sole purpose of having access to a service, a device or premises*, and without prior knowledge whether the targeted person will be present and can be

case of ‘real-time’ systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the ‘real-time’ use of the AI systems in question by providing for minor delays. ‘Real-time’ systems involve the use of ‘live’ or ‘near-live’ material, such as video footage, generated by a camera or other device with similar functionality. In the case of ‘post’ systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.

identified, irrespectively of the particular technology, processes or types of biometric data used. Considering their different characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between ‘real-time’ and ‘post’ remote biometric identification systems. In the case of ‘real-time’ systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the ‘real-time’ use of the AI systems in question by providing for minor delays. ‘Real-time’ systems involve the use of ‘live’ or ‘near-live’ material, such as video footage, generated by a camera or other device with similar functionality. In the case of ‘post’ systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.

Or. en

Amendment 378

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

Proposal for a regulation Recital 8

Text proposed by the Commission

(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a

Amendment

(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a

person's biometric data with the biometric data contained in a reference database, *and without prior knowledge whether the targeted person will be present and can be identified*, irrespectively of the particular technology, processes or types of biometric data used. *Considering their different characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between 'real-time' and 'post' remote biometric identification systems. In the case of 'real-time' systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the 'real-time' use of the AI systems in question by providing for minor delays. 'Real-time' systems involve the use of 'live' or 'near-'live' material, such as video footage, generated by a camera or other device with similar functionality.* In the case of 'post' systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.

person's biometric data with the biometric data contained in a reference database, irrespectively of the particular technology, processes or types of biometric data used. *The notion of 'at a distance' in Remote Biometric Identification (RBI) means the use of systems as described in Article 3(36), at a distance great enough that the system has the capacity to scan multiple persons in its field of view (or the equivalent generalised scanning of online / virtual spaces), which would mean that the identification could happen without one or more of the data subjects' knowledge. Because RBI relates to how a system is designed and installed, and not solely to whether or not data subjects have consented, this definition applies even when warning notices are placed in the location that is under the surveillance of the RBI system, and is not de facto annulled by pre-enrolment.*

Or. en

Amendment 379
Axel Voss, Deirdre Clune

Proposal for a regulation
Recital 8

Text proposed by the Commission

(8) The notion of remote biometric

Amendment

(8) The notion of remote biometric

identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference **database**, and without prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used. Considering their different characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between 'real-time' and 'post' remote biometric identification systems. In the case of 'real-time' systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the 'real-time' use of the AI systems in question by providing for minor delays. 'Real-time' systems involve the use of 'live' or 'near-'live' material, such as video footage, generated by a camera or other device with similar functionality. In the case of 'post' systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.

identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference **data repository**, and without prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used. Considering their different characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between 'real-time' and 'post' remote biometric identification systems. In the case of 'real-time' systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the 'real-time' use of the AI systems in question by providing for minor delays. 'Real-time' systems involve the use of 'live' or 'near-'live' material, such as video footage, generated by a camera or other device with similar functionality. In the case of 'post' systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.

Or. en

Amendment 380

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

Proposal for a regulation

Recital 9

Text proposed by the Commission

(9) For the purposes of this Regulation the notion of publicly accessible space should be understood as referring to any physical place that is accessible to the public, irrespective of whether the place in question is privately or publicly owned. Therefore, the notion ***does not cover*** places that are private in nature and normally not freely accessible for third parties, including law enforcement authorities, unless those parties have been specifically invited or authorised, such as homes, private clubs, ***offices, warehouses and factories.*** ***Online spaces are not covered either, as they are not physical spaces.*** However, the mere fact that certain conditions for accessing a particular space may apply, such as admission tickets or age restrictions, does not mean that the space is not publicly accessible within the meaning of this Regulation. Consequently, in addition to public spaces such as streets, relevant parts of government buildings and most transport infrastructure, spaces such as cinemas, theatres, shops and shopping centres are normally also publicly accessible. Whether a given space is accessible to the public should however be determined on a case-by-case basis, having regard to the specificities of the individual situation at hand.

Amendment

(9) For the purposes of this Regulation the notion of publicly accessible ***physical or virtual*** space should be understood as referring to any physical ***or virtual*** place that is accessible to the public, ***on a temporary or permanent basis,*** irrespective of whether the place in question is privately or publicly owned. Therefore, the notion ***covers*** places that are ***both*** private in nature, ***used for private purposes only, accessed completely voluntarily*** and normally not freely accessible for third parties, including law enforcement authorities, unless those parties have been specifically invited or authorised, such as homes ***and*** private clubs. However, the mere fact that certain conditions for accessing a particular space may apply, such as admission tickets or age restrictions, does not mean that the space is not publicly accessible within the meaning of this Regulation. Consequently, in addition to public spaces such as streets, relevant parts of government buildings and most transport infrastructure, spaces such as cinemas, theatres, ***sports grounds, virtual gaming environments, schools, universities, hospitals, amusement parks, festivals,*** shops and shopping centres, ***offices, warehouses and factories*** are normally also publicly accessible. Whether a given space is accessible to the public should however be determined on a case-by-case basis, having regard to the specificities of the individual situation at hand.

Or. en

Amendment 381

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

Proposal for a regulation

Recital 9

Text proposed by the Commission

(9) Aux fins du présent règlement, la notion d'espace accessible au public devrait être comprise comme désignant tous les lieux physiques accessibles au public, qu'ils appartiennent à un propriétaire privé ou public. Par conséquent, cette notion ne couvre pas les lieux qui sont privés par nature et qui en temps normal ne sont pas librement accessibles à des tiers, y compris aux autorités répressives, sauf si ces tiers ont été spécifiquement invités ou autorisés, comme les logements, les clubs privés, les bureaux, les entrepôts et les usines. Les espaces en ligne ne sont pas non plus couverts, car ce ne sont pas des espaces physiques. Cependant, le simple fait que l'accès à un espace donné soit soumis à certaines conditions, telles que des billets d'entrée ou des restrictions d'âge, ne signifie pas que l'espace n'est pas accessible au public au sens du présent règlement. Par conséquent, outre les espaces publics tels que les rues, les parties pertinentes de bâtiments du secteur public et la plupart des infrastructures de transport, les espaces tels que les cinémas, les théâtres, les magasins et les centres commerciaux sont normalement aussi accessibles au public. Le caractère accessible au public ou non d'un espace donné devrait cependant être déterminé au cas par cas, en tenant compte des particularités de la situation en question.

Amendment

(9) Aux fins du présent règlement, la notion d'espace accessible au public devrait être comprise comme désignant tous les lieux physiques accessibles au public, qu'ils appartiennent à un propriétaire privé ou public. Par conséquent, cette notion ne couvre pas les lieux qui sont privés par nature et qui en temps normal ne sont pas librement accessibles à des tiers, y compris aux autorités répressives, sauf si ces tiers ont été spécifiquement invités ou autorisés, comme les logements, les clubs privés, les bureaux, les entrepôts et les usines. Les espaces en ligne ne sont pas non plus couverts, car ce ne sont pas des espaces physiques. Cependant, le simple fait que l'accès à un espace donné soit soumis à certaines conditions, telles que des billets d'entrée ou des restrictions d'âge, ne signifie pas que l'espace n'est pas accessible au public au sens du présent règlement. Par conséquent, outre les espaces publics tels que les rues, les parties pertinentes de bâtiments du secteur public et la plupart des infrastructures de transport, les espaces tels que les cinémas, les théâtres, les magasins et les centres commerciaux sont normalement aussi accessibles au public. Le caractère accessible au public ou non d'un espace donné devrait cependant être déterminé au cas par cas *par l'autorité judiciaire ou administrative compétente*, en tenant compte des particularités de la situation en question.

Or. fr

Amendment 382

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
Recital 9

Text proposed by the Commission

(9) For the purposes of this Regulation the notion of publicly accessible space should be understood as referring to any physical place that is accessible to the public, irrespective of whether the place in question is privately or publicly owned. Therefore, the notion does not cover places that are private in nature and normally not freely accessible for third parties, including law enforcement authorities, unless those parties have been specifically invited or authorised, such as homes, private clubs, offices, warehouses and factories. ***Online spaces are not covered either, as they are not physical spaces.*** However, the mere fact that certain conditions for accessing a particular space may apply, such as admission tickets or age restrictions, does not mean that the space is not publicly accessible within the meaning of this Regulation. Consequently, in addition to public spaces such as streets, relevant parts of government buildings and most transport infrastructure, spaces such as cinemas, theatres, shops and shopping centres are normally also publicly accessible. Whether a given space is accessible to the public should however be determined on a case-by-case basis, having regard to the specificities of the individual situation at hand.

Amendment

(9) For the purposes of this Regulation the notion of publicly accessible space should be understood as referring to any physical place that is accessible to the public, irrespective of whether the place in question is privately or publicly owned. Therefore, the notion does not cover places that are private in nature and normally not freely accessible for third parties, including law enforcement authorities, unless those parties have been specifically invited or authorised, such as homes, private clubs, offices, warehouses and factories. However, the mere fact that certain conditions for accessing a particular space may apply, such as admission tickets or age restrictions, does not mean that the space is not publicly accessible within the meaning of this Regulation. Consequently, in addition to public spaces such as streets, relevant parts of government buildings and most transport infrastructure, spaces such as cinemas, theatres, shops and shopping centres are normally also publicly accessible. Whether a given space is accessible to the public should however be determined on a case-by-case basis, having regard to the specificities of the individual situation at hand.

Or. en

Amendment 383

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

Proposal for a regulation
Recital 9

Text proposed by the Commission

Amendment

(9) For the purposes of this Regulation the notion of publicly accessible space should be understood as referring to any physical place that is accessible to the public, irrespective of whether the place in question is privately or publicly owned. Therefore, the notion does not cover places that are private in nature and normally not freely accessible for third parties, including law enforcement authorities, unless those parties have been specifically invited or authorised, such as homes, private clubs, offices, warehouses and factories. ***Online spaces are not covered either, as they are not physical spaces.*** However, the mere fact that certain conditions for accessing a particular space may apply, such as admission tickets or age restrictions, does not mean that the space is not publicly accessible within the meaning of this Regulation. Consequently, in addition to public spaces such as streets, relevant parts of government buildings and most transport infrastructure, spaces such as cinemas, theatres, shops and shopping centres are normally also publicly accessible. Whether a given space is accessible to the public should however be determined on a case-by-case basis, having regard to the specificities of the individual situation at hand.

(9) For the purposes of this Regulation the notion of publicly accessible space should be understood as referring to any physical place that is accessible to the public, irrespective of whether the place in question is privately or publicly owned. Therefore, the notion does not cover places that are private in nature and normally not freely accessible for third parties, including law enforcement authorities, unless those parties have been specifically invited or authorised, such as homes, private clubs, offices, warehouses and factories. However, the mere fact that certain conditions for accessing a particular space may apply, such as admission tickets or age restrictions, does not mean that the space is not publicly accessible within the meaning of this Regulation. Consequently, in addition to public spaces such as streets, relevant parts of government buildings and most transport infrastructure, spaces such as cinemas, theatres, shops and shopping centres are normally also publicly accessible. Whether a given space is accessible to the public should however be determined on a case-by-case basis, having regard to the specificities of the individual situation at hand.

Or. en

Amendment 384

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation Recital 9

Text proposed by the Commission

(9) For the purposes of this Regulation the notion of publicly accessible space should be understood as referring to any physical place that is accessible to the public, irrespective of whether the place in question is privately or publicly owned.

Amendment

(9) For the purposes of this Regulation the notion of publicly accessible space should be understood as referring to any physical place that is accessible to the public, irrespective of whether the place in question is privately or publicly owned.

Therefore, the notion does not cover places that are private in nature and normally not freely accessible for third parties, including law enforcement authorities, unless those parties have been specifically invited or authorised, such as homes, private clubs, offices, warehouses and factories. ***Online spaces are not covered either, as they are not physical spaces.*** However, the mere fact that certain conditions for accessing a particular space may apply, such as admission tickets or age restrictions, does not mean that the space is not publicly accessible within the meaning of this Regulation. Consequently, in addition to public spaces such as streets, relevant parts of government buildings and most transport infrastructure, spaces such as cinemas, theatres, shops and shopping centres are normally also publicly accessible. Whether a given space is accessible to the public should however be determined on a case-by-case basis, having regard to the specificities of the individual situation at hand.

Therefore, the notion does not cover places that are private in nature and normally not freely accessible for third parties, including law enforcement authorities, unless those parties have been specifically invited or authorised, such as homes, private clubs, offices, warehouses and factories. However, the mere fact that certain conditions for accessing a particular space may apply, such as admission tickets or age restrictions, does not mean that the space is not publicly accessible within the meaning of this Regulation. Consequently, in addition to ***online and*** public spaces such as streets, relevant parts of government buildings and most transport infrastructure, spaces such as cinemas, theatres, shops and shopping centres are normally also publicly accessible. Whether a given space is accessible to the public should however be determined on a case-by-case basis, having regard to the specificities of the individual situation at hand.

Or. en

Amendment 385

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

Proposal for a regulation Recital 9 a (new)

Text proposed by the Commission

Amendment

(9 a) In order to ensure the rights of individuals and groups, and the growth of trustworthy AI, certain principles should be guaranteed across all AI systems, such as transparency, the right to an explanation and the right to object to a decision. This requires that discrimination, and detrimental power and information imbalances be prevented, control and oversight guaranteed, and that compliance is demonstrable and

subject to ongoing monitoring. Decision-making by, or supported by, AI systems, should be subject to specific transparency rules, as regards the logic and parameters on which decisions are made.

Or. en

Amendment 386

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

Proposal for a regulation

Recital 9 b (new)

Text proposed by the Commission

Amendment

(9 b) Requirements on transparency and on the explicability of AI decision-making should contribute to countering the deterrent effects of digital asymmetry, power and information imbalance, and so-called ‘dark patterns’ targeting individuals and their informed consent.

Or. en

Amendment 387

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

Proposal for a regulation

Recital 10

Text proposed by the Commission

Amendment

(10) In order to ensure a level playing field and an effective protection of rights and freedoms of individuals across the Union, the rules established by this Regulation should apply to providers of AI systems in a non-discriminatory manner, irrespective of whether they are established within the Union or in a third country, and to *users* of AI systems established within the Union.

(10) In order to ensure a level playing field and an effective protection of rights and freedoms of individuals across the Union, the rules established by this Regulation should apply to providers of AI systems in a non-discriminatory manner, irrespective of whether they are established within the Union or in a third country, and to *deployers* of AI systems established within the Union. ***This Regulation and the***

rules it establishes should take into account different development and business models and the fact that standard implementations, or Free and Open Source software development and licensing models might entail less knowledge about and little to no control over further use, modification, and deployment within an AI system.

Or. en

Amendment 388

Marion Walsmann

Proposal for a regulation

Recital 10

Text proposed by the Commission

(10) In order to ensure a level playing field and an effective protection of rights and freedoms of individuals across the Union, the rules established by this Regulation should apply to providers of AI systems in a non-discriminatory manner, irrespective of whether they are established within the Union or in a third country, and to users of AI systems established within the Union.

Amendment

(10) In order to ensure a level playing field and an effective protection of rights and freedoms of individuals across the Union **and on international level**, the rules established by this Regulation should apply to providers of AI systems in a non-discriminatory manner, irrespective of whether they are established within the Union or in a third country, and to users of AI systems established within the Union.

Or. en

Amendment 389

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte

Proposal for a regulation

Recital 11

Text proposed by the Commission

(11) Compte tenu de leur nature numérique, certains systèmes d'IA devraient relever du présent règlement même lorsqu'ils ne sont ni mis sur le marché, ni mis en service, ni utilisés dans

Amendment

(11) Compte tenu de leur nature numérique, certains systèmes d'IA devraient relever du présent règlement même lorsqu'ils ne sont ni mis sur le marché, ni mis en service, ni utilisés dans

l’Union. Cela devrait notamment être le cas lorsqu’un opérateur établi dans l’Union confie à un opérateur externe établi en dehors de l’Union la tâche d’exécuter certains services ayant trait à une activité devant être réalisée par un système d’IA, qui serait considéré comme étant à haut risque et dont les effets ont une incidence sur des personnes physiques situées dans l’Union. Dans ces circonstances, l’opérateur établi en dehors de l’Union pourrait utiliser un système d’IA pour traiter des données légalement collectées et transférées depuis l’Union, et fournir à l’opérateur contractant établi dans l’Union le résultat de ce traitement, sans que ce système d’IA soit mis sur le marché, mis en service ou utilisé dans l’Union. Afin d’éviter le contournement des règles du présent règlement et d’assurer une protection efficace des personnes physiques situées dans l’Union, le présent règlement devrait également s’appliquer aux fournisseurs et aux utilisateurs de systèmes d’IA qui sont établis dans un pays tiers, dans la mesure où le résultat produit par ces systèmes est utilisé dans l’Union.

Néanmoins, pour tenir compte des dispositions existantes et des besoins particuliers de coopération avec les partenaires étrangers avec lesquels des informations et des preuves sont échangées, le présent règlement ne devrait pas s’appliquer aux autorités publiques d’un pays tiers ni aux organisations internationales lorsqu’elles agissent dans le cadre d’accords internationaux conclus au niveau national ou au niveau européen pour la coopération des services répressifs et judiciaires avec l’Union ou avec ses États membres. De tels accords ont été conclus bilatéralement entre des États membres et des pays tiers ou entre l’Union européenne, Europol et d’autres agences de l’UE, des pays tiers et des organisations internationales.

l’Union. Cela devrait notamment être le cas lorsqu’un opérateur établi dans l’Union confie à un opérateur externe établi en dehors de l’Union la tâche d’exécuter certains services ayant trait à une activité devant être réalisée par un système d’IA, qui serait considéré comme étant à haut risque et dont les effets ont une incidence sur des personnes physiques situées dans l’Union. Dans ces circonstances, l’opérateur établi en dehors de l’Union pourrait utiliser un système d’IA pour traiter des données légalement collectées et transférées depuis l’Union, et fournir à l’opérateur contractant établi dans l’Union le résultat de ce traitement, sans que ce système d’IA soit mis sur le marché, mis en service ou utilisé dans l’Union. Afin d’éviter le contournement des règles du présent règlement et d’assurer une protection efficace des personnes physiques situées dans l’Union, le présent règlement devrait également s’appliquer aux fournisseurs et aux utilisateurs de systèmes d’IA qui sont établis dans un pays tiers, dans la mesure où le résultat produit par ces systèmes est utilisé dans l’Union.

Or. fr

Amendment 390

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

Recital 11

Text proposed by the Commission

(11) In light of their digital nature, certain AI systems should fall within the scope of this Regulation even when they are neither placed on the market, nor put into service, nor used in the Union. This is the case for example of an operator established in the Union that contracts certain services to an operator established outside the Union in relation to an activity to be performed by an AI system that would qualify as high-risk and whose effects impact natural persons located in the Union. In those circumstances, the AI system used by the operator outside the Union could process data lawfully collected in and transferred from the Union, and provide to the contracting operator in the Union the output of that AI system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and users of AI systems that are established in a third country, to the extent the output produced by those systems is used in the Union. *Nonetheless, to take into account existing arrangements and special needs for cooperation with foreign partners with whom information and evidence is exchanged, this Regulation should not apply to public authorities of a third country and international organisations when acting in the framework of international agreements concluded at national or European level for law enforcement and judicial cooperation with the Union or with its*

Amendment

(11) In light of their digital nature, certain AI systems should fall within the scope of this Regulation even when they are neither placed on the market, nor put into service, nor used in the Union. This is the case for example of an operator established in the Union that contracts certain services to an operator established outside the Union in relation to an activity to be performed by an AI system that would qualify as high-risk and whose effects impact natural persons located in the Union. In those circumstances, the AI system used by the operator outside the Union could process data lawfully collected in and transferred from the Union, and provide to the contracting operator in the Union the output of that AI system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and users of AI systems that are established in a third country, to the extent the output produced by those systems is used in the Union.

Member States. Such agreements have been concluded bilaterally between Member States and third countries or between the European Union, Europol and other EU agencies and third countries and international organisations.

Or. en

Justification

Consistent with the changes in Article 2.

Amendment 391

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

Proposal for a regulation

Recital 11

Text proposed by the Commission

(11) In light of their digital nature, certain AI systems should fall within the scope of this Regulation even when they are neither placed on the market, nor put into service, nor used in the Union. This is the case for example of an operator established in the Union that contracts certain services to an operator established outside the Union in relation to an activity to be performed by an AI system **that would qualify as high-risk and** whose effects impact natural persons located in the Union. In those circumstances, the AI system used by the operator outside the Union could process data lawfully collected in and transferred from the Union, and provide to the contracting operator in the Union the output of that AI system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and users of AI systems that are

Amendment

(11) In light of their digital nature, certain AI systems should fall within the scope of this Regulation even when they are neither placed on the market, nor put into service, nor used in the Union. This is the case for example of an operator established in the Union that contracts certain services to an operator established outside the Union in relation to an activity to be performed by an AI system whose effects impact natural persons located in the Union. In those circumstances, the AI system used by the operator outside the Union could process data lawfully collected in and transferred from the Union, and provide to the contracting operator in the Union the output of that AI system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and users of AI systems that are established in a third country, to the extent

established in a third country, to the extent the output produced by those systems is used in the Union. *Nonetheless, to take into account existing arrangements and special needs for cooperation with foreign partners with whom information and evidence is exchanged, this Regulation should not apply to public authorities of a third country and international organisations when acting in the framework of international agreements concluded at national or European level for law enforcement and judicial cooperation with the Union or with its Member States. Such agreements have been concluded bilaterally between Member States and third countries or between the European Union, Europol and other EU agencies and third countries and international organisations.*

the output produced by those systems is used in the Union *or it affects natural persons within* the Union.

Or. en

Amendment 392

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

Proposal for a regulation

Recital 11

Text proposed by the Commission

(11) In light of their digital nature, certain AI systems should fall within the scope of this Regulation even when they are neither placed on the market, nor put into service, nor used in the Union. This is the case for example of an operator established in the Union that contracts certain services to an operator established outside the Union in relation to an activity to be performed by an AI system that would qualify as high-risk and whose effects impact natural persons located in the Union. In those circumstances, the AI system used by the operator outside the Union could process data lawfully collected in and transferred from the

Amendment

(11) In light of their digital nature, certain AI systems should fall within the scope of this Regulation even when they are neither placed on the market, nor put into service, nor used in the Union. This is the case for example of an operator established in the Union that contracts certain services to an operator established outside the Union in relation to an activity to be performed by an AI system that would qualify as high-risk and whose effects impact natural persons located in the Union. In those circumstances, the AI system used by the operator outside the Union could process data lawfully collected in and transferred from the

Union, and provide to the contracting operator in the Union the output of that AI system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and *users* of AI systems that are established in a third country, to the extent the output produced by those systems is used in the Union. *Nonetheless, to take into account existing arrangements and special needs for cooperation with foreign partners with whom information and evidence is exchanged, this Regulation should not apply to public authorities of a third country and international organisations when acting in the framework of international agreements concluded at national or European level for law enforcement and judicial cooperation with the Union or with its Member States. Such agreements have been concluded bilaterally between Member States and third countries or between the European Union, Europol and other EU agencies and third countries and international organisations.*

Union, and provide to the contracting operator in the Union the output of that AI system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and *deployers* of AI systems that are established in a third country, to the extent the output produced by those systems is used in the Union *or affects people in* the Union.

Or. en

Amendment 393

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Andrus Ansip, Dita Charanzová, Alin Mituță

Proposal for a regulation Recital 11

Text proposed by the Commission

(11) In light of their digital nature, certain AI systems should fall within the scope of this Regulation even when they are neither placed on the market, nor put into service, nor used in the Union. This is

Amendment

(11) In light of their digital nature, certain AI systems should fall within the scope of this Regulation even when they are neither placed on the market, nor put into service, nor used in the Union. This is

the case for example of an operator established in the Union that contracts certain services to an operator established outside the Union in relation to an activity to be performed by an AI system that would qualify as high-risk and whose effects impact natural persons located in the Union. In those circumstances, the AI system used by the operator outside the Union could process data lawfully collected in and transferred from the Union, and provide to the contracting operator in the Union the output of that AI system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and users of AI systems that are established in a third country, to the extent the output produced by those systems is used in the Union. Nonetheless, to take into account existing arrangements and special needs for cooperation with foreign partners with whom information and evidence is exchanged, this Regulation should not apply to public authorities of a third country and international organisations when acting in the framework of international agreements concluded at national or European level for law enforcement and judicial cooperation with the Union or with its Member States. Such agreements have been concluded bilaterally between Member States and third countries or between the European Union, Europol and other EU agencies and third countries and international organisations.

the case for example of an operator established in the Union that contracts certain services to an operator established outside the Union in relation to an activity to be performed by an AI system that would qualify as high-risk and whose effects impact natural persons located in the Union. In those circumstances, the AI system used by the operator outside the Union could process data lawfully collected in and transferred from the Union, and provide to the contracting operator in the Union the output of that AI system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and users of AI systems that are established in a third country, to the extent the output produced by those systems is used in the Union. Nonetheless, to take into account existing arrangements and special needs for cooperation with foreign partners with whom information and evidence is exchanged, this Regulation should not apply to public authorities of a third country and international organisations when acting in the framework of international agreements concluded at national or European level for law enforcement and judicial cooperation with the Union or with its Member States. Such agreements have been concluded bilaterally between Member States and third countries or between the European Union, Europol and other EU agencies and third countries and international organisations. ***This exception should nevertheless be limited to trusted countries and international organizations that share the Union's values.***

Or. en

Amendment 394

Proposal for a regulation

Recital 11

Text proposed by the Commission

(11) In light of their digital nature, certain AI systems should fall within the scope of this Regulation even when they are neither placed on the market, nor put into service, nor used in the Union. This is the case for example of an operator established in the Union that contracts certain services to an operator established outside the Union in relation to an activity to be performed by an AI system that would qualify as high-risk **and whose effects impact natural persons located in the Union**. In those circumstances, the AI system used by the operator outside the Union could process data lawfully collected in and transferred from the Union, and provide to the contracting operator in the Union the output of that AI system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and users of AI systems that are established in a third country, to the extent the output produced by those systems is **used** in the Union. Nonetheless, to take into account existing arrangements and special needs for cooperation with foreign partners with whom information and evidence is exchanged, this Regulation should not apply to public authorities of a third country and international organisations when acting in the framework of international agreements concluded at national or European level for law enforcement and judicial cooperation with the Union or with its Member States. Such agreements have been concluded bilaterally between Member States and third countries or between the European

Amendment

(11) In light of their digital nature, certain AI systems should fall within the scope of this Regulation even when they are neither placed on the market, nor put into service, nor used in the Union. This is the case for example of an operator established in the Union that contracts certain services to an operator established outside the Union in relation to an activity to be performed by an AI system that would qualify as high-risk. In those circumstances, the AI system used by the operator outside the Union could process data lawfully collected in and transferred from the Union, and provide to the contracting operator in the Union the output of that AI system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and users of AI systems that are established in a third country, to the extent the output produced by those systems is **intended for use** in the Union. Nonetheless, to take into account existing arrangements and special needs for **future** cooperation with foreign partners with whom information and evidence is exchanged, this Regulation should not apply to public authorities of a third country and international organisations when acting in the framework of international agreements concluded at national or European level for law enforcement and judicial cooperation with the Union or with its Member States. Such agreements have been concluded bilaterally between Member States and third countries or between the European Union, Europol and other EU agencies and

Union, Europol and other EU agencies and third countries and international organisations.

third countries and international organisations.

Or. en

Amendment 395

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

Recital 12

Text proposed by the Commission

(12) This Regulation should also apply to Union institutions, offices, bodies and agencies when acting as a provider or user of an AI system. *AI systems exclusively developed or used for military purposes should be excluded from the scope of this Regulation where that use falls under the exclusive remit of the Common Foreign and Security Policy regulated under Title V of the Treaty on the European Union (TEU).* This Regulation should be without prejudice to the provisions regarding the liability of intermediary service providers set out in Directive 2000/31/EC of the European Parliament and of the Council [as amended by the Digital Services Act].

Amendment

(12) This Regulation should also apply to Union institutions, offices, bodies and agencies when acting as a provider or user of an AI system. This Regulation should be without prejudice to the provisions regarding the liability of intermediary service providers set out in Directive 2000/31/EC of the European Parliament and of the Council [as amended by the Digital Services Act].

Or. en

Amendment 396

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst

Proposal for a regulation

Recital 12

Text proposed by the Commission

(12) This Regulation should also apply to Union institutions, offices, bodies and agencies when acting as a provider or user

Amendment

(12) This Regulation should also apply to Union institutions, offices, bodies and agencies when acting as a provider or user

of an AI system. *AI systems exclusively developed or used for military purposes should be excluded from the scope of this Regulation where that use falls under the exclusive remit of the Common Foreign and Security Policy regulated under Title V of the Treaty on the European Union (TEU)*. This Regulation should be without prejudice to the provisions regarding the liability of intermediary service providers set out in Directive 2000/31/EC of the European Parliament and of the Council [as amended by the Digital Services Act].

of an AI system. This Regulation should be without prejudice to the provisions regarding the liability of intermediary service providers set out in Directive 2000/31/EC of the European Parliament and of the Council [as amended by the Digital Services Act].

Or. en

Amendment 397

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

Proposal for a regulation

Recital 12

Text proposed by the Commission

(12) This Regulation should also apply to Union institutions, offices, bodies and agencies when acting as a provider or *user* of an AI system. *AI systems exclusively developed or used for military purposes should be excluded from the scope of this Regulation where that use falls under the exclusive remit of the Common Foreign and Security Policy regulated under Title V of the Treaty on the European Union (TEU)*. This Regulation should be without prejudice to the provisions regarding the liability of intermediary service providers set out in Directive 2000/31/EC of the European Parliament and of the Council [as amended by the Digital Services Act].

Amendment

(12) This Regulation should also apply to Union institutions, offices, bodies and agencies when acting as a provider or *deployer* of an AI system. This Regulation should be without prejudice to the provisions regarding the liability of intermediary service providers set out in Directive 2000/31/EC of the European Parliament and of the Council [as amended by the Digital Services Act].

Or. en

Amendment 398

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

Garraud

Proposal for a regulation

Recital 12

Text proposed by the Commission

(12) Le présent règlement devrait également s'appliquer aux institutions, organismes, organes et agences de l'Union *lorsqu'ils agissent en tant que fournisseurs ou utilisateurs d'un système d'IA*. Les systèmes d'IA exclusivement développés ou utilisés à des fins militaires devraient être exclus du champ d'application du présent règlement *lorsque cette utilisation relève de la compétence exclusive de la politique étrangère et de sécurité commune régie par le titre V du traité sur l'Union européenne (TUE)*. Le présent règlement ne devrait pas porter atteinte aux dispositions relatives à la responsabilité des prestataires de services intermédiaires énoncées dans la directive 2000/31/CE du Parlement européen et du Conseil (telle que modifiée par la législation sur les services numériques).

Amendment

(12) Le présent règlement devrait également s'appliquer aux institutions, organismes, organes et agences de l'Union. Les systèmes d'IA exclusivement développés ou utilisés à des fins militaires devraient être exclus du champ d'application du présent règlement. Le présent règlement ne devrait pas porter atteinte aux dispositions relatives à la responsabilité des prestataires de services intermédiaires énoncées dans la directive 2000/31/CE du Parlement européen et du Conseil (telle que modifiée par la législation sur les services numériques).

Or. fr

Amendment 399

Svenja Hahn, Nicola Beer, Karen Melchior, Dita Charanzová, Andrus Ansip, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ondřej Kováčík, Jan-Christoph Oetjen

Proposal for a regulation

Recital 12 a (new)

Text proposed by the Commission

Amendment

(12 a) This Regulation should not undermine research and development activity and should respect freedom of science. It is therefore necessary to exclude from its scope AI systems specifically developed and put into service for the sole purpose of scientific research and development and to ensure that the

Regulation does not otherwise affect scientific research and development activity on AI systems. As regards product oriented research activity by providers, the provisions of this Regulation should apply insofar as such research leads to or entails placing of an AI system on the market or putting it into service. Under all circumstances, any research and development activity should be carried out in accordance with recognised ethical standards for scientific research.

Or. en

Amendment 400

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Recital 12 a (new)

Text proposed by the Commission

Amendment

(12 a) This Regulation should also ensure harmonisation and consistency in definitions and terminology as biometric techniques can, in the light of their primary function, be divided into techniques of biometric identification, authentication and verification. Biometric authentication means the process of matching an identifier to a specific stored identifier in order to grant access to a device or service, whilst biometric verification refers to the process of confirming that an individual is who they claim to be. As they do not involve any “one-to-many” comparison of biometric data that is the distinctive trait of identification, both biometric verification and authentication should be excluded from the scope of this Regulation.

Or. en

Amendment 401

Axel Voss, Deirdre Clune

**Proposal for a regulation
Recital 12 a (new)**

Text proposed by the Commission

Amendment

(12 a) This Regulation should also ensure harmonisation consistency in definitions and terminology as biometric techniques can, in the light of their primary function, be divided into techniques of biometric identification, authentication and verification. Biometric authentication means the process of matching an identifier to a specific stored identifier in order to grant access to a device or service, whilst biometric verification refers to the process of confirming that an individual is who they claim to be. As they do not involve any “one-to-many” comparison of biometric data that is the distinctive trait of identification, both biometric verification and authentication should be excluded from the scope of this Regulation.

Or. en

Amendment 402

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
Recital 12 a (new)**

Text proposed by the Commission

Amendment

(12 a) AI systems developed or used exclusively for military purposes should be excluded from the scope of this Regulation where that use falls under the exclusive remit of the Common Foreign and Security Policy regulated under Title V TEU. However, AI systems which are developed or used for military purposes but can also be used for civil purposes,

falling under the definition of “dual use items” pursuant to Regulation (EU) 2021/821 of the European Parliament and of the Council^{1a} should fall into the scope of this Regulation.

^{1a} Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items (OJ L 206 11.6.2021, p. 1).

Or. en

Amendment 403

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 12 a (new)

Text proposed by the Commission

Amendment

(12 a) In order to ensure a minimum level of transparency on the ecological sustainability aspects of an AI system, providers and users should document parameters including but not limited to resource consumption, resulting from the design, data management and training, the underlying infrastructures of the AI system, and of the methods to reduce such impact for any AI system.

Or. en

Amendment 404

Svenja Hahn, Nicola Beer, Dita Charanzová, Andrus Ansip, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Recital 12 b (new)

(12 b) Given the complexity of the value chain for AI systems, it is essential to clarify the role of persons who may contribute to the development of AI systems covered by this Regulation, without being providers and thus being obliged to comply with the obligations and requirements established herein. It is necessary to clarify that general purpose AI systems - understood as AI systems that are able to perform generally applicable functions such as image/speech recognition, audio/video generation, pattern detection, question answering, translation etc. - should not be considered as having an intended purpose within the meaning of this Regulation, unless those systems have been adapted to a specific intended purpose that falls within the scope of this Regulation. Initial providers of general purpose AI systems should therefore only have to comply with the provisions on accuracy, robustness and cybersecurity as laid down in Art. 15 of this Regulation. If a person adapts a general purpose AI application to a specific intended purpose and places it on the market or puts it into service, it shall be considered the provider and be subject to the obligations laid down in this Regulation. The initial provider of a general purpose AI application shall, after placing it on the market or putting it to service, and without compromising its own intellectual property rights or trade secrets, provide the new provider with all essential, relevant and reasonably expected information that is necessary to comply with the obligations set out in this Regulation.

Or. en

Amendment 405

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
Recital 12 b (new)**

Text proposed by the Commission

Amendment

(12 b) This Regulation should not affect the provisions aimed at improving working conditions in platform work set out in Directive 2021/762/EC.

Or. en

Amendment 406

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Recital 13**

Text proposed by the Commission

Amendment

(13) In order to ensure a consistent and high level of protection of public interests as regards health, safety and fundamental rights, common normative standards for all high-risk AI systems should be established. Those standards should be consistent with the Charter of fundamental rights of the European Union (the Charter) and should be non-discriminatory and in line with the Union's international trade commitments.

(13) In order to ensure a consistent and high level of protection of public interests as regards health, safety and fundamental rights, common normative standards for all high-risk AI systems should be established. Those standards should be consistent with the Charter of fundamental rights of the European Union (the Charter) and should be non-discriminatory and in line with the Union's international trade commitments.

In order to ensure a minimum level of transparency on the ecological sustainability aspects of an AI system, providers and users should document (i) parameters including, but not limited to, resource consumption resulting from the design, data management, training and from the underlying infrastructures of the AI system; as well as (ii) the methods to reduce such impact.

Or. en

Amendment 407

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Recital 13**

Text proposed by the Commission

(13) In order to ensure a consistent and high level of protection of public interests as regards health, safety and fundamental rights, common normative standards for *all high-risk AI systems* should be established. Those standards should be consistent with the Charter of fundamental rights of the European Union (the Charter) and should be non-discriminatory and in line with the Union's international *trade* commitments.

Amendment

(13) In order to ensure a consistent and high level of protection of public interests as regards health, safety, *the environment* and fundamental rights, *and values*, common normative standards for AI systems should be established. Those standards should be consistent with the Charter of fundamental rights of the European Union (the Charter), *the European Green Deal (The Green Deal), the Joint Declaration on Digital Rights of the Union (the Declaration) and the Ethics Guidelines for Trustworthy Artificial Intelligence (AI) of the High-Level Expert Group on Artificial Intelligence (AI HLEG)*, and should be non-discriminatory and in line with the Union's international commitments.

Or. en

Amendment 408

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

**Proposal for a regulation
Recital 13**

Text proposed by the Commission

(13) In order to ensure a consistent and high level of protection of public interests as regards health, safety and fundamental rights, common normative standards for all high-risk AI systems should be established. Those standards should be consistent with the Charter of fundamental rights of the European Union (the Charter) and should be non-discriminatory and in line with the Union's international trade commitments.

Amendment

(13) In order to ensure a consistent and high level of protection of public interests as regards health, safety, and fundamental rights, *as well as the environment, society, rule of law and democracy, economic interests and consumer protection*, common normative standards for all high-risk AI systems should be established. Those standards should be consistent with the Charter of Fundamental Rights of the European Union (the Charter) and should

be non-discriminatory and in line with the Union's international trade commitments.

Or. en

Amendment 409

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

Recital 13

Text proposed by the Commission

(13) In order to ensure a consistent and high level of protection of public interests as regards health, safety and fundamental rights, common normative standards for all high-risk AI systems should be established. Those standards should be consistent with the Charter of fundamental rights of the European Union (the Charter) and should be non-discriminatory and in line with the Union's international trade commitments.

Amendment

(13) In order to ensure a consistent and high level of protection of public interests as regards health, safety and fundamental rights, ***the environment and the Union values enshrined in Article 2 TEU***, common normative standards for all high-risk AI systems should be established. Those standards should be consistent with the Charter of fundamental rights of the European Union (the Charter) and should be non-discriminatory and in line with the Union's international trade commitments.

Or. en

Amendment 410

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

Proposal for a regulation

Recital 13

Text proposed by the Commission

(13) Afin d'assurer un niveau cohérent et élevé de protection des intérêts publics en ce qui concerne la santé, la sécurité et les droits fondamentaux, il convient d'établir des normes communes pour tous les systèmes d'IA à haut risque. Ces normes devraient être conformes à la

Amendment

(13) Afin d'assurer un niveau cohérent et élevé de protection des intérêts publics en ce qui concerne la santé, la sécurité et les droits fondamentaux, il convient d'établir des normes ***minimales*** communes pour tous les systèmes d'IA à haut risque. Ces normes devraient être conformes à la

charte des droits fondamentaux de l’Union européenne (ci-après la «charte»), non discriminatoires et compatibles avec les engagements **commerciaux** internationaux de l’Union.

charte des droits fondamentaux de l’Union européenne (ci-après la «charte»), non discriminatoires et compatibles avec les engagements internationaux de l’Union.

Or. fr

Amendment 411

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

Proposal for a regulation

Recital 13 a (new)

Text proposed by the Commission

Amendment

(13 a) AI systems and related ICT technology require significant natural resources, contribute to waste production, and have a significant overall impact on the environment. It is appropriate to design and develop in particular high-risk AI systems with methods and capabilities that measure, record, and reduce resource use and waste production, as well as energy use, and that increase their overall efficiency throughout their entire lifecycle. The Commission, the Member States and the European AI Board should contribute to these efforts by issuing guidelines and providing support to providers and deployers.

Or. en

Amendment 412

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

Proposal for a regulation

Recital 14

Text proposed by the Commission

Amendment

(14) Afin d’introduire un ensemble

(14) Afin d’introduire un ensemble

proportionné et efficace de règles contraignantes pour les systèmes d'IA, il convient de suivre une approche clairement définie fondée sur les risques. Cette approche devrait adapter le type et le contenu de ces règles à l'intensité et à la portée des risques que les systèmes d'IA peuvent générer. Il est donc nécessaire d'interdire certaines pratiques en matière d'intelligence artificielle, de fixer des exigences pour les systèmes d'IA à haut risque et des obligations pour les opérateurs concernés, ainsi que de fixer des obligations de transparence pour certains systèmes d'IA.

proportionné et efficace de règles contraignantes pour les systèmes d'IA, il convient de suivre une approche clairement définie fondée sur les risques. Cette approche devrait adapter le type et le contenu de ces règles à l'intensité et à la portée des risques que les systèmes d'IA peuvent générer. Il est donc nécessaire d'interdire certaines pratiques en matière d'intelligence artificielle, de fixer des exigences pour les systèmes d'IA à haut risque et des obligations pour les opérateurs concernés, ainsi que de fixer des obligations de transparence pour certains systèmes d'IA. *Il est également nécessaire de prévoir les critères et les conditions en fonction desquels un système d'IA appartient à l'une ou l'autre de ces catégories.*

Or. fr

Amendment 413

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation Recital 14

Text proposed by the Commission

(14) In order to introduce a proportionate and effective set of binding rules for AI systems, a clearly defined risk-based approach should be followed. That approach should tailor the type and content of such rules to the intensity and scope of the risks that AI systems can generate. It is therefore necessary to prohibit certain artificial intelligence practices, to lay down requirements for high-risk AI systems and obligations for the relevant operators, and to lay down transparency obligations for certain AI systems.

Amendment

(14) In order to introduce a proportionate and effective set of binding rules for AI systems, a clearly defined risk-based approach should be followed. That approach should tailor the type and content of such rules to the intensity and scope of the risks that AI systems can generate *for individuals and society, rather than depend on the type of technology*. It is therefore necessary to prohibit certain artificial intelligence practices, to lay down requirements for high-risk AI systems and obligations for the relevant operators, and to lay down transparency obligations for certain AI systems.

Or. en

Amendment 414

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

Proposal for a regulation

Recital 14

Text proposed by the Commission

(14) In order to introduce a proportionate and effective set of binding rules for AI systems, a clearly defined risk-based approach should be followed. That approach should tailor the type and content of such rules to the intensity and scope of the risks that AI systems can generate. It is therefore necessary to prohibit certain artificial intelligence practices, to lay down requirements for high-risk AI systems and obligations for the relevant operators, and to lay down transparency obligations for certain AI systems.

Amendment

(14) In order to introduce a proportionate and effective set of binding rules for AI systems, a clearly defined risk-based approach should be followed. That approach should tailor the type and content of such rules to the intensity and scope of the risks that AI systems can generate. It is therefore necessary to prohibit certain ***unacceptable*** artificial intelligence practices, to lay down requirements for high-risk AI systems and obligations for the relevant operators, and to lay down transparency obligations for certain AI systems.

Or. en

Amendment 415

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

Proposal for a regulation

Recital 15

Text proposed by the Commission

(15) ***Aside from the many beneficial uses of artificial intelligence, that technology*** can also be misused and provide novel and powerful tools for manipulative, exploitative and social control practices. Such practices are particularly harmful and should be prohibited because they contradict Union values of respect for human dignity, freedom, equality, democracy and the rule

Amendment

(15) ***AI systems*** can also be misused and provide novel and powerful tools for manipulative, exploitative and social control practices. Such practices are particularly harmful and should be prohibited because they contradict Union values of respect for human dignity, freedom, equality, democracy and the rule of law and Union fundamental rights, including the right to non-discrimination,

of law and Union fundamental rights, including the right to non-discrimination, data protection and privacy and the rights of the child.

data protection and privacy and the rights of the child. *All uses of AI systems which interfere with the essence of the fundamental rights of individuals should in any case be prohibited. The prohibitions listed in this Regulation should apply notwithstanding existing Union law and do not provide a new legal basis for the development placing on the market, deployment or use of AI systems. To keep up with rapid technological development and to ensure future-proof regulation, the Commission should keep the list of prohibited and high-risk AI systems under constant review.*

Or. en

Amendment 416

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

Proposal for a regulation

Recital 15

Text proposed by the Commission

(15) Si l'intelligence artificielle peut être utilisée à de nombreuses fins positives, cette technologie peut aussi être utilisée à mauvais escient et fournir des outils nouveaux et puissants à l'appui de pratiques de manipulation, d'exploitation et de contrôle social. De telles pratiques sont particulièrement néfastes et devraient être interdites, car elles sont contraires aux valeurs de *l'Union relatives au* respect de la dignité humaine, *à la* liberté, *à l'égalité*, *à la* démocratie et *à l'état* de droit, et elles portent atteinte aux droits fondamentaux de l'Union, y compris le droit à la non-discrimination, le droit à la protection des données et à la vie privée et les droits de l'enfant.

Amendment

(15) Si l'intelligence artificielle peut être utilisée à de nombreuses fins positives, cette technologie peut aussi être utilisée à mauvais escient et fournir des outils nouveaux et puissants à l'appui de pratiques de manipulation, d'exploitation et de contrôle social. De telles pratiques sont particulièrement néfastes et devraient être interdites, car elles sont contraires aux valeurs de *de* respect de la dignité humaine, *de* liberté, *d'égalité*, *de* démocratie et *d'État* de droit, *valeurs protégées par le droit de l'Union*, et elles portent atteinte aux droits fondamentaux de l'Union, y compris le droit à la non-discrimination, le droit à la protection des données et à la vie privée et les droits de l'enfant.

Or. fr

Amendment 417

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 15 a (new)

Text proposed by the Commission

Amendment

(15 a) As signatories to the United Nations Convention on the Rights of Persons with Disabilities (CRPD), the European Union and all Member States are legally obliged to protect persons with disabilities from discrimination and promote their equality, to ensure that persons with disabilities have access, on an equal basis with others, to information and communications technologies and systems, and to ensure respect for privacy of persons with disabilities. Given the growing importance and use of AI systems, the strict application of universal design principles to all new technologies and services should ensure full, equal, and unrestricted access for everyone potentially affected by or using AI technologies, including persons with disabilities, in a way that takes full account of their inherent dignity and diversity. It is essential to ensure that providers of AI systems design them, and users use them, in accordance with the accessibility requirements set out in Directive (EU) 2019/882.

Or. en

Amendment 418

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 15 a (new)

Text proposed by the Commission

Amendment

(15 a) As signatories to the United

Nations Convention on the Rights of Persons with Disabilities (CRPD), the European Union and all Member States are legally obliged to protect persons with disabilities from discrimination and promote their equality (Article 5). They are also obliged to ensure that persons with disabilities have access, on an equal basis with others, to information and communications technologies and systems. (Article 9). Finally, they are obliged to ensure respect for privacy of persons with disabilities (Article 22).

Or. en

Amendment 419

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Recital 15 a (new)**

Text proposed by the Commission

Amendment

(15 a) As signatories to the United Nations Convention on the Rights of Persons with Disabilities (CRPD), the European Union and all Member States are legally obliged to protect persons with disabilities from discrimination and promote their equality (Article 5). They are also obliged to ensure that persons with disabilities have access, on an equal basis with others, to information and communications technologies and systems. (Article 9). Finally, they are obliged to ensure respect for privacy of persons with disabilities (Article 22).

Or. en

Amendment 420

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

Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission

Amendment

(15 a) The European Union and its Member States as signatories to the United Nations Convention on the Rights of Persons with Disabilities (CRPD) are obliged to protect persons with disabilities from discrimination and to promote their equality. They are obliged to ensure that persons with disabilities have access, on an equal basis with others, to information and communications technologies and systems and to ensure respect for the fundamental rights, including that of privacy, of persons with disabilities.

Or. en

Amendment 421

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
Recital 15 a (new)

Text proposed by the Commission

Amendment

(15 a) As signatories to the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD), the European Union and all Member States should protect persons with disabilities from discrimination and promote their equality, ensure that persons with disabilities have access, on an equal basis with others, to information and communications technologies and systems and ensure respect for privacy of persons with disabilities.

Or. en

Amendment 422

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 15 b (new)

Text proposed by the Commission

Amendment

(15 b) Given the growing importance and use of AI systems, the strict application of universal design principles to all new technologies and services should ensure full, equal, and unrestricted access for everyone potentially affected by or using AI technologies, including persons with disabilities, in a way that takes full account of their inherent dignity and diversity. It is essential to ensure that providers of AI systems design them, and users use them, in accordance with the accessibility requirements set out in Directive (EU) 2019/882. Union law should be further developed, including through this Regulation, so that no one is left behind as result of digital innovation.

Or. en

Amendment 423

Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä, Sylwia Spurek

on behalf of the Verts/ALE Group

Proposal for a regulation

Recital 15 b (new)

Text proposed by the Commission

Amendment

(15 b) Providers of AI systems should ensure that these systems are designed in accordance with the accessibility requirements set out in Directive (EU) 2019/882 and guarantee full, equal, and unrestricted access for everyone potentially affected by or using AI systems, including persons with disabilities.

Amendment 424**Axel Voss, Deirdre Clune, Eva Maydell****Proposal for a regulation****Recital 16***Text proposed by the Commission*

(16) The placing on the market, putting into service or use of certain AI systems ***intended to distort*** human behaviour, whereby physical or psychological harms are likely to occur, should be forbidden. Such AI systems deploy subliminal components ***individuals*** cannot perceive or exploit vulnerabilities of ***children and people*** due to their age, ***physical or mental incapacities***. ***They do so*** with the ***intention to*** materially ***distort*** the behaviour of a person and in a manner that causes or is likely to cause harm to that or another person. The intention may not be presumed if the distortion of ***human behaviour*** results from factors external to the AI system which are outside of the control of the provider or the user. ***Research for legitimate purposes in relation to such AI systems should not be stifled by the prohibition, if such research does not amount to use of the AI system in human-machine relations that exposes natural persons to harm and such research is carried out in accordance with recognised ethical standards for scientific research.***

Amendment

(16) The placing on the market, putting into service or use of certain AI systems ***materially distorting*** human behaviour, whereby physical or psychological harms are likely to occur, should be forbidden. Such AI systems deploy subliminal components ***that persons*** cannot perceive or ***those systems otherwise*** exploit vulnerabilities of ***a specific group of persons*** due to their age, ***disability within the meaning of Directive (EU) 2019/882, or social or economic situation***. ***Such systems can be placed on the market, put into service or used with the objective to or the effect of*** materially ***distorting*** the behaviour of a person and in a manner that causes or is ***reasonably*** likely to cause ***physical or psychological*** harm to that or another person ***or groups of persons, including harms that may be accumulated over time***. The intention ***to distort the behaviour*** may not be presumed if the distortion results from factors external to the AI system which are outside of the control of the provider or the user ***meaning factors that may not be reasonably foreseen and mitigated*** by the provider or the user of the AI system. ***In any case, it is not necessary for the provider or the user to have the intention to cause the physical or psychological harm, as long as such harm results from the manipulative or exploitative AI-enabled practices. The prohibitions for such AI practices is complementary to the provisions contained in Directive [Unfair Commercial Practice Directive 2005/29/EC, as amended by Directive***

(EU) 2019/216], notably that unfair commercial practices leading to economic or financial harms to consumers are prohibited under all circumstances, irrespective of whether they are put in place through AI systems or otherwise.

Or. en

Amendment 425

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

Proposal for a regulation Recital 16

Text proposed by the Commission

(16) The placing on the market, putting into service or use of certain AI systems **intended to distort** human behaviour, whereby physical or psychological harms are likely to occur, should be forbidden. **Such** AI systems deploy subliminal components individuals **cannot** perceive or exploit vulnerabilities of **children and people due to their age, physical or mental incapacities**. **They do so with the intention to** materially distort the behaviour of a person **and** in a manner that causes or is likely to cause harm to that or another person. **The intention** may not be presumed if the distortion of human behaviour results from factors external to the AI system which are outside of the control of the provider or the user. Research for legitimate purposes in relation to such AI systems should not be **stifled** by the prohibition, if such research does not amount to use of the AI system in human-machine relations that exposes natural persons to harm and such research is carried out in accordance with recognised ethical standards for scientific research.

Amendment

(16) The placing on the market, putting into service or use of certain AI systems **with the effect or likely effect of distorting** human behaviour, whereby physical, **economic** or psychological harms **to individuals or society** are likely to occur, should be forbidden. **This includes** AI systems **that** deploy subliminal components **that** individuals **may not be able to** perceive or understand, or exploit vulnerabilities of **individuals**. **They** materially distort the behaviour of a person, **including** in a manner that causes or is likely to cause **physical, psychological or economic** harm to that or another person, **or to society, or lead them to make decisions they would not otherwise have taken**. **Manipulation** may not be presumed if the distortion of human behaviour **clearly** results from factors external to the AI system which are outside of the control of the provider or the user **and are not reasonably foreseeable at or during the deployment of the AI system**. Research for legitimate purposes in relation to such AI systems should not be **unduly limited** by the prohibition, if such research does not amount to use of the AI system in **non-supervised** human-machine relations that exposes natural persons to harm and

such research is carried out in accordance with recognised ethical standards for scientific research. *If necessary, further flexibilities in order to foster research, and thereby European innovation capacities, should be introduced by Member States under controlled circumstances only and with all relevant safeguards to protect health and safety, fundamental rights, environment, society, rule of law and democracy.*

Or. en

Amendment 426

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

Proposal for a regulation Recital 16

Text proposed by the Commission

(16) La mise sur le marché, la mise en service ou l'utilisation de certains systèmes d'IA destinés à altérer les comportements humains *d'une manière qui est susceptible de causer un préjudice psychologique ou physique* devraient être interdites. De tels systèmes d'IA déploient des composants subliminaux que les personnes ne peuvent pas percevoir, ou exploitent les vulnérabilités des enfants *et des* personnes vulnérables en raison de leur âge *ou* de leurs handicaps physiques ou mentaux. *Ces systèmes ont pour finalité d'altérer substantiellement le comportement d'une personne d'une manière qui cause ou est susceptible de causer un préjudice à cette personne ou à une autre personne. La finalité ne peut être présumée si l'altération du comportement humain résulte de facteurs externes au système d'IA, qui échappent au contrôle du fournisseur ou de l'utilisateur.* Les activités de recherche à des fins légitimes liées à de tels systèmes d'IA ne devraient pas être entravées par l'interdiction, tant

Amendment

(16) La mise sur le marché, la mise en service ou l'utilisation de certains systèmes d'IA destinés à altérer les comportements humains devraient être interdites. De tels systèmes d'IA déploient des composants subliminaux que les personnes ne peuvent pas percevoir, ou exploitent les vulnérabilités des *personnes telles que les* enfants *ou les* personnes vulnérables en raison de leur âge, de leurs handicaps physiques ou mentaux, *ou d'autres traits*. Les activités de recherche à des fins légitimes liées à de tels systèmes d'IA ne devraient pas être entravées par l'interdiction, tant que ces activités ne consistent pas à utiliser le système d'IA dans des relations homme-machine *auprès de tiers non informés ou non consentants*, *ou* qui exposent des personnes physiques à un préjudice, et tant qu'elles sont menées dans le respect de normes éthiques reconnues pour la recherche scientifique.

que ces activités ne consistent pas à utiliser le système d'IA dans des relations homme-machine qui exposent des personnes physiques à un préjudice et tant qu'elles sont menées dans le respect de normes éthiques reconnues pour la recherche scientifique.

Or. fr

Justification

Ce passage sur les finalités et les risques des systèmes d'I.A. altérant le comportement humain constitue en réalité une précision dangereuse. Elle signifie que seuls les systèmes ayant ces risques pour conséquence sont dangereux, et que les autres systèmes de cette nature (altération moyenne au lieu de substantielle, par exemple, ou absence de préjudice) seraient autorisés. Nous souhaitons quant à nous interdire l'altération par I.A. du comportement en toutes circonstances, ce qui suppose d'éliminer cette précision qui est, en réalité, une limitation.

Amendment 427

Brando Benifei, 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

Recital 16

Text proposed by the Commission

(16) The placing on the market, putting into service or use of certain AI systems **intended to distort** human behaviour, whereby physical **or** psychological harms are likely to occur, should be forbidden. Such AI systems deploy subliminal components individuals cannot perceive or exploit vulnerabilities of children and people due to their age, physical or mental incapacities. They do so with the **intention to** materially **distort** the behaviour of a person and in a manner that causes or is likely to cause harm to that or another person. **The intention may not be presumed if the distortion of human behaviour results from factors external to the AI system which are outside of the control of the provider or the user.**

Amendment

(16) The placing on the market, putting into service or use of certain AI systems **with the effect or likely effect of distorting** human behaviour, whereby **material or non-material harm, including** physical, psychological **or economic** harms are likely to occur, should be forbidden. **This limitation should be understood to include neuro-technologies assisted by AI systems that are used to monitor, use, or influence neural data gathered through brain-computer interfaces.** Such AI systems deploy subliminal components individuals cannot perceive or exploit vulnerabilities of children and people due to their age, physical or mental incapacities. They do so with the **effect of** materially **distorting** the behaviour of a person and in a manner that

Research for legitimate purposes in relation to such AI systems should not be stifled by the prohibition, if such research does not amount to use of the AI system in human-machine relations that exposes natural persons to harm and such research is carried out in accordance with recognised ethical standards for scientific research.

causes or is likely to cause harm to that or another person. Research for legitimate purposes in relation to such AI systems should not be stifled by the prohibition, if such research does not amount to use of the AI system in human-machine relations that exposes natural persons to harm and such research is carried out in accordance with recognised ethical standards for scientific research.

Or. en

Amendment 428

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Andrus Ansip, Dita Charanzová, Morten Løkkegaard, Alin Mituță

Proposal for a regulation Recital 16

Text proposed by the Commission

(16) The placing on the market, putting into service or use of certain AI systems intended to distort human behaviour, whereby physical or psychological harms are likely to occur, should be forbidden. *Such* AI systems deploy subliminal components *individuals* cannot perceive *or* exploit vulnerabilities of *children and people due to their age, physical or mental incapacities*. *They do so* with the intention to materially distort the behaviour of a person and in a manner that causes or is likely to cause harm to that or another person. The intention may not be presumed if the distortion of human behaviour results from factors external to the AI system which are outside of the control of the provider or the user. Research for legitimate purposes in relation to such AI systems should not be stifled by the prohibition, if such research does not amount to use of the AI system *in human-machine* relations that exposes natural persons to harm and such research is carried out in accordance with recognised

Amendment

(16) The placing on the market, putting into service or use of certain AI systems intended to distort human behaviour, whereby physical or psychological harms are likely to occur, should be forbidden. *In particular*, AI systems *that* deploy subliminal components *that natural persons* cannot perceive, *that* exploit *the* vulnerabilities of *any groups, or that use purposefully manipulative techniques* with the intention to materially distort the behaviour of a person and in a manner that causes or is likely to cause harm to that or another person *or to their rights or to the values of the Union should be prohibited*. The intention may not be presumed if the distortion of human behaviour results from factors external to the AI system which are outside of the control of the provider or the user. Research for legitimate purposes in relation to such AI systems should not be stifled by the prohibition, if such research does not amount to use of the AI system *inhuman-machine* relations that exposes natural persons to harm and such research

ethical standards for scientific research.

is carried out in accordance with recognised ethical standards for scientific research.

Or. en

Amendment 429

Maria-Manuel Leitão-Marques, Eva Kaili

Proposal for a regulation

Recital 16

Text proposed by the Commission

(16) The placing on the market, putting into service or use of certain AI systems intended to distort human behaviour, whereby physical or psychological harms are likely to occur, should be forbidden. Such AI systems deploy subliminal components individuals cannot perceive or exploit vulnerabilities of children and people due to their age, physical or mental incapacities. They do so with the intention to materially distort the behaviour of a person and in a manner that causes or is likely to cause harm to that or another person. The intention may not be presumed if the distortion of human behaviour results from factors external to the AI system which are outside of the control of the provider or the user. Research for legitimate purposes in relation to such AI systems should not be stifled by the prohibition, if such research does not amount to use of the AI system in human-machine relations that exposes natural persons to harm and such research is carried out in accordance with recognised ethical standards for scientific research.

Amendment

(16) The placing on the market, putting into service or use of certain AI systems intended to distort human behaviour, whereby physical or psychological harms are likely to occur, should be forbidden. Such AI systems deploy subliminal components individuals cannot perceive, **access brain or brain-generated data without consent**, or exploit vulnerabilities of children and people due to their age, physical or mental incapacities. They do so with the intention to materially distort the behaviour of a person and in a manner that causes or is likely to cause harm to that or another person. The intention may not be presumed if the distortion of human behaviour results from factors external to the AI system which are outside of the control of the provider or the user. Research for legitimate purposes in relation to such AI systems should not be stifled by the prohibition, if such research does not amount to use of the AI system in human-machine relations that exposes natural persons to harm and such research is carried out in accordance with recognised ethical standards for scientific research.

Or. en

Amendment 430

Svenja Hahn, Nicola Beer, Dita Charanzová, Andrus Ansip, Morten Løkkegaard,

Sandro Gozi, Vlad-Marius Boto , Abir Al-Sahlani, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

**Proposal for a regulation
Recital 16**

Text proposed by the Commission

(16) The placing on the market, putting into service or use of certain AI systems **intended to distort** human behaviour, whereby physical or psychological harms are likely to occur, should be forbidden. Such AI systems deploy subliminal components individuals cannot perceive or exploit vulnerabilities of **children and people** due to their age, **physical or mental incapacities**. They do so with the intention to materially distort the behaviour of a person and in a manner that causes or is likely to cause harm to that or another person. The intention may not be presumed if the distortion of human behaviour results from factors external to the AI system which are outside of the control of the provider or the user. Research for legitimate purposes in relation to such AI systems should not be stifled by the prohibition, if such research does not amount to use of the AI system **in human-machine** relations that exposes natural persons to harm and such research is carried out in accordance with recognised ethical standards for scientific research.

Amendment

(16) The placing on the market, putting into service or use of certain AI systems **with the objective to or the effect of distorting** human behaviour, whereby physical or psychological harms are **reasonably** likely to occur, should be forbidden. Such AI systems deploy subliminal components individuals cannot perceive or exploit vulnerabilities of **specific groups of persons** due to their age, **disabilities, social or economic situation**. They do so with the intention to materially distort the behaviour of a person and in a manner that causes or is likely to cause harm to that or another person. The intention may not be presumed if the distortion of human behaviour results from factors external to the AI system which are outside of the control of the provider or the user. Research for legitimate purposes in relation to such AI systems should not be stifled by the prohibition, if such research does not amount to use of the AI system **inhuman-machine** relations that exposes natural persons to harm and such research is carried out in accordance with recognised ethical standards for scientific research.

Or. en

Amendment 431

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

**Proposal for a regulation
Recital 16**

Text proposed by the Commission

Amendment

(16) The placing on the market, putting into service or use of certain AI systems intended to distort human behaviour, whereby physical or psychological harms are likely to occur, should be forbidden. Such AI systems deploy subliminal components individuals cannot perceive or exploit vulnerabilities of children and people due to their age, physical or mental incapacities. They do so with the intention to materially distort the behaviour of a person and in a manner that causes or is likely to cause harm to that or another person. The intention may not be presumed if the distortion of human behaviour results from factors external to the AI system which are outside of the control of the provider or the user. Research for legitimate purposes in relation to such AI systems should not be stifled by the prohibition, if such research does not amount to use of the AI system in human-machine relations that exposes natural persons to harm and such research is carried out in accordance with recognised ethical standards for scientific research.

(16) The placing on the market, putting into service or use of certain AI systems intended to distort human behaviour, whereby *with due diligence it could be predicted that* physical or psychological harms are likely to occur, should be forbidden. Such AI systems deploy subliminal components individuals cannot perceive or exploit vulnerabilities of children and people due to their age, physical or mental incapacities. They do so with the intention to materially distort the behaviour of a person and in a manner that causes or is likely to cause harm to that or another person. The intention may not be presumed if the distortion of human behaviour results from factors external to the AI system which are outside of the control of the provider or the user. Research for legitimate purposes in relation to such AI systems should not be stifled by the prohibition, if such research does not amount to use of the AI system in human-machine relations that exposes natural persons to harm and such research is carried out in accordance with recognised ethical standards for scientific research.

Or. en

Amendment 432

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

Proposal for a regulation Recital 17

Text proposed by the Commission

(17) Les systèmes d'IA permettant la notation sociale des personnes physiques *à des fins générales par les autorités publiques ou pour le compte de celles-ci peuvent conduire à des résultats discriminatoires et à l'exclusion de certains groupes. Ils peuvent porter atteinte au droit à la dignité et à la non-discrimination et sont contraires aux*

Amendment

(17) Les systèmes d'IA permettant la notation sociale des personnes physiques *sont par essence discriminatoires. Ils portent atteinte au droit à la dignité et à la non-discrimination et sont contraires aux valeurs d'égalité et de justice. Ces systèmes d'IA évaluent ou classent la fiabilité des personnes physiques en fonction de leur comportement social dans*

valeurs d'égalité et de justice. Ces systèmes d'IA évaluent ou classent la fiabilité des personnes physiques en fonction de leur comportement social dans plusieurs contextes ou de caractéristiques personnelles ou de personnalité connues ou prédictes. La note sociale obtenue à partir de ces systèmes d'IA ***peut conduire*** au traitement préjudiciable ou défavorable de personnes physiques ou de groupes entiers ***dans des contextes sociaux qui sont dissociés du contexte dans lequel les données ont été initialement générées ou collectées, ou à un traitement préjudiciable disproportionné ou injustifié au regard de la gravité de leur comportement social.*** Il convient donc d'interdire de tels systèmes d'IA.

plusieurs contextes ou de caractéristiques personnelles ou de personnalité connues ou prédictes. La note sociale obtenue à partir de ces systèmes d'IA ***conduit*** au traitement préjudiciable ou défavorable de personnes physiques ou de groupes entiers. Il convient donc d'interdire de tels systèmes d'IA.

Or. fr

Amendment 433

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 Recital 17

Text proposed by the Commission

(17) AI systems providing social scoring of natural persons for general purpose by public authorities or on their behalf may lead to discriminatory outcomes and the exclusion of certain groups. They may violate the right to dignity and non-discrimination and the values of equality and justice. Such AI systems evaluate or classify the trustworthiness of natural persons based on their social behaviour in multiple contexts or known or predicted personal or personality characteristics. ***The social score obtained from such AI systems may lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof in social contexts, which are unrelated to the***

Amendment

(17) AI systems providing social scoring of natural persons for general purpose by ***private or*** public authorities or on their behalf may lead to discriminatory outcomes and the exclusion of certain groups. They may violate the right to dignity and non-discrimination and the values of equality and justice. Such AI systems evaluate or classify the trustworthiness of natural persons based on their social behaviour in multiple contexts or known or predicted personal or personality characteristics. Such AI systems should be therefore prohibited.

context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. Such AI systems should be therefore prohibited.

Or. en

Amendment 434

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Morten Løkkegaard, Alin Mituță

Proposal for a regulation

Recital 17

Text proposed by the Commission

(17) AI systems providing social scoring of natural persons for general purpose by public authorities or on their behalf may lead to discriminatory outcomes and the exclusion of certain groups. They may violate the right to dignity and non-discrimination and the values of equality and justice. Such AI systems evaluate or classify ***the trustworthiness of*** natural persons based on their social behaviour in multiple contexts or known or predicted personal or personality characteristics. The social score obtained from such AI systems may lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof in social contexts, which are unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. Such AI systems should be therefore prohibited.

Amendment

(17) AI systems providing social scoring of natural persons for general purpose by public authorities or on their behalf may lead to discriminatory outcomes and the exclusion of certain groups. They may violate the right to dignity and non-discrimination and the values of equality and justice. Such AI systems evaluate or classify natural persons based on their social behaviour in multiple contexts or known or predicted personal or personality characteristics ***using trustworthiness, good citizenship, patriotism, deviancy, or any other such metric as a proxy.*** The social score obtained from such AI systems may lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof in social contexts, which are unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. ***This detrimental treatment can also be effected by providing undue and unjustified privileges to groups of people based on their social score.*** Such AI systems should be therefore prohibited.

Amendment 435

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

Proposal for a regulation

Recital 17

Text proposed by the Commission

(17) AI systems **providing** social **scoring** of natural persons **for general purpose by public authorities or on their behalf** may lead to discriminatory outcomes and the exclusion of certain groups. They may violate the right to dignity and non-discrimination and the values of equality and justice. Such AI systems evaluate or classify the trustworthiness of natural persons based on their social behaviour in multiple contexts or known or predicted personal or personality characteristics. The social score obtained from such AI systems may lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof **in social contexts**, which are unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. Such AI systems should be therefore prohibited.

Amendment

(17) AI systems **that evaluate, classify, rate or score the trustworthiness or social standing** of natural persons may lead to discriminatory outcomes and the exclusion of certain groups. They may violate the right to dignity and non-discrimination and the values of equality and justice. Such AI systems evaluate or classify the trustworthiness **or social standing** of natural persons based on **multiple data points related to** their social behaviour in multiple contexts or known, **inferred** or predicted personal or personality characteristics. The social score obtained from such AI systems may lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof, which are unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. Such AI systems should be therefore prohibited.

Amendment 436

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

Proposal for a regulation

Recital 17

Text proposed by the Commission

Amendment

(17) AI systems providing social scoring of natural persons for general purpose *by public authorities or on their behalf* may lead to discriminatory outcomes and the exclusion of certain groups. They may violate the right to dignity and non-discrimination and the values of equality and justice. Such AI systems evaluate or classify the trustworthiness of natural persons based on their social behaviour in multiple contexts or known or predicted personal or personality characteristics. The social score obtained from such AI systems may lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof in social contexts, which are unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. Such AI systems should be therefore prohibited.

(17) AI systems providing social scoring of natural persons for general purpose may lead to discriminatory outcomes and the exclusion of certain groups. They may violate the right to dignity and non-discrimination and the values of equality and justice. Such AI systems evaluate or classify the trustworthiness of natural persons based on their social behaviour in multiple contexts or known or predicted personal or personality characteristics. The social score obtained from such AI systems may lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof in social contexts, which are unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. Such AI systems should be therefore prohibited.

Or. en

Amendment 437

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation Recital 17

Text proposed by the Commission

(17) AI systems providing social scoring of natural persons for general purpose by public authorities or on their behalf may lead to discriminatory outcomes and the exclusion of certain groups. They *may* violate the right to dignity and non-discrimination and the values of equality and justice. Such AI systems evaluate or classify *the trustworthiness of* natural persons based on their social behaviour in multiple contexts or known or predicted personal or personality characteristics. The social score obtained from such AI systems *may* lead to the detrimental or unfavourable treatment of natural persons

Amendment

(17) AI systems providing social scoring of natural persons for general purpose by public authorities or on their behalf may lead to discriminatory outcomes and the exclusion of certain groups. They violate the right to dignity and non-discrimination and the values of equality and justice. Such AI systems evaluate or classify natural persons based on their social behaviour in multiple contexts or known or predicted personal or personality characteristics. The social score obtained from such AI systems lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof in social contexts, which are

or whole groups thereof in social contexts, which are unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. Such AI systems should be therefore prohibited.

unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. Such AI systems should be therefore prohibited.

Or. en

Amendment 438

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

Proposal for a regulation

Recital 17 a (new)

Text proposed by the Commission

Amendment

(17 a) The placing on the market, putting into service or use of certain AI systems that can be used or foreseeably misused for intrusive monitoring and flagging to identify or deter rule-breaking or fraud should be forbidden. The use of such intrusive monitoring and flagging in a relationship of power, such as the use of e-proctoring software by education institutions to monitor students and pupils, or the use of surveillance- or monitoring software by employers on workers poses an unacceptable risk to the fundamental rights of workers, students and pupils, including minors. Notably, these practices affect the right to private life, data protection and human dignity of students and pupils, including minors.

Or. en

Amendment 439

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 17 a (new)

Text proposed by the Commission

Amendment

(17 a) AI systems that are intended for use to protect consumers and prevent fraudulent activities should not necessarily be considered high-risk under this Regulation. As set by Article 94 of the Directive (EU) 2015/2366, payment systems and payment service providers should be allowed to process data to safeguard the prevention, investigation and detection of payment fraud. Therefore AI systems used to process data to safeguard the prevention, investigation and detection of fraud may not be considered as high-risk AI systems for the purpose of this Regulation.

Or. en

Amendment 440

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Brando Benifei

**Proposal for a regulation
Recital 17 a (new)**

Text proposed by the Commission

Amendment

(17 a) AI systems used by law enforcement authorities or on their behalf to make predictions, profiles or risk assessments based on data analysis or profiling of natural groups or locations, for the purpose of predicting the occurrence or reoccurrence of an actual or potential criminal offence(s) or other criminalised social behaviour, hold a particular risk of discrimination against certain persons or groups of persons, as they violate human dignity as well as the key legal principle of presumption of innocence. Such AI systems should therefore be prohibited.

Or. en

Amendment 441

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Recital 17 a (new)

Text proposed by the Commission

Amendment

(17 a) AI systems used in law enforcement and criminal justice contexts based on predictive methods, profiling and risk assessment pose an unacceptable risk to fundamental rights and in particular to the right of non-discrimination, insofar as they contradict the fundamental right to be presumed innocent and are reflective of historical, systemic, institutional and societal discrimination and other discriminatory practices. These AI systems should therefore be prohibited;

Or. en

Amendment 442

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

Recital 17 a (new)

Text proposed by the Commission

Amendment

(17 a) AI systems used by law enforcement authorities or on their behalf to predict the probability of a natural person to offend or to reoffend, based on profiling and individual or place-based risk-assessment hold a particular risk of discrimination against certain persons or groups of persons, as they violate human dignity as well as the key legal principle of presumption of innocence. Such AI systems should therefore be prohibited.

Or. en

Amendment 443

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Sandro Gozi, Vlad-Marius Boto, Samira Rafaela, Monica Semedo, Salima Yenbou, Abir Al-Sahlani, Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation**Recital 17 a (new)**

Text proposed by the Commission

Amendment

(17 a) AI systems used by law enforcement authorities or on their behalf to predict the probability of a natural person to offend or to reoffend, based on profiling and individual risk-assessment hold a particular risk of discrimination against certain persons or groups of persons, as they violate human dignity as well as the key legal principle of presumption of innocence. Such AI systems should therefore be prohibited.

Or. en

Justification

Predictive policing targeting natural persons should be prohibited without exemptions as it violates the presumption of innocence as well as human dignity.

Amendment 444

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

Proposal for a regulation**Recital 17 b (new)**

Text proposed by the Commission

Amendment

(17 b) Insofar as such systems could ever function as intended, AI-based emotion recognition systems carry unacceptable risk for the essence of fundamental rights, such as human dignity and freedom of expression and must be prohibited. Exceptions for therapeutic tools or assistive technologies for personal use only could, nonetheless, be envisaged.

However, this should only be permitted if the scientific basis and clinical validity of such systems have been demonstrated, where it can be shown that affected groups were active participants in the development process, and where the rights of everyone that is likely to be affected by the system, and not just the deployer, are clearly respected. Such systems should always be subject to careful oversight and transparency.

Or. en

Amendment 445

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

Proposal for a regulation

Recital 17 c (new)

Text proposed by the Commission

Amendment

(17 c) Similarly, ostensible truth-detection technologies, such as polygraphs, have a long and unsuccessful history of abuse, misselling, miscarriages of justice and failure. The problems underlying these failures are exacerbated in the field of migration, which thusfar has been tarnished by new failings due to, inter alia to incorrect cultural assumptions. Such technologies therefore cannot be used while protecting the essence of all relevant fundamental rights.

Or. en

Amendment 446

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Recital 18

Text proposed by the Commission

Amendment

(18) *The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement is considered particularly intrusive in the rights and freedoms of the concerned persons, to the extent that it may affect the private life of a large part of the population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems operating in ‘real-time’ carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities.*

deleted

Or. en

Justification

Instead of blanketly banning the law enforcement's use of facial recognition AI, these systems should be incorporated in the list of high-risk AI systems and subject to strict control. Such modern AI software can process information and images at lightning speed and with great precision - tasks that would take days for a human law enforcement agent to go through. Also with much less risk of bias, when the programs are diligently designed. Using such technology can help law enforcement not only prevent crimes, but also react rapidly when they occur, and provide a very powerful tool to investigate serious crimes.

Amendment 447

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Brando Benifei

**Proposal for a regulation
Recital 18**

Text proposed by the Commission

Amendment

(18) The use of AI systems for ‘**real-time**’ remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement is considered particularly intrusive in the

(18) The use of AI systems for remote biometric identification of natural persons in publicly **or privately** accessible spaces, **as well as online spaces**, for the purpose of law enforcement is considered particularly

rights and freedoms of the concerned persons, to the extent that it may affect the private life of a large part of the population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. In addition, *the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems operating in 'real-time' carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities.*

intrusive in the rights and freedoms of the concerned persons, to the extent that it may affect the private life of a large part of the population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. *Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities.* In addition, *whether such systems are used in 'real-time' or post factum, there is little difference on* the impact and the heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities. *The placing or making available on the market, the putting into service or use of those systems should therefore be prohibited.*

Or. en

Amendment 448

Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Marc Angel

Proposal for a regulation

Recital 18

Text proposed by the Commission

(18) The use of AI systems for '*real-time*' remote biometric identification of natural persons in publicly accessible spaces *for the purpose of law enforcement is considered* particularly intrusive in the rights and freedoms of the concerned persons, to the extent that it may affect the private life of a large part of the population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. *In addition, the immediacy of the impact and the limited opportunities for further checks or*

Amendment

(18) The use of AI systems for remote biometric identification of natural persons in publicly *or privately* accessible spaces *is* particularly intrusive in the rights and freedoms of the concerned persons, to the extent that it may affect the private life of a large part of the population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. Such systems *should therefore be prohibited.*

corrections in relation to the use of such systems operating in ‘real-time’ carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities.

Or. en

Amendment 449

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

Proposal for a regulation Recital 18

Text proposed by the Commission

(18) The use of AI systems for ‘**real-time**’ remote biometric identification of natural persons in publicly accessible spaces **for the purpose of law enforcement is considered** particularly **intrusive in** the rights and freedoms of the concerned persons, **to the extent that it may** affect the private life of a large part of the population, **evoke a** feeling of constant surveillance and indirectly dissuade the exercise of **the** freedom of assembly and other fundamental rights. **In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems operating in ‘real-time’ carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities.**

Amendment

(18) The use of AI systems for biometric identification of natural persons in publicly accessible spaces **is** particularly **corrosive to** the rights and freedoms of the concerned persons **and can ultimately** affect the private life of a large part of the population, **leave society with a justifiable** feeling of constant surveillance, **give parties deploying biometric identification in publicly accessible spaces a position of uncontrollable power** and indirectly dissuade **individuals from** the exercise of **their** freedom of assembly and other fundamental rights **at the core to the Rule of Law. Biometric identification not carried out in real time carries different but equally problematic risks. Due to the increase in pervasiveness, functionality and memory capacities of relevant devices, this would amount to a "surveillance time machine", which could be used to track movements and social interactions stretching back an indeterminate period into the past.**

Or. en

Amendment 450

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Ró a Thun und Hohenstein, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Recital 18

Text proposed by the Commission

(18) The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces **for the purpose of law enforcement** is considered particularly intrusive in the rights and freedoms of the concerned persons, to the extent that it may affect the private life of a large part of the population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems operating in ‘real-time’ carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities.

Amendment

(18) The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces is considered particularly intrusive in the rights and freedoms of the concerned persons, to the extent that it may affect the private life of a large part of the population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems operating in ‘real-time’ carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities. **The use of those systems in publicly accessible places should therefore be prohibited.**

Or. en

Amendment 451

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nută, Ramona Strugariu, Drago Pîslaru, Irena Joveva, Sophia in 't Veld, Karen Melchior, Svenja Hahn, Alin Mituță

Proposal for a regulation

Recital 18

Text proposed by the Commission

(18) The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces **for the purpose of law enforcement** is considered particularly intrusive in the rights and freedoms of the concerned

Amendment

(18) The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces is considered particularly intrusive in the rights and freedoms of the concerned persons, to the extent that it may affect the

persons, to the extent that it may affect the private life of a large part of the population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems operating in ‘real-time’ carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities.

private life of a large part of the population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems operating in ‘real-time’ carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities. *The use of those systems in publicly accessible places should therefore be prohibited.*

Or. en

Amendment 452

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 18

Text proposed by the Commission

(18) The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement is considered particularly intrusive in the rights and freedoms of the concerned persons, to the extent that it may affect the private life of a large part of the population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems operating in ‘real-time’ carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities.

Amendment

(18) The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement is considered particularly intrusive in the rights and freedoms of the concerned persons, to the extent that it may affect the private life of a large part of the population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems operating in ‘real-time’ carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities. *Such AI systems should be therefore prohibited.*

Or. en

Amendment 453

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 18

Text proposed by the Commission

(18) The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement is considered particularly intrusive in the rights and freedoms of the concerned persons, to the extent that it may affect the private life of a large part of the population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems operating in ‘real-time’ carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities.

Amendment

(18) The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible **or online** spaces for the purpose of law enforcement is considered particularly intrusive in the rights and freedoms of the concerned persons, to the extent that it may affect the private life of a large part of the population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems operating in ‘real-time’ carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities.

Or. en

Amendment 454

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Recital 18

Text proposed by the Commission

(18) The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces **for the purpose of law enforcement** is considered particularly intrusive in the rights and freedoms of the concerned persons, to the extent that it may affect the private life of a large part of the

Amendment

(18) The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces is considered particularly intrusive in the rights and freedoms of the concerned persons, to the extent that it may affect the private life of a large part of the population, evoke a feeling of constant

population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems operating in ‘real-time’ carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities.

surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems operating in ‘real-time’ carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities.

Or. en

Amendment 455

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

Proposal for a regulation Recital 18

Text proposed by the Commission

(18) L'utilisation de systèmes d'IA pour l'identification biométrique à distance «en temps réel» de personnes physiques dans des espaces accessibles au public à des fins répressives est **considérée comme** particulièrement intrusive pour les droits et les libertés des personnes concernées, dans la mesure où elle **peut toucher** la vie privée d'une grande partie de la population, **susciter un sentiment de** surveillance constante et **dissuader** indirectement l'exercice de la liberté de réunion et d'autres droits fondamentaux. En outre, du fait de l'immédiateté des effets et des possibilités limitées d'effectuer des vérifications ou des corrections supplémentaires, l'utilisation de systèmes fonctionnant «en temps réel» engendre des risques accrus pour les droits et les libertés des personnes concernées par les activités répressives.

Amendment

(18) L'utilisation de systèmes d'IA pour l'identification biométrique à distance «en temps réel» de personnes physiques dans des espaces accessibles au public à des fins répressives est particulièrement intrusive pour les droits et les libertés des personnes concernées, dans la mesure où elle **touche** la vie privée d'une grande partie de la population, **consiste en une** surveillance constante et **dissuade** indirectement l'exercice de la liberté de réunion et d'autres droits fondamentaux. En outre, du fait de l'immédiateté des effets et des possibilités limitées d'effectuer des vérifications ou des corrections supplémentaires, l'utilisation de systèmes fonctionnant «en temps réel» engendre des risques accrus pour les droits et les libertés des personnes concernées par les activités répressives.

Or. fr

Amendment 456

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

Proposal for a regulation

Recital 18 a (new)

Text proposed by the Commission

Amendment

(18 a) Despite progress regarding biometric identification technologies, the accuracy of the results still varies across technologies and depends on contextual factors. Even the relatively well-established fingerprint identification applications face challenges, in particular at the stage of the collection of biometric data (related to, for example, subject's age). The reliability of face recognition technologies in 'real world' settings is highly dependent on the quality of the images captured and on the quality of the algorithms used for biometric matching. During enrolment, poor quality images taken at e-gates or through a CCTV camera under variable environmental conditions may result in less accurate results. As in the case of automated fingerprint identification, changes in a person's physical characteristics over time may also affect the accuracy of facial recognition technologies. Research has found a considerable degradation in performance for face recognition algorithms on children as compared to the performance obtained on adults. In light of this, the placing or making available on the market, the putting into service or use of remote biometric identification systems should be prohibited.

Or. en

Amendment 457

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 18 a (new)

Text proposed by the Commission

Amendment

(18 a) The notion of ‘at a distance’ in Remote Biometric Identification (RBI) means the use of systems as described in Article 3(36), at a distance great enough that the system has the capacity to scan multiple persons in its field of view (or the equivalent generalised scanning of online / virtual spaces), which would mean that the identification could happen without one or more of the data subjects’ knowledge. Because RBI relates to how a system is designed and installed, and not solely to whether or not data subjects have consented, this definition applies even when warning notices are placed in the location that is under the surveillance of the RBI system, and is not de facto annulled by pre-enrolment.

Or. en

Amendment 458

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 18 a (new)

Text proposed by the Commission

Amendment

(18 a) The notion of ‘at a distance’ in Remote Biometric Identification (RBI) means the use of systems as described in Article 3(36), at a distance great enough that the system has the capacity to scan multiple persons in its field of view (or the equivalent generalised scanning of online / virtual spaces), which would mean that the identification could happen without one or more of the data subjects’ knowledge. Because RBI relates to how a system is designed and installed, and not solely to whether or not data subjects have consented, this definition applies even when warning notices are placed in the location that is under the surveillance of

the RBI system, and is not defacto annulled by pre-enrollment.

Or. en

Amendment 459

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

Proposal for a regulation

Recital 18 a (new)

Text proposed by the Commission

Amendment

(18 a) The use of data collected or generated by practices prohibited under this Regulation should also be prohibited. Within the framework of judicial and administrative proceedings, the responsible authorities should establish that data collected or generated by practices prohibited under this regulation should not be admissible.

Or. en

Amendment 460

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

Proposal for a regulation

Recital 18 b (new)

Text proposed by the Commission

Amendment

(18 b) There are serious concerns about the scientific basis of AI systems aiming to detect emotions from facial expressions. Facial expressions and perceptions thereof vary considerably across cultures and situations, and even within a single person. Among the key shortcomings of such technologies are the limited reliability (emotion categories are neither reliably expressed through, nor unequivocally associated with, a common

set of facial movements), the lack of specificity (facial expressions do not perfectly match emotion categories) and the limited generalisability (the effects of context and culture are not sufficiently considered). Reliability issues may also arise when deploying the system in real-life situations, for example, when dealing with subjects who actively seek (and train themselves) to fool the system. Therefore, the placing on the market, putting into service, or use of AI systems intended to be used as polygraphs and similar tools to detect the emotional state, trustworthiness or related characteristics of a natural person, should be prohibited.

Or. en

Amendment 461

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Recital 18 b (new)**

Text proposed by the Commission

Amendment

(18 b) ‘Biometric categorisation systems’ are defined as AI systems that assign natural persons to specific categories, or infer their characteristics or attributes. ‘Categorisation’ shall include any sorting of natural persons, whether into discrete categories (e.g. male/female, suspicious/not-suspicious), on a numerical scale (e.g. using the Fitzpatrick scale for skin type) or any other form of assigning labels or values to people. ‘Inferring an attribute or characteristic’ shall include any situation in which an AI system uses one type of data about a natural person (e.g. hair colour) to ascribe a different attribute or characteristic to that person (e.g. ethnic origin).

Or. en

Amendment 462

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Recital 19

Text proposed by the Commission

Amendment

(19) *The use of those systems for the purpose of law enforcement should therefore be prohibited, except in three exhaustively listed and narrowly defined situations, where the use is strictly necessary to achieve a substantial public interest, the importance of which outweighs the risks. Those situations involve the search for potential victims of crime, including missing children; certain threats to the life or physical safety of natural persons or of a terrorist attack; and the detection, localisation, identification or prosecution of perpetrators or suspects of the criminal offences referred to in Council Framework Decision 2002/584/JHA³⁸ if those criminal offences are punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years and as they are defined in the law of that Member State. Such threshold for the custodial sentence or detention order in accordance with national law contributes to ensure that the offence should be serious enough to potentially justify the use of ‘real-time’ remote biometric identification systems. Moreover, of the 32 criminal offences listed in the Council Framework Decision 2002/584/JHA, some are in practice likely to be more relevant than others, in that the recourse to ‘real-time’ remote biometric identification will foreseeably be necessary and proportionate to highly varying degrees for the practical pursuit of the detection, localisation, identification or prosecution of a perpetrator or suspect of the different*

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criminal offences listed and having regard to the likely differences in the seriousness, probability and scale of the harm or possible negative consequences.

³⁸ Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).

Or. en

Justification

Instead of blanketly banning the law enforcement's use of facial recognition AI, these systems should be incorporated in the list of high-risk AI systems and subject to strict control. Such modern AI software can process information and images at lightning speed and with great precision - tasks that would take days for a human law enforcement agent to go through. Also with much less risk of bias, when the programs are diligently designed. Using such technology can help law enforcement not only prevent crimes, but also react rapidly when they occur, and provide a very powerful tool to investigate serious crimes.

Amendment 463

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

**Proposal for a regulation
Recital 19**

Text proposed by the Commission

Amendment

(19) The use of those systems for the purpose of law enforcement should therefore be prohibited, except in three exhaustively listed and narrowly defined situations, where the use is strictly necessary to achieve a substantial public interest, the importance of which outweighs the risks. Those situations involve the search for potential victims of crime, including missing children; certain threats to the life or physical safety of natural persons or of a terrorist attack; and the detection, localisation, identification or prosecution of perpetrators or suspects of the criminal

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offences referred to in Council Framework Decision 2002/584/JHA³⁸ if those criminal offences are punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years and as they are defined in the law of that Member State. Such threshold for the custodial sentence or detention order in accordance with national law contributes to ensure that the offence should be serious enough to potentially justify the use of ‘real-time’ remote biometric identification systems. Moreover, of the 32 criminal offences listed in the Council Framework Decision 2002/584/JHA, some are in practice likely to be more relevant than others, in that the recourse to ‘real-time’ remote biometric identification will foreseeably be necessary and proportionate to highly varying degrees for the practical pursuit of the detection, localisation, identification or prosecution of a perpetrator or suspect of the different criminal offences listed and having regard to the likely differences in the seriousness, probability and scale of the harm or possible negative consequences.

³⁸ *Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).*

Or. en

Amendment 464

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Ró a Thun und Hohenstein, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Abir Al-Sahlani, Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation Recital 19

(19) *The use of those systems for the purpose of law enforcement should therefore be prohibited, except in three exhaustively listed and narrowly defined situations, where the use is strictly necessary to achieve a substantial public interest, the importance of which outweighs the risks. Those situations involve the search for potential victims of crime, including missing children; certain threats to the life or physical safety of natural persons or of a terrorist attack; and the detection, localisation, identification or prosecution of perpetrators or suspects of the criminal offences referred to in Council Framework Decision 2002/584/JHA³⁸ if those criminal offences are punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years and as they are defined in the law of that Member State. Such threshold for the custodial sentence or detention order in accordance with national law contributes to ensure that the offence should be serious enough to potentially justify the use of ‘real-time’ remote biometric identification systems. Moreover, of the 32 criminal offences listed in the Council Framework Decision 2002/584/JHA, some are in practice likely to be more relevant than others, in that the recourse to ‘real-time’ remote biometric identification will foreseeably be necessary and proportionate to highly varying degrees for the practical pursuit of the detection, localisation, identification or prosecution of a perpetrator or suspect of the different criminal offences listed and having regard to the likely differences in the seriousness, probability and scale of the harm or possible negative consequences.*

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³⁸ *Council Framework Decision 2002/584/JHA of 13 June 2002 on the*

*European arrest warrant and the
surrender procedures between Member
States (OJ L 190, 18.7.2002, p. 1).*

Or. en

Amendment 465

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Recital 19

Text proposed by the Commission

Amendment

(19) The use of those systems for the purpose of law enforcement should therefore be prohibited, except in three exhaustively listed and narrowly defined situations, where the use is strictly necessary to achieve a substantial public interest, the importance of which outweighs the risks. Those situations involve the search for potential victims of crime, including missing children; certain threats to the life or physical safety of natural persons or of a terrorist attack; and the detection, localisation, identification or prosecution of perpetrators or suspects of the criminal offences referred to in Council Framework Decision 2002/584/JHA³⁸ if those criminal offences are punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years and as they are defined in the law of that Member State. Such threshold for the custodial sentence or detention order in accordance with national law contributes to ensure that the offence should be serious enough to potentially justify the use of 'real-time' remote biometric identification systems. Moreover, of the 32 criminal offences listed in the Council Framework Decision 2002/584/JHA, some are in practice likely to be more relevant than others, in that the recourse to 'real-time' remote biometric

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identification will foreseeably be necessary and proportionate to highly varying degrees for the practical pursuit of the detection, localisation, identification or prosecution of a perpetrator or suspect of the different criminal offences listed and having regard to the likely differences in the seriousness, probability and scale of the harm or possible negative consequences.

³⁸ Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).

Or. en

Amendment 466

Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Marc Angel

**Proposal for a regulation
Recital 19**

Text proposed by the Commission

Amendment

(19) The use of those systems for the purpose of law enforcement should therefore be prohibited, except in three exhaustively listed and narrowly defined situations, where the use is strictly necessary to achieve a substantial public interest, the importance of which outweighs the risks. Those situations involve the search for potential victims of crime, including missing children; certain threats to the life or physical safety of natural persons or of a terrorist attack; and the detection, localisation, identification or prosecution of perpetrators or suspects of the criminal offences referred to in Council Framework Decision 2002/584/JHA³⁸ if those criminal offences are punishable in the Member State concerned by a

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custodial sentence or a detention order for a maximum period of at least three years and as they are defined in the law of that Member State. Such threshold for the custodial sentence or detention order in accordance with national law contributes to ensure that the offence should be serious enough to potentially justify the use of ‘real-time’ remote biometric identification systems. Moreover, of the 32 criminal offences listed in the Council Framework Decision 2002/584/JHA, some are in practice likely to be more relevant than others, in that the recourse to ‘real-time’ remote biometric identification will foreseeably be necessary and proportionate to highly varying degrees for the practical pursuit of the detection, localisation, identification or prosecution of a perpetrator or suspect of the different criminal offences listed and having regard to the likely differences in the seriousness, probability and scale of the harm or possible negative consequences.

³⁸ *Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).*

Or. en

Amendment 467

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Mituță, Ramona Strugariu, Drago Pîslaru, Irena Joveva, Sophia in 't Veld, Karen Melchior, Svenja Hahn, Alin Mituță

Proposal for a regulation Recital 19

Text proposed by the Commission

Amendment

(19) The use of those systems for the purpose of law enforcement should therefore be prohibited, except in three *deleted*

exhaustively listed and narrowly defined situations, where the use is strictly necessary to achieve a substantial public interest, the importance of which outweighs the risks. Those situations involve the search for potential victims of crime, including missing children; certain threats to the life or physical safety of natural persons or of a terrorist attack; and the detection, localisation, identification or prosecution of perpetrators or suspects of the criminal offences referred to in Council Framework Decision 2002/584/JHA³⁸ if those criminal offences are punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years and as they are defined in the law of that Member State. Such threshold for the custodial sentence or detention order in accordance with national law contributes to ensure that the offence should be serious enough to potentially justify the use of ‘real-time’ remote biometric identification systems. Moreover, of the 32 criminal offences listed in the Council Framework Decision 2002/584/JHA, some are in practice likely to be more relevant than others, in that the recourse to ‘real-time’ remote biometric identification will foreseeably be necessary and proportionate to highly varying degrees for the practical pursuit of the detection, localisation, identification or prosecution of a perpetrator or suspect of the different criminal offences listed and having regard to the likely differences in the seriousness, probability and scale of the harm or possible negative consequences.

³⁸ *Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).*

Or. en

Amendment 468
Jorge Buxadé Villalba

Proposal for a regulation
Recital 19

Text proposed by the Commission

(19) En consecuencia, debe prohibirse el uso de dichos sistemas con fines de aplicación de la ley, salvo *en tres situaciones enumeradas de manera limitativa y definidas con precisión en las que su utilización es estrictamente necesaria para lograr un interés público esencial cuya importancia es superior a los riesgos. Estas situaciones son la búsqueda de posibles víctimas de un delito, incluidos menores desaparecidos; determinadas amenazas para la vida o la seguridad física de las personas físicas o amenazas de atentado terrorista; y la detección, la localización, la identificación o el enjuiciamiento de los autores o sospechosos de los delitos mencionados en la Decisión Marco 2002/584/JAI del Consejo³⁸, si la normativa del Estado miembro implicado señala una pena o una medida de seguridad privativas de libertad cuya duración máxima sea de al menos de tres años, tal como se definan en el Derecho de dicho Estado miembro. Fijar ese umbral para la pena o la medida de seguridad privativas de libertad con arreglo al Derecho nacional contribuye a garantizar que el delito sea lo suficientemente grave como para llegar a justificar el uso de sistemas de identificación biométrica remota «en tiempo real». Por otro lado, en la práctica, algunos de los treinta y dos delitos enumerados en la Decisión Marco 2002/584/JAI del Consejo son probablemente más relevantes que otros en el sentido de que, previsiblemente, recurrir a la identificación biométrica remota «en tiempo real» se considerará*

Amendment

(19) En consecuencia, debe prohibirse el uso de dichos sistemas con fines de aplicación de la ley, salvo *para lo referido al control de fronteras y en el marco de la lucha antiterrorista.*

necesario y proporcionado en grados muy distintos para llevar a cabo la detección, la localización, la identificación o el enjuiciamiento de los autores o sospechosos de tales delitos, como también habrá enormes diferencias en la gravedad, la probabilidad y la magnitud de los perjuicios o las posibles consecuencias negativas que se deriven de ellos.

³⁸ Decisión Marco 2002/584/JAI del Consejo, de 13 de junio de 2002, relativa a la orden de detención europea y a los procedimientos de entrega entre Estados miembros (DO L 190 de 18.7.2002, p. 1).

Or. es

Amendment 469

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Recital 19**

Text proposed by the Commission

(19) The use of those systems for the purpose of law enforcement should therefore be prohibited, *except in three exhaustively listed and narrowly defined situations, where the use is strictly necessary to achieve a substantial public interest, the importance of which outweighs the risks. Those situations involve the search for potential victims of crime, including missing children; certain threats to the life or physical safety of natural persons or of a terrorist attack; and the detection, localisation, identification or prosecution of perpetrators or suspects of the criminal offences referred to in Council Framework Decision 2002/584/JHA³⁸ if those criminal offences are punishable in the Member State concerned by a custodial sentence or a detention order for*

Amendment

(19) The use of those systems for the purpose of law enforcement should therefore be prohibited.

a maximum period of at least three years and as they are defined in the law of that Member State. Such threshold for the custodial sentence or detention order in accordance with national law contributes to ensure that the offence should be serious enough to potentially justify the use of ‘real-time’ remote biometric identification systems. Moreover, of the 32 criminal offences listed in the Council Framework Decision 2002/584/JHA, some are in practice likely to be more relevant than others, in that the recourse to ‘real-time’ remote biometric identification will foreseeably be necessary and proportionate to highly varying degrees for the practical pursuit of the detection, localisation, identification or prosecution of a perpetrator or suspect of the different criminal offences listed and having regard to the likely differences in the seriousness, probability and scale of the harm or possible negative consequences.

³⁸ Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).

Or. en

Amendment 470

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

Proposal for a regulation Recital 19

Text proposed by the Commission

(19) The use of **those** systems for **the purpose of law enforcement should therefore be prohibited, except in three exhaustively listed and narrowly defined**

Amendment

(19) The use of **AI** systems for remote biometric identification **of individuals should therefore be prohibited**

situations, where the use is strictly necessary to achieve a substantial public interest, the importance of which outweighs the risks. Those situations involve the search for potential victims of crime, including missing children; certain threats to the life or physical safety of natural persons or of a terrorist attack; and the detection, localisation, identification or prosecution of perpetrators or suspects of the criminal offences referred to in Council Framework Decision 2002/584/JHA³⁸ if those criminal offences are punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years and as they are defined in the law of that Member State. Such threshold for the custodial sentence or detention order in accordance with national law contributes to ensure that the offence should be serious enough to potentially justify the use of 'real-time' remote biometric identification systems. Moreover, of the 32 criminal offences listed in the Council Framework Decision 2002/584/JHA, some are in practice likely to be more relevant than others, in that the recourse to 'real-time' remote biometric identification will foreseeably be necessary and proportionate to highly varying degrees for the practical pursuit of the detection, localisation, identification or prosecution of a perpetrator or suspect of the different criminal offences listed and having regard to the likely differences in the seriousness, probability and scale of the harm or possible negative consequences.

³⁸ Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).

Or. en

Amendment 471

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte

Proposal for a regulation

Recital 19

Text proposed by the Commission

(19) L'utilisation de ces systèmes à des fins répressives devrait donc être interdite, sauf dans trois situations précisément répertoriées et définies, dans lesquelles l'utilisation se limite au strict nécessaire à la réalisation d'objectifs d'intérêt général dont l'importance est considérée comme supérieure aux risques encourus. Ces situations comprennent la recherche de victimes potentielles d'actes criminels, y compris des enfants disparus; certaines menaces pour la vie ou la sécurité physique des personnes physiques, y compris les attaques terroristes; et la détection, la localisation, l'identification ou les poursuites à l'encontre des auteurs ou des suspects d'infractions pénales *visées dans la décision-cadre 2002/584/JAI³⁸ du Conseil si ces infractions pénales telles qu'elles sont définies dans le droit de l'État membre concerné* sont possibles d'une peine ou d'une mesure de sûreté *privative* de liberté pour une période maximale d'au moins *trois ans*. Le seuil fixé pour la peine ou la mesure de sûreté *privative* de liberté prévue par le droit national contribue à garantir que l'infraction soit suffisamment grave pour justifier l'utilisation de systèmes d'identification biométrique à distance «en temps réel». *En outre, sur les 32 infractions pénales énumérées dans la décision-cadre 2002/584/JAI du Conseil, certaines sont en pratique susceptibles d'être plus pertinentes que d'autres, dans le sens où le recours à l'identification biométrique à distance «en temps réel» sera vraisemblablement nécessaire et proportionné, à des degrés très divers, pour les mesures pratiques de détection,*

Amendment

(19) L'utilisation de ces systèmes à des fins répressives devrait donc être interdite, sauf dans trois situations précisément répertoriées et définies, dans lesquelles l'utilisation *est ponctuelle et* se limite au strict nécessaire à la réalisation d'objectifs d'intérêt général dont l'importance est considérée comme supérieure aux risques encourus. Ces situations comprennent la recherche de victimes potentielles d'actes criminels, y compris des enfants disparus; certaines menaces pour la vie ou la sécurité physique des personnes physiques, y compris les attaques terroristes; et la détection, la localisation, l'identification ou les poursuites à l'encontre des auteurs ou des suspects d'infractions pénales *si celles-ci* sont possibles d'une peine ou d'une mesure de sûreté *privatives* de liberté pour une période maximale d'au moins *dix ans dans le droit de l'État membre concerné*. Le seuil fixé pour la peine ou la mesure de sûreté *privatives* de liberté prévue par le droit national contribue à garantir que l'infraction soit suffisamment grave pour justifier l'utilisation de systèmes d'identification biométrique à distance «en temps réel». *La nature des infractions jugées suffisamment graves pour justifier une peine atteignant ce seuil relève de la législation nationale de chaque État membre en fonction de sa culture pénale particulière.*

de localisation, d'identification ou de poursuites à l'encontre d'un auteur ou d'un suspect de l'une des différentes infractions pénales répertoriées, compte tenu également des différences probables dans la gravité, la probabilité et l'ampleur du préjudice ou des éventuelles conséquences négatives.

³⁸ Décision-cadre 2002/584/JAI du Conseil du 13 juin 2002 relative au mandat d'arrêt européen et aux procédures de remise entre États membres (JO L 190 du 18.7.2002, p. 1).

Or. fr

Amendment 472

Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Marc Angel

Proposal for a regulation

Recital 20

Text proposed by the Commission

Amendment

(20) In order to ensure that those systems are used in a responsible and proportionate manner, it is also important to establish that, in each of those three exhaustively listed and narrowly defined situations, certain elements should be taken into account, in particular as regards the nature of the situation giving rise to the request and the consequences of the use for the rights and freedoms of all persons concerned and the safeguards and conditions provided for with the use. In addition, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement should be subject to appropriate limits in time and space, having regard in particular to the evidence or indications regarding the threats, the victims or perpetrator. The reference database of persons should be

deleted

appropriate for each use case in each of the three situations mentioned above.

Or. en

Amendment 473

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nută, Ramona Strugariu, Drago Pîslaru, Irena Joveva, Sophia in 't Veld, Karen Melchior, Svenja Hahn, Alin Mituța

Proposal for a regulation

Recital 20

Text proposed by the Commission

Amendment

(20) In order to ensure that those systems are used in a responsible and proportionate manner, it is also important to establish that, in each of those three exhaustively listed and narrowly defined situations, certain elements should be taken into account, in particular as regards the nature of the situation giving rise to the request and the consequences of the use for the rights and freedoms of all persons concerned and the safeguards and conditions provided for with the use. In addition, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement should be subject to appropriate limits in time and space, having regard in particular to the evidence or indications regarding the threats, the victims or perpetrator. The reference database of persons should be appropriate for each use case in each of the three situations mentioned above.

deleted

Or. en

Amendment 474

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Recital 20

Text proposed by the Commission

Amendment

(20) *In order to ensure that those systems are used in a responsible and proportionate manner, it is also important to establish that, in each of those three exhaustively listed and narrowly defined situations, certain elements should be taken into account, in particular as regards the nature of the situation giving rise to the request and the consequences of the use for the rights and freedoms of all persons concerned and the safeguards and conditions provided for with the use. In addition, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement should be subject to appropriate limits in time and space, having regard in particular to the evidence or indications regarding the threats, the victims or perpetrator. The reference database of persons should be appropriate for each use case in each of the three situations mentioned above.*

deleted

Or. en

Amendment 475

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

Proposal for a regulation

Recital 20

Text proposed by the Commission

Amendment

(20) *In order to ensure that those systems are used in a responsible and proportionate manner, it is also important to establish that, in each of those three exhaustively listed and narrowly defined situations, certain elements should be taken into account, in particular as regards the nature of the situation giving rise to the request and the consequences of the use for the rights and freedoms of*

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all persons concerned and the safeguards and conditions provided for with the use. In addition, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement should be subject to appropriate limits in time and space, having regard in particular to the evidence or indications regarding the threats, the victims or perpetrator. The reference database of persons should be appropriate for each use case in each of the three situations mentioned above.

Or. en

Amendment 476

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

Proposal for a regulation

Recital 20

Text proposed by the Commission

Amendment

(20) In order to ensure that those systems are used in a responsible and proportionate manner, it is also important to establish that, in each of those three exhaustively listed and narrowly defined situations, certain elements should be taken into account, in particular as regards the nature of the situation giving rise to the request and the consequences of the use for the rights and freedoms of all persons concerned and the safeguards and conditions provided for with the use. In addition, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement should be subject to appropriate limits in time and space, having regard in particular to the evidence or indications regarding the threats, the victims or perpetrator. The reference database of persons should be appropriate for each use case in each of

deleted

the three situations mentioned above.

Or. en

Amendment 477

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Ró a Thun und Hohenstein, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Abir Al-Sahlani, Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Recital 20

Text proposed by the Commission

Amendment

(20) In order to ensure that those systems are used in a responsible and proportionate manner, it is also important to establish that, in each of those three exhaustively listed and narrowly defined situations, certain elements should be taken into account, in particular as regards the nature of the situation giving rise to the request and the consequences of the use for the rights and freedoms of all persons concerned and the safeguards and conditions provided for with the use. In addition, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement should be subject to appropriate limits in time and space, having regard in particular to the evidence or indications regarding the threats, the victims or perpetrator. The reference database of persons should be appropriate for each use case in each of the three situations mentioned above.

deleted

Or. en

Amendment 478

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Recital 20

Text proposed by the Commission

Amendment

(20) *In order to ensure that those systems are used in a responsible and proportionate manner, it is also important to establish that, in each of those three exhaustively listed and narrowly defined situations, certain elements should be taken into account, in particular as regards the nature of the situation giving rise to the request and the consequences of the use for the rights and freedoms of all persons concerned and the safeguards and conditions provided for with the use. In addition, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement should be subject to appropriate limits in time and space, having regard in particular to the evidence or indications regarding the threats, the victims or perpetrator. The reference database of persons should be appropriate for each use case in each of the three situations mentioned above.*

Or. en

Justification

Instead of blanketly banning the law enforcement's use of facial recognition AI, these systems should be incorporated in the list of high-risk AI systems and subject to strict control. Such modern AI software can process information and images at lightning speed and with great precision - tasks that would take days for a human law enforcement agent to go through. Also with much less risk of bias, when the programs are diligently designed. Using such technology can help law enforcement not only prevent crimes, but also react rapidly when they occur, and provide a very powerful tool to investigate serious crimes.

Amendment 479

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 20

Text proposed by the Commission

Amendment

(20) In order to ensure that those systems are used in a responsible and

(20) In order to ensure that those systems are used in a responsible and

proportionate manner, it is also important to establish that, in ***each of those three*** exhaustively listed and narrowly defined situations, certain elements should be taken into account, in particular as regards the nature of the situation giving rise to the request and the consequences of the use for the rights and freedoms of all persons concerned and the safeguards and conditions provided for with the use. ***In addition, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement should be subject to appropriate limits in time and space, having regard in particular to the evidence or indications regarding the threats, the victims or perpetrator. The reference database of persons should be appropriate for each use case in each of the three situations mentioned above.***

proportionate manner, it is also important to establish that, in exhaustively listed and narrowly defined situations, certain elements should be taken into account, in particular as regards the nature of the situation giving rise to the request and the consequences of the use for the rights and freedoms of all persons concerned and the safeguards and conditions provided for with the use.

Or. en

Amendment 480

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 20

Text proposed by the Commission

(20) In order to ensure that those systems are used in a responsible and proportionate manner, it is also important to establish that, in each of those three exhaustively listed and narrowly defined situations, certain elements should be taken into account, in particular as regards the nature of the situation giving rise to the request and the consequences of the use for the rights and freedoms of all persons concerned and the safeguards and conditions provided for with the use. In addition, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement should be subject to

Amendment

(20) In order to ensure that those systems are used in a responsible and proportionate manner, it is also important to establish that, in each of those three exhaustively listed and narrowly defined situations, certain elements should be taken into account, in particular as regards the nature of the situation giving rise to the request and the consequences of the use for the rights and freedoms of all persons concerned and the safeguards and conditions provided for with the use. In addition, the use of ‘real-time’ remote biometric identification systems in publicly accessible ***or online*** spaces for the purpose of law enforcement should be subject to

appropriate limits in time and space, having regard in particular to the evidence or indications regarding the threats, the victims or perpetrator. The reference database of persons should be appropriate for each use case in each of the three situations mentioned above.

appropriate limits in time and space, having regard in particular to the evidence or indications regarding the threats, the victims or perpetrator. The reference database of persons should be appropriate for each use case in each of the three situations mentioned above.

Or. en

Amendment 481

Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Marc Angel

Proposal for a regulation

Recital 21

Text proposed by the Commission

Amendment

(21) Each use of a ‘real-time’ remote biometric identification system in publicly accessible spaces for the purpose of law enforcement should be subject to an express and specific authorisation by a judicial authority or by an independent administrative authority of a Member State. Such authorisation should in principle be obtained prior to the use, except in duly justified situations of urgency, that is, situations where the need to use the systems in question is such as to make it effectively and objectively impossible to obtain an authorisation before commencing the use. In such situations of urgency, the use should be restricted to the absolute minimum necessary and be subject to appropriate safeguards and conditions, as determined in national law and specified in the context of each individual urgent use case by the law enforcement authority itself. In addition, the law enforcement authority should in such situations seek to obtain an authorisation as soon as possible, whilst providing the reasons for not having been able to request it earlier.

deleted

Or. en

Amendment 482

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

Proposal for a regulation

Recital 21

Text proposed by the Commission

Amendment

(21) *Each use of a ‘real-time’ remote biometric identification system in publicly accessible spaces for the purpose of law enforcement should be subject to an express and specific authorisation by a judicial authority or by an independent administrative authority of a Member State. Such authorisation should in principle be obtained prior to the use, except in duly justified situations of urgency, that is, situations where the need to use the systems in question is such as to make it effectively and objectively impossible to obtain an authorisation before commencing the use. In such situations of urgency, the use should be restricted to the absolute minimum necessary and be subject to appropriate safeguards and conditions, as determined in national law and specified in the context of each individual urgent use case by the law enforcement authority itself. In addition, the law enforcement authority should in such situations seek to obtain an authorisation as soon as possible, whilst providing the reasons for not having been able to request it earlier.*

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Or. en

Amendment 483

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan nuță, Ramona Strugariu, Drago Pîslaru, Irena Joveva, Sophia in 't Veld, Karen Melchior, Svenja Hahn, Alin Mituță

Proposal for a regulation

Recital 21

Text proposed by the Commission

Amendment

(21) *Each use of a ‘real-time’ remote biometric identification system in publicly accessible spaces for the purpose of law enforcement should be subject to an express and specific authorisation by a judicial authority or by an independent administrative authority of a Member State. Such authorisation should in principle be obtained prior to the use, except in duly justified situations of urgency, that is, situations where the need to use the systems in question is such as to make it effectively and objectively impossible to obtain an authorisation before commencing the use. In such situations of urgency, the use should be restricted to the absolute minimum necessary and be subject to appropriate safeguards and conditions, as determined in national law and specified in the context of each individual urgent use case by the law enforcement authority itself. In addition, the law enforcement authority should in such situations seek to obtain an authorisation as soon as possible, whilst providing the reasons for not having been able to request it earlier.*

Or. en

Amendment 484

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

Proposal for a regulation

Recital 21

Text proposed by the Commission

Amendment

(21) *Each use of a ‘real-time’ remote biometric identification system in publicly accessible spaces for the purpose of law enforcement should be subject to an express and specific authorisation by a*

judicial authority or by an independent administrative authority of a Member State. Such authorisation should in principle be obtained prior to the use, except in duly justified situations of urgency, that is, situations where the need to use the systems in question is such as to make it effectively and objectively impossible to obtain an authorisation before commencing the use. In such situations of urgency, the use should be restricted to the absolute minimum necessary and be subject to appropriate safeguards and conditions, as determined in national law and specified in the context of each individual urgent use case by the law enforcement authority itself. In addition, the law enforcement authority should in such situations seek to obtain an authorisation as soon as possible, whilst providing the reasons for not having been able to request it earlier.

Or. en

Amendment 485

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 21

Text proposed by the Commission

Amendment

(21) Each use of a ‘real-time’ remote biometric identification system in publicly accessible spaces for the purpose of law enforcement should be subject to an express and specific authorisation by a judicial authority or by an independent administrative authority of a Member State. Such authorisation should in principle be obtained prior to the use, except in duly justified situations of urgency, that is, situations where the need to use the systems in question is such as to make it effectively and objectively impossible to obtain an authorisation before commencing the use. In such

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situations of urgency, the use should be restricted to the absolute minimum necessary and be subject to appropriate safeguards and conditions, as determined in national law and specified in the context of each individual urgent use case by the law enforcement authority itself. In addition, the law enforcement authority should in such situations seek to obtain an authorisation as soon as possible, whilst providing the reasons for not having been able to request it earlier.

Or. en

Amendment 486

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Ró a Thun und Hohenstein, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Abir Al-Sahlani, Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Recital 21

Text proposed by the Commission

Amendment

(21) *Each use of a ‘real-time’ remote biometric identification system in publicly accessible spaces for the purpose of law enforcement should be subject to an express and specific authorisation by a judicial authority or by an independent administrative authority of a Member State. Such authorisation should in principle be obtained prior to the use, except in duly justified situations of urgency, that is, situations where the need to use the systems in question is such as to make it effectively and objectively impossible to obtain an authorisation before commencing the use. In such situations of urgency, the use should be restricted to the absolute minimum necessary and be subject to appropriate safeguards and conditions, as determined in national law and specified in the context of each individual urgent use case by the law enforcement authority itself. In addition, the law enforcement authority*

deleted

should in such situations seek to obtain an authorisation as soon as possible, whilst providing the reasons for not having been able to request it earlier.

Or. en

Amendment 487

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Recital 21

Text proposed by the Commission

Amendment

(21) *Each use of a ‘real-time’ remote biometric identification system in publicly accessible spaces for the purpose of law enforcement should be subject to an express and specific authorisation by a judicial authority or by an independent administrative authority of a Member State. Such authorisation should in principle be obtained prior to the use, except in duly justified situations of urgency, that is, situations where the need to use the systems in question is such as to make it effectively and objectively impossible to obtain an authorisation before commencing the use. In such situations of urgency, the use should be restricted to the absolute minimum necessary and be subject to appropriate safeguards and conditions, as determined in national law and specified in the context of each individual urgent use case by the law enforcement authority itself. In addition, the law enforcement authority should in such situations seek to obtain an authorisation as soon as possible, whilst providing the reasons for not having been able to request it earlier.*

Or. en

Amendment 488

**Proposal for a regulation
Recital 21**

Text proposed by the Commission

(21) Each use of a ‘real-time’ remote biometric identification system in publicly accessible spaces for the purpose of law enforcement should be subject to an express and specific authorisation by a judicial authority or by an independent administrative authority of a Member State. Such authorisation should in principle be obtained prior to the use, except in duly justified situations of urgency, that is, situations where the need to use the systems in question is such as to make it effectively and objectively impossible to obtain an authorisation before commencing the use. In such situations of urgency, the use should be restricted to the absolute minimum necessary and be subject to appropriate safeguards and conditions, as determined in national law and specified in the context of each individual urgent use case by the law enforcement authority itself. In addition, the law enforcement authority should in such situations seek to obtain an authorisation as soon as possible, whilst providing the reasons for not having been able to request it earlier.

Amendment

(21) Each use of a ‘real-time’ remote biometric identification system in publicly accessible **or online** spaces for the purpose of law enforcement should be subject to an express and specific authorisation by a judicial authority or by an independent administrative authority of a Member State. Such authorisation should in principle be obtained prior to the use, except in duly justified situations of urgency, that is, situations where the need to use the systems in question is such as to make it effectively and objectively impossible to obtain an authorisation before commencing the use. In such situations of urgency, the use should be restricted to the absolute minimum necessary and be subject to appropriate safeguards and conditions, as determined in national law and specified in the context of each individual urgent use case by the law enforcement authority itself. In addition, the law enforcement authority should in such situations seek to obtain an authorisation as soon as possible, whilst providing the reasons for not having been able to request it earlier.

Or. en

Amendment 489

Jörgen Warborn, Arba Kokalari, Tomas Tobé

**Proposal for a regulation
Recital 21**

Text proposed by the Commission

(21) **Each** use of a ‘real-time’ remote biometric identification system in publicly accessible spaces for the purpose of law

Amendment

(21) Use of a ‘real-time’ remote biometric identification system in publicly accessible spaces for the purpose of law

enforcement should be subject to *an express and specific* authorisation by a judicial authority or by an independent administrative authority of a Member State. Such authorisation should in principle be obtained prior to the use, except in duly justified situations of urgency, that is, situations where the need to use the systems in question is such as to make it effectively and objectively impossible to obtain an authorisation before commencing the use. In such situations of urgency, the use should be restricted to the absolute minimum necessary and be subject to appropriate safeguards and conditions, as determined in national law and specified in the context of each individual urgent use case by the law enforcement authority itself. In addition, the law enforcement authority should in such situations seek to obtain an authorisation as soon as possible, whilst providing the reasons for not having been able to request it earlier.

enforcement should be subject to authorisation by a judicial authority or by an independent administrative authority of a Member State. Such authorisation should in principle be obtained prior to the use, except in duly justified situations of urgency, that is, situations where the need to use the systems in question is such as to make it effectively and objectively impossible to obtain an authorisation before commencing the use. In such situations of urgency, the use should be restricted to the absolute minimum necessary and be subject to appropriate safeguards and conditions, as determined in national law and specified in the context of each individual urgent use case by the law enforcement authority itself. In addition, the law enforcement authority should in such situations seek to obtain an authorisation as soon as possible, whilst providing the reasons for not having been able to request it earlier.

Or. en

Amendment 490

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Mituță, Ramona Strugariu, Drago Pîslaru, Lucia Šuriš Nicholsonová, Irena Joveva, Sophia in 't Veld, Karen Melchior, Svenja Hahn, Alin Mituță

Proposal for a regulation Recital 22

Text proposed by the Commission

(22) Furthermore, it is appropriate to provide, within the exhaustive framework set by this Regulation that such use in the territory of a Member State in accordance with this Regulation should only be possible where and in as far as the Member State in question has decided to expressly provide for the possibility to authorise such use in its detailed rules of national law. Consequently, Member States remain free under this Regulation

Amendment

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not to provide for such a possibility at all or to only provide for such a possibility in respect of some of the objectives capable of justifying authorised use identified in this Regulation.

Or. en

Amendment 491

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

**Proposal for a regulation
Recital 22**

Text proposed by the Commission

Amendment

(22) *Furthermore, it is appropriate to provide, within the exhaustive framework set by this Regulation that such use in the territory of a Member State in accordance with this Regulation should only be possible where and in as far as the Member State in question has decided to expressly provide for the possibility to authorise such use in its detailed rules of national law. Consequently, Member States remain free under this Regulation not to provide for such a possibility at all or to only provide for such a possibility in respect of some of the objectives capable of justifying authorised use identified in this Regulation.*

deleted

Or. en

Amendment 492

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

**Proposal for a regulation
Recital 22**

Text proposed by the Commission

Amendment

(22) *Furthermore, it is appropriate to provide, within the exhaustive framework set by this Regulation that such use in the territory of a Member State in accordance with this Regulation should only be possible where and in as far as the Member State in question has decided to expressly provide for the possibility to authorise such use in its detailed rules of national law. Consequently, Member States remain free under this Regulation not to provide for such a possibility at all or to only provide for such a possibility in respect of some of the objectives capable of justifying authorised use identified in this Regulation.*

deleted

Or. en

Amendment 493

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

Proposal for a regulation

Recital 22

Text proposed by the Commission

Amendment

(22) *Furthermore, it is appropriate to provide, within the exhaustive framework set by this Regulation that such use in the territory of a Member State in accordance with this Regulation should only be possible where and in as far as the Member State in question has decided to expressly provide for the possibility to authorise such use in its detailed rules of national law. Consequently, Member States remain free under this Regulation not to provide for such a possibility at all or to only provide for such a possibility in respect of some of the objectives capable of justifying authorised use identified in this Regulation.*

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Or. en

Amendment 494

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Ró a Thun und Hohenstein, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Abir Al-Sahlani, Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Recital 22

Text proposed by the Commission

Amendment

(22) *Furthermore, it is appropriate to provide, within the exhaustive framework set by this Regulation that such use in the territory of a Member State in accordance with this Regulation should only be possible where and in as far as the Member State in question has decided to expressly provide for the possibility to authorise such use in its detailed rules of national law. Consequently, Member States remain free under this Regulation not to provide for such a possibility at all or to only provide for such a possibility in respect of some of the objectives capable of justifying authorised use identified in this Regulation.*

deleted

Or. en

Amendment 495

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Recital 22

Text proposed by the Commission

Amendment

(22) *Furthermore, it is appropriate to provide, within the exhaustive framework set by this Regulation that such use in the territory of a Member State in accordance with this Regulation should only be possible where and in as far as the Member State in question has decided to expressly provide for the possibility to authorise such use in its detailed rules of*

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national law. Consequently, Member States remain free under this Regulation not to provide for such a possibility at all or to only provide for such a possibility in respect of some of the objectives capable of justifying authorised use identified in this Regulation.

Or. en

Amendment 496

Jörgen Warborn, Arba Kokalari, Tomas Tobé

**Proposal for a regulation
Recital 22**

Text proposed by the Commission

(22) Furthermore, it is appropriate to provide, *within the exhaustive framework set by this Regulation* that such use in the territory of a Member State in accordance with this Regulation should only be possible where and in as far as the Member State in question has decided to expressly provide for the possibility to authorise such use in its detailed rules of national law. Consequently, Member States remain free under this Regulation not to provide for such a possibility at all or to only provide *for such a possibility in respect of some of the objectives capable of justifying authorised use identified* in this Regulation.

Amendment

(22) Furthermore, it is appropriate to provide that such use in the territory of a Member State in accordance with this Regulation should only be possible where and in as far as the Member State in question has decided to expressly provide for the possibility to authorise such use in its detailed rules of national law. Consequently, Member States remain free under this Regulation not to provide for such a possibility at all or to only provide *limited possibilities* in this *regard*.

Or. en

Amendment 497

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Róza Thun und Hohenstein, Vlad-Marius Botoș, Samira Rafaela, Monica Semedo, Salima Yenbou, Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

**Proposal for a regulation
Recital 23**

(23) *The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement necessarily involves the processing of biometric data. The rules of this Regulation that prohibit, subject to certain exceptions, such use, which are based on Article 16 TFEU, should apply as lex specialis in respect of the rules on the processing of biometric data contained in Article 10 of Directive (EU) 2016/680, thus regulating such use and the processing of biometric data involved in an exhaustive manner. Therefore, such use and processing should only be possible in as far as it is compatible with the framework set by this Regulation, without there being scope, outside that framework, for the competent authorities, where they act for purpose of law enforcement, to use such systems and process such data in connection thereto on the grounds listed in Article 10 of Directive (EU) 2016/680. In this context, this Regulation is not intended to provide the legal basis for the processing of personal data under Article 8 of Directive 2016/680. However, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for purposes other than law enforcement, including by competent authorities, should not be covered by the specific framework regarding such use for the purpose of law enforcement set by this Regulation. Such use for purposes other than law enforcement should therefore not be subject to the requirement of an authorisation under this Regulation and the applicable detailed rules of national law that may give effect to it.*

deleted

Or. en

Amendment 498

**Proposal for a regulation
Recital 23**

Text proposed by the Commission

Amendment

(23) *The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement necessarily involves the processing of biometric data. The rules of this Regulation that prohibit, subject to certain exceptions, such use, which are based on Article 16 TFEU, should apply as lex specialis in respect of the rules on the processing of biometric data contained in Article 10 of Directive (EU) 2016/680, thus regulating such use and the processing of biometric data involved in an exhaustive manner. Therefore, such use and processing should only be possible in as far as it is compatible with the framework set by this Regulation, without there being scope, outside that framework, for the competent authorities, where they act for purpose of law enforcement, to use such systems and process such data in connection thereto on the grounds listed in Article 10 of Directive (EU) 2016/680. In this context, this Regulation is not intended to provide the legal basis for the processing of personal data under Article 8 of Directive 2016/680. However, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for purposes other than law enforcement, including by competent authorities, should not be covered by the specific framework regarding such use for the purpose of law enforcement set by this Regulation. Such use for purposes other than law enforcement should therefore not be subject to the requirement of an authorisation under this Regulation and the applicable detailed rules of national law that may give effect to it.*

deleted

Amendment 499

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Sophia in 't Veld, Irena Joveva, Karen Melchior, Svenja Hahn, Alin Mituța

Proposal for a regulation

Recital 23

Text proposed by the Commission

Amendment

(23) *The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement necessarily involves the processing of biometric data. The rules of this Regulation that prohibit, subject to certain exceptions, such use, which are based on Article 16 TFEU, should apply as lex specialis in respect of the rules on the processing of biometric data contained in Article 10 of Directive (EU) 2016/680, thus regulating such use and the processing of biometric data involved in an exhaustive manner. Therefore, such use and processing should only be possible in as far as it is compatible with the framework set by this Regulation, without there being scope, outside that framework, for the competent authorities, where they act for purpose of law enforcement, to use such systems and process such data in connection thereto on the grounds listed in Article 10 of Directive (EU) 2016/680. In this context, this Regulation is not intended to provide the legal basis for the processing of personal data under Article 8 of Directive 2016/680. However, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for purposes other than law enforcement, including by competent authorities, should not be covered by the specific framework regarding such use for the purpose of law enforcement set by this Regulation. Such*

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use for purposes other than law enforcement should therefore not be subject to the requirement of an authorisation under this Regulation and the applicable detailed rules of national law that may give effect to it.

Or. en

Amendment 500

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

**Proposal for a regulation
Recital 23**

Text proposed by the Commission

Amendment

(23) *The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement necessarily involves the processing of biometric data. The rules of this Regulation that prohibit, subject to certain exceptions, such use, which are based on Article 16 TFEU, should apply as lex specialis in respect of the rules on the processing of biometric data contained in Article 10 of Directive (EU) 2016/680, thus regulating such use and the processing of biometric data involved in an exhaustive manner. Therefore, such use and processing should only be possible in as far as it is compatible with the framework set by this Regulation, without there being scope, outside that framework, for the competent authorities, where they act for purpose of law enforcement, to use such systems and process such data in connection thereto on the grounds listed in Article 10 of Directive (EU) 2016/680. In this context, this Regulation is not intended to provide the legal basis for the processing of personal data under Article 8 of Directive 2016/680. However, the use of ‘real-time’ remote biometric identification systems in*

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publicly accessible spaces for purposes other than law enforcement, including by competent authorities, should not be covered by the specific framework regarding such use for the purpose of law enforcement set by this Regulation. Such use for purposes other than law enforcement should therefore not be subject to the requirement of an authorisation under this Regulation and the applicable detailed rules of national law that may give effect to it.

Or. en

Amendment 501

Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Marc Angel

**Proposal for a regulation
Recital 23**

Text proposed by the Commission

Amendment

(23) *The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement necessarily involves the processing of biometric data. The rules of this Regulation that prohibit, subject to certain exceptions, such use, which are based on Article 16 TFEU, should apply as lex specialis in respect of the rules on the processing of biometric data contained in Article 10 of Directive (EU) 2016/680, thus regulating such use and the processing of biometric data involved in an exhaustive manner. Therefore, such use and processing should only be possible in as far as it is compatible with the framework set by this Regulation, without there being scope, outside that framework, for the competent authorities, where they act for purpose of law enforcement, to use such systems and process such data in connection thereto on the grounds listed in Article 10 of*

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Directive (EU) 2016/680. In this context, this Regulation is not intended to provide the legal basis for the processing of personal data under Article 8 of Directive 2016/680. However, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for purposes other than law enforcement, including by competent authorities, should not be covered by the specific framework regarding such use for the purpose of law enforcement set by this Regulation. Such use for purposes other than law enforcement should therefore not be subject to the requirement of an authorisation under this Regulation and the applicable detailed rules of national law that may give effect to it.

Or. en

Amendment 502

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

Proposal for a regulation Recital 23

Text proposed by the Commission

(23) The use of AI systems for ‘**real-time**’ **remote** biometric identification of natural persons in publicly accessible spaces **for the purpose of law enforcement** necessarily involves the processing of biometric data. The rules of this Regulation that prohibit, subject to certain exceptions, such use, which are based on Article 16 TFEU, should apply as lex specialis in respect of the rules on the processing of biometric data contained in Article 10 of Directive (EU) 2016/680, thus regulating such use and the processing of biometric data involved in an exhaustive manner.

Therefore, such use and processing should only be possible in as far as it is compatible with the framework set by this

Amendment

(23) The use of AI systems for biometric identification of natural persons in publicly accessible spaces necessarily involves the processing of biometric **and biometrics-based** data. The rules of this Regulation that prohibit, subject to certain exceptions, such use, which are based on Article 16 TFEU, should apply as lex specialis in respect of the rules on the processing of biometric data contained in Article 10 of Directive (EU) 2016/680 **and Article 9 of Regulation 2016/679**, thus regulating such use and the processing of biometric data involved in an exhaustive manner.

Regulation, without there being scope, outside that framework, for the competent authorities, where they act for purpose of law enforcement, to use such systems and process such data in connection thereto on the grounds listed in Article 10 of Directive (EU) 2016/680. In this context, this Regulation is not intended to provide the legal basis for the processing of personal data under Article 8 of Directive 2016/680. However, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for purposes other than law enforcement, including by competent authorities, should not be covered by the specific framework regarding such use for the purpose of law enforcement set by this Regulation. Such use for purposes other than law enforcement should therefore not be subject to the requirement of an authorisation under this Regulation and the applicable detailed rules of national law that may give effect to it.

Or. en

Amendment 503

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation Recital 23

Text proposed by the Commission

(23) The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement necessarily involves the processing of biometric data. The rules of this Regulation that prohibit, *subject to certain exceptions*, such use, which are based on Article 16 TFEU, should apply as lex specialis in respect of the rules on the processing of biometric data contained in Article 10 of Directive (EU) 2016/680, *thus regulating such use and the processing of biometric*

Amendment

(23) The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement necessarily involves the processing of biometric data. The rules of this Regulation that prohibit such use, which are based on Article 16 TFEU, should apply as lex specialis in respect of the rules on the processing of biometric data contained in Article 10 of Directive (EU) 2016/680. However, the use of ‘real-time’ remote biometric identification systems in publicly

data involved in an exhaustive manner. Therefore, such use and processing should only be possible in as far as it is compatible with the framework set by this Regulation, without there being scope, outside that framework, for the competent authorities, where they act for purpose of law enforcement, to use such systems and process such data in connection thereto on the grounds listed in Article 10 of Directive (EU) 2016/680. In this context, this Regulation is not intended to provide the legal basis for the processing of personal data under Article 8 of Directive 2016/680. However, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for purposes **other than law enforcement**, including by competent authorities, should not be covered by the specific framework regarding such use for the purpose of law enforcement set by this Regulation. Such use for purposes other than law enforcement should therefore not be subject to the requirement of an authorisation under this Regulation and the applicable detailed rules of national law that may give effect to it.

accessible spaces for purposes, including by competent authorities, should not be covered by the specific framework regarding such use for the purpose of law enforcement set by this Regulation. Such use for purposes other than law enforcement should therefore not be subject to the requirement of an authorisation under this Regulation and the applicable detailed rules of national law that may give effect to it. ***The lex specialis nature of the prohibition on RBI does not provide a legal basis for law enforcement uses of RBI, nor does it weaken existing protections of biometric data under the Data Protection Law Enforcement Directive (LED) or national implementations of the LED.***

Or. en

Amendment 504

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation Recital 23

Text proposed by the Commission

(23) The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement necessarily involves the processing of biometric data. ***The rules of this Regulation that prohibit, subject to certain exceptions, such use, which are based on Article 16 TFEU, should apply***

Amendment

(23) The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible **or online** spaces for the purpose of law enforcement necessarily involves the processing of biometric data. Therefore, such use and processing should only be possible in as far as it is compatible with the framework set by this Regulation,

as lex specialis in respect of the rules on the processing of biometric data contained in Article 10 of Directive (EU) 2016/680, thus regulating such use and the processing of biometric data involved in an exhaustive manner. Therefore, such use and processing should only be possible in as far as it is compatible with the framework set by this Regulation, without there being scope, outside that framework, for the competent authorities, where they act for purpose of law enforcement, to use such systems and process such data in connection thereto on the grounds listed in Article 10 of Directive (EU) 2016/680. In this context, this Regulation is not intended to provide the legal basis for the processing of personal data under Article 8 of Directive 2016/680. However, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for purposes other than law enforcement, including by competent authorities, should not be covered by the specific framework regarding such use for the purpose of law enforcement set by this Regulation. Such use for purposes other than law enforcement should therefore not be subject to the requirement of an authorisation under this Regulation and the applicable detailed rules of national law that may give effect to it.

without there being scope, outside that framework, for the competent authorities, where they act for purpose of law enforcement, to use such systems and process such data in connection thereto on the grounds listed in Article 10 of Directive (EU) 2016/680. In this context, this Regulation is not intended to provide the legal basis for the processing of personal data under Article 8 of Directive 2016/680. However, the use of ‘real-time’ remote biometric identification systems in publicly accessible **or online** spaces for purposes other than law enforcement, including by competent authorities, should not be covered by the specific framework regarding such use for the purpose of law enforcement set by this Regulation. Such use for purposes other than law enforcement should therefore not be subject to the requirement of an authorisation under this Regulation and the applicable detailed rules of national law that may give effect to it.

Or. en

Amendment 505

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte

Proposal for a regulation Recital 23

Text proposed by the Commission

(23) L’utilisation de systèmes d’IA pour l’identification biométrique à distance «en temps réel» de personnes physiques dans des espaces accessibles au public à des fins répressives passe nécessairement par le

Amendment

(23) L’utilisation de systèmes d’IA pour l’identification biométrique à distance «en temps réel» de personnes physiques dans des espaces accessibles au public à des fins répressives passe nécessairement par le

traitement de données biométriques. Les règles du présent règlement qui interdisent, sous réserve de certaines exceptions, une telle utilisation, et qui sont fondées sur l'article 16 du TFUE, devraient s'appliquer en tant que lex specialis pour ce qui est des règles sur le traitement des données biométriques figurant à l'article 10 de la directive (UE) 2016/680, réglementant ainsi de manière exhaustive cette utilisation et le traitement des données biométriques qui en résulte. Par conséquent, une telle utilisation et un tel traitement ne devraient être possibles que dans la mesure où ils sont compatibles avec le cadre fixé par le présent règlement, sans qu'il soit possible pour les autorités compétentes, lorsqu'elles agissent à des fins répressives en dehors de ce cadre, d'utiliser ces systèmes et de traiter les données y afférentes pour les motifs énumérés à l'article 10 de la directive (UE) 2016/680. Dans ce contexte, le présent règlement ne vise pas à fournir la base juridique pour le traitement des données à caractère personnel en vertu de l'article 8 de la directive (UE) 2016/680.

Cependant, l'utilisation de systèmes d'identification biométrique à distance «en temps réel» dans des espaces accessibles au public à des fins autres que répressives, y compris par les autorités compétentes, **ne devrait pas** être couverte par le cadre **spécifique concernant l'utilisation à des fins répressives** établi par le présent règlement. **L'utilisation à des fins autres que répressives ne devrait donc pas être subordonnée à l'exigence d'une autorisation au titre du présent règlement et des règles détaillées du droit national applicable susceptibles de lui donner effet.**

traitement de données biométriques. Les règles du présent règlement qui interdisent, sous réserve de certaines exceptions, une telle utilisation, et qui sont fondées sur l'article 16 du TFUE, devraient s'appliquer en tant que lex specialis pour ce qui est des règles sur le traitement des données biométriques figurant à l'article 10 de la directive (UE) 2016/680, réglementant ainsi de manière exhaustive cette utilisation et le traitement des données biométriques qui en résulte. Par conséquent, une telle utilisation et un tel traitement ne devraient être possibles que dans la mesure où ils sont compatibles avec le cadre fixé par le présent règlement, sans qu'il soit possible pour les autorités compétentes, lorsqu'elles agissent à des fins répressives en dehors de ce cadre, d'utiliser ces systèmes et de traiter les données y afférentes pour les motifs énumérés à l'article 10 de la directive (UE) 2016/680. Dans ce contexte, le présent règlement ne vise pas à fournir la base juridique pour le traitement des données à caractère personnel en vertu de l'article 8 de la directive (UE) 2016/680.

L'utilisation de systèmes d'identification biométrique, y compris à les systèmes d'identification biométrique à distance «en temps réel» dans des espaces accessibles au public à des fins autres que répressives, y compris par les autorités compétentes, devrait être couverte par le cadre établi par le présent règlement, **à l'exception des formalités douanières et de l'authentification individuelle.**

Or. fr

Amendment 506
Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation
Recital 23

Text proposed by the Commission

(23) The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement necessarily involves the processing of biometric data. The rules of this Regulation **that prohibit, subject to certain exceptions, such use**, which are based on Article 16 TFEU, should apply as lex specialis in respect of the rules on the processing of biometric data contained in Article 10 of Directive (EU) 2016/680, thus regulating such use and the processing of biometric data involved in an exhaustive manner. Therefore, such use and processing should only be possible in as far as it is compatible with the framework set by this Regulation, without there being scope, outside that framework, for the competent authorities, where they act for purpose of law enforcement, to use such systems and process such data in connection thereto on the grounds listed in Article 10 of Directive (EU) 2016/680. In this context, this Regulation is not intended to provide the legal basis for the processing of personal data under Article 8 of Directive 2016/680. However, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for purposes other than law enforcement, including by competent authorities, should not be covered by the specific framework regarding such use for the purpose of law enforcement set by this Regulation. Such use for purposes other than law enforcement should therefore not be subject to the requirement of an authorisation under this Regulation and the applicable detailed rules of national law that may give effect to it.

Amendment

(23) The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement necessarily involves the processing of biometric data. The rules of this Regulation which are based on Article 16 TFEU, should apply as lex specialis in respect of the rules on the processing of biometric data contained in Article 10 of Directive (EU) 2016/680, thus regulating such use and the processing of biometric data involved in an exhaustive manner. Therefore, such use and processing should only be possible in as far as it is compatible with the framework set by this Regulation, without there being scope, outside that framework, for the competent authorities, where they act for purpose of law enforcement, to use such systems and process such data in connection thereto on the grounds listed in Article 10 of Directive (EU) 2016/680. In this context, this Regulation is not intended to provide the legal basis for the processing of personal data under Article 8 of Directive 2016/680. However, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for purposes other than law enforcement, including by competent authorities, should not be covered by the specific framework regarding such use for the purpose of law enforcement set by this Regulation. Such use for purposes other than law enforcement should therefore not be subject to the requirement of an authorisation under this Regulation and the applicable detailed rules of national law that may give effect to it.

Or. en

Justification

Instead of blanketly banning the law enforcement's use of facial recognition AI, these systems

should be incorporated in the list of high-risk AI systems and subject to strict control. Such modern AI software can process information and images at lightning speed and with great precision - tasks that would take days for a human law enforcement agent to go through. Also with much less risk of bias, when the programs are diligently designed. Using such technology can help law enforcement not only prevent crimes, but also react rapidly when they occur, and provide a very powerful tool to investigate serious crimes.

Amendment 507

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 23 a (new)

Text proposed by the Commission

Amendment

(23 a) ‘Biometric categorisation systems’ are defined as AI systems that assign natural persons to specific categories, or infer their characteristics or attributes. ‘Categorisation’ shall include any sorting of natural persons, whether into discrete categories (e.g. male/female, suspicious/not-suspicious), on a numerical scale (e.g. using the Fitzpatrick scale for skin type) or any other form of assigning labels or values to people. ‘Inferring an attribute or characteristic’ shall include any situation in which an AI system uses one type of data about a natural person (e.g. hair colour) to ascribe a different attribute or characteristic to that person (e.g. ethnic origin).

Or. en

Amendment 508

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Recital 24

Text proposed by the Commission

Amendment

(24) Any processing of biometric data and other personal data involved in the

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use of AI systems for biometric identification, other than in connection to the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement as regulated by this Regulation, including where those systems are used by competent authorities in publicly accessible spaces for other purposes than law enforcement, should continue to comply with all requirements resulting from Article 9(1) of Regulation (EU) 2016/679, Article 10(1) of Regulation (EU) 2018/1725 and Article 10 of Directive (EU) 2016/680, as applicable.

Or. en

Amendment 509

Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Marc Angel

Proposal for a regulation

Recital 24

Text proposed by the Commission

Amendment

(24) Any processing of biometric data and other personal data involved in the use of AI systems for biometric identification, other than in connection to the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement as regulated by this Regulation, including where those systems are used by competent authorities in publicly accessible spaces for other purposes than law enforcement, should continue to comply with all requirements resulting from Article 9(1) of Regulation (EU) 2016/679, Article 10(1) of Regulation (EU) 2018/1725 and Article 10 of Directive (EU) 2016/680, as applicable.

deleted

Or. en

Amendment 510

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

Proposal for a regulation

Recital 24

Text proposed by the Commission

(24) Any processing of biometric data and other personal data involved in the use of AI systems for biometric identification, *other than in connection to the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement as regulated by this Regulation, including where those systems are used by competent authorities in publicly accessible spaces for other purposes than law enforcement*, should continue to comply with all requirements resulting from Article 9(1) of Regulation (EU) 2016/679, Article 10(1) of Regulation (EU) 2018/1725 and Article 10 of Directive (EU) 2016/680, as applicable.

Amendment

(24) Any processing of biometric data and other personal data involved in the use of AI systems for biometric identification should continue to comply with all requirements resulting from Article 9(1) of Regulation (EU) 2016/679, Article 10(1) of Regulation (EU) 2018/1725 and Article 10 of Directive (EU) 2016/680, as applicable.

Or. en

Amendment 511

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Ró a Thun und Hohenstein, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Recital 24

Text proposed by the Commission

(24) Any processing of biometric data and other personal data involved in the use of AI systems for biometric identification, *other than in connection to the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement as regulated by this Regulation, including where those systems are used by competent*

Amendment

(24) Any processing of biometric data and other personal data involved in the use of AI systems for biometric identification, including where those systems are used by competent authorities in publicly accessible spaces for other purposes than law enforcement, should continue to comply with all requirements resulting from Article 9(1) of Regulation (EU)

authorities in publicly accessible spaces for other purposes than law enforcement, should continue to comply with all requirements resulting from Article 9(1) of Regulation (EU) 2016/679, Article 10(1) of Regulation (EU) 2018/1725 and Article 10 of Directive (EU) 2016/680, as applicable.

2016/679, Article 10(1) of Regulation (EU) 2018/1725 and Article 10 of Directive (EU) 2016/680, as applicable.

Or. en

Amendment 512

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Irena Joveva, Karen Melchior, Svenja Hahn, Alin Mituță

Proposal for a regulation

Recital 24

Text proposed by the Commission

(24) Any processing of biometric data and other personal data involved in the use of AI systems for biometric identification, *other than in connection to the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement as regulated by this Regulation*, including where those systems are used by competent authorities in publicly accessible spaces for other purposes than law enforcement, should continue to comply with all requirements resulting from Article 9(1) of Regulation (EU) 2016/679, Article 10(1) of Regulation (EU) 2018/1725 and Article 10 of Directive (EU) 2016/680, as applicable.

Amendment

(24) Any processing of biometric data and other personal data involved in the use of AI systems for biometric identification, including where those systems are used by competent authorities in publicly accessible spaces for other purposes than law enforcement, should continue to comply with all requirements resulting from Article 9(1) of Regulation (EU) 2016/679, Article 10(1) of Regulation (EU) 2018/1725 and Article 10 of Directive (EU) 2016/680, as applicable.

Or. en

Amendment 513

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

Proposal for a regulation

Recital 24

Text proposed by the Commission

(24) Any processing of biometric data and other personal data involved in the use of AI systems for biometric identification, other than in connection to the use of '*real-time' remote* biometric identification systems in publicly accessible spaces *for the purpose of law enforcement* as regulated by this Regulation, *including where those systems are used by competent authorities in publicly accessible spaces for other purposes than law enforcement*, should continue to comply with all requirements resulting from Article 9(1) of Regulation (EU) 2016/679, Article 10(1) of Regulation (EU) 2018/1725 and Article 10 of Directive (EU) 2016/680, as applicable.

Amendment

(24) Any processing of biometric ***data, biometrics-based*** data and other personal data involved in the use of AI systems for biometric identification, other than in connection to the use of biometric identification systems in publicly accessible spaces as regulated by this Regulation, should continue to comply with all requirements resulting from Article 9(1) of Regulation (EU) 2016/679, Article 10(1) of Regulation (EU) 2018/1725 and Article 10 of Directive (EU) 2016/680, as applicable.

Or. en

Amendment 514

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Recital 24**

Text proposed by the Commission

(24) Any processing of biometric data and other personal data involved in the use of AI systems for biometric identification, other than in connection to the use of '*real-time' remote* biometric identification systems in publicly accessible spaces for the purpose of law enforcement as regulated by this Regulation, including where those systems are used by competent authorities in publicly accessible spaces for other purposes than law enforcement, should continue to comply with all requirements resulting from Article 9(1) of Regulation (EU) 2016/679, Article 10(1) of Regulation (EU) 2018/1725 and Article 10 of Directive (EU) 2016/680, as applicable.

Amendment

(24) Any processing of biometric data and other personal data involved in the use of AI systems for biometric identification, other than in connection to the use of '*real-time' remote* biometric identification systems in publicly accessible ***or online*** spaces for the purpose of law enforcement as regulated by this Regulation, including where those systems are used by competent authorities in publicly accessible ***or online*** spaces for other purposes than law enforcement, should continue to comply with all requirements resulting from Article 9(1) of Regulation (EU) 2016/679, Article 10(1) of Regulation (EU) 2018/1725 and Article 10 of Directive (EU) 2016/680, as applicable.

Amendment 515

Svenja Hahn, Nicola Beer, Karen Melchior, Dita Charanzová, Andrus Ansip, Morten Løkkegaard, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Recital 24 a (new)

Text proposed by the Commission

Amendment

(24 a) Fundamental rights in the digital sphere have to be guaranteed to the same extent as in the offline world. The right to privacy needs to be ensured, amongst others through end-to-end encryption in private online communication and the protection of private content against any kind of general or targeted surveillance, be it by public or private actors. Therefore, the use of AI systems violating the right to privacy in online communication services should be prohibited.

Amendment 516

Brando Benifei, 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

Recital 25

Text proposed by the Commission

Amendment

(25) In accordance with Article 6a of Protocol No 21 on the position of the United Kingdom and Ireland in respect of the area of freedom, security and justice, as annexed to the TEU and to the TFEU, Ireland is not bound by the rules laid down in Article 5(1), point (d), **(2) and (3)** of this Regulation adopted on the basis of Article

(25) In accordance with Article 6a of Protocol No 21 on the position of the United Kingdom and Ireland in respect of the area of freedom, security and justice, as annexed to the TEU and to the TFEU, Ireland is not bound by the rules laid down in Article 5(1), point (d) of this Regulation adopted on the basis of Article 16 of the

16 of the TFEU which relate to the processing of personal data by the Member States when carrying out activities falling within the scope of Chapter 4 or Chapter 5 of Title V of Part Three of the TFEU, where Ireland is not bound by the rules governing the forms of judicial cooperation in criminal matters or police cooperation which require compliance with the provisions laid down on the basis of Article 16 of the TFEU.

TFEU which relate to the processing of personal data by the Member States when carrying out activities falling within the scope of Chapter 4 or Chapter 5 of Title V of Part Three of the TFEU, where Ireland is not bound by the rules governing the forms of judicial cooperation in criminal matters or police cooperation which require compliance with the provisions laid down on the basis of Article 16 of the TFEU.

Or. en

Amendment 517

Brando Benifei, 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 Recital 26

Text proposed by the Commission

(26) In accordance with Articles 2 and 2a of Protocol No 22 on the position of Denmark, annexed to the TEU and TFEU, Denmark is not bound by rules laid down in Article 5(1), point (d), **(2) and (3)** of this Regulation adopted on the basis of Article 16 of the TFEU, or subject to their application, which relate to the processing of personal data by the Member States when carrying out activities falling within the scope of Chapter 4 or Chapter 5 of Title V of Part Three of the TFEU.

Amendment

(26) In accordance with Articles 2 and 2a of Protocol No 22 on the position of Denmark, annexed to the TEU and TFEU, Denmark is not bound by rules laid down in Article 5(1), point (d) of this Regulation adopted on the basis of Article 16 of the TFEU, or subject to their application, which relate to the processing of personal data by the Member States when carrying out activities falling within the scope of Chapter 4 or Chapter 5 of Title V of Part Three of the TFEU.

Or. en

Amendment 518

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 Recital 26 a (new)

Text proposed by the Commission

Amendment

(26 a) AI systems capable of reading facial expressions to infer emotional states hold no scientific basis, while at the same time running a high risk of inaccuracy, in particular for certain groups of individuals whose facial traits are not easily readable by such systems, as several examples have shown. Therefore, due to the particular risk of discrimination, these systems should be prohibited.

Or. en

Amendment 519

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

Proposal for a regulation

Recital 27

Text proposed by the Commission

(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be *limited to those that* have a significant harmful impact on the health, safety and fundamental rights of *persons* in the Union *and such limitation minimises any potential restriction to international trade, if any.*

Amendment

(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be *classified as such when they* have a significant harmful impact on the health, safety, *economic status* and fundamental rights of *individuals* in the Union, *and also on the environment, society, rule of law, democracy or consumer protection. Given the rapid path of technological development, but also given the potential changes in the use and the aim of authorised AI systems, regardless of whether they are high-risk or lower risk,*

the limited list of high-risk systems and areas of high risk systems in Annex III should nonetheless be subject to permanent review through the exercise of regular assessment as provided in Title III of this Regulation.

Or. en

Amendment 520

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

**Proposal for a regulation
Recital 27**

Text proposed by the Commission

(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any.

Amendment

(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any. *In particular, the classification as high-risk according to Article 6 should not apply to AI systems whose intended purpose demonstrates that the generated output is a recommendation, provided it is delivered with the information on its accuracy or other relevant methodical aspects necessary for the decision making. A human intervention is required to convert this recommendation into an action.*

Or. en

Amendment 521**Deirdre Clune, Axel Voss, Andreas Schwab****Proposal for a regulation****Recital 27***Text proposed by the Commission*

(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any.

Amendment

(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. *To ensure alignment with sectoral legislation, requirements for certain high-risk AI systems and uses will take account of sectoral legislation which already lay out sufficient requirements for high-risk AI systems included within this Act, such as Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In Vitro Diagnostic Devices and Directive 2006/42/EC on Machinery.* Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any.

Or. en

Amendment 522**Axel Voss, Deirdre Clune, Eva Maydell****Proposal for a regulation****Recital 27***Text proposed by the Commission*

(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain

Amendment

(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain

mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any.

mandatory requirements. *To ensure alignment with sectoral legislation, requirements for certain high-risk AI systems and uses will take account of sectoral legislation which already lay out sufficient requirements for high-risk AI systems included within this Act, such as Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In Vitro Diagnostic Devices and Directive 2006/42/EC on Machinery.* Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any.

Or. en

Amendment 523

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

Proposal for a regulation Recital 27

Text proposed by the Commission

(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and

Amendment

(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and

fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any.

fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any. *In particular, the classification as high-risk according to Article 6 should not apply to AI systems whose intended purpose demonstrates that the generated output is a recommendation and a human intervention is required to convert this recommendation into an action.*

Or. en

Amendment 524

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

Proposal for a regulation

Recital 27

Text proposed by the Commission

(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the **health, safety and fundamental rights of persons in the Union** and such limitation minimises any potential restriction to international trade, if any.

Amendment

(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law **and do not breach the Union values enshrined in Article 2 TEU or the principles applicable to all AI systems as per this Regulation**. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the fundamental rights of persons, **their health and safety** and such limitation minimises any potential restriction to international trade, if any.

Or. en

Amendment 525

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
Recital 27**

Text proposed by the Commission

(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any.

Amendment

(27) High-risk AI systems should only be placed on the Union market or put into service ***or used*** if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law ***and do not contravene the Union values enshrined in Article 2 TEU***. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and ***the*** fundamental rights of persons in the Union ***or the environment*** and such limitation minimises any potential restriction to international trade, if any.

Or. en

Amendment 526

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

**Proposal for a regulation
Recital 27**

Text proposed by the Commission

(27) Les systèmes d'IA à haut risque ne devraient être mis sur le marché de l'Union ou mis en service que s'ils satisfont à certaines exigences obligatoires. Ces exigences devraient garantir que les systèmes d'IA à haut risque disponibles dans l'Union ou dont les résultats sont utilisés d'une autre manière dans l'Union ne présentent pas de risques inacceptables pour d'importants intérêts publics de

Amendment

(27) Les systèmes d'IA à haut risque ne devraient être mis sur le marché de l'Union ou mis en service que s'ils satisfont à certaines exigences obligatoires. Ces exigences devraient garantir que les systèmes d'IA à haut risque disponibles dans l'Union ou dont les résultats sont utilisés d'une autre manière dans l'Union ne présentent pas de risques inacceptables pour d'importants intérêts publics de

l’Union tels qu’ils sont reconnus et protégés par le droit de l’Union. Les systèmes d’IA désignés comme étant à haut risque devraient être limités aux systèmes qui ont une incidence préjudiciable significative sur la santé, la sécurité et les droits fondamentaux des citoyens dans l’Union, une telle limitation permettant, le cas échéant, de réduire au minimum toute éventuelle restriction au commerce international.

l’Union tels qu’ils sont reconnus et protégés par le droit de l’Union. Les systèmes d’IA désignés comme étant à haut risque devraient être limités aux systèmes qui ont une incidence préjudiciable significative sur la santé, la sécurité et les droits fondamentaux des citoyens dans l’Union, *ainsi que l’ordre public et la sécurité nationale des États membres*, une telle limitation permettant, le cas échéant, de réduire au minimum toute éventuelle restriction au commerce international.

Or. fr

Amendment 527

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Alin Mituța, Michal Šimeka

Proposal for a regulation

Recital 27

Text proposed by the Commission

(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any.

Amendment

(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union *or to Union values as enshrined in Article 2 TEU* and such limitation minimises any potential restriction to international trade, if any.

Or. en

Amendment 528

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 27

Text proposed by the Commission

(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a ***significant*** harmful impact on the health, safety and fundamental rights of persons in the Union ***and such limitation minimises any potential restriction to international trade, if any.***

Amendment

(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a harmful impact on the health, safety and fundamental rights of persons, ***but also on the environment, democracy and the rule of law*** in the Union..

Or. en

Amendment 529

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Recital 28

Text proposed by the Commission

(28) AI systems could produce adverse outcomes to health and safety of persons, in particular when such systems operate as components of products. Consistently with the objectives of Union harmonisation legislation to facilitate the free movement of products in the internal market and to ensure that only safe and otherwise compliant products find their way into the market, it is important that the safety risks that may be generated by a product as a whole due to its digital components,

Amendment

(28) AI systems could produce adverse outcomes to health and safety of persons, in particular when such systems operate as components of products. Consistently with the objectives of Union harmonisation legislation to facilitate the free movement of products in the internal market and to ensure that only safe and otherwise compliant products find their way into the market, it is important that the safety risks that may be generated by a product as a whole due to its digital components,

including AI systems, are duly prevented and mitigated. For instance, increasingly autonomous robots, whether in the context of manufacturing or personal assistance and care should be able to safely operate and perform their functions in complex environments. Similarly, in the health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate. The extent of the adverse impact caused by the AI system on the fundamental rights protected by the Charter is of particular relevance when classifying an AI system as high-risk. Those rights include the right to human dignity, respect for private and family life, protection of personal data, freedom of expression and information, freedom of assembly and of association, and non-discrimination, consumer protection, workers' rights, rights of persons with disabilities, right to an effective remedy and to a fair trial, right of defence and the presumption of innocence, right to good administration. In addition to those rights, it is important to highlight that children have specific rights as enshrined in Article 24 of the EU Charter and in the United Nations Convention on the Rights of the Child (further elaborated in the UNCRC General Comment No. 25 as regards the digital environment), both of which require consideration of the children's vulnerabilities and provision of such protection and care as necessary for their well-being. The fundamental right to a high level of environmental protection enshrined in the Charter and implemented in Union policies should also be considered when assessing the severity of the harm that an AI system can cause, including in relation to the health and safety of persons.

including AI systems, are duly prevented and mitigated. For instance, increasingly autonomous robots, whether in the context of manufacturing or personal assistance and care should be able to safely operate and perform their functions in complex environments. Similarly, in the health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate.

Conversely, industrial robots used in manufacturing processes that operate within a predefined and restricted area entail considerably lower safety risks and are already subject to harmonised safety legislation. The extent of the adverse impact caused by the AI system on the fundamental rights protected by the Charter is of particular relevance when classifying an AI system as high-risk. Those rights include the right to human dignity, respect for private and family life, protection of personal data, freedom of expression and information, freedom of assembly and of association, and non-discrimination, consumer protection, workers' rights, rights of persons with disabilities, right to an effective remedy and to a fair trial, right of defence and the presumption of innocence, right to good administration. In addition to those rights, it is important to highlight that children have specific rights as enshrined in Article 24 of the EU Charter and in the United Nations Convention on the Rights of the Child (further elaborated in the UNCRC General Comment No. 25 as regards the digital environment), both of which require consideration of the children's vulnerabilities and provision of such protection and care as necessary for their well-being. The fundamental right to a high level of environmental protection enshrined in the Charter and implemented in Union policies should also be considered when assessing the severity of the harm that an AI system can cause, including in

relation to the health and safety of persons.

Or. en

Amendment 530

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

Proposal for a regulation

Recital 28

Text proposed by the Commission

(28) AI systems could **produce** adverse **outcomes to health and safety of** persons, in particular when such systems operate as components of products. Consistently with the objectives of Union harmonisation legislation to facilitate the free movement of products in the internal market and to ensure that only safe and otherwise compliant products find their way into the market, it is important that the safety risks that may be generated by a product as a whole due to its digital components, including AI systems, are duly prevented and mitigated. For instance, increasingly autonomous robots, whether in the context of manufacturing or personal assistance and care should be able to safely operate and performs their functions in complex environments. Similarly, in the health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate. The extent of the adverse impact caused by the AI system on the fundamental rights protected by the Charter is of particular relevance when classifying an AI system as high-risk. Those rights include the right to human dignity, respect for private and family life, protection of personal data, freedom of expression and information, freedom of assembly and of association, and non-discrimination, consumer protection, workers' rights, rights of persons with

Amendment

(28) AI systems could **have an** adverse **impact on** persons, in particular when such systems operate as components of products. Consistently with the objectives of Union harmonisation legislation to facilitate the free movement of products in the internal market and to ensure that only safe and otherwise compliant products find their way into the market, it is important that the safety risks that may be generated by a product as a whole due to its digital components, including AI systems, are duly prevented and mitigated. For instance, increasingly autonomous robots, whether in the context of manufacturing or personal assistance and care should be able to safely operate and performs their functions in complex environments. Similarly, in the health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate. The extent of the adverse impact caused by the AI system on the fundamental rights protected by the Charter is of particular relevance when classifying an AI system as high-risk. Those rights include the right to human dignity, respect for private and family life, protection of personal data, freedom of expression and information, freedom of assembly and of association, and non-discrimination, consumer protection, workers' rights, rights of persons with disabilities, right to an effective remedy

disabilities, right to an effective remedy and to a fair trial, right of defence and the presumption of innocence, right to good administration. In addition to those rights, it is important to highlight that children have specific rights as enshrined in Article 24 of the EU Charter and in the United Nations Convention on the Rights of the Child (further elaborated in the UNCRC General Comment No. 25 as regards the digital environment), both of which require consideration of the children's vulnerabilities and provision of such protection and care as necessary for their well-being. The fundamental right to a high level of environmental protection enshrined in the Charter and implemented in Union policies should also be considered when assessing the severity of the harm that an AI system can cause, *including in relation to the health and safety of persons.*

and to a fair trial, right of defence and the presumption of innocence, right to good administration. In addition to those rights, it is important to highlight that children have specific rights as enshrined in Article 24 of the EU Charter and in the United Nations Convention on the Rights of the Child (further elaborated in the UNCRC General Comment No. 25 as regards the digital environment), both of which require consideration of the children's vulnerabilities and provision of such protection and care as necessary for their well-being. The fundamental right to a high level of environmental protection enshrined in the Charter and implemented in Union policies should also be considered when assessing the severity of the harm that an AI system can cause.

Or. en

Amendment 531

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

Proposal for a regulation Recital 28 a (new)

Text proposed by the Commission

Amendment

(28 a) The risk-assessment of AI systems as regards their environmental impact and use of resources should not only focus on sectors related to the protection of the environment, but be common to all sectors, as environmental impacts can stem from any kind of AI systems, including those not originally directly related to the protection of the environment, in terms of energy production and distribution, waste management and emissions control.

Or. en

Amendment 532

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 29

Text proposed by the Commission

(29) As regards high-risk AI systems that are safety components of products or systems, or which are themselves products or systems falling within the scope of Regulation (EC) No 300/2008 of the European Parliament and of the Council³⁹, Regulation (EU) No 167/2013 of the European Parliament and of the Council⁴⁰, Regulation (EU) No 168/2013 of the European Parliament and of the Council⁴¹, Directive 2014/90/EU of the European Parliament and of the Council⁴², Directive (EU) 2016/797 of the European Parliament and of the Council⁴³, Regulation (EU) 2018/858 of the European Parliament and of the Council⁴⁴, Regulation (EU) 2018/1139 of the European Parliament and of the Council⁴⁵, and Regulation (EU) 2019/2144 of the European Parliament and of the Council⁴⁶, it is appropriate to amend those acts to ensure that the Commission takes into account, on the basis of the technical and regulatory specificities of each sector, and without interfering with existing governance, conformity assessment and enforcement mechanisms and authorities established therein, the mandatory requirements for high-risk AI systems laid down in this Regulation when adopting any relevant future delegated or implementing acts on the basis of those acts.

Amendment

(29) As regards high-risk AI systems that are safety components of products or systems, or which are themselves products or systems falling within the scope of Regulation (EC) No 300/2008 of the European Parliament and of the Council³⁹, Regulation (EU) No 167/2013 of the European Parliament and of the Council⁴⁰, Regulation (EU) No 168/2013 of the European Parliament and of the Council⁴¹, Directive 2014/90/EU of the European Parliament and of the Council⁴², Directive (EU) 2016/797 of the European Parliament and of the Council⁴³, Regulation (EU) 2018/858 of the European Parliament and of the Council⁴⁴, Regulation (EU) 2018/1139 of the European Parliament and of the Council⁴⁵, and Regulation (EU) 2019/2144 of the European Parliament and of the Council⁴⁶, **Regulation (EU) 2017/745 of the European Parliament and of the Council, and Regulation (EU) 2017/746 of the European Parliament and of the Council**, it is appropriate to amend those acts to ensure that the Commission takes into account, on the basis of the technical and regulatory specificities of each sector, and without interfering with existing governance, conformity assessment, **market surveillance** and enforcement mechanisms and authorities established therein, the mandatory requirements for high-risk AI systems laid down in this Regulation when adopting any relevant future delegated or implementing acts on the basis of those acts.

³⁹ Regulation (EC) No 300/2008 of the European Parliament and of the Council of

³⁹ Regulation (EC) No 300/2008 of the European Parliament and of the Council of

11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72).

⁴⁰ Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1).

⁴¹ Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52).

⁴² Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146).

⁴³ Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44).

⁴⁴ Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1).

⁴⁵ Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the

11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72).

⁴⁰ Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1).

⁴¹ Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52).

⁴² Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146).

⁴³ Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44).

⁴⁴ Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1).

⁴⁵ Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the

European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1).

⁴⁶ Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1).

European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1).

⁴⁶ Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1).

Or. en

Amendment 533

Deirdre Clune, Axel Voss, Andreas Schwab

Proposal for a regulation Recital 29

Text proposed by the Commission

(29) As regards high-risk AI systems that are safety components of products or systems, or which are themselves products or systems falling within the scope of Regulation (EC) No 300/2008 of the European Parliament and of the Council³⁹, Regulation (EU) No 167/2013 of the European Parliament and of the Council⁴⁰, Regulation (EU) No 168/2013 of the

Amendment

(29) As regards high-risk AI systems that are safety components of products or systems, or which are themselves products or systems falling within the scope of Regulation (EC) No 300/2008 of the European Parliament and of the Council³⁹, Regulation (EU) No 167/2013 of the European Parliament and of the Council⁴⁰, Regulation (EU) No 168/2013 of the

European Parliament and of the Council⁴¹ , Directive 2014/90/EU of the European Parliament and of the Council⁴² , Directive (EU) 2016/797 of the European Parliament and of the Council⁴³ , Regulation (EU) 2018/858 of the European Parliament and of the Council⁴⁴ , Regulation (EU) 2018/1139 of the European Parliament and of the Council⁴⁵ , and Regulation (EU) 2019/2144 of the European Parliament and of the Council⁴⁶ , it is appropriate to amend those acts to ensure that the Commission takes into account, on the basis of the technical and regulatory specificities of each sector, and without interfering with existing governance, conformity assessment and enforcement mechanisms and authorities established therein, the mandatory requirements for high-risk AI systems laid down in this Regulation when adopting any relevant future delegated or implementing acts on the basis of those acts.

European Parliament and of the Council⁴¹ , Directive 2014/90/EU of the European Parliament and of the Council⁴² , Directive (EU) 2016/797 of the European Parliament and of the Council⁴³ , Regulation (EU) 2018/858 of the European Parliament and of the Council⁴⁴ , Regulation (EU) 2018/1139 of the European Parliament and of the Council⁴⁵ , and Regulation (EU) 2019/2144 of the European Parliament and of the Council⁴⁶ , **Regulation (EU)2017/745 of the European Parliament and of the Council, and Regulation (EU)2017/746 of the European Parliament and of the Council**, it is appropriate to amend those acts to ensure that the Commission takes into account, on the basis of the technical and regulatory specificities of each sector, and without interfering with existing governance, conformity assessment and enforcement mechanisms and authorities established therein, the mandatory requirements for high-risk AI systems laid down in this Regulation when adopting any relevant future delegated or implementing acts on the basis of those acts.

³⁹ Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72).

⁴⁰ Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1).

⁴¹ Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52).

⁴² Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing

³⁹ Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72).

⁴⁰ Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1).

⁴¹ Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52).

⁴² Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing

Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146).

⁴³ Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44).

⁴⁴ Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1).

⁴⁵ Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1).

⁴⁶ Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No

Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146).

⁴³ Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44).

⁴⁴ Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1).

⁴⁵ Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1).

⁴⁶ Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No

672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1).

672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1).

Or. en

Amendment 534

Svenja Hahn, Nicola Beer, Dita Charanzová, Andrus Ansip, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ěej Kova ěk, Jan-Christoph Oetjen

Proposal for a regulation

Recital 30

Text proposed by the Commission

(30) As regards AI systems that are safety components of products, or which are themselves products, falling within the scope of certain Union harmonisation legislation, it is appropriate to classify them as high-risk under this Regulation if the product in question undergoes the conformity assessment procedure with a third-party conformity assessment body pursuant to that relevant Union harmonisation legislation. In particular, such products are machinery, toys, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, radio equipment, pressure equipment, recreational craft equipment, cableway installations, appliances burning gaseous fuels, medical devices, and in vitro diagnostic medical devices.

Amendment

(30) As regards AI systems that are safety components of products, or which are themselves products, falling within the scope of certain Union harmonisation legislation, it is appropriate to classify them as high-risk under this Regulation if the product in question undergoes the conformity assessment procedure *in order to ensure compliance with essential safety requirements* with a third-party conformity assessment body pursuant to that relevant Union harmonisation legislation. In particular, such products are machinery, toys, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, radio equipment, pressure equipment, recreational craft equipment, cableway installations, appliances burning gaseous fuels, medical devices, and in vitro diagnostic medical devices.

Or. en

Amendment 535

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Recital 30**

Text proposed by the Commission

(30) As regards AI systems that are safety components of products, or which are themselves products, falling within the scope of certain Union harmonisation legislation, it is appropriate to classify them as high-risk under this Regulation if the product in question undergoes the conformity assessment procedure with a third-party conformity assessment body pursuant to that relevant Union harmonisation legislation. In particular, such products are machinery, toys, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, radio equipment, pressure equipment, recreational craft equipment, cableway installations, appliances burning gaseous fuels, medical devices, and in vitro diagnostic medical devices.

Amendment

(30) As regards AI systems that are safety components of products, or which are themselves products, falling within the scope of certain Union harmonisation legislation (*as specified in Annex II*), it is appropriate to classify them as high-risk under this Regulation if the product in question undergoes the conformity assessment procedure with a third-party conformity assessment body pursuant to that relevant Union harmonisation legislation. In particular, such products are machinery, toys, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, radio equipment, pressure equipment, recreational craft equipment, cableway installations, appliances burning gaseous fuels, medical devices, and in vitro diagnostic medical devices.

Or. en

Amendment 536

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

**Proposal for a regulation
Recital 31**

Text proposed by the Commission

(31) La classification d'un système d'IA comme étant à haut risque en application du présent règlement ne devrait pas nécessairement signifier que le produit utilisant un système d'IA en tant que composant de sécurité, ou que le système d'IA lui-même en tant que produit, est considéré comme étant «à haut risque» selon les critères établis dans la législation

Amendment

(31) La classification d'un système d'IA comme étant à haut risque en application du présent règlement ne devrait pas nécessairement signifier que le produit utilisant un système d'IA en tant que composant de sécurité, ou que le système d'IA lui-même en tant que produit, est considéré comme étant «à haut risque» selon les critères établis dans la législation

d'harmonisation de l'Union correspondante qui s'applique au produit en question. Tel est notamment le cas pour le règlement (UE) 2017/745 du Parlement européen et du Conseil⁴⁷ et le règlement (UE) 2017/746 du Parlement européen et du Conseil⁴⁸, dans le cadre desquels une évaluation de la conformité par un tiers est prévue pour les produits à risque moyen et les produits à haut risque.

d'harmonisation de l'Union correspondante qui s'applique au produit en question. Tel est notamment le cas pour le règlement (UE) 2017/745 du Parlement européen et du Conseil⁴⁷ et le règlement (UE) 2017/746 du Parlement européen et du Conseil⁴⁸, dans le cadre desquels une évaluation de la conformité par un tiers est prévue pour les produits à risque moyen et les produits à haut risque. *Toutefois, la classification d'un système d'I.A. comme étant à haut risque aux seules fins du présent règlement s'applique à tous les produits utilisant ce système d'I.A. ou qui sont eux-mêmes des systèmes d'I.A., quelle que soit leur classification par la législation sectorielle d'harmonisation de l'Union dont ils relèvent par ailleurs.*

⁴⁷ Règlement (UE) 2017/745 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux, modifiant la directive 2001/83/CE, le règlement (CE) n° 178/2002 et le règlement (CE) n° 1223/2009 et abrogeant les directives 90/385/CEE et 93/42/CEE du Conseil (JO L 117 du 5.5.2017, p. 1).

⁴⁸ Règlement (UE) 2017/746 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux de diagnostic in vitro et abrogeant la directive 98/79/CE et la décision 2010/227/UE de la Commission (JO L 117 du 5.5.2017, p. 176).

⁴⁷ Règlement (UE) 2017/745 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux, modifiant la directive 2001/83/CE, le règlement (CE) n° 178/2002 et le règlement (CE) n° 1223/2009 et abrogeant les directives 90/385/CEE et 93/42/CEE du Conseil (JO L 117 du 5.5.2017, p. 1).

⁴⁸ Règlement (UE) 2017/746 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux de diagnostic in vitro et abrogeant la directive 98/79/CE et la décision 2010/227/UE de la Commission (JO L 117 du 5.5.2017, p. 176).

Or. fr

Amendment 537

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation Recital 31

Text proposed by the Commission

(31) The classification of an AI system as high-risk pursuant to this Regulation

Amendment

(31) The classification of an AI system as high-risk pursuant to this Regulation

should not necessarily mean that the product whose safety component is the AI system, or the AI system itself as a product, is considered ‘high-risk’ under the criteria established in the relevant Union harmonisation legislation that applies to the product. This is notably the case for Regulation (EU) 2017/745 of the European Parliament and of the Council⁴⁷ and Regulation (EU) 2017/746 of the European Parliament and of the Council⁴⁸, **where a third-party conformity assessment is provided for medium-risk and high-risk products.**

⁴⁷ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

⁴⁸ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

shall not mean that the product whose safety component is the AI system, or the AI system itself as a product, is considered ‘high-risk’ under the criteria established in the relevant Union harmonisation legislation that applies to the product. This is notably the case for Regulation (EU) 2017/745 of the European Parliament and of the Council⁴⁷ and Regulation (EU) 2017/746 of the European Parliament and of the Council⁴⁸.

⁴⁷ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

⁴⁸ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

Or. en

Amendment 538

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Alin Mituța

Proposal for a regulation Recital 32

Text proposed by the Commission

(32) As regards stand-alone AI systems, meaning high-risk AI systems other than those that are safety components of products, or which are themselves products, it is appropriate to classify them

Amendment

(32) As regards stand-alone AI systems, meaning high-risk AI systems other than those that are safety components of products, or which are themselves products, it is appropriate to classify them

as high-risk if, in the light of their intended purpose, they pose a high risk of harm to the health **and** safety or the fundamental rights of persons, taking into account both the severity of the possible harm and its probability of occurrence and they are used in a number of specifically pre-defined areas specified in the Regulation. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems.

as high-risk if, in the light of their intended purpose, they pose a high risk of harm to the health, safety or the fundamental rights of persons **or to Union values as enshrined in Article 2 TEU**, taking into account both the severity of the possible harm and its probability of occurrence and they are used in a number of specifically pre-defined areas specified in the Regulation. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems. ***Such systems should be classified as high-risk only insofar as they are built and operated with biometric, biometrics-based, or personal data or they influence decisions of natural persons or make decisions or influence decisions affecting natural persons. This ensures that, when referencing AI systems in pre-defined areas of human activity, this Regulation does not inadvertently apply to AI systems that can have no impact on the health, safety, fundamental rights of natural persons or the values of the Union as enshrined in Article 2 TEU.***

Or. en



*Committee on the Internal Market and Consumer Protection
Committee on Civil Liberties, Justice and Home Affairs*

2021/0106(COD)

13.6.2022

AMENDMENTS

539 - 773

Draft report
Brando Benifei, Drago 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))

AM_Com_LegReport

Amendment 539

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

Proposal for a regulation

Recital 32

Text proposed by the Commission

(32) As regards stand-alone AI systems, meaning high-risk AI systems other than those that are safety components of products, or which are themselves products, it is appropriate to classify them as high-risk if, in the light of their intended purpose, they pose a **high** risk of harm to the health and safety or the fundamental rights of persons, taking into account both the severity of the possible harm and its probability of occurrence and they are used in a number of specifically pre-defined areas specified in the Regulation. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems.

Amendment

(32) As regards stand-alone AI systems, meaning high-risk AI systems other than those that are safety components of products, or which are themselves products, it is appropriate to classify them as high-risk if, in the light of their intended purpose, they pose a **significant** risk of harm to the health and safety or the fundamental rights of persons, *as well as the environment, society, rule of law, democracy, economic interests and consumer protection*, taking into account both the severity of the possible harm and its probability of occurrence and they are used in a number of specifically pre-defined areas specified in the Regulation. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems. *Such classification should take place before the placing onto the market but also during the life-cycle of an AI system.*

Or. en

Amendment 540

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 32

Text proposed by the Commission

(32) As regards stand-alone AI systems, meaning high-risk AI systems other than those that are safety components of products, or which are themselves

Amendment

(32) As regards stand-alone AI systems, meaning high-risk AI systems other than those that are safety components of products, or which are themselves

products, it is appropriate to classify them as high-risk if, in the light of their intended purpose, they pose a high risk of harm to the health and safety or the fundamental rights of persons, taking into account both the severity of the possible harm and its probability of occurrence and they are used in a number of specifically pre-defined areas specified in the Regulation. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems.

products, it is appropriate to classify them as high-risk if, in the light of their intended purpose **or reasonably foreseeable uses**, they pose a high risk of harm to the health and safety or the fundamental rights of persons, taking into account both the severity of the possible harm and its probability of occurrence and they are used in a number of specifically pre-defined areas specified in the Regulation. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems.

(This amendment should apply throughout the text, i.e. any occurrence of "intended purpose" should be followed by "or reasonably foreseeable uses")

Or. en

Amendment 541

Kosma Złotowski, Patryk Jaki, Adam Bielan

Proposal for a regulation Recital 32

Text proposed by the Commission

(32) As regards stand-alone AI systems, meaning high-risk AI systems other than those that are safety components of products, or which are themselves products, it is appropriate to classify them as high-risk if, in the light of their intended purpose, they pose a high risk of harm to the health and safety or the fundamental rights of persons, taking into account both the severity of the possible harm and its probability of occurrence and they are used in a number of specifically pre-defined areas specified in the Regulation. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems.

Amendment

(32) As regards stand-alone AI systems, meaning high-risk AI systems other than those that are safety components of products, or which are themselves products, it is appropriate to classify them as high-risk if, in the light of their intended purpose, they pose a high risk of harm to the health, **natural environment**, and safety or the fundamental rights of persons, taking into account both the severity of the possible harm and its probability of occurrence and they are used in a number of specifically pre-defined areas specified in the Regulation. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems.

Amendment 542

Kate ina Kone ná, Fernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 32

Text proposed by the Commission

(32) As regards stand-alone AI systems, meaning high-risk AI systems other than those that are safety components of products, or which are themselves products, it is appropriate to classify them as high-risk if, in the light of their *intended purpose*, they pose a high risk of harm to the health and safety or the fundamental rights of persons, taking into account both the severity of the possible harm and its probability of occurrence and they are used in a number of specifically pre-defined areas specified in the Regulation. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems.

Amendment

(32) As regards stand-alone AI systems, meaning high-risk AI systems other than those that are safety components of products, or which are themselves products, it is appropriate to classify them as high-risk if, in the light of their *foreseeable uses*, they pose a high risk of harm to the health and safety or the fundamental rights of persons, taking into account both the severity of the possible harm and its probability of occurrence and they are used in a number of specifically pre-defined areas specified in the Regulation. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems.

Amendment 543

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

Proposal for a regulation

Recital 32 a (new)

Text proposed by the Commission

Amendment

(32 a) In the light of the nature and complexity of the value chain for AI systems, it is essential to consider the foreseeable high-risks they can create when combined. Particular attention should be paid to the foreseeable uses and

reasonably foreseeable misuses of AI systems with indeterminate uses.

Or. en

Amendment 544

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

Proposal for a regulation

Recital 33

Text proposed by the Commission

Amendment

(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, ‘real-time’ and ‘post’ remote biometric identification systems should be classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.

deleted

Or. en

Justification

Moved under prohibited practices

Amendment 545

Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Marc Angel

Proposal for a regulation

Recital 33

Text proposed by the Commission

Amendment

(33) Technical inaccuracies of AI systems intended for the remote biometric

deleted

identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, ‘real-time’ and ‘post’ remote biometric identification systems should be classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.

Or. en

Amendment 546

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Dita Charanzová, Andrus Ansip, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ondej Kováč, Jan-Christoph Oetjen

Proposal for a regulation

Recital 33

Text proposed by the Commission

(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, ‘real-time’ and ‘post’ remote biometric identification systems should be classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.

Amendment

(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, ‘real-time’ and ‘post’ remote biometric identification systems should be classified as high-risk, *except for verification or authentication systems whose sole purpose is to confirm that a specific natural person is the person he or she claims to be, and systems that are used to confirm the identity of a natural person for the sole purpose of having access to a service, a device or premises.* In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.

Or. en

Amendment 547
Axel Voss, Deirdre Clune

Proposal for a regulation
Recital 33

Text proposed by the Commission

(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, ‘real-time’ and ‘post’ remote biometric identification systems should be classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.

Amendment

(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, ‘real-time’ and ‘post’ remote biometric identification systems should be classified as high-risk, *except for the purpose of remote client on-boarding or verification of a user through a device*. In view of the risks that they *may* pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and, *when appropriate and justified by a proven added value to the protection of health, safety and fundamental rights*, human oversight.

Or. en

Amendment 548
Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation
Recital 33

Text proposed by the Commission

(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, ‘real-time’ and ‘post’ remote biometric identification systems should be

Amendment

(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, ‘real-time’ and ‘post’ remote biometric identification systems should be

classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.

classified as high-risk. In view of the risks that they *may* pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and, *when appropriate and justified by a proven added value to the protection of health, safety and fundamental rights*, human oversight.

Or. en

Amendment 549

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

Proposal for a regulation

Recital 33

Text proposed by the Commission

(33) Technical inaccuracies of AI systems intended for the **remote** biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, ‘real-time’ and ‘post’ remote biometric identification systems should be classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.

Amendment

(33) Technical inaccuracies of AI systems intended for the biometric identification of natural persons, **including remote biometric identification**, can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, ‘real-time’ and ‘post’ remote biometric identification systems, **including remote biometric identification**, should be classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.

Or. en

Amendment 550

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 33

Text proposed by the Commission

(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, ‘real-time’ and ‘post’ remote biometric identification systems should be classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be ***subject to specific requirements on logging capabilities and human oversight.***

Amendment

(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, ‘real-time’ and ‘post’ remote biometric identification systems should be classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be ***prohibited.***

Or. en

Amendment 551

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

Proposal for a regulation

Recital 33

Text proposed by the Commission

(33) Technical inaccuracies ***of*** AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. ***Therefore, ‘real-time’ and ‘post’ remote biometric identification systems should be classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.***

Amendment

(33) Technical inaccuracies, ***as well as conscious or subconscious design decisions, and the use of training data which codify and reinforce structural inequalities, mean that*** AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. ***As a result, ‘real-time’ and ‘post’ remote biometric identification systems undermine the essence of fundamental rights and therefore must be prohibited.***

Or. en

Amendment 552

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

**Proposal for a regulation
Recital 33 a (new)**

Text proposed by the Commission

Amendment

(33 a) Human oversight should target high-risk AI systems as a priority, with the aim of serving human-centric objectives. The individuals to whom human oversight is assigned shall be provided with adequate education and training on the functioning of the application, its capabilities to influence or make decisions, and to have harmful effects, notably on fundamental rights. The persons in charge of the assignment of these individuals shall provide them with relevant staff and psychological support.

Or. en

Amendment 553
Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Recital 34**

Text proposed by the Commission

Amendment

(34) As regards the management and operation of critical infrastructure, it is appropriate to classify as high-risk the AI systems intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity, since their failure or malfunctioning may put at risk the life and health of persons at large scale and lead to appreciable disruptions in the ordinary conduct of social and economic activities.

(34) As regards the management and operation of critical infrastructure, it is appropriate to classify as high-risk the AI systems intended to be used as safety **or security** components in the management and operation of road traffic and the supply of water, gas, heating and electricity, since their failure or malfunctioning may **infringe the security and integrity of such critical infrastructure and thus** put at risk the life and health of persons at large scale and lead to appreciable disruptions in the ordinary conduct of social and economic activities.

Or. en

Amendment 554

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Andrus Ansip, Dita Charanzová, Alin Mituța, Michal Šimečka

Proposal for a regulation

Recital 34

Text proposed by the Commission

(34) As regards the management and operation of critical infrastructure, it is appropriate to classify as high-risk the AI systems intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity, since their failure or malfunctioning may put at risk the life and health of persons at large scale and lead to appreciable disruptions in the ordinary conduct of social and economic activities.

Amendment

(34) As regards the management and operation of critical infrastructure, it is appropriate to classify as high-risk the AI systems intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity, **and internet**, since their failure or malfunctioning may put at risk the life and health of persons at large scale and lead to appreciable disruptions in the ordinary conduct of social and economic activities.

Or. en

Amendment 555

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

Proposal for a regulation

Recital 34

Text proposed by the Commission

(34) ***En ce qui concerne la gestion et l'exploitation des infrastructures critiques***, il convient de classer comme étant à haut risque les systèmes d'IA destinés à être utilisés en tant que composants de sécurité dans la gestion et l'exploitation ***du*** trafic routier ***et dans*** la fourniture d'eau, de gaz, de chauffage et d'électricité, car leur défaillance ou leur dysfonctionnement peut mettre en danger la vie et la santé de personnes à grande échelle et entraîner des perturbations

Amendment

(34) Il convient de classer comme étant à haut risque les systèmes d'IA destinés à être utilisés en tant que composants de sécurité dans la gestion et l'exploitation ***des infrastructures critiques telles que le*** trafic routier ***ou*** la fourniture d'eau, de gaz, de chauffage et d'électricité, car leur défaillance ou leur dysfonctionnement peut mettre en danger la vie et la santé de personnes à grande échelle et entraîner des perturbations importantes dans la conduite ordinaire des activités sociales et

importantes dans la conduite ordinaire des activités sociales et économiques.

économiques.

Or. fr

Amendment 556

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 35

Text proposed by the Commission

(35) AI systems used in education or vocational training, notably for determining access or assigning persons to educational and vocational training institutions or to evaluate persons on tests as part of or as a precondition for their education should be considered high-risk, since they may determine the educational and professional course of a person's life and therefore affect their ability to secure their livelihood. When improperly designed and used, such systems may violate the right to education and training as well as the right not to be discriminated against and perpetuate historical patterns of discrimination.

Amendment

(35) AI systems used in education or vocational training, notably for determining access or assigning persons to educational and vocational training institutions or to evaluate persons on tests as part of or as a precondition for their education should be considered high-risk, since they may determine the educational and professional course of a person's life and therefore affect their ability to secure their livelihood. When improperly designed and used, such systems may violate the right to education and training as well as the right not to be discriminated against and perpetuate historical patterns of discrimination. ***Therefore, AI systems in education shall be prohibited to be used by public authorities in education of underaged children to meet the requirement in this regulation, to not exploit any of the vulnerabilities of the group of persons due to their age.***

Or. en

Amendment 557

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

Proposal for a regulation

Recital 35

Text proposed by the Commission

(35) AI systems used in education or vocational training, notably for determining access or assigning persons to educational and vocational training institutions or to evaluate persons on tests as part of or as a precondition for their education should be considered high-risk, since they may determine the educational and professional course of a person's life and therefore affect their ability to secure their livelihood. **When improperly designed and used, such systems may violate the right to education and training as well as the right not to be discriminated against and perpetuate historical patterns of discrimination.**

Amendment

(35) AI systems used in education or vocational training, notably for determining access or assigning persons to educational and vocational training institutions or to evaluate persons on tests as part of or as a precondition for their education should be considered high-risk, since they may determine the educational and professional course of a person's life and therefore affect their ability to secure their livelihood. **AI systems that are designed to constantly monitor individuals are particularly intrusive and violate the right to education and training, the right not to be discriminated against and perpetuate historical patterns of discrimination and should therefore be prohibited.**

Or. en

Amendment 558

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

Proposal for a regulation

Recital 35

Text proposed by the Commission

(35) Les systèmes d'IA utilisés dans l'éducation ou la formation professionnelle, notamment pour déterminer l'accès ou l'affectation de personnes aux établissements d'enseignement et de formation professionnelle ou pour évaluer les personnes sur la base d'épreuves dans le cadre de leur formation ou comme condition préalable à celle-ci devraient être considérés comme étant à haut risque, car ils peuvent déterminer le parcours éducatif et professionnel d'une personne et ont par conséquent une incidence sur la capacité de cette personne à assurer sa propre subsistance. Lorsqu'ils sont mal conçus et

Amendment

(35) Les systèmes d'IA utilisés dans l'éducation ou la formation professionnelle, notamment pour déterminer l'accès ou l'affectation de personnes aux établissements d'enseignement et de formation professionnelle ou pour évaluer les personnes sur la base d'épreuves dans le cadre de leur formation ou comme condition préalable à celle-ci devraient être considérés comme étant à haut risque, car ils peuvent déterminer le parcours éducatif et professionnel d'une personne et ont par conséquent une incidence sur la capacité de cette personne à assurer sa propre subsistance. Lorsqu'ils sont mal conçus et

utilisés, ces systèmes peuvent mener à des violations du droit à l'éducation et à la formation ainsi que du droit à ne pas subir de discriminations, *et perpétuer des schémas historiques de discrimination*.

utilisés, ces systèmes peuvent mener à des violations du droit à l'éducation et à la formation ainsi que du droit à ne pas subir de discriminations.

Or. fr

Amendment 559

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 Recital 35

Text proposed by the Commission

(35) AI systems used in education or vocational training, notably for determining access or assigning persons to educational and vocational training institutions or to evaluate persons on tests as part of or as a precondition for their education should be considered high-risk, since they may determine the educational and professional course of a person's life and therefore affect their ability to secure their livelihood. When improperly designed and used, such systems may violate the right to education and training as well as the right not to be discriminated against and perpetuate historical patterns of discrimination.

Amendment

(35) AI systems used in education or vocational training, notably for determining access or assigning persons to educational and vocational training institutions or to evaluate **or monitor** persons on tests as part of or as a precondition for their education should be considered high-risk, since they may determine the educational and professional course of a person's life and therefore affect their ability to secure their livelihood. When improperly designed and used, such systems may violate the right to education and training as well as the right not to be discriminated against and perpetuate historical patterns of discrimination.

Or. en

Amendment 560

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

Proposal for a regulation Recital 36

Text proposed by the Commission

(36) AI systems used in employment, workers management and access to self-employment, notably **for the** recruitment and selection of persons, for making decisions on promotion and **termination and** for task allocation, monitoring **or** evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems may appreciably impact future career prospects and livelihoods of these persons. Relevant work-related contractual relationships should involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. **Such persons should in principle not be considered users within the meaning of this Regulation.** Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may perpetuate historical patterns of discrimination, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation. AI systems used to monitor the performance and behaviour of these persons may also **impact** their rights to data protection and privacy.

Amendment

(36) AI systems used in employment, workers management and access to self-employment, notably **affecting the initiation, establishment, implementation and termination of an employment relationship, including AI systems intended to support collective legal and regulatory matters should be high risk.** **Particularly AI affecting** recruitment and selection of persons, for making decisions on promotion and for task allocation, **for measuring and monitoring of performance or for** evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems may appreciably impact future career prospects and livelihoods of these persons. **AI systems used for constant monitoring of workers pose an unacceptable risk to their fundamental rights, and should be therefore prohibited.** Relevant work-related contractual relationships should **meaningfully** involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may perpetuate historical patterns of discrimination, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation. AI systems used to monitor the performance and behaviour of these persons may also **undermine the essence of** their **fundamental** rights to data protection and privacy. **This Regulation applies without prejudice to Union and Member State competences to provide for more specific rules for the use of AI-systems in the employment context.**

Or. en

Amendment 561

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Mituță, Ramona Strugariu, Drago Pîslaru, Lucia Šuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Recital 36

Text proposed by the Commission

(36) AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making decisions on promotion and termination and for task allocation, monitoring or evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems may appreciably impact future career prospects and livelihoods of these persons. Relevant work-related contractual relationships should involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. Such persons should in principle not be considered users within the meaning of this Regulation. Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may perpetuate historical patterns of discrimination, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation. AI systems used to monitor the performance and behaviour of these persons may also impact their rights to data protection and privacy.

Amendment

(36) AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making decisions on promotion and termination and for **personalised** task allocation **based on personal or biometric data**, monitoring or evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems may appreciably impact future career prospects and livelihoods of these persons. Relevant work-related contractual relationships should involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. Such persons should in principle not be considered users within the meaning of this Regulation. Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may perpetuate historical patterns of discrimination, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation. AI systems used to monitor the performance and behaviour of these persons may also impact their rights to data protection and privacy.

Or. en

Amendment 562

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

Proposal for a regulation
Recital 36

Text proposed by the Commission

(36) Les systèmes d'IA utilisés pour des questions liées à l'emploi, à la gestion de la main-d'œuvre et à l'accès à l'emploi indépendant, notamment pour le recrutement et la sélection de personnes, pour la prise de décisions de promotion et de licenciement, pour l'attribution des tâches et pour le suivi ou l'évaluation des personnes dans le cadre de relations professionnelles contractuelles, devraient également être classés comme étant à haut risque, car ces systèmes peuvent avoir une incidence considérable sur les perspectives de carrière et les moyens de subsistance de ces personnes. Les relations professionnelles contractuelles en question devraient concerner également celles qui lient les employés et les personnes qui fournissent des services sur des plateformes telles que celles visées dans le programme de travail de la Commission pour 2021. Ces personnes ne devraient en principe pas être considérées comme des utilisateurs au sens du présent règlement. Tout au long du processus de recrutement et lors de l'évaluation, de la promotion ou du maintien des personnes dans des relations professionnelles contractuelles, les systèmes d'IA peuvent *perpétuer des schémas historiques de discrimination*, par exemple à l'égard des femmes, de certains groupes d'âge et des personnes handicapées, ou de certaines personnes en raison de leur origine raciale ou ethnique ou de leur orientation sexuelle. Les systèmes d'IA utilisés pour surveiller les performances et le comportement de ces personnes peuvent aussi avoir une incidence sur leurs droits à la protection des données et à la vie privée.

Amendment

(36) Les systèmes d'IA utilisés pour des questions liées à l'emploi, à la gestion de la main-d'œuvre et à l'accès à l'emploi indépendant, notamment pour le recrutement et la sélection de personnes, pour la prise de décisions de promotion et de licenciement, pour l'attribution des tâches et pour le suivi ou l'évaluation des personnes dans le cadre de relations professionnelles contractuelles, devraient également être classés comme étant à haut risque *dans la mesure où cette utilisation ne correspond pas à des pratiques interdites par le présent règlement*, car ces systèmes peuvent avoir une incidence considérable sur les perspectives de carrière et les moyens de subsistance de ces personnes. Les relations professionnelles contractuelles en question devraient concerner également celles qui lient les employés et les personnes qui fournissent des services sur des plateformes telles que celles visées dans le programme de travail de la Commission pour 2021. Ces personnes ne devraient en principe pas être considérées comme des utilisateurs au sens du présent règlement. Tout au long du processus de recrutement et lors de l'évaluation, de la promotion ou du maintien des personnes dans des relations professionnelles contractuelles, les systèmes d'IA peuvent *conduire à des discriminations*, par exemple à l'égard des femmes, de certains groupes d'âge et des personnes handicapées, ou de certaines personnes en raison de leur origine raciale ou ethnique ou de leur orientation sexuelle. Les systèmes d'IA utilisés pour surveiller les performances et le comportement de ces personnes peuvent aussi avoir une incidence sur leurs droits à la protection des données et à la vie privée.

Or. fr

Amendment 563

Svenja Hahn, Nicola Beer, Karen Melchior, Dita Charanzová, Andrus Ansip, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ondřej Kováčik, Jan-Christoph Oetjen

Proposal for a regulation

Recital 36

Text proposed by the Commission

(36) AI systems used in employment, workers management and access to self-employment, notably for the **recruitment and** selection of persons, for making decisions on promotion and termination and for **task allocation**, monitoring or evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems may appreciably impact future career prospects and livelihoods of these persons. Relevant work-related contractual relationships should involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. Such persons should in principle not be considered users within the meaning of this Regulation. Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may perpetuate historical patterns of discrimination, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation. AI systems used to monitor the performance and behaviour of these persons may also impact their rights to data protection and privacy.

Amendment

(36) AI systems used **for making autonomous decisions or materially influencing decisions** in employment, workers management and access to self-employment, notably for the selection of persons, for making decisions on promotion and termination and for monitoring or evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems may appreciably impact future career prospects and livelihoods of these persons. Relevant work-related contractual relationships should involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. Such persons should in principle not be considered users within the meaning of this Regulation. Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may perpetuate historical patterns of discrimination, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation. AI systems used to monitor the performance and behaviour of these persons may also impact their rights to data protection and privacy.

Or. en

Amendment 564

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst

**Proposal for a regulation
Recital 36**

Text proposed by the Commission

(36) AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making decisions on promotion and termination and for task allocation, monitoring or evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems **may appreciably** impact future career prospects **and** livelihoods of these persons. Relevant work-related contractual relationships should involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. Such persons should in principle not be considered users within the meaning of this Regulation. Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may perpetuate historical patterns of discrimination, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation. AI systems used to monitor the performance and behaviour of these persons may also impact their rights to data protection and privacy.

Amendment

(36) AI systems used in employment, workers management and access to self-employment, notably **but not limited to**, for the recruitment and selection of persons, for making decisions on promotion and termination and for task allocation, monitoring or evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems impact future career prospects, livelihoods of these persons **and workers' rights**. Relevant work-related contractual relationships should involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. Such persons should in principle not be considered users within the meaning of this Regulation. Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may perpetuate historical patterns of discrimination, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation. AI systems used to monitor the performance and behaviour of these persons may also impact their rights to data protection and privacy.

Or. en

Amendment 565

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Recital 36**

Text proposed by the Commission

(36) AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making decisions on promotion and termination **and for task allocation**, monitoring or evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems may appreciably impact future career prospects and livelihoods of these persons. Relevant work-related contractual relationships should involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. Such persons should in principle not be considered users within the meaning of this Regulation. Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may perpetuate historical patterns of discrimination, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation. AI systems used to monitor the performance and behaviour of these persons may also impact their rights to data protection and privacy.

Amendment

(36) AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making decisions on promotion and termination, monitoring or evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems may appreciably impact future career prospects and livelihoods of these persons. Relevant work-related contractual relationships should involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. Such persons should in principle not be considered users within the meaning of this Regulation. Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may perpetuate historical patterns of discrimination, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation. AI systems used to monitor the performance and behaviour of these persons may also impact their rights to data protection and privacy.

Or. en

Amendment 566

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Recital 36 a (new)

Text proposed by the Commission

Amendment

(36 a) In line with Article 114 (2) TFEU, this Regulation does not in any way affect the rights and interests of employed persons. This Regulation is without prejudice to Community law on social

policy and national labour law and practice.

Or. en

Amendment 567

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 36 b (new)

Text proposed by the Commission

Amendment

(36 b) Given the significance of Artificial Intelligence impact assessments according to the usage Artificial Intelligence applications in the workplace, the EU will consider a corresponding directive with specific provisions for an impact assessment to ensure the protection of the rights and freedoms of workers affected by AI systems through collective agreements of national legislation.

Or. en

Amendment 568

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

Proposal for a regulation

Recital 37

Text proposed by the Commission

Amendment

(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to

(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems **that automatically generate models** used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since

financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used *for this purpose* may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use. Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. *Nonetheless*, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. *In contrast, ancillary applications to those systems determining whether an individual should be granted access to credit, such as AI applications used for the acceleration of the credit disbursement process, in the valuation of collateral, or for the internal process efficiency, as well as other subsequent applications based on the credit scoring which do not create high risks for individuals should be exempt from the scope.* AI systems used *to evaluate the credit score or creditworthiness* may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use. Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. *Infact*, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems,

provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

Or. en

Amendment 569

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

Proposal for a regulation

Recital 37

Text proposed by the Commission

(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. ***Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use.***

Amendment

(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for

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Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

Or. en

Amendment 570

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation Recital 37

Text proposed by the Commission

(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems

Amendment

(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems

used to evaluate the credit score or creditworthiness of natural persons should be **classified as high-risk AI systems**, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use. Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. ***Those systems should therefore be classified as high-risk.*** ***Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons.*** Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of

used to evaluate the credit score or creditworthiness of natural persons should be **prohibited**, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use. Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

persons and their property.

Or. en

Amendment 571

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

Proposal for a regulation

Recital 37

Text proposed by the Commission

(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be *classified as high-risk AI systems*, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose *may* lead to discrimination *of* persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. *Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use.* Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied,

Amendment

(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be *prohibited*, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose lead to *an unacceptably high risk of* discrimination *against* persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they have a significant impact on persons' livelihood and infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should

reduced, revoked or reclaimed by authorities, they **may** have a significant impact on persons' livelihood and **may** infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be **classified as high-risk**. Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

therefore be **prohibited**. Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

Or. en

Amendment 572

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

Proposal for a regulation

Recital 37

Text proposed by the Commission

(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems

Amendment

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Due to the fact that AI systems related to low-value credits for the purchase of movables do not cause high risk, it is proposed to exclude this category from the scope of high-risk AI category as well.

Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

Amendment 573**Andrea Caroppo, Salvatore De Meo****Proposal for a regulation****Recital 37***Text proposed by the Commission*

(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used *for this purpose* may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. *Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use.* Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may

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infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk.

Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

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Or. en

Amendment 574

Kosma Złotowski, Patryk Jaki, Eugen Jurzyca

Proposal for a regulation Recital 37

Text proposed by the Commission

(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to

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Due to the fact that AI systems related to low-value credits for the purchase of moveables does not cause high risk, it is proposed to exclude this category from the scope of high-risk AI category as well.

Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of

persons and their property.

Or. en

Amendment 575

Jean-Lin Lacapelle, Markus Buchheit, Hélène Laporte

Proposal for a regulation

Recital 37

Text proposed by the Commission

(37) Un autre domaine dans lequel l'utilisation des systèmes d'IA mérite une attention particulière est l'accès et le droit à certains services et prestations essentiels, publics et privés, devant permettre aux citoyens de participer pleinement à la société ou d'améliorer leur niveau de vie. En particulier, les systèmes d'IA utilisés pour évaluer la note de crédit ou la solvabilité des personnes physiques devraient être classés en tant que systèmes d'IA à haut risque, car ils déterminent l'accès de ces personnes à des ressources financières ou à des services essentiels tels que le logement, l'électricité et les services de télécommunication. Les systèmes d'IA utilisés à cette fin peuvent conduire à *la discrimination* à l'égard de personnes ou de groupes *et perpétuer des schémas historiques de discrimination*, par exemple fondés sur les origines raciales ou ethniques, les handicaps, l'âge ou l'orientation sexuelle, ou créer de nouvelles formes d'incidences discriminatoires. Compte tenu de l'incidence très limitée et des solutions de remplacement disponibles sur le marché, il convient d'exempter les systèmes d'IA utilisés à des fins d'évaluation de la solvabilité et de notation de crédit lorsqu'ils sont mis en service par des petits fournisseurs pour leur usage propre. Les personnes physiques sollicitant ou recevant des prestations sociales et des services fournis par des autorités publiques sont généralement tributaires de ces prestations

Amendment

(37) Un autre domaine dans lequel l'utilisation des systèmes d'IA mérite une attention particulière est l'accès et le droit à certains services et prestations essentiels, publics et privés, devant permettre aux citoyens de participer pleinement à la société ou d'améliorer leur niveau de vie. En particulier, les systèmes d'IA utilisés pour évaluer la note de crédit ou la solvabilité des personnes physiques devraient être classés en tant que systèmes d'IA à haut risque, *dans la mesure où cette utilisation ne correspond pas à des pratiques interdites par le présent règlement*, car ils déterminent l'accès de ces personnes à des ressources financières ou à des services essentiels tels que le logement, l'électricité et les services de télécommunication. Les systèmes d'IA utilisés à cette fin peuvent conduire à *des discriminations* à l'égard de personnes ou de groupes, par exemple fondés sur les origines raciales ou ethniques, les handicaps, l'âge ou l'orientation sexuelle, ou créer de nouvelles formes d'incidences discriminatoires. Compte tenu de l'incidence très limitée et des solutions de remplacement disponibles sur le marché, il convient d'exempter les systèmes d'IA utilisés à des fins d'évaluation de la solvabilité et de notation de crédit lorsqu'ils sont mis en service par des petits fournisseurs pour leur usage propre. Les personnes physiques sollicitant ou recevant des prestations sociales et des services fournis par des autorités publiques sont

et services et se trouvent dans une position vulnérable par rapport aux autorités responsables. Lorsque les systèmes d'IA sont utilisés pour déterminer si ces prestations et services devraient être refusés, réduits, révoqués ou récupérés par les autorités, ils ***peuvent avoir*** une grande incidence sur les moyens de subsistance des personnes et ***porter*** atteinte à leurs droits fondamentaux, tels que le droit à la protection sociale, le principe de non-discrimination, le droit à la dignité humaine ou le droit à un recours effectif. Il convient donc de classer ces systèmes comme étant à haut risque. ***Néanmoins***, le présent règlement ***ne devrait pas entraver la mise en place et l'utilisation***, dans l'administration publique, d'approches innovantes qui bénéficiaient d'une utilisation plus large de systèmes d'IA conformes et sûrs, ***à condition que ces systèmes n'entraînent pas de risque élevé pour les personnes morales et physiques.*** Enfin, les systèmes d'IA utilisés pour envoyer ou établir des priorités dans l'envoi des services d'intervention d'urgence devraient ***aussi être classés comme étant à haut risque***, car ils prennent des décisions dans des situations très critiques pour la vie, la santé et les biens matériels des personnes.

généralement tributaires de ces prestations et services et se trouvent dans une position vulnérable par rapport aux autorités responsables. Lorsque les systèmes d'IA sont utilisés pour déterminer si ces prestations et services devraient être refusés, réduits, révoqués ou récupérés par les autorités, ils ***ont*** une grande incidence sur les moyens de subsistance des personnes et ***portent*** atteinte à leurs droits fondamentaux, tels que le droit à la protection sociale, le principe de non-discrimination, le droit à la dignité humaine ou le droit à un recours effectif. Il convient donc de classer ces systèmes comme étant à haut risque. Le présent règlement devrait ***cependant permettre l'expérimentation***, dans l'administration publique, ***dans le cadre d'un bac à sable réglementaire***, d'approches innovantes qui bénéficiaient d'une utilisation plus large de systèmes d'IA conformes et sûrs, ***dans le respect de règles d'encadrement déterminées.*** Enfin, les systèmes d'IA utilisés pour envoyer ou établir des priorités dans l'envoi des services d'intervention d'urgence devraient ***être interdits***, car ils prennent des décisions dans des situations très critiques pour la vie, la santé et les biens matériels des personnes, ***et relèvent de choix éthiques qui ne sauraient être abandonnés à des systèmes informatiques.***

Or. fr

Justification

L'interdiction des systèmes d'I.A. utilisés pour envoyer ou établir des priorités dans l'envoi des services d'intervention d'urgence s'applique aux seuls systèmes qui prennent des décisions en la matière, et non à ceux qui fournissent de simples recommandations.

Amendment 576

Svenja Hahn, Drago Tudorache, Nicola Beer, Dita Charanzová, Andrus Ansip, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Ondej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Recital 37

Text proposed by the Commission

(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by **small-scale providers** for their own use. Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public

Amendment

(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by **SMEs and start-ups** for their own use. Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public

administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

Or. en

Amendment 577

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

Proposal for a regulation Recital 37 a (new)

Text proposed by the Commission

Amendment

(37 a) Given the speed at which AI applications are being developed around the world, it is not feasible to compile an exhaustive listing of applications that should be prohibited or considered high-risk. What is needed is a clear and coherent governance model guaranteeing both the fundamental rights of individuals and legal clarity for operators, considering the continuous evolution of technology. Nevertheless, given the role and responsibility of police and judicial authorities, and the impact of decisions they take for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, the use of AI applications has to be categorised as high-risk in instances where there is the potential to significantly affect the lives of individuals.

Or. en

Amendment 578

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

Proposal for a regulation

Recital 38

Text proposed by the Commission

(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and documented. It is therefore appropriate to classify as **high-risk** a number of AI systems intended to be used in the law enforcement context **where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress.** **In view of the nature of the activities in question and the risks relating thereto, those high-risk AI systems should include in particular AI systems intended to be used by law enforcement authorities for individual risk assessments, polygraphs and similar tools or to detect the emotional state of natural person, to detect 'deep fakes', for the evaluation of the reliability of evidence in criminal proceedings, for**

Amendment

(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. **In addition, some applications, such as to make predictions, profiles, or risk assessments based on data analysis or profiling of groups or individuals for the purpose of predicting the occurrence or recurrence of actual or potential offences or rule-breaking undermine the essence of fundamental rights and should be prohibited.** Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and documented. It is therefore appropriate to classify as **prohibited** a number of AI systems intended to be used in the law enforcement context as well as for crime analytics regarding natural persons.

predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons, or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups, for profiling in the course of detection, investigation or prosecution of criminal offences, as well as for crime analytics regarding natural persons. AI systems specifically intended to be used for administrative proceedings by tax and customs authorities should not be considered high-risk AI systems used by law enforcement authorities for the purposes of prevention, detection, investigation and prosecution of criminal offences.

Or. en

Amendment 579

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

Proposal for a regulation

Recital 38

Text proposed by the Commission

(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well

Amendment

(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of *its performance, including* its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective

as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and documented. It is therefore appropriate to classify as high-risk a number of AI systems intended to be used in the law enforcement context where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress. *In view of the nature of the activities in question and the risks relating thereto, those high-risk AI systems should include in particular AI systems intended to be used by law enforcement authorities for individual risk assessments, polygraphs and similar tools or to detect the emotional state of natural person, to detect 'deep fakes', for the evaluation of the reliability of evidence in criminal proceedings, for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons, or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups, for profiling in the course of detection, investigation or prosecution of criminal offences, as well as for crime analytics regarding natural persons.* AI systems specifically intended to be used for administrative proceedings by tax and customs authorities should not be considered high-risk AI systems used by law enforcement authorities for the purposes of prevention, detection, investigation and prosecution of criminal offences.

remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and documented. It is therefore appropriate to classify as high-risk a number of AI systems intended to be used in the law enforcement context where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress. AI systems specifically intended to be used for administrative proceedings by tax and customs authorities should not be considered high-risk AI systems used by law enforcement authorities for the purposes of prevention, detection, investigation and prosecution of criminal offences.

Or. en

Amendment 580

Jean-Lin Lacapelle, Markus Buchheit, Hélène Laporte

Proposal for a regulation

Recital 38

Text proposed by the Commission

(38) Les actions des autorités répressives qui supposent certaines utilisations de systèmes d'IA sont caractérisées par un degré important de déséquilibre des forces et peuvent conduire à la surveillance, à l'arrestation ou à la privation de la liberté d'une personne physique ainsi qu'à d'autres conséquences négatives sur des droits fondamentaux garantis par la charte. En particulier, si le système d'IA n'est pas entraîné avec des données de haute qualité, ne répond pas aux exigences appropriées en matière d'exactitude ou de robustesse, ou n'est pas correctement conçu et mis à l'essai avant d'être mis sur le marché ou mis en service d'une autre manière, il risque de traiter des personnes de manière discriminatoire ou, plus généralement, incorrecte ou injuste. En outre, l'exercice d'importants droits fondamentaux procéduraux, tels que le droit à un recours effectif et à accéder à un tribunal impartial, ainsi que les droits de la défense et la présomption d'innocence, pourrait être entravé, en particulier lorsque ces systèmes d'IA ne sont pas suffisamment transparents, explicables et documentés. ***Il convient donc de classer comme systèmes à haut risque un certain nombre de systèmes d'IA*** destinés à être utilisés dans un contexte répressif où l'exactitude, la fiabilité et la transparence sont particulièrement importantes pour éviter les conséquences négatives, conserver la confiance du public et garantir que des comptes soient rendus et que des recours efficaces puissent être exercés. Compte tenu de la nature des activités en question et des risques y afférents, ces systèmes d'IA à haut risque devraient comprendre en particulier les systèmes d'IA destinés à être utilisés par les autorités répressives pour réaliser des évaluations individuelles des risques, pour servir de polygraphes ou d'outils similaires ou pour analyser l'état émotionnel de personnes physiques, pour détecter les hypertrucages, pour évaluer la fiabilité des preuves dans

Amendment

(38) Les actions des autorités répressives qui supposent certaines utilisations de systèmes d'IA sont caractérisées par un degré important de déséquilibre des forces et peuvent conduire à la surveillance, à l'arrestation ou à la privation de la liberté d'une personne physique ainsi qu'à d'autres conséquences négatives sur des droits fondamentaux garantis par la charte. En particulier, si le système d'IA n'est pas entraîné avec des données de haute qualité, ne répond pas aux exigences appropriées en matière d'exactitude ou de robustesse, ou n'est pas correctement conçu et mis à l'essai avant d'être mis sur le marché ou mis en service d'une autre manière, il risque de traiter des personnes de manière discriminatoire ou, plus généralement, incorrecte ou injuste. En outre, l'exercice d'importants droits fondamentaux procéduraux, tels que le droit à un recours effectif et à accéder à un tribunal impartial, ainsi que les droits de la défense et la présomption d'innocence, pourrait être entravé, en particulier lorsque ces systèmes d'IA ne sont pas suffisamment transparents, explicables et documentés. ***Ces systèmes d'IA, lorsqu'ils sont destinés à évaluer ou à établir un classement de la fiabilité des personnes physiques, à permettre l'identification de personnes physiques sur la base de données biométriques, à servir de polygraphes ou d'outils similaires, à analyser l'état émotionnel de personnes physiques, à prédire la survenance ou la répétition d'une infraction pénale réelle ou potentielle sur la base du profilage de personnes physiques, ou à évaluer les traits de personnalité de personnes physiques ou de groupes à des fins de profilage dans le cadre d'activités de détection, d'enquête ou de poursuite relatives à des infractions pénales, sont interdits à l'exception des trois cas spécifiques prévus dans le présent règlement. En ce qui concerne les systèmes d'IA autres que ceux précités et***

les procédures pénales, *pour prédire la survenance ou la répétition d'une infraction pénale réelle ou potentielle sur la base du profilage de personnes physiques*, ou pour évaluer *les traits de personnalité*, les caractéristiques ou les antécédents délictuels de personnes physiques ou de groupes à des fins de profilage dans le cadre d'activités de détection, d'enquête ou de poursuite relatives à des infractions pénales, ainsi que d'analyse de la criminalité des personnes physiques. Les systèmes d'IA spécifiquement destinés à être utilisés pour des procédures administratives par les autorités fiscales et douanières ne devraient pas être considérés comme des systèmes d'IA à haut risque utilisés par les autorités répressives dans le cadre d'activités de prévention, de détection, d'enquête et de poursuite relatives à des infractions pénales.

destinés à être utilisés dans un contexte répressif où l'exactitude, la fiabilité et la transparence sont particulièrement importantes, *il convient de les classer comme systèmes d'IA à haut risque* pour éviter les conséquences négatives, conserver la confiance du public et garantir que des comptes soient rendus et que des recours efficaces puissent être exercés. Compte tenu de la nature des activités en question et des risques y afférents, ces systèmes d'IA à haut risque devraient comprendre en particulier les systèmes d'IA destinés à être utilisés par les autorités répressives pour réaliser des évaluations individuelles des risques, pour détecter les hypertrucages, pour évaluer la fiabilité des preuves dans les procédures pénales, ou pour évaluer les caractéristiques ou les antécédents délictuels de personnes physiques ou de groupes à des fins de profilage dans le cadre d'activités de détection, d'enquête ou de poursuite relatives à des infractions pénales, ainsi que d'analyse de la criminalité des personnes physiques. Les systèmes d'IA spécifiquement destinés à être utilisés pour des procédures administratives par les autorités fiscales et douanières ne devraient pas être considérés comme des systèmes d'IA à haut risque utilisés par les autorités répressives dans le cadre d'activités de prévention, de détection, d'enquête et de poursuite relatives à des infractions pénales.

Or. fr

Amendment 581

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 Recital 38

Text proposed by the Commission

Amendment

(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and documented. It is therefore appropriate to classify as high-risk a number of AI systems intended to be used in the law enforcement context where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress. In view of the nature of the activities in question and the risks relating thereto, those high-risk AI systems should include in particular AI systems intended to be used by law enforcement authorities *for individual risk assessments, polygraphs and similar tools or to detect the emotional state of natural person*, to detect 'deep fakes', for the evaluation of the reliability of evidence in criminal proceedings, *for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons, or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups, for profiling in the course of detection, investigation or prosecution of criminal offences*, as well as for crime analytics regarding natural persons. AI systems

(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and documented. It is therefore appropriate to classify as high-risk a number of AI systems intended to be used in the law enforcement context where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress. In view of the nature of the activities in question and the risks relating thereto, those high-risk AI systems should include in particular AI systems intended to be used by law enforcement authorities *or on their behalf* to detect 'deep fakes', for the evaluation of the reliability of evidence in criminal proceedings, as well as for crime analytics regarding natural persons. AI systems specifically intended to be used for administrative proceedings by tax and customs authorities should not be considered high-risk AI systems used by law enforcement authorities for the purposes of prevention, detection, investigation and prosecution of criminal offences.

specifically intended to be used for administrative proceedings by tax and customs authorities should not be considered high-risk AI systems used by law enforcement authorities for the purposes of prevention, detection, investigation and prosecution of criminal offences.

Or. en

Justification

Moved to prohibitions.

Amendment 582

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Abir Al-Sahlani, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Recital 38

Text proposed by the Commission

(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and

Amendment

(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and

documented. It is therefore appropriate to classify as high-risk a number of AI systems intended to be used in the law enforcement context where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress. In view of the nature of the activities in question and the risks relating thereto, those high-risk AI systems should include in particular AI systems intended to be used by law enforcement authorities for individual risk assessments, polygraphs and similar tools or to detect the emotional state of natural person, to detect 'deep fakes', for the evaluation of the reliability of evidence in criminal proceedings, for *predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons, or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups*, for profiling in the course of detection, investigation or prosecution of criminal offences, as well as for crime analytics regarding natural persons. AI systems specifically intended to be used for administrative proceedings by tax and customs authorities should not be considered high-risk AI systems used by law enforcement authorities for the purposes of prevention, detection, investigation and prosecution of criminal offences.

documented. It is therefore appropriate to classify as high-risk a number of AI systems intended to be used in the law enforcement context where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress. In view of the nature of the activities in question and the risks relating thereto, those high-risk AI systems should include in particular AI systems intended to be used by law enforcement authorities for individual risk assessments, polygraphs and similar tools or to detect the emotional state of natural person, to detect 'deep fakes', for the evaluation of the reliability of evidence in criminal proceedings, for profiling in the course of detection, investigation or prosecution of criminal offences, as well as for crime analytics regarding natural persons. AI systems specifically intended to be used for administrative proceedings by tax and customs authorities should not be considered high-risk AI systems used by law enforcement authorities for the purposes of prevention, detection, investigation and prosecution of criminal offences.

Or. en

Justification

Predictive policing moved to prohibited practices.

Amendment 583

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Karen Melchior, Svenja Hahn, Alin Mituța

Proposal for a regulation

Recital 38

Text proposed by the Commission

(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and documented. It is therefore appropriate to classify as high-risk a number of AI systems intended to be used in the law enforcement context where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress. In view of the nature of the activities in question and the risks relating thereto, those high-risk AI systems should include in particular AI systems intended to be used by law enforcement authorities for individual risk assessments, polygraphs and similar tools or to detect the emotional state of natural person, to detect 'deep fakes', for the evaluation of the reliability of evidence in criminal proceedings, for *predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons, or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups,*

Amendment

(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and documented. It is therefore appropriate to classify as high-risk a number of AI systems intended to be used in the law enforcement context where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress. In view of the nature of the activities in question and the risks relating thereto, those high-risk AI systems should include in particular AI systems intended to be used by law enforcement authorities for individual risk assessments, polygraphs and similar tools or to detect the emotional state of natural person, to detect 'deep fakes', for the evaluation of the reliability of evidence in criminal proceedings, for profiling in the course of detection, investigation or prosecution of criminal offences, as well as for crime analytics regarding natural persons. AI systems specifically intended to be used for administrative proceedings by tax and

for profiling in the course of detection, investigation or prosecution of criminal offences, as well as for crime analytics regarding natural persons. AI systems specifically intended to be used for administrative proceedings by tax and customs authorities should not be considered high-risk AI systems used by law enforcement authorities for the purposes of prevention, detection, investigation and prosecution of criminal offences.

customs authorities should not be considered high-risk AI systems used by law enforcement authorities for the purposes of prevention, detection, investigation and prosecution of criminal offences.

Or. en

Amendment 584

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation Recital 38

Text proposed by the Commission

(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and documented. It is therefore appropriate to *classify as high-risk a number of AI*

Amendment

(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and documented *and where a redress procedure is not foreseen*. It is therefore

systems intended to be used in the law enforcement context where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress. In view of the nature of the activities in question and the risks relating thereto, those **high-risk AI** systems should include in particular AI systems intended to be used by law enforcement authorities for individual risk assessments, polygraphs and similar tools or to detect the emotional state of natural person, ***to detect 'deep fakes', for the evaluation of the reliability of evidence in criminal proceedings***, for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons, or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups, for profiling in the course of detection, investigation or prosecution of criminal offences, ***as well as for crime analytics regarding natural persons***. AI systems specifically intended to be used for administrative proceedings by tax and customs authorities should not be ***considered high-risk AI systems used by law enforcement authorities for the purposes of prevention, detection, investigation and prosecution of criminal offences.***

appropriate to **prohibit some** AI systems intended to be used in the law enforcement context where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress, ***including the availability of redress-by-design mechanisms and procedures***. In view of the nature of the activities in question and the risks relating thereto, those **prohibited** systems should include in particular AI systems intended to be used by law enforcement authorities for individual risk assessments, polygraphs and similar tools or to detect the emotional state of natural person, for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons, or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups, for profiling in the course of detection, investigation or prosecution of criminal offences. AI systems specifically intended to be used for administrative proceedings by tax and customs authorities should not be ***included in such a ban.***

Or. en

Amendment 585

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

Proposal for a regulation Recital 38 a (new)

Text proposed by the Commission

Amendment

(38 a) The use of AI tools by law enforcement and judicial authorities should not become a factor of inequality,

social fracture or exclusion. The impact of the use of AI tools on the defence rights of suspects should not be ignored, notably the difficulty in obtaining meaningful information on their functioning and the consequent difficulty in challenging their results in court, in particular by individuals under investigation.

Or. en

Amendment 586

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 39

Text proposed by the Commission

(39) AI systems used in migration, asylum and border control management affect people who are often in particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. ***It is therefore appropriate to classify as high-risk AI systems intended to be used by the competent public authorities charged with tasks in the fields of migration, asylum and border control management as polygraphs and similar tools or to detect the emotional state of a natural person; for assessing certain risks posed by natural persons entering the territory of a Member State or applying for visa or asylum; for verifying the authenticity of the relevant documents of natural persons; for assisting competent public authorities for the examination of***

Amendment

(39) AI systems used in migration, asylum and border control management affect people who are often in particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council⁴⁹, the Regulation (EC) No 810/2009 of the European Parliament and of the Council⁵⁰ and other relevant legislation.

applications for asylum, visa and residence permits and associated complaints with regard to the objective to establish the eligibility of the natural persons applying for a status. AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council⁴⁹, the Regulation (EC) No 810/2009 of the European Parliament and of the Council⁵⁰ and other relevant legislation.

⁴⁹ Directive 2013/32/EU of the European Parliament and of the Council of 26 June 2013 on common procedures for granting and withdrawing international protection (OJ L 180, 29.6.2013, p. 60).

⁵⁰ Regulation (EC) No 810/2009 of the European Parliament and of the Council of 13 July 2009 establishing a Community Code on Visas (Visa Code) (OJ L 243, 15.9.2009, p. 1).

⁴⁹ Directive 2013/32/EU of the European Parliament and of the Council of 26 June 2013 on common procedures for granting and withdrawing international protection (OJ L 180, 29.6.2013, p. 60).

⁵⁰ Regulation (EC) No 810/2009 of the European Parliament and of the Council of 13 July 2009 establishing a Community Code on Visas (Visa Code) (OJ L 243, 15.9.2009, p. 1).

Or. en

Amendment 587

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

Proposal for a regulation

Recital 39

Text proposed by the Commission

(39) AI systems used in migration, asylum and border control management affect people who are often in particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the

Amendment

(39) AI systems used in migration, asylum and border control management affect people who are often in particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the

fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. It is therefore appropriate to classify as high-risk AI systems intended to be used by the competent public authorities charged with tasks in the fields of migration, asylum and border control management ***as polygraphs and similar tools or to detect the emotional state of a natural person; for assessing certain risks posed by natural persons entering the territory of a Member State or applying for visa or asylum; for verifying the authenticity of the relevant documents of natural persons; for assisting competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the objective to establish the eligibility of the natural persons applying for a status.*** AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council⁴⁹, the Regulation (EC) No 810/2009 of the European Parliament and of the Council⁵⁰ and other relevant legislation.

⁴⁹ Directive 2013/32/EU of the European Parliament and of the Council of 26 June 2013 on common procedures for granting and withdrawing international protection (OJ L 180, 29.6.2013, p. 60).

⁵⁰ Regulation (EC) No 810/2009 of the European Parliament and of the Council of 13 July 2009 establishing a Community Code on Visas (Visa Code) (OJ L 243, 15.9.2009, p. 1).

fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. It is therefore appropriate to classify as high-risk AI systems intended to be used by the competent public authorities charged with tasks in the fields of migration, asylum and border control management. AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council⁴⁹, the Regulation (EC) No 810/2009 of the European Parliament and of the Council⁵⁰ and other relevant legislation.

⁴⁹ Directive 2013/32/EU of the European Parliament and of the Council of 26 June 2013 on common procedures for granting and withdrawing international protection (OJ L 180, 29.6.2013, p. 60).

⁵⁰ Regulation (EC) No 810/2009 of the European Parliament and of the Council of 13 July 2009 establishing a Community Code on Visas (Visa Code) (OJ L 243, 15.9.2009, p. 1).

Or. en

Amendment 588

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

Recital 39

Text proposed by the Commission

(39) AI systems used in migration, asylum and border control management affect people who are often in particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. It is therefore appropriate to classify as high-risk AI systems intended to be used by the competent public authorities charged with tasks in the fields of migration, asylum and border control management ***as polygraphs and similar tools or to detect the emotional state of a natural person; for assessing certain risks posed by natural persons entering the territory of a Member State or applying for visa or asylum;*** for verifying the authenticity of the relevant documents of natural persons; ***for assisting competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the objective to establish the eligibility of the natural persons applying for a status.*** AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council⁴⁹, the Regulation (EC) No 810/2009 of the

Amendment

(39) AI systems used in migration, asylum and border control management affect people who are often in particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. It is therefore appropriate to classify as high-risk AI systems intended to be used by the competent public authorities charged with tasks in the fields of migration, asylum and border control management; for verifying the authenticity of the relevant documents of natural persons; AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council, the Regulation (EC) No 810/2009 of the European Parliament and of the Council and other relevant legislation.

European Parliament and of the Council⁴⁹
and other relevant legislation.

⁴⁹ Directive 2013/32/EU of the European Parliament and of the Council of 26 June 2013 on common procedures for granting and withdrawing international protection (OJ L 180, 29.6.2013, p. 60).

⁵⁰ Regulation (EC) No 810/2009 of the European Parliament and of the Council of 13 July 2009 establishing a Community Code on Visas (Visa Code) (OJ L 243, 15.9.2009, p. 1).

Or. en

Amendment 589

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

Proposal for a regulation

Recital 39

Text proposed by the Commission

(39) AI systems used in migration, asylum and border control management affect people who are often in particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. It is therefore appropriate to classify as high-risk AI systems intended to be used by the competent public authorities charged with tasks in the fields of migration, asylum and border control management as ***polygraphs and similar tools or to detect the***

Amendment

(39) AI systems used in migration, asylum and border control management affect people who are often in ***a*** particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. It is therefore appropriate to classify as high-risk AI systems intended to be used by the competent public authorities charged with tasks in the fields of migration, asylum and border control management as applying for visa or asylum; for verifying the

emotional state of a natural person; for assessing certain risks posed by natural persons entering the territory of a Member State or applying for visa or asylum; for verifying the authenticity of the relevant documents of natural persons; for assisting competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the objective to establish the eligibility of the natural persons applying for a status. AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council⁴⁹, the Regulation (EC) No 810/2009 of the European Parliament and of the Council⁵⁰ and other relevant legislation.

⁴⁹ Directive 2013/32/EU of the European Parliament and of the Council of 26 June 2013 on common procedures for granting and withdrawing international protection (OJ L 180, 29.6.2013, p. 60).

⁵⁰ Regulation (EC) No 810/2009 of the European Parliament and of the Council of 13 July 2009 establishing a Community Code on Visas (Visa Code) (OJ L 243, 15.9.2009, p. 1).

authenticity of the relevant documents of natural persons; for assisting competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the objective to establish the eligibility of the natural persons applying for a status. AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council, the Regulation (EC) No 810/2009 of the European Parliament and of the Council and other relevant legislation

Or. en

Amendment 590

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte

Proposal for a regulation Recital 39

Text proposed by the Commission

(39) Les systèmes d'IA utilisés dans le domaine de la gestion de la migration, de l'asile et des contrôles aux frontières touchent des personnes qui sont *souvent*

Amendment

(39) Les systèmes d'IA utilisés dans le domaine de la gestion de la migration, de l'asile et des contrôles aux frontières touchent des personnes qui sont *parfois*

dans une position ***particulièrement*** vulnérable et qui dépendent du résultat des actions des autorités publiques compétentes. L'exactitude, la nature non discriminatoire et la transparence des systèmes d'IA utilisés dans ces contextes sont donc particulièrement importantes pour garantir le respect des droits fondamentaux des personnes concernées, notamment leurs droits à la libre circulation, à la non-discrimination, à la protection de la vie privée et des données à caractère personnel, à une protection internationale et à une bonne administration. Il convient donc de classer comme étant à haut risque les systèmes d'IA destinés à être utilisés par les autorités publiques compétentes chargées de tâches dans les domaines de la gestion de la migration, de l'asile et des contrôles aux frontières pour servir de polygraphes ou d'outils similaires ou pour analyser l'état émotionnel d'une personne physique; pour évaluer certains risques posés par des personnes physiques entrant sur le territoire d'un État membre ou faisant une demande de visa ou d'asile; pour vérifier l'authenticité des documents pertinents de personnes physiques; et pour aider les autorités publiques compétentes à examiner les demandes d'asile, de visa et de permis de séjour ainsi que les plaintes connexes, l'objectif étant de vérifier l'éligibilité des personnes physiques qui demandent un statut. Les systèmes d'IA utilisés dans le domaine de la gestion de la migration, de l'asile et des contrôles aux frontières couverts par le présent règlement devraient être conformes aux exigences procédurales pertinentes fixées par la directive 2013/32/UE du Parlement européen et du Conseil⁴⁹, le règlement (CE) n° 810/2009 du Parlement européen et du Conseil⁵⁰ et toute autre législation pertinente.

⁴⁹ Directive 2013/32/UE du Parlement européen et du Conseil du 26 juin 2013 relative à des procédures communes pour

dans une position vulnérable et qui dépendent du résultat des actions des autorités publiques compétentes. L'exactitude, la nature non discriminatoire et la transparence des systèmes d'IA utilisés dans ces contextes sont donc particulièrement importantes pour garantir le respect des droits fondamentaux des personnes concernées, notamment, ***lorsqu'ils sont applicables***, leurs droits à la libre circulation, à la non-discrimination, à la protection de la vie privée et des données à caractère personnel, à une protection internationale et à une bonne administration. Il convient donc de classer comme étant à haut risque les systèmes d'IA destinés à être utilisés par les autorités publiques compétentes chargées de tâches dans les domaines de la gestion de la migration, de l'asile et des contrôles aux frontières pour servir de polygraphes ou d'outils similaires ou pour analyser l'état émotionnel d'une personne physique; pour évaluer certains risques posés par des personnes physiques entrant sur le territoire d'un État membre ou faisant une demande de visa ou d'asile; pour vérifier l'authenticité des documents pertinents de personnes physiques; et pour aider les autorités publiques compétentes à examiner les demandes d'asile, de visa et de permis de séjour ainsi que les plaintes connexes, l'objectif étant de vérifier l'éligibilité des personnes physiques qui demandent un statut. Les systèmes d'IA utilisés dans le domaine de la gestion de la migration, de l'asile et des contrôles aux frontières couverts par le présent règlement devraient être conformes aux exigences procédurales pertinentes fixées par la directive 2013/32/UE du Parlement européen et du Conseil⁴⁹, le règlement (CE) n° 810/2009 du Parlement européen et du Conseil⁵⁰ et toute autre législation pertinente.

⁴⁹ Directive 2013/32/UE du Parlement européen et du Conseil du 26 juin 2013 relative à des procédures communes pour

l'octroi et le retrait de la protection internationale (JO L 180 du 29.6.2013, p. 60).

⁵⁰ Règlement (CE) n° 810/2009 du Parlement européen et du Conseil du 13 juillet 2009 établissant un code communautaire des visas (code des visas) (JO L 243 du 15.9.2009, p. 1).

l'octroi et le retrait de la protection internationale (JO L 180 du 29.6.2013, p. 60).

⁵⁰ Règlement (CE) n° 810/2009 du Parlement européen et du Conseil du 13 juillet 2009 établissant un code communautaire des visas (code des visas) (JO L 243 du 15.9.2009, p. 1).

Or. fr

Amendment 591

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

Proposal for a regulation

Recital 39 a (new)

Text proposed by the Commission

Amendment

(39 a) The use of AI systems in migration, asylum and border control management should in no circumstances be used by Member States or European Union institutions as a means to circumvent their international obligations under the Convention of 28 July 1951 relating to the Status of Refugees as amended by the Protocol of 31 January 1967, nor should they be used to in any way infringe on the principle of non-refoulement, or deny safe and effective legal avenues into the territory of the Union, including the right to international protection;

Or. en

Amendment 592

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Recital 39 a (new)

Text proposed by the Commission

Amendment

(39 a) The use of AI systems in migration, asylum and border control management should in no circumstances be used by Member States or European Union institutions as a means to circumvent their international obligations under the Convention of 28 July 1951 relating to the Status of Refugees as amended by the Protocol of 31 January 1967, nor should they be used to in any way infringe on the principle of non-refoulement, or deny safe and effective legal avenues into the territory of the Union, including the right to international protection;

Or. en

Amendment 593

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 39 a (new)

Text proposed by the Commission

Amendment

(39 a) The use of AI systems in migration, asylum and border control management should in no circumstances be used by Member States or European Union institutions as a means to circumvent their international obligations under the Convention of 28 July 1951 relating to the Status of Refugees as amended by the Protocol of 31 January 1967, nor should they be used to in any way infringe on the principle of non-refoulement, or deny safe and effective legal avenues into the territory of the Union, including the right to international protection;

Or. en

Amendment 594

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 39 a (new)

Text proposed by the Commission

Amendment

(39 a) The use of AI systems in migration, asylum and border control management should in no circumstances be used by Member States or European Union institutions as a means to circumvent their international obligations under the Convention of 28 July 1951 relating to the Status of Refugees as amended by the Protocol of 31 January 1967, nor should they be used to in any way infringe on the principle of non-refoulement, or deny safe and effective legal avenues into the territory of the Union, including the right to international protection;

Or. en

Amendment 595

Abir Al-Sahlani, Svenja Hahn, Samira Rafaela, Monica Semedo

Proposal for a regulation

Recital 39 a (new)

Text proposed by the Commission

Amendment

(39 a) The use of AI systems in migration, asylum and border management should however not, at any point, be used by Member States or by the institutions or agencies of the Union to infringe on the principle of non-refoulement, the right to asylum or to circumvent international obligations under the Convention of 28 July 1951 relating to the Status of Refugees as amended by the Protocol of 31 January 1967.

Or. en

Amendment 596

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

Proposal for a regulation

Recital 40

Text proposed by the Commission

(40) Certain AI systems intended for the administration of justice and democratic processes should be classified as high-risk, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. In particular, to address the risks of potential biases, errors and opacity, it is appropriate to qualify as high-risk AI systems intended to assist judicial authorities in researching and interpreting facts and the law and in applying the law *to a concrete set of facts*. Such qualification should not extend, however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks or allocation of resources.

Amendment

(40) Certain AI systems intended for the administration of justice and democratic processes should be classified as high-risk, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. *The use of Artificial Intelligence tools can support, but should not interfere with the decision-making power of judges or judicial independence, as the final decision-making must remain a human-driven activity and decision.* In particular, to address the risks of potential biases, errors and opacity, it is appropriate to qualify as high-risk AI systems intended to assist judicial authorities in researching and interpreting facts and the law and in applying the law. Such qualification should not extend, however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks or allocation of resources

Or. en

Amendment 597

Vincenzo Sofo, Kosma Złotowski

Proposal for a regulation

Recital 40

Text proposed by the Commission

(40) Certain AI systems intended for the administration of justice and democratic processes should be classified as high-risk, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. In particular, to address the risks of potential biases, errors and opacity, it is appropriate to qualify as high-risk AI systems intended to assist judicial authorities in researching *and interpreting* facts and the law *and in applying the law to a concrete set of facts*. Such qualification should not extend, however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks or allocation of resources.

Amendment

(40) Certain AI systems intended for the administration of justice and democratic processes should be classified as high-risk, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. In particular, to address the risks of potential biases, errors and opacity, it is appropriate to qualify as high-risk AI systems intended to assist judicial authorities in researching facts and the law. Such qualification should not extend, however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks or allocation of resources.

Or. en

Amendment 598

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte

**Proposal for a regulation
Recital 40**

Text proposed by the Commission

(40) Certains systèmes d'IA destinés à être utilisés pour l'administration de la justice et les processus démocratiques devraient être *classés comme étant à haut risque*, compte tenu de leur incidence potentiellement significative sur la démocratie, l'état de droit, les libertés individuelles ainsi que le droit à un recours effectif et à accéder à un tribunal impartial. En particulier, pour faire face aux risques de biais, d'erreurs et d'opacité, il convient *de classer comme étant à haut risque les*

Amendment

(40) Certains systèmes d'IA destinés à être utilisés pour l'administration de la justice et les processus démocratiques devraient être *interdits*, compte tenu de leur incidence potentiellement significative sur la démocratie, l'état de droit, les libertés individuelles ainsi que le droit à un recours effectif et à accéder à un tribunal impartial. En particulier, pour faire face aux risques de biais, d'erreurs et d'opacité, il convient *d'interdire l'utilisation des* systèmes d'IA destinés à aider les autorités

systèmes d'IA destinés à aider les autorités judiciaires à rechercher et à interpréter les faits et la loi, et à appliquer la loi à un ensemble concret de faits. Cette qualification ne devrait cependant pas s'étendre aux systèmes d'IA destinés à être utilisés pour des activités administratives purement accessoires qui n'ont aucune incidence sur l'administration réelle de la justice dans des cas individuels, telles que l'anonymisation ou la pseudonymisation de décisions judiciaires, de documents ou de données, la communication entre membres du personnel, les tâches administratives ou l'allocation des ressources.

judiciaires à rechercher et à interpréter les faits et la loi, et à appliquer la loi à un ensemble concret de faits. Cette qualification ne devrait cependant pas s'étendre aux systèmes d'IA destinés à être utilisés pour des activités administratives purement accessoires qui n'ont aucune incidence sur l'administration réelle de la justice dans des cas individuels, telles que l'anonymisation ou la pseudonymisation de décisions judiciaires, de documents ou de données, la communication entre membres du personnel, les tâches administratives ou l'allocation des ressources.

Or. fr

Amendment 599

Svenja Hahn, Nicola Beer, Dita Charanzová, Andrus Ansip, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation Recital 40

Text proposed by the Commission

(40) Certain AI systems intended for the administration of justice and democratic processes should be classified as high-risk, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. In particular, to address the risks of potential biases, errors and opacity, it is appropriate to qualify as high-risk AI systems intended to assist judicial authorities in **researching and** interpreting facts **and** the law **and in** applying the law to a concrete set of facts. Such qualification should not extend, however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel,

Amendment

(40) Certain AI systems intended for the administration of justice and democratic processes should be classified as high-risk, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. In particular, to address the risks of potential biases, errors and opacity, it is appropriate to qualify as high-risk AI systems intended to assist judicial authorities in interpreting facts **or** the law **for** applying the law to a concrete set of facts. Such qualification should not extend, however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks or

administrative tasks or allocation of resources.

allocation of resources.

Or. en

Amendment 600

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 40 a (new)

Text proposed by the Commission

Amendment

(40 a) Another area in which the use of AI systems deserves special consideration is the use for health-related purposes, including healthcare. Next to medical devices (as per EU regulation 2017/745), other health-related AI systems also bring about risks which should be regulated. These include systems that influence individual's health outcomes but do not meet the criteria for a medical device, systems that influence population health outcomes or health equality, systems that impact the distribution of healthcare resources and systems used by pharmaceutical and medical technology companies in research and development, pharmacovigilance, market optimisation and pharmaceutical marketing. Bias and errors in health-related AI systems can have major and immediate consequences for individuals' and populations' health and wellbeing. Further, many systems will use sensitive and personal data, which needs to be justified, and about which patients need to be properly informed. What is more, systems that work on hospital, health system, or population level may have a major effect on societal health because they influence the distribution of healthcare resources and health policy design. For these reasons, there is a need for trustworthy AI in healthcare, meaning people must be able to trust that systems used in healthcare are scientifically, technically and

clinically valid, safe and accountable, and safeguard individuals' autonomy and privacy.

Or. en

Amendment 601

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

Recital 40 a (new)

Text proposed by the Commission

Amendment

(40 a) Certain AI systems should at the same time be subject to transparency requirements and be classified as high-risk AI systems, given their potential to deceive and cause both individual and societal harm. In particular, AI systems that generate deep fakes representing existing persons have the potential to both manipulate the natural persons that are exposed to those deep fakes and harm the persons they are representing or misrepresenting, while AI systems that, based on limited human input, generate complex text such as news articles, opinion articles, novels, scripts and scientific articles have the potential to manipulate, to deceive, or to expose natural persons to built-in biases or inaccuracies. These should not include AI systems intended to translate text, or cases where the content forms part of an evidently artistic, creative or fictional cinematographic and analogous work.

Or. en

Amendment 602

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituță

Proposal for a regulation
Recital 40 a (new)

Text proposed by the Commission

Amendment

(40 a) When the “deep fake” content forms part of an evidently artistic, creative, or fictional cinematographic and analogous work, or when the “AI authors” generate content that undergoes human review and for the publication of which a natural or legal person established in the Union is liable or holds editorial responsibility, the AI systems should not be considered high-risk but should nevertheless be subject to adequate transparency requirements, where appropriate.

Or. en

Amendment 603

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

Proposal for a regulation
Recital 40 a (new)

Text proposed by the Commission

Amendment

(40 a) Certain AI-systems used in the area of healthcare that are not covered by Regulation (EU) 2017/745 (Regulation on Medical Devices) should be high-risk. Uses such as software impacting diagnostics, treatments or medical prescriptions and access to health insurance can clearly impact health and safety, but also can also obstruct access to health services, impact the right to health care and cause physical harm in the long run.

Or. en

Amendment 604
Andrea Caroppo, Salvatore De Meo

Proposal for a regulation
Recital 40 a (new)

Text proposed by the Commission

Amendment

(40 a) Transparency requirements shall not apply where the content forms part of an evidently artistic, creative, satirical, fictional or analogous work or programme.

Or. en

Amendment 605
Morten Løkkegaard

Proposal for a regulation
Recital 40 a (new)

Text proposed by the Commission

Amendment

(40 a) Transparency requirements shall not apply where the content forms part of an evidently artistic, creative, satirical, fictional and analogous work or programme.

Or. en

Amendment 606
Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia urîș Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation
Recital 40 b (new)

Text proposed by the Commission

Amendment

(40 b) Subliminal techniques are techniques that expose natural persons to sensorial stimuli that the natural persons cannot consciously perceive but that are

assumed to register in the brain unconsciously, such as flashing images or text for fractions of a second or playing sounds outside the range of perceptible hearing. AI systems deploying such techniques should be prohibited, because these techniques are by their very nature intended to be manipulative. Nevertheless, exceptions are warranted for AI systems using subliminal techniques for research and therapeutical purposes, based on the consent of the natural persons that are being exposed to them. In such limited cases, the AI systems should be considered high-risk and comply with the requirements for high-risk AI systems as set forth in this Regulation.

Or. en

Amendment 607

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

Proposal for a regulation
Recital 40 b (new)

Text proposed by the Commission

Amendment

(40 b) Certain AI-systems used in the area of media, particularly in the area of social media, due to their potentially large reach and the specific risk of large scale spread of disinformation and exacerbation of societal polarisation should be high-risk due to their potential impact on individuals' rights, but also on society and democracy at large.

Or. en

Amendment 608

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

Proposal for a regulation

Recital 41

Text proposed by the Commission

(41) The fact that an AI system is classified as high risk under this Regulation should not be interpreted as indicating that the use of the system is necessarily lawful under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data, *on the use of polygraphs and similar tools or other systems to detect the emotional state of natural persons*. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of secondary Union law and national law. This Regulation should not be understood as providing for the legal ground for processing of personal data, including special categories of personal data, *where relevant*.

Amendment

(41) The fact that an AI system is classified as high risk under this Regulation should not be interpreted as indicating that the use of the system is necessarily lawful under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of secondary Union law and national law. This Regulation should not be understood as providing for the legal ground for processing of personal data, including special categories of personal data.

Or. en

Amendment 609

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

Recital 41

Text proposed by the Commission

(41) The fact that an AI system is classified as high risk under this Regulation should not be interpreted as indicating that the use of the system is necessarily lawful under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data, *on the use of polygraphs and similar tools or other systems to detect the emotional state of natural persons*. Any such use should

Amendment

(41) The fact that an AI system is classified as high risk under this Regulation should not be interpreted as indicating that the use of the system is necessarily lawful under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter

continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of secondary Union law and national law. This Regulation should not be understood as providing for the legal ground for processing of personal data, including special categories of personal data, where relevant.

and from the applicable acts of secondary Union law and national law. This Regulation should not be understood as providing for the legal ground for processing of personal data, including special categories of personal data, where relevant.

Or. en

Amendment 610

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

Proposal for a regulation

Recital 41

Text proposed by the Commission

(41) The fact that an AI system is classified as high risk under this Regulation should not be interpreted as indicating that the use of the system is necessarily lawful under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data, *on the use of polygraphs and similar tools or other systems to detect the emotional state of natural persons*. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of secondary Union law and national law. This Regulation should not be understood as providing for the legal ground for processing of personal data, including special categories of personal data, where relevant.

Amendment

(41) The fact that an AI system is classified as high risk under this Regulation should not be interpreted as indicating that the use of the system is necessarily lawful under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of secondary Union law and national law. This Regulation should not be understood as providing for the legal ground for processing of personal data, including special categories of personal data, where relevant.

Or. en

Amendment 611

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 41

Text proposed by the Commission

(41) The fact that an AI system is **classified as high risk** under this Regulation should not be interpreted as indicating that the use of the system is necessarily **lawful** under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data, on the use of polygraphs and similar tools or other systems to detect the emotional state of natural persons. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of secondary Union law and national law. This Regulation **should not** be understood as providing for the legal ground for processing of personal data, **including special categories of personal data**, where relevant.

Amendment

(41) The fact that an AI system is **compliant with the requirements for high-risk AI** under this Regulation should not be interpreted as indicating that the use of the system is necessarily **unlawful** under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data, on the use of polygraphs and similar tools or other systems to detect the emotional state of natural persons. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of secondary Union law and national law. **As far as is applicable and proportionate**, this Regulation **may, where duly justified**, be understood as providing for the legal ground for processing of personal data where relevant.

Or. en

Amendment 612
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 41 a (new)

Text proposed by the Commission

Amendment

(41 a) AI systems do not operate in a lawless world. A number of legally binding rules at European, national and international level already apply or are relevant to AI systems today. Legal sources include, but are not limited to EU primary law (the Treaties of the European Union and its Charter of Fundamental Rights), EU secondary law (such as the General Data Protection Regulation, the Product Liability Directive, the

Regulation on the Free Flow of Non-Personal Data, anti-discrimination Directives, consumer law and Safety and Health at Work Directives), the UN Human Rights treaties and the Council of Europe conventions (such as the European Convention on Human Rights), and numerous EU Member State laws. Besides horizontally applicable rules, various domain-specific rules exist that apply to particular AI applications (such as for instance the Medical Device Regulation in the healthcare sector).

Or. en

Amendment 613

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Malik Azmani, Svenja Hahn, Andrus Ansip, Dita Charanzová, Morten Løkkegaard, Alin Mituța

Proposal for a regulation

Recital 42

Text proposed by the Commission

(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory requirements should apply, taking into account the intended purpose of the use of the system and according to the risk management system to be established by the provider.

Amendment

(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory requirements should apply, taking into account the intended purpose of the use of the system and according to the risk management system to be established by the provider. *These requirements should be objective-driven, fit to purpose, reasonable and effective, without adding undue regulatory burdens or costs on operators.*

Or. en

Amendment 614

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 42

Text proposed by the Commission

(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory requirements should apply, taking into account the intended purpose of the use of the system and according to the risk management system to be established by the provider.

Amendment

(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory requirements should apply, taking into account the intended purpose of the use of the system, *level of reliance of the user or business user on the output of the AI system for the final decision or outcome* and according to the risk management system to be established by the provider.

Or. en

Amendment 615

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

Proposal for a regulation

Recital 42

Text proposed by the Commission

(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for *users and affected persons*, certain mandatory requirements should apply, taking into account the intended purpose *of the use* of the system *and according to* the risk management system to be established by the provider.

Amendment

(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for *deployers and AI subjects*, certain mandatory requirements should apply, taking into account the intended purpose, *the potential or reasonably foreseeable use or misuse* of the system, *and should be in accordance with* the risk management system to be established by the provider.

Or. en

Amendment 616

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 42

Text proposed by the Commission

(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory requirements should apply, taking into account the intended purpose *of the* use of the system and according to the risk management system to be established by the provider.

Amendment

(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory requirements should apply, taking into account the intended purpose *or reasonably foreseeable* use of the system and according to the risk management system to be established by the provider.

Or. en

Amendment 617

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 42

Text proposed by the Commission

(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory requirements should apply, taking into account the *intended purpose of the use* of the system and according to the risk management system to be established by the provider.

Amendment

(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory requirements should apply, taking into account the *foreseeable uses* of the system and according to the risk management system to be established by the provider.

Or. en

Amendment 618

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

Proposal for a regulation

Recital 43

Text proposed by the Commission

(43) Requirements should apply to high-risk AI systems as regards the quality of data sets used, technical documentation

Amendment

(43) Requirements should apply to high-risk AI systems as regards the quality *and relevance* of data sets used, technical

and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and **cybersecurity**. Those requirements are necessary to effectively mitigate the risks for health, safety and fundamental rights, as applicable in the light of the intended purpose of the system, and no other less trade restrictive measures are reasonably available, thus avoiding unjustified restrictions to trade.

documentation and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and **security**. Those requirements are necessary to effectively mitigate the risks for health, safety and fundamental rights, as **well as the environment, society, rule of law, democracy, economic interests and consumer protection**, as applicable in the light of the intended purpose, **the potential or reasonably foreseeable use or misuse** of the system, and no other less trade restrictive measures are reasonably available, thus avoiding unjustified restrictions to trade.

Or. en

Amendment 619

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

Recital 43

Text proposed by the Commission

(43) Requirements should apply to high-risk AI systems as regards the quality of data sets used, technical documentation and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and cybersecurity. Those requirements are necessary to effectively mitigate the risks for health, safety **and** fundamental rights, as applicable in the light of the intended purpose of the system, and no other less trade restrictive measures are reasonably available, thus avoiding unjustified restrictions to trade.

Amendment

(43) Requirements should apply to high-risk AI systems as regards the quality of data sets used, technical documentation and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and cybersecurity. Those requirements are necessary to effectively mitigate the risks for health, safety, fundamental rights, **the environment and the Union values enshrined in Article 2 TEU**, as applicable in the light of the intended purpose **or reasonably foreseeable use** of the system, and no other less trade restrictive measures are reasonably available, thus avoiding unjustified restrictions to trade.

Or. en

Amendment 620

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 43

Text proposed by the Commission

(43) Requirements should apply to high-risk AI systems as regards the quality of data sets used, technical documentation and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and cybersecurity. Those requirements are necessary to effectively mitigate the risks for health, safety and fundamental rights, as applicable in the light of the intended purpose of the system, and no other less trade restrictive measures are reasonably available, thus avoiding unjustified restrictions to trade.

Amendment

(43) Requirements should apply to high-risk AI systems as regards the quality of data sets used, technical documentation and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and cybersecurity. Those requirements are necessary to effectively mitigate the risks for health, safety and fundamental rights, as applicable in the light of the intended purpose *or reasonably foreseeable use* of the system, and no other less trade restrictive measures are reasonably available, thus avoiding unjustified restrictions to trade.

Or. en

Amendment 621

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 43

Text proposed by the Commission

(43) Requirements should apply to high-risk AI systems as regards the quality of data sets used, technical documentation and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and cybersecurity. Those requirements are necessary to effectively mitigate the risks for health, safety and fundamental rights, as applicable in the light of the *intended purpose* of the system, and no other less trade restrictive measures are reasonably

Amendment

(43) Requirements should apply to high-risk AI systems as regards the quality of data sets used, technical documentation and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and cybersecurity. Those requirements are necessary to effectively mitigate the risks for health, safety and fundamental rights, as applicable in the light of the *foreseeable uses* of the system, and no other less trade restrictive measures are reasonably

available, thus avoiding unjustified restrictions to trade.

available, thus avoiding unjustified restrictions to trade.

Or. en

Amendment 622

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

Proposal for a regulation

Recital 43 a (new)

Text proposed by the Commission

Amendment

(43 a) Fundamental rights impact assessments for high-risk AI systems may include a clear outline of the intended purpose for which the system will be used, a clear outline of the intended geographic and temporal scope of the system's use, categories of natural persons and groups likely to be affected by the use of the system or any specific risk of harm likely to impact marginalised persons or groups at risk of discrimination, or increase societal inequalities;

Or. en

Amendment 623

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 44

Text proposed by the Commission

Amendment

(44) High data quality *is* essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. High quality training, validation and testing data sets

*(44) High data quality **and having simple and accessible data plays a vital role in providing structure and ground truth for AI and are** essential for **purpose-ready data analytics and** the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended*

require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant, representative ***and free of errors and complete*** in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers ***should be*** able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems.

and safely and it does not become the source of discrimination prohibited by Union law. ***To achieve simple access to and usability of high quality data for AI, the Commission should examine ways to facilitate the lawful processing of personal data to train legitimate AI systems by appropriate amendments to applicable laws.*** High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, ***machine learning*** validation and testing data sets should be sufficiently relevant ***and*** representative in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, ***machine learning*** validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. ***If it is necessary for the aforementioned purpose to use existing sets of data that includes personal data originally collected and stored for a different purpose, their use for the aforementioned purpose should be deemed compatible with the original purpose so long as the personal data is not transferred to any third party.*** In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers ***should be*** able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems.

Or. en

Amendment 624

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

Proposal for a regulation

Recital 44

Text proposed by the Commission

(44) Une haute qualité des données est essentielle au bon fonctionnement de nombreux systèmes d'IA, en particulier lorsque des techniques axées sur l'entraînement de modèles sont utilisées, afin de garantir que le système d'IA à haut risque fonctionne comme prévu et en toute sécurité et qu'il ne devient pas une source de discrimination interdite par le droit de l'Union. Des jeux de données d'entraînement, de validation et de test de haute qualité nécessitent la mise en œuvre de pratiques de gouvernance et de gestion des données appropriées. Les jeux de données d'entraînement, de validation et de test devraient être suffisamment pertinents, représentatifs, exempts d'erreurs et complets au regard de la destination du système. Ils devraient également avoir les propriétés statistiques appropriées, notamment en ce qui concerne les personnes ou les groupes de personnes sur lesquels le système d'IA à haut risque est destiné à être utilisé. En particulier, les jeux de données d'entraînement, de validation et de test devraient prendre en considération, dans la mesure requise au regard de leur destination, les propriétés, les caractéristiques ou les éléments qui sont particuliers au cadre ou au contexte géographique, comportemental ou fonctionnel spécifique dans lequel le système d'IA est destiné à être utilisé. *Afin de protéger le droit d'autres personnes contre la discrimination qui pourrait résulter des biais dans les systèmes d'IA, les fournisseurs devraient être en mesure de traiter également des catégories spéciales de données à caractère personnel, pour des raisons d'intérêt public important, afin d'assurer la*

Amendment

(44) Une haute qualité des données est essentielle au bon fonctionnement de nombreux systèmes d'IA, en particulier lorsque des techniques axées sur l'entraînement de modèles sont utilisées, afin de garantir que le système d'IA à haut risque fonctionne comme prévu et en toute sécurité et qu'il ne devient pas une source de discrimination interdite par le droit de l'Union. Des jeux de données d'entraînement, de validation et de test de haute qualité nécessitent la mise en œuvre de pratiques de gouvernance et de gestion des données appropriées. Les jeux de données d'entraînement, de validation et de test devraient être suffisamment pertinents, représentatifs, exempts d'erreurs et complets au regard de la destination du système. Ils devraient également avoir les propriétés statistiques appropriées, notamment en ce qui concerne les personnes ou les groupes de personnes sur lesquels le système d'IA à haut risque est destiné à être utilisé. En particulier, les jeux de données d'entraînement, de validation et de test devraient prendre en considération, dans la mesure requise au regard de leur destination, les propriétés, les caractéristiques ou les éléments qui sont particuliers au cadre ou au contexte géographique, comportemental ou fonctionnel spécifique dans lequel le système d'IA est destiné à être utilisé.

Amendment 625
Andrea Caroppo, Salvatore De Meo

Proposal for a regulation
Recital 44

Text proposed by the Commission

(44) High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant, representative ***and free of errors and*** complete in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers should be able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the bias monitoring,

Amendment

(44) High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant, representative ***as complete and close to zero error as possible. A procedure to check data and completeness*** in view of the intended purpose of the system ***should be implemented.*** They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the ***unfair*** bias in AI systems, the providers should be able to process also special categories of personal data, as a

detection and correction in relation to high-risk AI systems.

matter of substantial public interest, in order to ensure the *unfair* bias monitoring, detection and correction in relation to high-risk AI systems.

Or. en

Amendment 626

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 44

Text proposed by the Commission

(44) High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant, representative and free of errors and complete in view of the *intended purpose* of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their *intended purpose*, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers *should be able to process also special categories of personal data, as a matter of substantial public interest, in*

Amendment

(44) High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant, representative and free of errors and complete in view of the *foreseeable uses* of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their *foreseeable uses*, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers *should* ensure the bias monitoring, detection and correction in

order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems.

relation to high-risk AI systems.

Or. en

Amendment 627

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 44

Text proposed by the Commission

(44) High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant, representative and free of errors and complete in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers **should be** able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the bias monitoring,

Amendment

(44) High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant, representative and free of errors and complete in view of the intended purpose **or reasonably foreseeable use** of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their intended purpose **or reasonably foreseeable use**, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended **or foreseeable** to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers **should be** able to process also special categories of personal

detection and correction in relation to high-risk AI systems.

data, as a matter of substantial public interest, in order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems.

Or. en

Amendment 628

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

Proposal for a regulation

Recital 44

Text proposed by the Commission

(44) High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become *the* source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant, representative and free of errors *and* complete in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons *on which* the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent *required* in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers *should be* able to process *also* special categories of personal data, as a

Amendment

(44) High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become *a* source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant, representative and free of errors, *statistically complete and relevant* in view of the intended purpose of the system *and the context of its use*. They should also have the appropriate statistical properties, including as regards the persons or groups of persons *in relation to whom* the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent *necessary* in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. *Solely* in order to protect the right of others from the discrimination that might result from the bias in AI systems,

matter of substantial public interest, in order to ensure *the* bias monitoring, detection and correction in relation to high-risk AI systems.

the providers **should be** able to process special categories of personal data, as a matter of substantial public interest, in order to ensure bias monitoring, detection and correction in relation to high-risk AI systems.

Or. en

Amendment 629

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

Proposal for a regulation Recital 44

Text proposed by the Commission

(44) High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing ***data sets should be sufficiently*** relevant, representative ***and*** free of errors and complete ***in view of the intended purpose of the system***. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, ***training, validation and testing*** data sets should take into account, to the extent required ***in the light of their*** intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. ***In order to protect the right of others from the discrimination that might result from the bias in AI systems, the***

Amendment

(44) High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training ***datasets, and where applicable***, validation and testing ***datasets, including the labels, shall be*** relevant, representative, ***up-to-date, and to the best extent possible***, free of errors and complete. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, data sets ***should*** take into account, to the extent required ***by the*** intended purpose, ***the foreseeable uses and reasonably foreseeable misuses of AI systems with indeterminate uses***, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to

providers should be able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems.

be used.

Or. en

Amendment 630

Marion Walsmann

Proposal for a regulation

Recital 44

Text proposed by the Commission

(44) High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant, representative ***and free of errors and complete*** in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers should be able to process also

Amendment

(44) High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant, representative in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers should be able to process also special categories of

special categories of personal data, as a matter of substantial public interest, in order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems.

personal data, as a matter of substantial public interest, in order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems.

Or. en

Amendment 631

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Brando Benifei

Proposal for a regulation

Recital 44 a (new)

Text proposed by the Commission

Amendment

(44 a) Biases can be inherent in underlying datasets, especially when historical data is being used, introduced by the developers of the algorithms, or generated when the systems are implemented in real world settings. Any result provided by an AI system is necessarily influenced by the quality of the data used, and such inherent biases are inclined to gradually increase and thereby perpetuate and amplify existing discrimination, in particular for persons belonging to certain ethnic groups or racialised communities.

Or. en

Amendment 632

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

Proposal for a regulation

Recital 45

Text proposed by the Commission

Amendment

(45) Pour le développement de systèmes d'IA à haut risque, certains acteurs, tels que les fournisseurs, les organismes

(45) Pour le développement de systèmes d'IA à haut risque, certains acteurs, tels que les fournisseurs, les organismes

notifiés et d'autres entités pertinentes, telles que les pôles d'innovation numérique, les installations d'expérimentation et d'essai et les centres de recherche, devraient être en mesure d'obtenir et d'utiliser des jeux de données de haute qualité dans leurs domaines d'activité respectifs liés au présent règlement. Les espaces européens communs des données créés par la Commission et la facilitation du partage de données d'intérêt public entre les entreprises et avec le gouvernement seront essentiels pour fournir un accès fiable, responsable et non discriminatoire à des données de haute qualité pour l'entraînement, la validation et la mise à l'essai des systèmes d'IA. Par exemple, dans le domaine de la santé, l'espace européen des données de santé facilitera l'accès non discriminatoire aux données de santé et l'entraînement d'algorithmes d'intelligence artificielle à l'aide de ces jeux de données, d'une manière respectueuse de la vie privée, sûre, rapide, transparente et digne de confiance, et avec une gouvernance institutionnelle appropriée. Les autorités compétentes concernées, y compris les autorités sectorielles, qui fournissent ou facilitent l'accès aux données peuvent aussi faciliter la fourniture de données de haute qualité pour l'entraînement, la validation et la mise à l'essai des systèmes d'IA.

notifiés et d'autres entités pertinentes, telles que les pôles d'innovation numérique, les installations d'expérimentation et d'essai et les centres de recherche, devraient être en mesure d'obtenir et d'utiliser des jeux de données de haute qualité dans leurs domaines d'activité respectifs liés au présent règlement. Les espaces européens communs des données créés par la Commission, *conçus et opérés par des acteurs européens et exempts de tout transfert de données hors du territoire ou de la compétence juridique de l'Union européenne*, et la facilitation du partage de données d'intérêt public entre les entreprises et avec le gouvernement seront essentiels pour fournir un accès fiable, responsable et non discriminatoire à des données de haute qualité pour l'entraînement, la validation et la mise à l'essai des systèmes d'IA. Par exemple, dans le domaine de la santé, l'espace européen des données de santé facilitera l'accès non discriminatoire aux données de santé et l'entraînement d'algorithmes d'intelligence artificielle à l'aide de ces jeux de données, d'une manière respectueuse de la vie privée, sûre, rapide, transparente et digne de confiance, et avec une gouvernance institutionnelle appropriée. Les autorités compétentes concernées, y compris les autorités sectorielles, qui fournissent ou facilitent l'accès aux données peuvent aussi faciliter la fourniture de données de haute qualité pour l'entraînement, la validation et la mise à l'essai des systèmes d'IA.

Or. fr

Amendment 633
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 45

Text proposed by the Commission

(45) For the development of high-risk AI systems, certain actors, such as providers, notified bodies and other relevant entities, such as digital innovation hubs, testing experimentation facilities and researchers, should be able to access and use high quality datasets within their respective fields of activities which are related to this Regulation. European common data spaces established by the Commission and the facilitation of data sharing between businesses and with government in the public interest will be instrumental to provide trustful, accountable and non-discriminatory access to high quality data for the training, validation and testing of AI systems. For example, in health, the European health data space will facilitate non-discriminatory access to health data and the training of artificial intelligence algorithms on those datasets, in a privacy-preserving, secure, timely, transparent and trustworthy manner, and with an appropriate institutional governance. Relevant competent authorities, including sectoral ones, providing or supporting the access to data may also support the provision of high-quality data for the training, validation and testing of AI systems.

Amendment

(45) For the development **and assessment** of high-risk AI systems, certain actors, such as providers, notified bodies and other relevant entities, such as digital innovation hubs, testing experimentation facilities and researchers, should be able to access and use high quality datasets within their respective fields of activities which are related to this Regulation. European common data spaces established by the Commission and the facilitation of data sharing between businesses and with government in the public interest will be instrumental to provide trustful, accountable and non-discriminatory access to high quality data for the training, validation and testing of AI systems. For example, in health, the European health data space will facilitate non-discriminatory access to health data and the training of artificial intelligence algorithms on those datasets, in a privacy-preserving, secure, timely, transparent and trustworthy manner, and with an appropriate institutional governance. Relevant competent authorities, including sectoral ones, providing or supporting the access to data may also support the provision of high-quality data for the training, validation and testing of AI systems.

Or. en

Amendment 634

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation
Recital 46

Text proposed by the Commission

(46) Having information on how high-risk AI systems have been developed and how they perform throughout their lifecycle is essential to verify compliance with the requirements under this

Amendment

(46) Having information on how high-risk AI systems have been developed and how they perform throughout their lifecycle is essential to verify compliance with the requirements under this

Regulation. This requires keeping records and the availability of a technical documentation, containing information which is necessary to assess the compliance of the AI system with the relevant requirements. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date.

Regulation. This requires keeping records and the availability of a technical documentation, containing information which is necessary to assess the compliance of the AI system with the relevant requirements. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date.

The required technical documentation may contain trade secrets in accordance with Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure. Possible trade secrets in the required documentation must be treated and kept in accordance with national legislation put in place in accordance with mentioned directive.

Or. en

Amendment 635

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

Proposal for a regulation

Recital 46

Text proposed by the Commission

(46) Having information on how high-risk AI systems have been developed and how they perform throughout their lifecycle is essential to verify compliance with the requirements under this Regulation. This requires keeping records and the availability of a technical documentation, containing information which is necessary to assess the compliance of the AI system with the

Amendment

(46) Having information on how high-risk AI systems have been developed and how they perform throughout their lifecycle is essential to verify compliance with the requirements under this Regulation. This requires keeping records and the availability of a technical documentation, containing information which is necessary to assess the compliance of the AI system with the

relevant requirements. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date.

relevant requirements. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date *throughout the entire lifecycle of the AI system.*

Or. en

Amendment 636

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 46

Text proposed by the Commission

(46) Having information on how high-risk AI systems have been developed and how they perform throughout their *lifecycle* is essential to verify compliance with the requirements under this Regulation. This requires keeping records and the availability of a technical documentation, containing information which is necessary to assess the compliance of the AI system with the relevant requirements. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date.

Amendment

(46) Having information on how high-risk AI systems have been developed and how they perform throughout their *lifetime* is essential to verify compliance with the requirements under this Regulation. This requires keeping records and the availability of a technical documentation, containing information which is necessary to assess the compliance of the AI system with the relevant requirements, *while preserving trade secrets*. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date.

Or. en

Amendment 637

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

Proposal for a regulation
Recital 47

Text proposed by the Commission

(47) To address the opacity that may make certain AI systems incomprehensible to or too complex for natural persons, a certain degree of transparency should be required for high-risk AI systems. *Users* should be able to interpret the *system* output and use it appropriately. High-risk AI systems should therefore be accompanied by relevant documentation and instructions of use and include concise and clear information, including in relation to possible risks to fundamental rights and discrimination, where appropriate.

Amendment

(47) To address the opacity that may make certain AI systems incomprehensible to or too complex for natural persons, a certain degree of transparency should be required for high-risk AI systems. *Deployers* should be able to interpret the *system's goals, priorities and* output and use it appropriately. High-risk AI systems should therefore be accompanied by relevant documentation and instructions of use and include concise and clear information, including in relation to possible risks to fundamental rights and discrimination, where appropriate. *Where individuals are passively subject to AI systems (AI subjects), information to ensure an appropriate type and degree of transparency should be made publicly available, with full respect to the privacy, personality, and related rights of subjects.*

Or. en

Amendment 638

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

Proposal for a regulation
Recital 47 a (new)

Text proposed by the Commission

Amendment

(47 a) It is vital to ensure that the development, deployment and use of AI systems for the judiciary and law enforcement comply with fundamental rights, and are trusted by citizens, as well as in order to ensure that results generated by AI algorithms can be rendered intelligible to users and to those subject to these systems, and that there is transparency on the source data and how the system arrived at a certain conclusion.

To this aim, law enforcement or judiciary authorities in the Union should use only such AI systems whose algorithms and logic are auditable and accessible at least to the police and the judiciary, as well as independent auditors, to allow for their evaluation, auditing and vetting, and such systems should not be closed or labelled as proprietary by the vendors.

Or. en

Amendment 639

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 48

Text proposed by the Commission

(48) High-risk AI systems should be designed and developed in such a way that natural persons *can* oversee their functioning. For this purpose, appropriate human oversight measures should be identified by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints *that cannot be overridden by the system itself and is responsive to the human operator, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role.*

Amendment

(48) High-risk AI systems should be designed and developed in such a way that natural persons *may, when appropriate,* oversee their functioning. For this purpose, *when it brings proven added value to the protection of health, safety and fundamental rights*, appropriate human oversight measures should be identified by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints *and are responsive to the human operator during the expected lifetime of the device where necessary to reduce risks as far as possible and achieve performance in consideration of the generally acknowledged state-of-the-art and technological and scientific progress*, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role. *By way of derogation regarding high-risk AI systems within the scope of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 of the European Parliament and of the*

Council, the established benefit-risk ratio requirements under the sectoral medical device legislation should apply.

Or. en

Amendment 640

Deirdre Clune, Axel Voss, Andreas Schwab

Proposal for a regulation

Recital 48

Text proposed by the Commission

(48) High-risk AI systems should be designed and developed in such a way that natural persons *can* oversee their functioning. For this purpose, appropriate human oversight measures should be identified by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints *that cannot be overridden by the system itself and is* responsive to the human operator, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role.

Amendment

(48) High-risk AI systems should be designed and developed in such a way that natural persons *may, when appropriate,* oversee their functioning. For this purpose, *when it brings proven added value to the protection of health, safety and fundamental rights*, appropriate human oversight measures should be identified by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints *and are* responsive to the human operator *during the expected lifetime of the device where necessary to reduce risks as far as possible and achieve performance in consideration of the generally acknowledged state-of-the-art technological and scientific progress*, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role. *By way of derogation regarding high-risk AI systems within the scope of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 of the European Parliament and of the Council, the established benefit-risk ratio requirements under the sectoral medical device legislation should apply.*

Or. en

Amendment 641

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki

Proposal for a regulation

Recital 48

Text proposed by the Commission

(48) High-risk AI systems should be designed and developed in such a way that natural persons *can* oversee their functioning. For this purpose, appropriate human oversight measures should be identified by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints that cannot be overridden by the system itself and is responsive to the human operator, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role.

Amendment

(48) High-risk AI systems should be designed and developed in such a way that natural persons *may, when appropriate,* oversee their functioning. For this purpose, *when it brings a proven added value to the protection of health, safety and fundamental rights*, appropriate human oversight measures should be identified by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints that cannot be overridden by the system itself and is responsive to the human operator, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role.

Or. en

Amendment 642

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

Proposal for a regulation

Recital 48

Text proposed by the Commission

(48) Les systèmes d'IA à haut risque devraient être conçus et développés de manière à ce que les personnes physiques *pussent contrôler* leur fonctionnement. À cette fin, des mesures appropriées de contrôle humain devraient être établies par

Amendment

(48) Les systèmes d'IA à haut risque devraient être conçus et développés de manière à ce que les personnes physiques *contrôlent effectivement* leur fonctionnement. À cette fin, des mesures appropriées de contrôle humain devraient

le fournisseur du système avant sa mise sur le marché ou sa mise en service. En particulier, le cas échéant, de telles mesures devraient garantir que le système est soumis à des contraintes opérationnelles intégrées qui ne peuvent pas être ignorées par le système lui-même, que le système répond aux ordres de l'opérateur humain et que les personnes physiques auxquelles le contrôle humain a été confié ont les compétences, la formation et l'autorité nécessaires pour s'acquitter de ce rôle.

être établies par le fournisseur du système avant sa mise sur le marché ou sa mise en service. En particulier, le cas échéant, de telles mesures devraient garantir que le système est soumis à des contraintes opérationnelles intégrées qui ne peuvent pas être ignorées par le système lui-même, que le système ***ne peut prendre de décision sans validation de l'opérateur humain, que le système*** répond aux ordres de l'opérateur humain et que les personnes physiques auxquelles le contrôle humain a été confié ont les compétences, la formation et l'autorité nécessaires pour s'acquitter de ce rôle.

Or. fr

Justification

Les systèmes d'I.A. à haut risque ne doivent techniquement pas être capables de prendre une décision sans consigne ou contrôle. Le verbe « pouvoir » laisse penser qu'un tel contrôle est facultatif. Il convient en outre que les opérateurs humains, par ailleurs soumis à un devoir de conformité dans leur utilisation des systèmes d'I.A. à haut risque, ne puissent ignorer l'action de ces systèmes ni se décharger sur eux de la vigilance qui s'impose lors de l'utilisation de tels systèmes, eu égard à leur gravité.

Amendment 643

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

Proposal for a regulation Recital 48

Text proposed by the Commission

(48) High-risk AI systems should be designed and developed in such a way that natural persons can oversee their functioning. For this purpose, appropriate human oversight measures should be ***identified*** by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints that cannot be overridden by the system itself and is

Amendment

(48) High-risk AI systems should be designed and developed in such a way that natural persons can ***meaningfully*** oversee ***and regulate*** their functioning ***or investigate in case of an accident***. For this purpose, appropriate human oversight measures should be ***ensured*** by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints

responsive to the human operator, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role.

that cannot be overridden by the system itself and is responsive to the human operator, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role.

Or. en

Amendment 644

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

Recital 48 a (new)

Text proposed by the Commission

Amendment

(48 a) In order to protect natural persons that are developers or users of AI systems against retaliation from their employers and colleagues, and to prevent misconduct or breaches of this Regulation and other relevant Union law, they should have the right to rely on the whistleblower protections set in Directive (EU) 2019/1937 of the European Parliament and of the Council.

Or. en

Amendment 645

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 49

Text proposed by the Commission

Amendment

(49) High-risk AI systems should perform consistently throughout their *lifecycle* and meet an appropriate level of accuracy, robustness and cybersecurity in accordance with the generally acknowledged state of the art. The level of

(49) High-risk AI systems should perform consistently throughout their *lifetime* and meet an appropriate level of accuracy, robustness and cybersecurity in accordance with the generally acknowledged state of the art. The level of

accuracy and accuracy metrics should be communicated to the users.

accuracy and accuracy metrics should be communicated to the users. *While standardisation organisations exist to establish standards, coordination on benchmarking is needed to establish how these standards should be met and measured. The European Artificial Intelligence Board should bring together national metrology and benchmarking authorities and provide guidance to address the technical aspects of how to measure the appropriate levels of accuracy and robustness. Their work should not be seen as a replacement of the standardisation organisations, but as a complementary function to provide specific technical expertise on measurement.*

Or. en

Amendment 646

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

Proposal for a regulation Recital 49

Text proposed by the Commission

(49) Les systèmes d'IA à haut risque devraient produire des résultats d'une qualité constante tout au long de leur cycle de vie et assurer un niveau approprié d'exactitude, de robustesse et de cybersécurité conformément à l'état de la technique généralement reconnu. Le degré d'exactitude et les critères de mesure de l'exactitude devraient être communiqués aux utilisateurs.

Amendment

(49) Les systèmes d'IA à haut risque devraient produire des résultats d'une qualité constante tout au long de leur cycle de vie et assurer un niveau approprié d'exactitude, de robustesse et de cybersécurité conformément à l'état de la technique généralement reconnu. Le degré d'exactitude et les critères de mesure de l'exactitude devraient être *définis par de normes ou des spécifications techniques communes et être* communiqués aux utilisateurs. *La Commission européenne devrait avoir la faculté de déterminer de telles normes ou spécifications techniques communes, ou de se les approprier si elles ont été élaborées par des tiers tels que des fournisseurs, des parties prenantes ou des*

organismes de normalisation.

Or. fr

Amendment 647

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

Proposal for a regulation

Recital 49

Text proposed by the Commission

(49) High-risk AI systems should perform consistently throughout their lifecycle and meet an appropriate level of accuracy, robustness **and cybersecurity** in accordance with the generally acknowledged state of the art. The level of accuracy and accuracy metrics should be communicated to the **users**.

Amendment

(49) High-risk AI systems should perform consistently throughout their lifecycle and meet an appropriate level of accuracy, robustness, **reliability and security** in accordance with the generally acknowledged state of the art. The level of accuracy and accuracy metrics should be communicated to the **deployers**.

Or. en

Amendment 648

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

Proposal for a regulation

Recital 50

Text proposed by the Commission

(50) **The** technical robustness is a key requirement for high-risk AI systems. They should be resilient against risks connected to the limitations of the system (e.g. errors, faults, inconsistencies, unexpected situations) as well as against malicious actions that may compromise the security of the AI system and result in harmful or otherwise undesirable behaviour. Failure to protect against these risks could lead to safety impacts or negatively affect **the** fundamental rights, for example due to erroneous decisions or wrong or biased

Amendment

(50) Technical robustness is a key requirement for high-risk AI systems. They should be resilient against risks connected to the limitations of the system (e.g. errors, faults, inconsistencies, unexpected situations) as well as **adequately protected** against malicious actions that may compromise the security of the AI system and result in harmful or otherwise undesirable behaviour. Failure to protect against these risks could lead to safety impacts or negatively affect fundamental rights, for example due to erroneous

outputs generated by the AI system.

decisions or wrong or biased outputs generated by the AI system.

Or. en

Amendment 649

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 51

Text proposed by the Commission

(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can leverage AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, *suitable* measures should therefore be taken by the providers of high-risk AI systems, *also taking into account as* appropriate *the* underlying ICT infrastructure.

Amendment

(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can leverage AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, *state-of-the-art* measures should therefore be taken *into account* by the providers of high-risk AI systems *but also by the national competent authorities, market surveillance authorities and notified bodies that are accessing the data of providers of high-risk AI systems, next to* appropriate underlying ICT infrastructure. *It should be further taken into account that AI in the form of machine learning is a critical defence against malware representing a legitimate interest of the AI user.*

Or. en

Amendment 650

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan, Vincenzo Sofo

Proposal for a regulation

Recital 51

Text proposed by the Commission

(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can leverage AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, suitable measures should therefore be taken by the providers of high-risk AI systems, also taking into account as appropriate the underlying ICT infrastructure.

Amendment

(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can leverage AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, suitable measures should therefore be taken by the providers of high-risk AI systems, *as well as the notified bodies, competent national authorities and market surveillance authorities accessing the data of providers of high-risk AI systems*, also taking into account as appropriate the underlying ICT infrastructure.

Or. en

Amendment 651

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 51

Text proposed by the Commission

(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can leverage AI specific assets,

Amendment

(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can leverage AI specific assets,

such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, suitable measures should therefore be taken by the providers of high-risk AI systems, also taking into account as appropriate the underlying ICT infrastructure.

such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, suitable measures should therefore be taken by the providers of high-risk AI systems, *as well as the notified bodies, competent national authorities and market surveillance authorities*, also taking into account as appropriate the underlying ICT infrastructure.

Or. en

Amendment 652
Karlo Ressler

Proposal for a regulation
Recital 51

Text proposed by the Commission

(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can leverage AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, suitable measures should therefore be taken by the providers of high-risk AI systems, also taking into account as appropriate the underlying ICT infrastructure.

Amendment

(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can leverage AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, suitable measures should therefore be taken by the providers of high-risk AI systems, *as well as the competent public authorities accessing the data of providers of high-risk AI systems*, also taking into account as appropriate the underlying ICT infrastructure.

Amendment 653

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

Proposal for a regulation

Recital 51

Text proposed by the Commission

(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can *leverage* AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, suitable measures should therefore be taken by the providers of high-risk AI systems, also taking into account as appropriate the underlying ICT infrastructure.

Amendment

(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can *target* AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, suitable measures should therefore be taken by the providers of high-risk AI systems, also taking into account as appropriate the underlying ICT infrastructure.

Amendment 654

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

Proposal for a regulation

Recital 51

Text proposed by the Commission

(51) La cybersécurité joue un rôle crucial pour garantir la résilience des systèmes d'IA face aux tentatives de détourner leur utilisation, leur

Amendment

(51) La cybersécurité joue un rôle crucial pour garantir la résilience des systèmes d'IA face aux tentatives de détourner leur utilisation, leur

comportement, leurs performances ou de compromettre leurs propriétés de sûreté par des tiers malveillants exploitant les vulnérabilités du système. Les cyberattaques contre les systèmes d'IA peuvent faire usage de ressources spécifiques à l'IA, telles que des jeux de données d'entraînement (par exemple l'empoisonnement de données) ou des modèles entraînés (par exemple les attaques adversaires), ou exploiter les vulnérabilités des ressources numériques du système d'IA ou de l'infrastructure TIC sous-jacente. Pour garantir un niveau de cybersécurité adapté aux risques, des mesures appropriées devraient donc être prises par les fournisseurs de systèmes d'IA à haut risque, en tenant également compte, *si nécessaire*, de l'infrastructure TIC sous-jacente.

comportement, leurs performances ou de compromettre leurs propriétés de sûreté par des tiers malveillants exploitant les vulnérabilités du système. Les cyberattaques contre les systèmes d'IA peuvent faire usage de ressources spécifiques à l'IA, telles que des jeux de données d'entraînement (par exemple l'empoisonnement de données) ou des modèles entraînés (par exemple les attaques adversaires), ou exploiter les vulnérabilités des ressources numériques du système d'IA ou de l'infrastructure TIC sous-jacente. Pour garantir un niveau de cybersécurité adapté aux risques, des mesures appropriées devraient donc être prises par les fournisseurs de systèmes d'IA à haut risque, en tenant également compte de l'infrastructure TIC sous-jacente.

Or. fr

Amendment 655

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

Proposal for a regulation

Recital 53

Text proposed by the Commission

(53) Il convient qu'une personne physique ou morale spécifique, définie comme étant le fournisseur, assume la responsabilité de la mise sur le marché ou de la mise en service d'un système d'IA à haut risque, indépendamment du fait que cette personne physique ou morale soit ou non la personne qui a conçu ou développé le système.

Amendment

(53) Il convient qu'une personne physique ou morale spécifique, définie comme étant le fournisseur, assume la responsabilité de la mise sur le marché ou de la mise en service d'un système d'IA à haut risque, indépendamment du fait que cette personne physique ou morale soit ou non la personne qui a conçu ou développé le système, *sans préjudice du droit pour un fournisseur de se retourner contre le fabricant dudit système*.

Or. fr

Amendment 656

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

Proposal for a regulation

Recital 53

Text proposed by the Commission

(53) It is appropriate that a specific natural or legal person, defined as the provider, takes the responsibility for the placing on the market *or* putting into service of a high-risk AI system, regardless of whether that natural or legal person is the person who designed or developed the system.

Amendment

(53) It is appropriate that a specific natural or legal person, defined as the provider, takes the responsibility for the placing on the market, putting into service *or deploying* of a high-risk AI system, regardless of whether that natural or legal person is the person who designed or developed the system.

Or. en

Amendment 657

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

Proposal for a regulation

Recital 54

Text proposed by the Commission

(54) The provider should establish a sound quality management system, ensure the accomplishment of the required conformity assessment procedure, draw up the relevant documentation and establish a robust post-market monitoring system. Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in question.

Amendment

(54) The provider *and, where applicable, deployer* should establish a sound quality management system, ensure the accomplishment of the required conformity assessment procedure, draw up the relevant documentation and establish a robust post-market monitoring system. Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in question. *Deployers should have strategies in place to ensure that the data management, including data acquisition,*

data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data during the deployment lifetime of high-risk AI systems, complies with applicable rules and ensure regulatory compliance, in particular regarding modifications to the high-risk AI systems.

Or. en

Amendment 658

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Recital 54

Text proposed by the Commission

(54) The provider should establish a sound quality management system, ensure the accomplishment of the required conformity assessment procedure, draw up the relevant documentation and establish a robust post-market monitoring system. Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in question.

Amendment

(54) The provider should establish a sound quality management system, ensure the accomplishment of the required conformity assessment procedure, draw up the relevant documentation *in the language of the Member State concerned* and establish a robust post-market monitoring system. *All elements, from design to future development, must be transparent for the user.* Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in question.

Or. en

Amendment 659

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Recital 54

Text proposed by the Commission

(54) The provider should establish a sound quality management system, ensure the accomplishment of the required conformity assessment procedure, draw up the relevant documentation and establish a robust post-market monitoring system. Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in question.

Amendment

(54) *Unless the provider has already implemented a risk management system warranting quality and conformity*, the provider should establish a sound quality management system, ensure the accomplishment of the required conformity assessment procedure, draw up the relevant documentation and establish a robust post-market monitoring system. Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in question.

Or. en

Amendment 660

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

Proposal for a regulation

Recital 54

Text proposed by the Commission

(54) The provider should establish a sound quality management system, ensure the accomplishment of the required conformity assessment procedure, draw up the relevant documentation and establish a robust post-market monitoring system. Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the

Amendment

(54) *In case there are no risk management systems already in place*, the provider should establish a sound quality management system, ensure the accomplishment of the required conformity assessment procedure, draw up the relevant documentation and establish a robust post-market monitoring system. Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national

sector and the competences and organisation of the public authority in question.

or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in question.

Or. en

Amendment 661

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

Proposal for a regulation

Recital 56

Text proposed by the Commission

(56) To enable enforcement of this Regulation and create a level-playing field for operators, and taking into account the different forms of making available of digital products, it is important to ensure that, under all circumstances, a person established in the Union can provide authorities with all the necessary information on the compliance of an AI system. Therefore, prior to ***making their AI systems available in*** the Union, where an importer cannot be identified, ***providers*** established outside the Union ***shall***, by written mandate, appoint ***an authorised*** representative established in the Union.

Amendment

(56) To enable enforcement of this Regulation and create a level-playing field for operators, and taking into account the different forms of making available of digital products, it is important to ensure that, under all circumstances, a person established in the Union can provide authorities with all the necessary information on the compliance of an AI system. Therefore, prior to ***placing any AI system on*** the Union ***market, putting it into service or using it***, where an importer cannot be identified, ***operators*** established outside the Union ***should***, by written mandate, appoint ***a legal*** representative established in the Union. ***The legal representative should act on behalf of the operator and may be addressed by any competent authorities for the purpose of this Regulation. The designation of such a legal representative does not affect the responsibility or liability of the operator under this Regulation. Such a legal representative should perform its tasks according to the mandate received from the operator, including cooperating with the national supervisory authorities with regard to any action taken to ensure compliance with this Regulation. The designated legal representative should be subject to enforcement proceedings in the***

event of non-compliance by the operator.

Or. en

Amendment 662

Svenja Hahn, Drago Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Recital 56

Text proposed by the Commission

(56) To enable enforcement of this Regulation and create a level-playing field for operators, and taking into account the different forms of making available of digital products, it is important to ensure that, under all circumstances, a person established in the Union can provide authorities with all the necessary information on the compliance of an AI system. Therefore, prior to making their AI systems available in the Union, ***where an importer cannot be identified***, providers established outside the Union shall, by written mandate, appoint an authorised representative established in the Union.

Amendment

(56) To enable enforcement of this Regulation and create a level-playing field for operators, and taking into account the different forms of making available of digital products, it is important to ensure that, under all circumstances, a person established in the Union can provide authorities with all the necessary information on the compliance of an AI system. Therefore, prior to making their AI systems available in the Union, providers established outside the Union shall, by written mandate, appoint an authorised representative established in the Union.

Or. en

Amendment 663

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Sophia in 't Veld, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Morten Løkkegaard, Ró a Thun und Hohenstein, Alin Mituță

Proposal for a regulation

Recital 58

Text proposed by the Commission

(58) Given the nature of AI systems and the risks to safety and fundamental rights possibly associated with their use, including as regard the need to ensure

Amendment

(58) Given the nature of AI systems and the risks to safety and fundamental rights possibly associated with their use, including as regard the need to ensure

proper monitoring of the performance of an AI system in a real-life setting, it is appropriate to set specific responsibilities for users. Users should in particular use high-risk AI systems in accordance with the instructions of use and certain other obligations should be provided for with regard to monitoring of the functioning of the AI systems and with regard to record-keeping, as appropriate.

proper monitoring of the performance of an AI system in a real-life setting, it is appropriate to set specific responsibilities for users. Users should in particular use high-risk AI systems in accordance with the instructions of use and certain other obligations should be provided for with regard to monitoring of the functioning of the AI systems and with regard to record-keeping, as appropriate. *Given the potential impact and the need for democratic oversight and scrutiny, users of high-risk AI systems that are public authorities or Union institutions, bodies, offices and agencies should be required to conduct a fundamental rights impact assessment prior to commencing the use of a high-risk AI system should be required to register the use of any high-risk AI systems in a public database.*

Or. en

Amendment 664

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

Proposal for a regulation

Recital 58

Text proposed by the Commission

(58) Compte tenu de la nature des systèmes d'IA et des risques pour la sécurité et les droits fondamentaux potentiellement associés à leur utilisation, notamment en ce qui concerne la nécessité d'assurer un suivi adéquat des performances d'un système d'IA dans un contexte réel, il convient de définir des responsabilités spécifiques pour les utilisateurs. Les utilisateurs devraient en particulier être tenus d'utiliser les systèmes *d'IA* à haut risque conformément à la notice d'utilisation, et certaines autres obligations devraient être prévues en ce qui concerne la surveillance du fonctionnement des systèmes d'IA et la tenue de registres,

Amendment

(58) Compte tenu de la nature des systèmes d'IA et des risques pour la sécurité et les droits fondamentaux potentiellement associés à leur utilisation, notamment en ce qui concerne la nécessité d'assurer un suivi adéquat des performances d'un système d'IA dans un contexte réel, il convient de définir des responsabilités spécifiques pour les utilisateurs. Les utilisateurs devraient en particulier être tenus d'utiliser les systèmes *d'I.A.* à haut risque conformément à *leur finalité et à la notice d'utilisation, les systèmes d'I.A. à haut risque devraient, à cette fin, limiter structurellement et autant que possible la possibilité technique pour*

selon le cas.

*un utilisateur d'utiliser ces systèmes d'IA.
d'une autre manière*, et certaines autres obligations devraient être prévues en ce qui concerne la surveillance du fonctionnement des systèmes d'IA et la tenue de registres, selon le cas.

Or. fr

Amendment 665

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

Proposal for a regulation Recital 58

Text proposed by the Commission

(58) Given the nature of AI systems and the risks to safety and fundamental rights possibly associated with their use, including as *regard* the need to ensure proper monitoring of the performance of an AI system in a real-life setting, it is appropriate to set specific responsibilities for *users*. *Users* should in particular use high-risk AI systems in accordance with the instructions of use and certain other obligations should be provided for with regard to monitoring of the functioning of the AI systems and with regard to record-keeping, as appropriate.

Amendment

(58) Given the nature of AI systems and the risks to safety and fundamental rights possibly associated with their use, including as *regards* the need to ensure proper monitoring of the performance of an AI system in a real-life setting, it is appropriate to set specific responsibilities for *deployers*. *Deployers* should in particular use high-risk AI systems in accordance with the instructions of use and certain other obligations should be provided for with regard to monitoring of the functioning of the AI systems and with regard to record-keeping *and quality management*, as appropriate.

Or. en

Amendment 666

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 Recital 58 a (new)

Text proposed by the Commission

Amendment

(58 a) Whilst risks related to AI systems can generate from the way such systems are designed, risks can as well stem from how such AI systems are used. Users of high-risk AI system therefore play a critical role in ensuring that fundamental rights are protected, complementing the obligations of the provider when developing the AI system. Users are best placed to understand how the high-risk AI system will be used concretely and can therefore identify potential risks that were not foreseen in the development phase, thanks to a more precise knowledge of the context of use, the people or groups of people likely to be affected, including marginalised and vulnerable groups. In order to efficiently ensure that fundamental rights are protected, the user of high-risk AI systems should therefore carry out a fundamental rights impact assessment on how it intends to use such AI systems, and prior to putting it into use. The impact assessment should be accompanied by a detailed plan describing the measures or tools that will help mitigating the risks to fundamental rights identified. When performing this impact assessment, the user should notify the national supervisory authority, the market surveillance authority as well as relevant stakeholders. It should also involve representatives of groups of persons likely to be affected by the AI system in order to collect relevant information which is deemed necessary to perform the impact assessment.

Or. en

Amendment 667

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

Proposal for a regulation

Recital 58 a (new)

Text proposed by the Commission

Amendment

(58 a) To ensure that fundamental rights, the environment and the public interest are effectively protected where an AI-system is classified as high-risk under Annex III, both producers and deployers before each deployment should perform a fundamental rights impact assessment of the systems' impact in the context of use throughout the entire lifecycle and include measures to mitigate any impact on fundamental rights, the environment or the public interest. The fundamental rights impact assessment should be registered in the public EU database for stand-alone high-risk AI systems and be publicly accessible. The supervisory authority should have the power to review these fundamental rights impact assessments.

Or. en

Amendment 668

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

Proposal for a regulation

Recital 58 a (new)

Text proposed by the Commission

Amendment

(58 a) Risks for people affected by AI systems often arise from uses of an AI system in a specific context and with respect to a specific group of people, and might not always be foreseeable for the provider. Therefore, prior to putting a high-risk AI system into use, the user should conduct an assessment of the system's impact on the fundamental rights in particular, within the context of use, and publish the results.

Or. en

Amendment 669

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

Proposal for a regulation**Recital 59***Text proposed by the Commission*

(59) Il convient d'envisager que l'utilisateur du système d'IA soit la personne physique ou morale, l'autorité publique, l'agence ou tout autre organisme sous l'autorité duquel le système d'IA est exploité, *sauf lorsque l'utilisation s'inscrit dans le cadre d'une activité personnelle à caractère non professionnel.*

Amendment

(59) Il convient d'envisager que l'utilisateur du système d'IA soit la personne physique ou morale, l'autorité publique, l'agence ou tout autre organisme sous l'autorité duquel le système d'IA est exploité.

Or. fr

Amendment 670

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

Proposal for a regulation**Recital 59***Text proposed by the Commission*

(59) It is appropriate to envisage that the *user* of the AI system should be the natural or legal person, public authority, agency or other body under whose authority the AI system is operated except where the use is made in the course of a personal non-professional activity.

Amendment

(59) It is appropriate to envisage that the *deployer* of the AI system should be the natural or legal person, public authority, agency or other body under whose authority the AI system is operated except where the use is made in the course of a personal non-professional activity.

Or. en

Amendment 671

Axel Voss, Deirdre Clune

Proposal for a regulation**Recital 60**

Text proposed by the Commission

(60) In the light of the complexity of the artificial intelligence value chain, relevant third parties, notably the ones involved in the sale and the supply of software, software tools and components, pre-trained models and data, or providers of network services, should cooperate, as appropriate, with providers and users to enable their compliance with the obligations under this Regulation and with competent authorities established under this Regulation.

Amendment

(60) In the light of the complexity of the artificial intelligence value chain, relevant third parties, notably the ones involved in the sale and the supply of software, software tools and components, pre-trained models and data, or providers of network services, should cooperate, as appropriate, with providers and users to enable their compliance with the obligations under this Regulation and with competent authorities established under this Regulation. *This provision shall qualify as a legal obligation in the context of the processing of personal data where necessary for the cooperation between the relevant providers.*

Or. en

Amendment 672

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

Proposal for a regulation

Recital 60

Text proposed by the Commission

(60) In the light of the complexity of the artificial intelligence value chain, relevant third parties, notably the ones involved in the sale and the supply of software, software tools and components, pre-trained models and data, or providers of network services, should cooperate, as appropriate, with providers and **users** to enable their compliance with the obligations under this Regulation and with competent authorities established under this Regulation.

Amendment

(60) In the light of the complexity of the artificial intelligence value chain, relevant third parties, notably the ones involved in the sale and the supply of software, software tools and components, pre-trained models and data, or providers of network services, should cooperate, as appropriate, with providers and **deployers** to enable their compliance with the obligations under this Regulation and with competent authorities established under this Regulation.

Or. en

Amendment 673

**Proposal for a regulation
Recital 61**

Text proposed by the Commission

(61) La normalisation devrait jouer un rôle essentiel pour fournir des solutions techniques aux fournisseurs afin de garantir la conformité avec présent règlement. *Le respect des normes harmonisées telles que définies dans le règlement (UE) n° 1025/2012 du Parlement européen et du Conseil⁵⁴ devrait être un moyen pour les fournisseurs de démontrer la conformité aux exigences du présent règlement.* Cependant, la Commission pourrait adopter des spécifications techniques communes dans les domaines où il n'existe pas de normes harmonisées ou où elles sont insuffisantes.

Amendment

(61) La normalisation devrait jouer un rôle essentiel pour fournir des solutions techniques aux fournisseurs afin de garantir la conformité avec présent règlement, *notamment en ce qui concerne les niveaux et les métriques d'exactitude et de robustesse auxquels sont soumis les systèmes d'I.A. à haut risque.* La Commission *devrait pouvoir* adopter des spécifications techniques communes dans les domaines où il n'existe pas de normes harmonisées ou où elles sont insuffisantes. *Elle devrait également pouvoir s'approprier les normes ou les spécifications techniques communes élaborées par des tiers tels que des fournisseurs, des parties prenantes ou des organismes de normalisation.* *Le respect des spécifications techniques communes adoptées par la Commission devrait être un moyen pour les fournisseurs de démontrer la conformité aux exigences du présent règlement.* *Le respect des autres normes harmonisées telles que définies dans le règlement (UE) n° 1025/2012 du Parlement européen et du Conseil⁵⁴ devrait également contribuer à la démonstration par les fournisseurs de la conformité aux exigences du présent règlement, sans disposer d'une force probante identique à celle des spécifications techniques communes adoptées par la Commission.*

⁵⁴ Règlement (UE) n° 1025/2012 du Parlement européen et du Conseil du 25 octobre 2012 relatif à la normalisation européenne, modifiant les directives 89/686/CEE et 93/15/CEE du Conseil ainsi que les directives 94/9/CE, 94/25/CE, 95/16/CE, 97/23/CE, 98/34/CE,

⁵⁴ Règlement (UE) n° 1025/2012 du Parlement européen et du Conseil du 25 octobre 2012 relatif à la normalisation européenne, modifiant les directives 89/686/CEE et 93/15/CEE du Conseil ainsi que les directives 94/9/CE, 94/25/CE, 95/16/CE, 97/23/CE, 98/34/CE,

2004/22/CE, 2007/23/CE, 2009/23/CE et 2009/105/CE du Parlement européen et du Conseil et abrogeant la décision 87/95/CEE du Conseil et la décision n° 1673/2006/CE du Parlement européen et du Conseil (JO L 316 du 14.11.2012, p. 12).

2004/22/CE, 2007/23/CE, 2009/23/CE et 2009/105/CE du Parlement européen et du Conseil et abrogeant la décision 87/95/CEE du Conseil et la décision n° 1673/2006/CE du Parlement européen et du Conseil (JO L 316 du 14.11.2012, p. 12).

Or. fr

Amendment 674

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation Recital 61

Text proposed by the Commission

(61) Standardisation should play a key role to provide technical solutions to providers to ensure compliance with this Regulation. Compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council⁵⁴ should be a means for providers to demonstrate conformity with the requirements of this Regulation. However, the Commission could adopt common technical specifications in areas where no harmonised standards exist or where they are insufficient.

Amendment

(61) Standardisation should play a key role to provide technical solutions to providers to ensure compliance with this Regulation. Compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council⁵⁴ should be a means for providers to demonstrate conformity with the requirements of this Regulation. However, the Commission could adopt common technical specifications in areas where no harmonised standards exist *and are not expected to be published within a reasonable period* or where they are insufficient, *only after consulting the Artificial Intelligence Board, the European standardisation organisations as well as the relevant stakeholders. The Commission should duly justify why it decided not to use harmonised standards.*

⁵⁴ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC

⁵⁴ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC

of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

Or. en

Amendment 675

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Recital 61

Text proposed by the Commission

(61) Standardisation should play a key role to provide technical solutions to providers to ensure compliance with this Regulation. Compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council⁵⁴ should be a means for providers to demonstrate conformity with the requirements of this Regulation. However, the Commission *could* adopt common technical specifications in areas where no harmonised standards exist or where they are insufficient.

Amendment

(61) Standardisation should play a key role to provide technical solutions to providers to ensure compliance with this Regulation. Compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council⁵⁴ should be a means for providers to demonstrate conformity with the requirements of this Regulation. However, *in exceptional cases, where industry and technical experts consider that pressing and specific safety or fundamental rights concerns cannot be addressed by established standardisation processes*, the Commission *may* adopt common technical specifications in areas where no harmonised standards exist or where they are *evidently* insufficient.

⁵⁴ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No

⁵⁴ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No

1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

Or. en

Amendment 676

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

Proposal for a regulation

Recital 61 a (new)

Text proposed by the Commission

Amendment

(61 a) As part of the new legal framework on corporate sustainable reporting and due diligence, minimum common standards for the reporting of businesses on the societal and environmental impacts of the AI systems that they develop, sell or distribute should be established and used at an early stage of the development and life-cycle of AI systems. Such common standard obligations should notably consist of mandatory human rights due diligence rules, thus enabling a level-playing field among European businesses and non-European businesses operating in the EU.

Or. en

Amendment 677

Jörgen Warborn, Tomas Tobé, Arba Kokalari

Proposal for a regulation

Recital 61 a (new)

Text proposed by the Commission

Amendment

(61 a) Striving for regulatory alignment on AI with likeminded global partners is key to fostering mutual innovation and cross-border partnerships within the field of AI. Coordination with international

standardisation bodies is therefore of great importance.

Or. en

Amendment 678

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 62

Text proposed by the Commission

(62) In order to ensure a high level of trustworthiness of high-risk AI systems, those systems should be subject to a conformity assessment prior to their placing on the market or putting into service.

Amendment

(62) In order to ensure a high level of trustworthiness of high-risk AI systems, those systems should be subject to a conformity assessment prior to their placing on the market or putting into service. *AI systems, including general purpose AI systems, that may not necessarily be high-risk, are frequently used as components of other AI or non-AI software systems. In order to increase trust in the value chain and to give certainty to businesses about the performance of their systems, providers may voluntarily apply for a third-party conformity assessment.*

Or. en

Amendment 679

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

Proposal for a regulation

Recital 62

Text proposed by the Commission

(62) In order to ensure a high level of trustworthiness of high-risk AI systems, those systems should be subject to a conformity assessment prior to their placing on the market or putting into service.

Amendment

(62) In order to ensure a high level of trustworthiness of high-risk AI systems, those systems should be subject to a *third party* conformity assessment prior to their placing on the market or putting into service.

Amendment 680

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

Proposal for a regulation**Recital 63***Text proposed by the Commission*

(63) Afin de réduire au minimum la charge pesant sur les opérateurs et d'éviter les éventuels doubles emplois, la conformité avec les exigences du présent règlement des systèmes d'IA à haut risque liés à des produits couverts par la législation d'harmonisation existante de l'Union relevant du nouveau cadre législatif devrait être évaluée dans le cadre de l'évaluation de la conformité déjà prévue en vertu de cette législation. L'applicabilité des exigences du présent règlement ne devrait donc pas avoir d'incidence sur la logique, la méthode ou la structure générale propres à l'évaluation de la conformité au titre des actes législatifs spécifiques pertinents relevant du nouveau cadre législatif. Cette approche se reflète parfaitement dans l'interaction entre le présent règlement et le [règlement relatif aux machines et équipements]. Les exigences du présent règlement traitent des risques pour la sécurité posés par les systèmes d'IA assurant les fonctions de sécurité des machines, tandis que certaines exigences spécifiques du [règlement relatif aux machines et équipements] garantiront l'intégration sûre du système d'IA dans la machine de façon à ne pas compromettre la sécurité de la machine dans son ensemble. Le [règlement relatif aux machines et équipements] applique la même définition pour le système d'IA que le présent règlement.

Amendment

(63) Afin de réduire au minimum la charge pesant sur les opérateurs et d'éviter les éventuels doubles emplois, la conformité avec les exigences du présent règlement des systèmes d'IA à haut risque liés à des produits couverts par la législation d'harmonisation existante de l'Union relevant du nouveau cadre législatif devrait être évaluée dans le cadre de l'évaluation de la conformité déjà prévue en vertu de cette législation. L'applicabilité des exigences du présent règlement ne devrait donc pas avoir d'incidence sur la logique, la méthode ou la structure générale propres à l'évaluation de la conformité au titre des actes législatifs spécifiques pertinents relevant du nouveau cadre législatif. Cette approche se reflète parfaitement dans l'interaction entre le présent règlement et le [règlement relatif aux machines et équipements]. Les exigences du présent règlement traitent des risques pour la sécurité posés par les systèmes d'IA assurant les fonctions de sécurité des machines, tandis que certaines exigences spécifiques du [règlement relatif aux machines et équipements] garantiront l'intégration sûre du système d'IA dans la machine de façon à ne pas compromettre la sécurité de la machine dans son ensemble. Le [règlement relatif aux machines et équipements] applique la même définition pour le système d'IA que le présent règlement. *Toutefois, par hypothèse, dans le cas où le présent règlement et un autre acte législatif de l'Union porteraient sur le même produit ou élément de produit et*

emploieraient des définitions divergentes ou prévoiraient des obligations de sécurité différentes, le texte applicable devrait être celui qui propose la définition ou les obligations de sécurité les plus protectrices pour les personnes, les États membres, la société et les droits fondamentaux.

Or. fr

Amendment 681

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

Recital 64

Text proposed by the Commission

Amendment

(64) Given the more extensive experience of professional pre-market certifiers in the field of product safety and the different nature of risks involved, it is appropriate to limit, at least in an initial phase of application of this Regulation, the scope of application of third-party conformity assessment for high-risk AI systems other than those related to products. Therefore, the conformity assessment of such systems should be carried out as a general rule by the provider under its own responsibility, with the only exception of AI systems intended to be used for the remote biometric identification of persons, for which the involvement of a notified body in the conformity assessment should be foreseen, to the extent they are not prohibited.

deleted

Or. en

Amendment 682

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

Garraud

Proposal for a regulation

Recital 64

Text proposed by the Commission

(64) Étant donné l'expérience plus étendue des organismes professionnels de certification avant mise sur le marché dans le domaine de la sécurité des produits et de la nature différente des risques encourus, il convient de *limiter, au moins dans une phase initiale d'application du présent règlement, le champ d'application des évaluations de la conformité réalisées par un tiers aux systèmes d'IA à haut risque autres que ceux liés à des produits.* Par conséquent, l'évaluation de la conformité de ces systèmes devrait en règle générale être réalisée par le fournisseur sous sa propre responsabilité, à la seule exception des systèmes d'IA destinés à être utilisés pour l'identification biométrique à distance de personnes, pour lesquels l'intervention d'un organisme notifié dans l'évaluation de la conformité devrait être prévue, pour autant qu'ils ne soient pas interdits.

Amendment

(64) Étant donné l'expérience plus étendue des organismes professionnels de certification avant mise sur le marché dans le domaine de la sécurité des produits et de la nature différente des risques encourus, il convient de *leur permettre d'effectuer* l'évaluation de la conformité des systèmes d'IA, y compris les systèmes d'IA à haut risque, en qualité d'organismes notifiés, pour autant que ces systèmes ne soient pas interdits.

Or. fr

Amendment 683

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Recital 64

Text proposed by the Commission

(64) Given the more extensive experience of professional pre-market certifiers in the field of product safety and the different nature of risks involved, it is appropriate to limit, at least in an initial phase of application of this Regulation, the

Amendment

(64) Given the more extensive experience of professional pre-market certifiers in the field of product safety and the different nature of risks involved, it is appropriate to limit, at least in an initial phase of application of this Regulation, the

scope of application of third-party conformity assessment for high-risk AI systems other than those related to products. Therefore, the conformity assessment of such systems should be carried out as a general rule by the provider under its own responsibility, with the *only* exception of AI systems intended to be used for the remote biometric identification of persons, *for which* the involvement of a notified body in the conformity assessment should be foreseen, to the extent they are not prohibited.

scope of application of third-party conformity assessment for high-risk AI systems other than those related to products. Therefore, the conformity assessment of such systems should be carried out as a general rule by the provider under its own responsibility, with the exception of AI systems intended to be used for the remote biometric identification of persons *and AI systems intended to be used to make inferences on the basis of biometric data that produce legal effects or affect the rights and freedoms of natural persons. For those types of AI systems* the involvement of a notified body in the conformity assessment should be foreseen, to the extent they are not prohibited..

Or. en

Amendment 684

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

Proposal for a regulation

Recital 64

Text proposed by the Commission

(64) Given the more extensive experience of professional pre-market certifiers in the field of product safety and the different nature of risks involved, it is *appropriate to limit, at least in an initial phase of* application of this Regulation, the *scope of* application of third-party conformity assessment for high-risk AI systems other than those related to products. Therefore, the conformity assessment of such systems should be carried out as a general rule by the provider under its own responsibility, *with the only exception of AI systems intended to be used for the remote biometric identification of persons, for which the involvement of a notified body in the conformity assessment should be*

Amendment

(64) Given the more extensive experience of professional pre-market certifiers in the field of product safety and the different nature of risks involved, it is *essential to ensure, particularly in the period before* application of this Regulation, the *development of adequate capacity for the* application of third-party conformity assessment for high-risk AI systems other than those related to products. Therefore, the conformity assessment of such systems should be carried out as a general rule by the provider under its own responsibility.

foreseen, to the extent they are not prohibited.

Or. en

Amendment 685

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Recital 64

Text proposed by the Commission

(64) Given the more extensive experience of professional pre-market certifiers in the field of product safety and the different nature of risks involved, it is appropriate to limit, at least in an initial phase of application of this Regulation, the scope of application of third-party conformity assessment for high-risk AI systems other than those related to products. Therefore, the conformity assessment of such systems should be carried out as a general rule by the provider under its own responsibility, with the only exception of AI systems intended to be used for the remote biometric identification of persons, for which the involvement of a notified body in the conformity assessment should be foreseen, *to the extent they are not prohibited.*

Amendment

(64) Given the more extensive experience of professional pre-market certifiers in the field of product safety and the different nature of risks involved, it is appropriate to limit, at least in an initial phase of application of this Regulation, the scope of application of third-party conformity assessment for high-risk AI systems other than those related to products. Therefore, the conformity assessment of such systems should be carried out as a general rule by the provider under its own responsibility, with the only exception of AI systems intended to be used for the remote biometric identification of persons, for which the involvement of a notified body in the conformity assessment should be foreseen.

Or. en

Justification

Instead of blanketly banning the law enforcement's use of facial recognition AI, these systems should be incorporated in the list of high-risk AI systems and subject to strict control. Such modern AI software can process information and images at lightning speed and with great precision - tasks that would take days for a human law enforcement agent to go through. Also with much less risk of bias, when the programs are diligently designed. Using such technology can help law enforcement not only prevent crimes, but also react rapidly when they occur, and provide a very powerful tool to investigate serious crimes.

Amendment 686

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

**Proposal for a regulation
Recital 65**

Text proposed by the Commission

Amendment

(65) *In order to carry out third-party conformity assessment for AI systems intended to be used for the remote biometric identification of persons, notified bodies should be designated under this Regulation by the national competent authorities, provided they are compliant with a set of requirements, notably on independence, competence and absence of conflicts of interests.*

deleted

Or. en

Amendment 687
Axel Voss, Deirdre Clune

**Proposal for a regulation
Recital 65**

Text proposed by the Commission

Amendment

(65) In order to carry out third-party conformity assessment for AI systems intended to be used for the remote biometric identification of persons, notified bodies should be designated under this Regulation by the national competent authorities, provided they are compliant with a set of requirements, notably on independence, competence **and** absence of conflicts of interests.

(65) In order to carry out third-party conformity assessment for AI systems intended to be used for the remote biometric identification of persons, notified bodies should be designated under this Regulation by the national competent authorities, provided they are compliant with a set of requirements, notably on independence, competence, absence of conflicts of interests **and minimum cybersecurity requirements**.

Or. en

Amendment 688
Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani,

Karen Melchior, Alin Mituță

**Proposal for a regulation
Recital 65**

Text proposed by the Commission

(65) In order to carry out third-party conformity *assessment for AI systems intended to be used for the remote biometric identification of persons*, notified bodies should be designated under this Regulation by the national competent authorities, provided they are compliant with a set of requirements, notably on independence, competence and absence of conflicts of interests.

Amendment

(65) In order to carry out third-party conformity *assessments when so required*, notified bodies should be designated under this Regulation by the national competent authorities, provided they are compliant with a set of requirements, notably on independence, competence and absence of conflicts of interests.

Or. en

Amendment 689

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
Recital 65**

Text proposed by the Commission

(65) In order to carry out third-party conformity assessment for AI systems intended to be used for *the remote biometric identification of persons*, notified bodies should be designated under this Regulation by the national competent authorities, provided they are compliant with a set of requirements, notably on independence, competence and absence of conflicts of interests.

Amendment

(65) In order to carry out third-party conformity assessment for AI systems intended to be used for *any of the use-cases listed in Annex III*, notified bodies should be designated under this Regulation by the national competent authorities, provided they are compliant with a set of requirements, notably on independence, competence and absence of conflicts of interests.

Or. en

Amendment 690

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

Proposal for a regulation
Recital 65 a (new)

Text proposed by the Commission

Amendment

(65 a) Third party conformity assessments for products listed in Annex III are essential as a precautionary measure and to ensure that trust is not lost in AI products, to the detriment of innovation, competition and growth. Due to the particularly sensitive nature of the tasks at hand, third party conformity assessments in the fields of law enforcement, asylum and immigration should be carried out by the market surveillance authority.

Or. en

Amendment 691
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 66

Text proposed by the Commission

Amendment

(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may affect the compliance of the system with this Regulation or when the intended purpose of the system changes. In addition, as regards AI systems which continue to ‘learn’ after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been **pre-determined** by the provider and assessed at the moment of the conformity assessment

(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may **create a new or increased risk and significantly** affect the compliance of the system with this Regulation or when the intended purpose of the system changes. **If such a case materialises, the provider should follow a clear procedure with fixed deadlines, transparency requirements and reporting duties involving, where appropriate and applicable, external oversight by notified bodies or, where it is covered already under the relevant sectoral legislation, post market monitoring if that is needed.**

should not constitute a substantial modification.

In addition, as regards AI systems which continue to ‘learn’ after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been **considered** by the provider and assessed at the moment of the conformity assessment should not constitute a substantial modification. ***In addition, it should not be considered a substantial modification if the user trains an AI system. In this situation, the user should clearly delimit the effects that the learning can have for the AI system. The notion of substantial modification should be assessed in light of the essential requirements set in this Regulation and be left to the manufacturer to determine if a modification is deemed to be substantial.***

Or. en

Amendment 692

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

Proposal for a regulation

Recital 66

Text proposed by the Commission

(66) Conformément à la notion communément établie de modification substantielle pour les produits réglementés par la législation d’harmonisation de l’Union, il convient que les systèmes d’IA fassent l’objet d’une nouvelle évaluation de la conformité chaque fois qu’ils subissent une modification susceptible d’avoir une incidence sur leur conformité avec le présent règlement ou que la destination du système change. En outre, pour les systèmes d’IA qui continuent à «apprendre» après avoir été mis sur le marché ou mis en service (c’est-à-dire qui adaptent automatiquement la façon dont les

Amendment

(66) Conformément à la notion communément établie de modification substantielle pour les produits réglementés par la législation d’harmonisation de l’Union, il convient que les systèmes d’IA fassent l’objet d’une nouvelle évaluation de la conformité chaque fois qu’ils subissent une modification susceptible d’avoir une incidence sur leur conformité avec le présent règlement ou que la destination du système change. En outre, pour les systèmes d’IA qui continuent à «apprendre» après avoir été mis sur le marché ou mis en service (c’est-à-dire qui adaptent automatiquement la façon dont les

fonctions sont exécutées), il est nécessaire *de prévoir des règles établissant* que les modifications de l'algorithme et de ses performances qui ont été prédéterminées par le fournisseur et évaluées au moment de l'évaluation de la conformité *ne devraient pas constituer une modification substantielle.*

fonctions sont exécutées), il est nécessaire que les modifications de l'algorithme et de ses performances qui *constituent des modifications substantielles entraînent également la réalisation de nouvelles évaluations de la conformité, y compris lorsque ces modifications substantielles* ont été prédéterminées par le fournisseur et évaluées au moment de l'évaluation *initiale* de la conformité.

Or. fr

Amendment 693

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 66

Text proposed by the Commission

(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may affect the compliance of the system with this Regulation or when the intended purpose of the system changes. In addition, as regards AI systems which continue to ‘learn’ after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been pre-determined by the provider and assessed at the moment of the conformity assessment should not constitute a substantial modification.

Amendment

(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may affect the compliance of the system with this Regulation or when the intended purpose *or reasonably foreseeable use* of the system changes. In addition, as regards AI systems which continue to ‘learn’ after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been pre-determined by the provider and assessed at the moment of the conformity assessment should not constitute a substantial modification.

Or. en

Amendment 694

**Proposal for a regulation
Recital 66**

Text proposed by the Commission

(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may affect the compliance of the system with this Regulation or when the intended purpose of the system changes. In addition, as regards AI systems which continue to ‘learn’ after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been pre-determined by the provider and assessed at the moment of the conformity assessment should not constitute a substantial modification.

Amendment

(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new **third party** conformity assessment whenever a change occurs which may affect the compliance of the system with this Regulation or when the intended purpose of the system changes. In addition, as regards AI systems which continue to ‘learn’ after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been pre-determined by the provider and assessed at the moment of the conformity assessment should not constitute a substantial modification.

Or. en

Amendment 695

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Recital 66**

Text proposed by the Commission

(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may affect the compliance of the system with this Regulation or when the **intended purpose**

Amendment

(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may affect the compliance of the system with this Regulation or when the **foreseeable uses** of

of the system changes. In addition, as regards AI systems which continue to ‘learn’ after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been pre-determined by the provider and assessed at the moment of the conformity assessment should not constitute a substantial modification.

the system changes. In addition, as regards AI systems which continue to ‘learn’ after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been pre-determined by the provider and assessed at the moment of the conformity assessment should not constitute a substantial modification.

Or. en

Amendment 696

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 66 a (new)

Text proposed by the Commission

Amendment

(66 a) To prevent any deterioration in the expected safety of the algorithm subject to significant changes independent of the providers control, a clearly developed plan to address such significant changes should be subject to oversight by the relevant competent authorities or notified bodies when it is already addressed in principle in the respective sectoral Union harmonisation legislation regarding post-market monitoring

Or. en

Amendment 697

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Recital 67

Text proposed by the Commission

Amendment

(67) High-risk AI systems should bear the CE marking to indicate their

(67) High-risk AI systems should bear the CE marking to indicate their

conformity with this Regulation so that they can move freely within the internal market. Member States should not create ***unjustified*** obstacles to the placing on the market or putting into service of high-risk AI systems that comply with the requirements laid down in this Regulation and bear the CE marking.

conformity with this Regulation so that they can move freely within the internal market. Member States should not create obstacles to the placing on the market or putting into service of high-risk AI systems that comply with the requirements laid down in this Regulation and bear the CE marking.

Or. en

Amendment 698

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tef Nută, Ramona Strugariu, Drago Pîslaru, Sophia in 't Veld, Lucia Ūriš Nicholsonová, Irena Joveva, Karen Melchior, Alin Mituță

Proposal for a regulation

Recital 68

Text proposed by the Commission

(68) Under certain conditions, rapid availability of innovative technologies may be crucial for health and safety of persons and for society as a whole. It is thus appropriate that under exceptional reasons of public security or protection of life and health of natural persons and the protection of industrial and commercial property, Member States could authorise the placing on the market or putting into service of AI systems which have not undergone a conformity assessment.

Amendment

deleted

Or. en

Amendment 699

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

Proposal for a regulation

Recital 68

Text proposed by the Commission

(68) Under certain conditions, rapid

Amendment

deleted

availability of innovative technologies may be crucial for health and safety of persons and for society as a whole. It is thus appropriate that under exceptional reasons of public security or protection of life and health of natural persons and the protection of industrial and commercial property, Member States could authorise the placing on the market or putting into service of AI systems which have not undergone a conformity assessment.

Or. en

Amendment 700

Vincenzo Sofo, Kosma Złotowski

Proposal for a regulation

Recital 68

Text proposed by the Commission

Amendment

(68) Under certain conditions, rapid availability of innovative technologies may be crucial for health and safety of persons and for society as a whole. It is thus appropriate that under exceptional reasons of public security or protection of life and health of natural persons and the protection of industrial and commercial property, Member States could authorise the placing on the market or putting into service of AI systems which have not undergone a conformity assessment.

deleted

Or. en

Amendment 701

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

Proposal for a regulation

Recital 68

Text proposed by the Commission

Amendment

(68) Under certain conditions, rapid availability of innovative technologies may be crucial for health and safety of persons and for society as a whole. It is thus appropriate that under exceptional reasons of public security or protection of life and health of natural persons and the protection of industrial and commercial property, Member States could authorise the placing on the market or putting into service of AI systems which have not undergone a conformity assessment.

deleted

Or. en

Amendment 702

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Recital 69**

Text proposed by the Commission

(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system in a EU database, to be established and managed by the Commission. The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council⁵⁵. In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report.

Amendment

(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers **and users** of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system **or the use thereof** in a EU database, to be established and managed by the Commission. **Certain AI systems listed in Article 52 (1b) and (2) and uses thereof shall be registered in the EU database. In order to facilitate this, users shall request information listed in Annex VIII point 2(g) from providers of AI systems. Any uses of AI systems by public authorities or on their behalf shall also be registered in the EU database. In order to facilitate this, public authorities shall request information listed in Annex VIII point 3(g) from providers of AI systems.** The Commission should be the controller of that database, in accordance

with Regulation (EU) 2018/1725 of the European Parliament and of the Council. In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report. *In order to maximise the availability and use of the database by the public, the database, including the information made available through it, should comply with requirements under the European Accessibility Act.*

⁵⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

Or. en

Amendment 703

Fernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation Recital 69

Text proposed by the Commission

(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system in a EU database, to be established and managed by the Commission. The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the

Amendment

(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers *and users* of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system *or the use thereof* in a EU database, to be established and managed by the Commission. The Commission should be the controller of that database, in accordance with

European Parliament and of the Council⁵⁵. In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report.

Regulation (EU) 2018/1725 of the European Parliament and of the Council⁵⁵. In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report. *In order to maximise the availability and use of the database by the public, the database, including the information made available through it, should comply with requirements under the European Accessibility Act.*

⁵⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

⁵⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

Or. en

Amendment 704

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

Proposal for a regulation Recital 69

Text proposed by the Commission

(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system in a EU database, to be established and managed by the Commission. The Commission should be the controller of that database, in accordance with

Amendment

(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, **both** providers **and users** of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system in a EU database, to be established and managed by the Commission. **Users who are public authorities or European Union**

Regulation (EU) 2018/1725 of the European Parliament and of the Council⁵⁵. In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report.

institutions, bodies, offices and agencies or users acting on their behalf should also register in the EU database before putting into service or using any AI system. The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council⁵⁵. In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report.

⁵⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

⁵⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

Or. en

Amendment 705

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

Proposal for a regulation Recital 69

Text proposed by the Commission

(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers of high-risk AI systems *other than those related to products falling within the scope of relevant existing Union harmonisation legislation*, should be required to register their high-risk AI system in a EU database, to be established and managed by the Commission. The Commission should be

Amendment

(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers *and deployers* of high-risk AI systems should be required to register their high-risk AI system in a EU database, to be established and managed by the Commission. The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and

the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council⁵⁵. In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report.

⁵⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

of the Council⁵⁵. In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report.

⁵⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

Or. en

Amendment 706

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation Recital 69

Text proposed by the Commission

(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards **the public**, providers of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system in a EU database, to be established and managed by the Commission. The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council⁵⁵. In order to ensure the full functionality of the database, when deployed, the procedure

Amendment

(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards **regulators**, providers of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system in a EU database, to be established and managed by the Commission. The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council⁵⁵. In order to ensure the full functionality of the database, when

for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report.

deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report.

⁵⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

⁵⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

Or. en

Amendment 707

Geoffroy Didier

Proposal for a regulation

Recital 70

Text proposed by the Commission

(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation *or* deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image,

Amendment

(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation, deception *or EU principles and values* irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image,

audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

audio, *text, script*, or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin. *Besides, recommendation systems, in particular automated decision-making algorithms that disseminate and order cultural and creative content displayed to users, should be designed in such a way that their personalised suggestions are explainable and non-discriminatory. A clear explanation of the parameters used for the personalised suggestions should be easily accessible and understandable to the users. Natural persons should have a right to opt out of recommended and personalised services without affecting their right to use the core service.*

Or. en

Justification

In line with the changes made in Article 52 (3) and (3bis)

Amendment 708

Andrea Caroppo, Salvatore De Meo

**Proposal for a regulation
Recital 70**

Text proposed by the Commission

(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In particular, natural persons should be

Amendment

(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In particular, natural persons should be

notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin. *Images generated through the use of AI in the creation of audio-visual content such as films and video game visuals should not be considered “deep fakes” as defined in Article 52 (3), which must be consistent with the principle of artistic freedom under the Charter of Fundamental Rights.*

Or. en

Amendment 709
Morten Løkkegaard

Proposal for a regulation
Recital 70

Text proposed by the Commission

(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In

Amendment

(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In

particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin. *Images generated through the use of AI in the creation of audiovisual content such as films and video game visuals should not be considered “deep fakes” as defined in Article 52 (3), which must be consistent with the principle of artistic freedom under the Charter of Fundamental Rights.*

Or. en

Amendment 710

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 70

Text proposed by the Commission

(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and

Amendment

(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and

obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use *or where the content forms part of an evidently creative, satirical, artistic or fictional cinematographic, video game visuals or analogous work*. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose *in an appropriate, clear and visible manner* that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

Or. en

Amendment 711

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

Proposal for a regulation

Recital 70

Text proposed by the Commission

(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In

Amendment

(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In

particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use.

Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, ***users***, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, ***deployers***, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin. ***Additionally, the use of an AI system to generate or manipulate image, audio or video content that appreciably resembles a natural person should be permitted only when used for freedom of expression and artistic purposes and while respecting the limits of these purposes, or with the explicit consent of that person.***

Or. en

Amendment 712

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

Proposal for a regulation Recital 70

Text proposed by the Commission

(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI

Amendment

(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI

system, unless this is obvious from the circumstances and the context of use. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

Or. en

Amendment 713

Svenja Hahn, Drago Tudorache, Nicola Beer, Dita Charanzová, Andrus Ansip, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ondej Kováčik, Jan-Christoph Oetjen

Proposal for a regulation Recital 70

Text proposed by the Commission

(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric

Amendment

(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use *or where the content is part of an obviously artistic, creative or fictional cinematographic work.* Moreover, natural

categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose, *in an appropriate, clear and visible manner*, that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

Or. en

Amendment 714

Brando Benifei, 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

Recital 70

Text proposed by the Commission

(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. **Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system.** Such information and notifications should be provided in

Amendment

(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably

accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

Or. en

Amendment 715

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

Proposal for a regulation Recital 70

Text proposed by the Commission

(70) Certains systèmes d'IA destinés à interagir avec des personnes physiques ou à générer du contenu peuvent présenter des risques spécifiques d'usurpation d'identité ou de tromperie, qu'ils soient ou non considérés comme étant à haut risque. Dans certaines circonstances, l'utilisation de ces systèmes devrait donc être soumise à des obligations de transparence spécifiques sans préjudice des exigences et obligations relatives aux systèmes d'IA à haut risque. En particulier, les personnes physiques devraient être informées du fait qu'elles interagissent avec un système d'IA, *à moins que cela ne soit évident en raison des circonstances et du contexte d'utilisation*. En outre, les personnes physiques devraient être informées du fait qu'elles sont exposées à un système de reconnaissance des émotions ou à un système de catégorisation biométrique. Ces informations devraient être fournies dans des formats accessibles aux personnes handicapées. En outre, les *utilisateurs qui se servent d'un système d'IA* pour générer

Amendment

(70) Certains systèmes d'IA destinés à interagir avec des personnes physiques ou à générer du contenu peuvent présenter des risques spécifiques d'usurpation d'identité ou de tromperie, qu'ils soient ou non considérés comme étant à haut risque. Dans certaines circonstances, l'utilisation de ces systèmes devrait donc être soumise à des obligations de transparence spécifiques sans préjudice des exigences et obligations relatives aux systèmes d'IA à haut risque. En particulier, les personnes physiques devraient être informées du fait qu'elles interagissent avec un système d'IA. En outre, les personnes physiques devraient être informées du fait qu'elles sont exposées à un système de reconnaissance des émotions ou à un système de catégorisation biométrique. Ces informations devraient être fournies dans des formats accessibles aux personnes handicapées. En outre, les *systèmes d'IA utilisés* pour générer ou manipuler des images ou des contenus audio ou vidéo dont la ressemblance avec des personnes,

ou manipuler des images ou des contenus audio ou vidéo dont la ressemblance avec des personnes, des lieux ou des événements existants pourrait porter à croire qu'il s'agit de documents authentiques, devraient *déclarer que le* contenu a été créé ou manipulé artificiellement *en étiquetant le résultat produit par le système d'intelligence artificielle en conséquence et en mentionnant son origine artificielle.*

des lieux ou des événements existants pourrait porter à croire qu'il s'agit de documents authentiques, devraient *systématiquement apposer sur le contenu généré un marquage indiquant que ce contenu a été créé ou manipulé artificiellement, et les utilisateurs qui se servent de tels systèmes d'I.A. ou réutilisent le contenu généré ne devraient pas être autorisés à retirer ou à dissimuler ce marquage.*

Or. fr

Amendment 716

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 70 a (new)

Text proposed by the Commission

Amendment

(70 a) In light of the nature and complexity of the value chain for AI systems, it is essential to clarify the role of humans who may contribute to the development of AI systems covered by this Regulation, without being providers, no longer being providers or when other natural or legal persons have also become providers. Therefore, it is particularly important to clarify the legal situation when it comes to general purpose AI systems. Those AI system are able to perform generally applicable functions such as image/speech recognition, audio/video generation, pattern detection, question answering or translation in a plurality of contexts. Every natural or legal person can become a new provider by adapting a general purpose AI system, already placed on the market or put into service, to a specific intended purpose. Due to their peculiar nature and in order to ensure a fair sharing of responsibilities along the AI value chain, such general purpose AI system should however already be subject to proportionate and

tailored requirements and obligations under this Regulation even before placing it on the Union market or putting it into service. The original provider of a general purpose AI system should furthermore cooperate, as appropriate, with the new provider to enable its compliance with the relevant obligations under this Regulation.

Or. en

Amendment 717

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Recital 70 a (new)

Text proposed by the Commission

Amendment

(70 a) Suppliers of general purpose AI systems and, as relevant, other third parties that may supply other software tools and components, including pre-trained models and data, should cooperate, as appropriate, with providers that use such systems or components for an intended purpose under this Regulation in order to enable their compliance with applicable obligations under this Regulation and their cooperation, as appropriate, with the competent authorities established under this Regulation. In such cases, the provider may, by written agreement, specify the information or other assistance that such supplier will furnish in order to enable the provider to comply with its obligations herein.

Or. en

Amendment 718

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 71

Text proposed by the Commission

(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, national competent authorities from one or more Member States should be encouraged to establish artificial intelligence regulatory sandboxes to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service.

Amendment

(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe **and fully controlled** space for experimentation, while ensuring responsible innovation and integration of appropriate **ethical** safeguards and risk mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, national competent authorities from one or more Member States should be encouraged to establish artificial intelligence regulatory sandboxes to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service. **Regulatory sandboxes involving activities that may impact health, safety and fundamental rights, democracy and the rule of law or the environment should be developed in accordance with redress-by-design principles. Any significant risks identified during the development and testing of such systems should result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place. The legal basis of such sandboxes should comply with the requirements established in the existing data protection framework and should be consistent with the Charter of fundamental rights of the European Union.**

Or. en

Amendment 719

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

Proposal for a regulation Recital 71

Text proposed by the Commission

(71) Artificial intelligence is a rapidly developing family of technologies that requires *novel forms of* regulatory oversight *and* a safe space for experimentation, *while* ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that is *innovation-friendly*, future-proof and resilient to disruption, national competent authorities from one or more Member States should be encouraged to *establish* artificial intelligence regulatory sandboxes to facilitate the development and testing of *innovative* AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service.

Amendment

(71) Artificial intelligence is a rapidly developing family of technologies that *benefits from clear rules and legal certainty, and* requires regulatory oversight. *In order to fulfill its potential to benefit society*, a safe space for *controlled* experimentation, ensuring *respect for Union law and the protection of fundamental rights, can help foster* responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that *promotes sustainable innovation*, is future-proof and resilient to disruption, national competent authorities from one or more Member States should be encouraged to *cooperate in establishing* artificial intelligence regulatory sandboxes to facilitate the development and testing of AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service.

Or. en

Amendment 720

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tefnuță, Ramona Strugariu, Drago Pîslaru, Lucia Uriș, Nicholsonová, Irena Joveva, Malik Azmani, Andrus Ansip, Dita Charanzová, Morten Løkkegaard, Alin Mituță

Proposal for a regulation

Recital 71

Text proposed by the Commission

(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, *national competent*

Amendment

(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, Member States

authorities from one or more Member States should **be encouraged to** establish artificial intelligence regulatory sandboxes to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service.

should establish artificial intelligence regulatory sandboxes to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service.

Member States should ensure that the regulatory sandboxes have the adequate financial and human resources for their proper functioning.

Or. en

Amendment 721
Karlo Ressler

Proposal for a regulation
Recital 71

Text proposed by the Commission

(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, national competent authorities from one or more Member States should **be encouraged to** establish artificial intelligence regulatory sandboxes to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service.

Amendment

(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, national competent authorities from one or more Member States should establish artificial intelligence regulatory sandboxes to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service. **All other relevant actors should be encouraged to do so as well.**

Or. en

Amendment 722
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation
Recital 71

Text proposed by the Commission

(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, national **competent** authorities from one or more Member States **should be encouraged to** establish artificial intelligence regulatory sandboxes to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service.

Amendment

(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that **safeguards fundamental rights and** is innovation-friendly, future-proof and resilient to disruption, national **supervisory** authorities from one or more Member States **could** establish artificial intelligence regulatory sandboxes to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service.

Or. en

Amendment 723
Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation
Recital 71

Text proposed by the Commission

(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, national competent authorities from one or more Member States should **be encouraged to** establish artificial intelligence regulatory sandboxes

Amendment

(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, national competent authorities from one or more Member States should establish artificial intelligence regulatory sandboxes to

to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service.

facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service.

Or. en

Amendment 724

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

Proposal for a regulation

Recital 72

Text proposed by the Commission

(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. ***This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of***

Amendment

(72) The objectives of the regulatory sandboxes should be to foster AI innovation ***for the benefit of society*** by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring ***respect for and protection of fundamental rights***, compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. Personal data ***that had originally been*** collected for ***different purposes should be processed in a sandbox only under specified conditions and*** within the ***limits*** of Regulation (EU) 2016/679. ***Such further processing should***

Directive (EU) 2016/680. Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any **high-risks** to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

be considered as for statistical purposes in the meaning of Article 5(1)(b) of that Regulation. Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any **risks** to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide **over the suspending or banning them from participating in the sandbox, or** whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680. **This Regulation should also provide the legal basis for the use of data protected by intellectual property or trade-secrets for developing certain AI systems in the public interest within the AI regulatory sandbox, without prejudice to Directive (EU) 2019/790 and to Directive (EU) 2016/943. The authorised use of data protected by intellectual property or trade-secrets under Article 54 of this Regulation should be covered by Article 4 of Directive (EU) 2019/790.**

Or. en

Amendment 725

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation Recital 72

Text proposed by the Commission

(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation

Amendment

(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a **strictly** controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems

and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, ***and*** to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680. Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

with this Regulation and other relevant Union and Member States legislation, ***as well as with the Charter of Fundamental Rights of the European Union and the General Data Protection Regulation;*** to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, ***to provide safeguards needed to build trust and reliance on AI systems,*** to accelerate access to markets, including by removing barriers for ***the public sector,*** small and medium enterprises (SMEs) and start-ups; ***and to contribute to the development of ethical, socially responsible and environmentally sustainable AI systems.*** To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680. Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

Amendment 726

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**Recital 72***Text proposed by the Commission*

(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. ***This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680.*** Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting

Amendment

(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and

expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

Article 57 of Directive 2016/680.

Or. en

Justification

Consistent with the deletion of Article 54.

Amendment 727

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

Proposal for a regulation

Recital 72

Text proposed by the Commission

(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the *competent* authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the *relevant* authorities involved in the

Amendment

(72) The objectives of the regulatory sandboxes should be to foster AI innovation, *while safeguarding fundamental rights and the values enshrined in Article 2 TFEU*, by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the *national supervisory* authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules

supervision of the sandboxes. ***This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680.*** Participants in the sandbox should ensure appropriate safeguards and cooperate with the ***competent*** authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

for the regulatory sandboxes' implementation and a framework for cooperation between the ***national supervisory*** authorities involved in the supervision of the sandboxes. Participants in the sandbox should ensure appropriate safeguards and cooperate with the ***national supervisory*** authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

Or. en

Amendment 728

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 Recital 72 a (new)

Text proposed by the Commission

Amendment

(72 a) To ensure that Artificial Intelligence leads to socially and environmentally beneficial outcomes, Member States should support and promote research and development of AI in support of socially and environmentally beneficial outcomes by allocating sufficient resources, including public and Union funding, and giving priority access to regulatory sandboxes to projects led by civil society. Such projects should be

based on the principle of interdisciplinary cooperation between AI developers, experts on inequality and non-discrimination, accessibility, consumer, environmental, and digital rights, as well as academics.

Or. en

Amendment 729

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 73

Text proposed by the Commission

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

Amendment

(73) In order to promote and protect innovation, it is important that the interests of *SME* providers and users of AI systems are taken into particular account. To this objective, *AI solutions and services designed to combat fraud and protect consumers against fraudulent activities should not be considered high-risk, nor be prohibited. As a matter of substantial public interest, it is vital that this Regulation does not undermine the incentive of industry to create and roll out solutions designed to combat fraud across the Union. Furthermore*, Member States should develop initiatives, which are targeted at those operators, including on awareness raising and information communication. Moreover, the specific interests and needs of *SME* providers shall be taken into account when Notified Bodies set conformity assessment fees. Translation costs related to mandatory documentation and communication with authorities may constitute a significant cost for providers and other operators, notably those of a smaller scale. Member States should possibly ensure that one of the languages determined and accepted by them for relevant providers' documentation and for communication with operators is one which is broadly understood by the

largest possible number of cross-border users. ***Member States should also be encouraged to do the same for small and medium enterprises, which may sometimes lack the requisite administrative and legal resources to ensure proper understanding and compliance with the provisions under this act. In the event that Member States request it, the Commission may also provide assistance in this regard.***

Or. en

Amendment 730
Marion Walsmann

Proposal for a regulation
Recital 73

Text proposed by the Commission

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

Amendment

(73) In order to promote and protect innovation, it is important that the interests of small-scale providers, ***like SMEs, micro-enterprises*** and users of AI systems are taken into particular account. ***SMEs are the backbone of the European economy and they face more challenges adapting to new legislations therefore measures should be foreseen to support them to cope with the new obligations or to exclude them from certain requirements.*** To this objective, Member States should develop initiatives, which are targeted at those operators, including on awareness raising and information communication. Moreover, the specific interests and needs of small-scale providers shall be taken into account when Notified Bodies set conformity assessment fees. Translation costs related to mandatory documentation and communication with authorities may constitute a significant cost for providers and other operators, notably those of a smaller scale. Member States should ensure that one of the languages determined and accepted by them for

relevant providers' documentation and for communication with operators is one which is broadly understood by the largest possible number of cross-border users.

Or. en

Amendment 731

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

Proposal for a regulation

Recital 73

Text proposed by the Commission

(73) Afin de promouvoir et de protéger l'innovation, il est important que les intérêts des petits fournisseurs et utilisateurs de systèmes d'IA bénéficient d'une attention particulière. Pour atteindre cet objectif, les États membres devraient prendre des initiatives à l'intention de ces opérateurs, notamment en matière de sensibilisation et de communication d'informations. En outre, les intérêts et les besoins spécifiques des petits fournisseurs doivent être pris en considération lorsque les organismes notifiés fixent les redevances d'évaluation de la conformité. Les frais de traduction liés à la documentation obligatoire et à la communication avec les autorités peuvent constituer un coût important pour les fournisseurs et d'autres opérateurs, en particulier pour ceux de plus petite envergure. *Les États membres devraient éventuellement veiller à ce qu'une des langues qu'ils choisissent et acceptent pour la documentation pertinente des fournisseurs et pour la communication avec les opérateurs soit une langue comprise par le plus grand nombre possible d'utilisateurs transfrontières.*

Amendment

(73) Afin de promouvoir et de protéger l'innovation, il est important que les intérêts des petits fournisseurs et utilisateurs de systèmes d'IA bénéficient d'une attention particulière. Pour atteindre cet objectif, les États membres devraient prendre des initiatives à l'intention de ces opérateurs, notamment en matière de sensibilisation et de communication d'informations. En outre, les intérêts et les besoins spécifiques des petits fournisseurs doivent être pris en considération lorsque les organismes notifiés fixent les redevances d'évaluation de la conformité. Les frais de traduction liés à la documentation obligatoire et à la communication avec les autorités peuvent constituer un coût important pour les fournisseurs et d'autres opérateurs, en particulier pour ceux de plus petite envergure.

Or. fr

Amendment 732

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

Proposal for a regulation

Recital 73

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 733

Svenja Hahn, Drago Tudorache, Nicola Beer, Dita Charanzová, Andrus Ansip, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Recital 73

Text proposed by the Commission

(73) In order to promote and protect innovation, it is important that the interests

Amendment

(73) In order to promote and protect innovation, it is important that the interests

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

of *start-ups and SME* providers and users of AI systems are taken into particular account. To this objective, Member States should develop initiatives, which are targeted at those operators, including on awareness raising and information communication. Moreover, the specific interests and needs of *SMEs and start-ups* shall be taken into account when Notified Bodies set conformity assessment fees. Translation costs related to mandatory documentation and communication with authorities may constitute a significant cost for providers and other operators, notably those of a smaller scale. Member States should possibly ensure that one of the languages determined and accepted by them for relevant providers' documentation and for communication with operators is one which is broadly understood by the largest possible number of cross-border users.

Or. en

Amendment 734

Kosma Złotowski, Patryk Jaki, Adam Bielan

Proposal for a regulation

Recital 73 a (new)

Text proposed by the Commission

Amendment

(73 a) AI solutions and services designed to combat fraud and protect consumers against fraudulent activities should not be considered high risk, nor prohibited. As a matter of substantial public interest, it is vital that this Regulation does not undermine the incentive of the industry to create and roll out solutions designed to combat fraud across the European Union.

Or. en

Amendment 735

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Recital 74**

Text proposed by the Commission

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

Amendment

(74) In order to minimise the risks to implementation resulting from lack of knowledge and expertise in the market as well as to facilitate compliance of providers and notified bodies with their obligations under this Regulation, **Member States should utilise existing dedicated channels for communication with SMEs and start-ups. Such existing channels could include but are not limited to ENISA's Computer Security Incident Response Teams, National data protection agencies**, the AI-on demand platform, the European Digital Innovation Hubs and the Testing and Experimentation Facilities established by the Commission and the Member States at national or EU level. Within their respective mission and fields of competence, they may provide in particular technical and scientific support to providers and notified bodies.

Or. en

Amendment 736

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Recital 74**

Text proposed by the Commission

(74) In order to minimise the risks to implementation resulting from lack of knowledge and expertise in the market as well as to facilitate compliance of providers and notified bodies with their obligations under this Regulation, the AI-on demand platform, the European Digital Innovation Hubs and the Testing and Experimentation Facilities established by

Amendment

(74) In order to minimise the risks to implementation resulting from lack of knowledge and expertise in the market as well as to facilitate compliance of providers and notified bodies with their obligations under this Regulation, the AI-on demand platform, the European Digital Innovation Hubs and the Testing and Experimentation Facilities established by

the Commission and the Member States at national or EU level should *possibly* contribute to the implementation of this Regulation. Within their respective mission and fields of competence, they may provide in particular technical and scientific support to providers and notified bodies.

the Commission and the Member States at national or EU level, *as well as the ENISA, the EU Agency for Fundamental Rights, EIGE, and the European Data Protection Supervisor* should *constantly* contribute to the implementation of this Regulation. Within their respective mission and fields of competence, they may provide in particular technical and scientific support to providers and notified bodies.

Or. en

Amendment 737

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

Proposal for a regulation

Recital 74

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 738

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

Proposal for a regulation
Recital 76

Text proposed by the Commission

(76) In order to facilitate a smooth, effective and **harmonised** implementation of this Regulation **a** European Artificial Intelligence Board should be established. The Board should be responsible for a number of **advisory** tasks, including issuing opinions, recommendations, advice or guidance on matters related to the implementation of this Regulation, including on technical specifications or existing standards regarding the requirements established in this Regulation and providing advice to and assisting the Commission on specific questions related to artificial intelligence.

Amendment

(76) In order to facilitate a smooth, effective and **consistent** implementation of this Regulation **an independent** European Artificial Intelligence Board should be established. The Board should be responsible for a number of tasks, including issuing opinions, recommendations, advice or guidance on matters related to the implementation of this Regulation, including on technical specifications or existing standards regarding the requirements established in this Regulation and providing advice to and assisting the Commission on specific questions related to artificial intelligence, *including on possible amendments of the annexes, in particular the annex listing high-risk AI systems. To contribute to the effective and harmonised enforcement of this Regulation, the Board should also be able to adopt binding decisions for the settlement of cases involving two or more Member States in which the national supervisory authorities are in disagreement or when it is not clear who the lead national supervisory authority is. The Board should also be able to adopt a binding decision in those cases when a national supervisory authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a risk to the compliance with obligations under Union or national law intended to protect fundamental rights, the principles of Article 4a, the values as enshrined in Article 2 TEU, the environment, or to other aspects of public interest protection.*

Or. en

Amendment 739

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tef Nută, Ramona Strugariu, Drago Pîslaru, Lucia Ūriš Nicholsonová, Irena Joveva, Karen Melchior, Alin Mituța

**Proposal for a regulation
Recital 76**

Text proposed by the Commission

(76) In order to *facilitate a smooth, effective and harmonised implementation of this Regulation* a **European Artificial Intelligence Board** should be established. The Board should be responsible for *a number of advisory tasks, including issuing opinions, recommendations, advice or guidance on matters related to the implementation of this Regulation, including on technical specifications or existing standards regarding the requirements established in this Regulation and providing advice to and assisting the Commission on specific questions related to artificial intelligence.*

Amendment

(76) In order to *ensure an effective and harmonised implementation of this Regulation, to achieve a high level of trustworthiness and of protection of health, safety, fundamental rights and the Union values enshrined in Article 2 TEU across the Union with regards to artificial intelligence systems, to actively support Member States, Union institutions, bodies, offices and agencies in matters pertaining to this Regulation, to reduce the fragmentation of the internal market, and to increase the uptake of artificial intelligence throughout the Union, an European Union Artificial Intelligence Office* should be established. The **AI Office** should have legal personality, should act in full independence, and should be adequately funded and staffed. Member States should provide the strategic direction and control of the AI Office through the management board of the AI Office, alongside the Commission, the EDPS, and the FRA. An executive director should be responsible for the coordination of the AI Office's operations and for the implementation of its work programme. Industry, start-ups and SMEs, and civil society should formally participate in the work of the AI Office through an advisory forum that should ensure varied stakeholder representation and should advise the AI Office on matters pertaining to this Regulation.

Or. en

Amendment 740

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

on behalf of the Verts/ALE Group

**Proposal for a regulation
Recital 76**

Text proposed by the Commission

(76) In order to facilitate a smooth, effective and harmonised implementation of this Regulation a European Artificial Intelligence Board should be established. The Board should be responsible for a number of advisory tasks, including issuing opinions, recommendations, advice or guidance on matters related to the implementation of this Regulation, including on technical specifications or existing standards regarding the requirements established in this Regulation and providing advice to and assisting the Commission on specific questions related to artificial intelligence.

Amendment

(76) In order to facilitate a smooth, effective and harmonised implementation of this Regulation a European Artificial Intelligence Board should be established. The Board should be **independent and** responsible for a number of advisory **and enforcement** tasks, including issuing **decisions**, opinions, recommendations, advice or guidance on matters related to the implementation of this Regulation, including on technical specifications or existing standards regarding the requirements established in this Regulation and providing advice to and assisting the Commission on specific questions related to artificial intelligence. **In order to ensure a consistent and appropriate enforcement vis-à-vis very large undertakings, the Board should be the supervisory authority for undertakings that meet the criteria of 'community dimension' as defined in Article 1(3) of Regulation 139/200 (Merger Regulation). The Board should have a secretariat with sufficient resources and expertise to be able to fulfil its role. In this respect, the secretariat should establish a European Centre of Excellence for Artificial Intelligence (ECE-AI).**

Or. en

Amendment 741

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

**Proposal for a regulation
Recital 76**

Text proposed by the Commission

(76) In order to facilitate a smooth, effective and harmonised implementation of this Regulation a European Artificial Intelligence Board should be established. The Board should be responsible for a number of advisory tasks, including issuing opinions, recommendations, advice or guidance on matters related to the implementation of this Regulation, including on technical specifications or existing standards regarding the requirements established in this Regulation and providing advice to and assisting the Commission on specific questions related to artificial intelligence.

Amendment

(76) In order to facilitate a smooth, effective and harmonised implementation of this Regulation a European Artificial Intelligence Board should be established **as a body of the Union and should have legal personality**. The Board should be responsible for a number of advisory tasks, including issuing opinions, recommendations, advice or guidance on matters related to the implementation of this Regulation, including on technical specifications or existing standards regarding the requirements established in this Regulation and providing advice to and assisting the Commission **and the national competent authorities** on specific questions related to artificial intelligence.

Or. en

Amendment 742

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

**Proposal for a regulation
Recital 76 a (new)**

Text proposed by the Commission

Amendment

(76 a) An AI advisory council ('the Advisory Council') should be established as a sub-group of the Board consisting of relevant representatives from industry, research, academia, civil society, standardisation organisations, relevant common European data spaces, and other relevant stakeholders, including social partners, where appropriate depending on the subject matter discussed, representing all Member States to maintain geographical balance. The Advisory Council should support the work of the Board by providing advice relating to the tasks of the Board. The Advisory Council should nominate a representative to attend meetings of the Board and to

participate in its work.

Or. en

Amendment 743

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 76 a (new)

Text proposed by the Commission

Amendment

(76 a) The Commission should re-establish the High Level Expert Group or a similar body with a new and balanced membership comprising an equal number of experts from SMEs and start-ups, large enterprises, academia and Research, and civil society. This new High Level Expert Group should not only act as advisory body to the Commission but also to the Board. At least every quarter, the new High Level Expert Group must have the chance to share its practical and technical expertise in a special meeting with the Board.

Or. en

Amendment 744

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

Proposal for a regulation

Recital 77

Text proposed by the Commission

Amendment

(77) Member States hold a key role in the application and enforcement of this Regulation. In this respect, each Member State should designate one or more national competent authorities for the purpose of supervising the application and implementation of this Regulation. In order to increase organisation efficiency on the

(77) Member States hold a key role in the application and enforcement of this Regulation. In this respect, each Member State should designate one or more national competent authorities for the purpose of supervising the application and implementation of this Regulation. In order to increase organisation efficiency on the

side of Member States and to set an official point of contact vis-à-vis the public and other counterparts at Member State and Union levels, in each Member State one national authority should be designated as national supervisory authority.

side of Member States and to set an official point of contact vis-à-vis the public and other counterparts at Member State and Union levels, in each Member State one national authority should be designated as national supervisory authority. *In order to avoid duplication and combine expertise and competences, this should be a supervisory authority established under Regulation (EU) 2016/679 (General Data Protection Regulation). The supervisory authorities should have sufficient investigative and corrective powers.*

Or. en

Amendment 745

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

Proposal for a regulation

Recital 77

Text proposed by the Commission

(77) ***Member States hold a key role in the application and enforcement of this Regulation. In this respect, each Member State should designate one or more national competent authorities for the purpose of supervising the application and implementation of this Regulation. In order to increase organisation efficiency on the side of Member States and to set an official point of contact vis-à-vis the public and other counterparts at Member State and Union levels, in each Member State one national authority should be designated as national supervisory authority.***

Amendment

(77) Each Member State should establish or designate a single national supervisory authority to act as the lead authority and be responsible for ensuring the effective coordination between the national competent authorities regarding the implementation of this Regulation. It should also represent its Member State on the Board. Each national supervisory authority should act with complete independence in performing its tasks and exercising its powers in accordance with this Regulation.

Or. en

Amendment 746

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

Proposal for a regulation
Recital 77 a (new)

Text proposed by the Commission

Amendment

(77 a) The national supervisory authorities should monitor the application of the provisions pursuant to this Regulation and contribute to its consistent application throughout the Union. For that purpose, the national supervisory authorities should cooperate with each other, with the market surveillance authorities and with the Commission, without the need for any agreement between Member States on the provision of mutual assistance or on such cooperation.

Or. en

Amendment 747

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

Proposal for a regulation
Recital 78

Text proposed by the Commission

Amendment

(78) Afin de garantir que les fournisseurs de systèmes d'IA à haut risque puissent prendre en considération l'expérience acquise dans l'utilisation de systèmes d'IA à haut risque pour améliorer leurs systèmes et le processus de conception et de développement, ou qu'ils puissent prendre d'éventuelles mesures correctives en temps utile, tous les fournisseurs devraient avoir mis en place un système de surveillance après commercialisation. Ce système est aussi essentiel pour garantir que les risques potentiels découlant des systèmes d'IA qui continuent à «apprendre» après avoir été mis sur le marché ou mis en service puissent être traités plus efficacement et en

(78) Afin de garantir que les fournisseurs de systèmes d'IA à haut risque puissent prendre en considération l'expérience acquise dans l'utilisation de systèmes d'IA à haut risque pour améliorer leurs systèmes et le processus de conception et de développement, ou qu'ils puissent prendre d'éventuelles mesures correctives en temps utile, tous les fournisseurs devraient avoir mis en place un système de surveillance après commercialisation. *En raison de la nature sensible des systèmes d'I.A. à haut risque, ce système de surveillance après commercialisation ne peut consister en un envoi automatisé de données ou de rapports d'erreurs au fournisseur par le*

temps utile. Dans ce contexte, les fournisseurs devraient également être tenus de mettre en place un système pour signaler aux autorités compétentes tout incident grave ou toute violation du droit national ou de l'Union en matière de droits fondamentaux résultant de l'utilisation de leurs systèmes d'IA.

système d'IA. Ce système est aussi essentiel pour garantir que les risques potentiels découlant des systèmes d'IA qui continuent à «apprendre» après avoir été mis sur le marché ou mis en service puissent être traités plus efficacement et en temps utile. Dans ce contexte, les fournisseurs devraient également être tenus de mettre en place un système pour signaler aux autorités compétentes tout incident grave ou toute violation du droit national ou de l'Union en matière de droits fondamentaux résultant de l'utilisation de leurs systèmes d'IA.

Or. fr

Amendment 748

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

Proposal for a regulation

Recital 78

Text proposed by the Commission

(78) In order to ensure that providers of high-risk AI systems can take into account the experience on the use of high-risk AI systems for improving their systems and the design and development process or can take any possible corrective action in a timely manner, all providers should have a post-market monitoring system in place. This system is also key to ensure that the possible risks emerging from AI systems which continue to ‘learn’ after being placed on the market or put into service can be more efficiently and timely addressed. In this context, providers should also be required to have a system in place to report to the relevant authorities any serious incidents or any breaches to national and Union law protecting fundamental rights resulting from the use of their AI systems.

Amendment

(78) In order to ensure that providers of high-risk AI systems can take into account the experience on the use of high-risk AI systems for improving their systems and the design and development process or can take any possible corrective action in a timely manner, all providers should have a post-market monitoring system in place. This system is also key to ensure that the possible risks emerging from AI systems which continue to ‘learn’ after being placed on the market or put into service can be more efficiently and timely addressed. In this context, providers should also be required to have a system in place to report to the relevant authorities any serious incidents or any breaches to national and Union law, *including those* protecting fundamental *rights and consumer rights, resulting from the use of their AI systems*.

Amendment 749

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Recital 78

Text proposed by the Commission

(78) In order to ensure that providers of high-risk AI systems can take into account the experience on the use of high-risk AI systems for improving their systems and the design and development process or can take any possible corrective action in a timely manner, all providers should have a post-market monitoring system in place. This system is also key to ensure that the possible risks emerging from AI systems which continue to ‘learn’ after being placed on the market or put into service can be more efficiently and timely addressed. In this context, providers should also be required to **have a system in place to** report to the relevant authorities any serious incidents or any breaches to national and Union law protecting fundamental rights resulting from the use of their AI systems.

Amendment

(78) In order to ensure that providers of high-risk AI systems can take into account the experience on the use of high-risk AI systems for improving their systems and the design and development process or can take any possible corrective action in a timely manner, all providers should have a post-market monitoring system in place. This system is also key to ensure that the possible risks emerging from AI systems which continue to ‘learn’ after being placed on the market or put into service can be more efficiently and timely addressed. In this context, providers should also be required to report to the relevant authorities any serious incidents or any breaches to national and Union law protecting fundamental rights resulting from the use of their AI systems.

Amendment 750

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

Proposal for a regulation

Recital 79

Text proposed by the Commission

(79) In order to ensure an appropriate and effective enforcement of the requirements and obligations set out by this Regulation, which is Union harmonisation

Amendment

(79) In order to ensure an appropriate and effective enforcement of the requirements and obligations set out by this Regulation, which is Union harmonisation

legislation, the system of market surveillance and compliance of products established by Regulation (EU) 2019/1020 should apply in its entirety. Where necessary for their mandate, national public authorities or bodies, which supervise the application of Union law protecting fundamental rights, including equality bodies, should also have access to any documentation created under this Regulation.

legislation, the system of market surveillance and compliance of products established by Regulation (EU) 2019/1020 should apply in its entirety. Where necessary for their mandate, national public authorities or bodies, which supervise the application of Union law protecting fundamental rights, including equality bodies, should also have access to any documentation created under this Regulation. *A reasonable suspicion of breach of fundamental rights, which may arise from a complaint from an individual or a notification of a breach submitted by a civil society organisation, should be deemed as a sufficient reason for the commencement of an evaluation of an AI system at national level.*

Or. en

Amendment 751

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

Proposal for a regulation Recital 79 a (new)

Text proposed by the Commission

Amendment

(79 a) As the rights and freedoms of individuals can be seriously undermined by AI systems, it is essential that affected individuals have meaningful access to reporting and redress mechanisms. They should be able to report infringements of this Regulation to their national supervisory authority and have the right to be heard and to be informed about the outcome of their complaint and the right to a timely decision. In addition, they should have the right to an effective remedy against competent authorities who fail to enforce these rights and the right to redress. Where applicable, deployers should provide internal complaints mechanisms to be used by affected individuals and should be liable for

pecuniary and non-pecuniary damages in cases of breaches of individuals' or groups' rights. Collective representation of affected individuals must be possible.

Or. en

Amendment 752

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

Proposal for a regulation

Recital 80

Text proposed by the Commission

(80) Union legislation on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the authorities responsible for the supervision and enforcement of the financial services legislation, including where applicable the European Central Bank, should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, including for market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council⁵⁶, it is also appropriate to integrate the conformity assessment procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive

Amendment

(80) Union legislation on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the authorities responsible for the supervision and enforcement of the financial services legislation, including where applicable the European Central Bank, should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, including for market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council⁵⁶, it is also appropriate to integrate the conformity assessment procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive

2013/36/EU. In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality management system of providers and the monitoring obligation placed on users of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU.

2013/36/EU. In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality management system of providers and the monitoring obligation placed on users of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU. ***With regard to use case 5(b) in Annex III, areas covered by this Regulation relate to those outlined in Article 1(a). All other procedures relating to creditworthiness assessment are covered by the Directive of the European Parliament and of the Council on consumer credits .***

⁵⁶ Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

⁵⁶ Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

Or. en

Amendment 753

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation Recital 80

Text proposed by the Commission

(80) Union legislation on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the authorities responsible for the supervision

Amendment

(80) Union legislation on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the authorities responsible for the supervision

and enforcement of the financial services legislation, including where applicable the European Central Bank, should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, including for market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council⁵⁶, it is also appropriate to integrate the conformity assessment procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive 2013/36/EU. In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality management system of providers and the monitoring obligation placed on users of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU.

and enforcement of the financial services legislation, including where applicable the European Central Bank, should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, including for market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council⁵⁶, it is also appropriate to integrate the conformity assessment procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive 2013/36/EU. In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality management system of providers and the monitoring obligation placed on users of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU. ***With regard to use case 5(b) in Annex III, areas covered by this Regulation relate to those outlined in Article 1(a). All other procedures relating to creditworthiness assessment are covered by the Directive of the European Parliament and of the Council on consumer credits.***

⁵⁶ Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

⁵⁶ Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

Or. en

Amendment 754

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

Proposal for a regulation

Recital 80

Text proposed by the Commission

(80) Union legislation on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the authorities responsible for the supervision and enforcement of the financial services legislation, including where applicable the European Central Bank, should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, including for market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council⁵⁶, it is also appropriate to integrate the conformity assessment procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive 2013/36/EU. ***In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality management system of providers and the monitoring obligation placed on users of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU.***

Amendment

(80) Union legislation on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the authorities responsible for the supervision and enforcement of the financial services legislation, including where applicable the European Central Bank, should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, including for market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council⁵⁶, it is also appropriate to integrate the conformity assessment procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive 2013/36/EU.

⁵⁶ Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

⁵⁶ Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

Or. en

Amendment 755

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 80

Text proposed by the Commission

(80) Union legislation on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the authorities responsible for the supervision and enforcement of the financial services legislation, including where applicable the European **Central Bank**, should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, *including for* market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council⁵⁶, it is also appropriate to integrate the conformity assessment

Amendment

(80) Union legislation on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the **competent authorities** responsible for the supervision and enforcement of the financial services legislation, including where applicable the **competent authorities as defined in Directive 2013/36/EU of the European Parliament and of the Council**, should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, *excluding* market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of

procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive 2013/36/EU. In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality management system of providers and the monitoring obligation placed on users of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU.

the European Parliament and of the Council⁵⁶, it is also appropriate to integrate *certain aspects of* the conformity assessment procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive 2013/36/EU. In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality management system of providers and the monitoring obligation placed on users of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU.

⁵⁶ Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

⁵⁶ Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

Or. en

Amendment 756

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 Recital 80 a (new)

Text proposed by the Commission

Amendment

(80 a) Where the national market surveillance authority has not taken measures against an infringement to this Regulation, the Commission should be in possession of all the necessary resources, in terms of staffing, expertise, and financial means, for the performance of its tasks instead of the national market surveillance authority under this

Regulation. In order to ensure the availability of the resources necessary for the adequate investigation and enforcement measures that the Commission could undertake under this Regulation, the Commission should charge fees on national market surveillance authorities, the level of which should be established on a case-by-case basis. The overall amount of fees charged should be established on the basis of the overall amount of the costs incurred by the Commission to exercise its investigation and enforcement powers under this Regulation. Such an amount should include costs relating to the exercise of the specific powers and tasks connected to Chapter 4 of Title VIII of this Regulation. The external assigned revenues resulting from the fees could be used to finance additional human resources, such as contractual agents and seconded national experts, and other expenditure related to the fulfilment of these tasks entrusted to the Commission by this Regulation.

Or. en

Justification

Consistent with the new Article on Commission fees.

Amendment 757

Morten Løkkegaard

Proposal for a regulation

Recital 81

Text proposed by the Commission

(81) The development of AI systems other than high-risk AI systems in **accordance with the requirements of this Regulation** may lead to a larger uptake of trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should be encouraged to create

Amendment

(81) The development of AI systems other than high-risk AI systems in **a safe, trustworthy, and ethical manner** may lead to a larger uptake of trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should be encouraged to create **voluntary market-based** codes of

codes of conduct *intended to foster the voluntary application of the mandatory requirements applicable to high-risk AI systems*. Providers should also be encouraged to apply on a voluntary basis additional requirements related, for example, to environmental sustainability, accessibility to persons with disability, stakeholders' participation in the design and development of AI systems, and diversity of the development teams. The Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI development, including on data access infrastructure, semantic and technical interoperability of different types of data.

conduct *based on the requirements applicable to high-risk AI systems, adapted in light of the intended purpose of the systems and the lower risk involved*. Providers should also be encouraged to apply on a voluntary basis additional requirements related, for example, to environmental sustainability, accessibility to persons with disability, stakeholders' participation in the design and development of AI systems, and diversity of the development teams. *Compliance with the codes of conduct can be signaled through a label, where relevant. The Digital Europe Programme should support the development and uptake of these codes of conduct*. The Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI development, including on data access infrastructure, semantic and technical interoperability of different types of data.

Or. en

Justification

Voluntary codes of conduct can be an important tool to foster safe, trustworthy, and ethical application of all AI systems. For the codes of conduct to be relevant and appropriate for non-high-risk AI systems they should however not oblige the companies to live up to all high-risk requirements in Chapter 2. This amendment seeks to introduce more flexibility for the code of conduct to be adapted to the lower risk involved in non-high-risk applications. In addition, it is suggested to specify that compliance with the codes of conduct can be signaled through a label. In this way the codes of conduct can be a stepping-stone for providers, particularly the small ones, as well as a tool for users to identify providers that apply safe, trustworthy, and ethical AI, hence driving a market-based transition towards more safe, trustworthy, and ethical use of AI. The Digital Europe Programme is an important instrument to support the development of the voluntary codes of conduct.

Amendment 758 Christel Schaldemose

Proposal for a regulation Recital 81

Text proposed by the Commission

(81) The development of AI systems other than high-risk AI systems in ***accordance with the requirements of this Regulation*** may lead to a larger uptake of trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should be encouraged to create codes of conduct ***intended to foster the voluntary application of the mandatory*** requirements applicable to high-risk AI systems. Providers should also be encouraged to apply on a voluntary basis additional requirements related, for example, to environmental sustainability, accessibility to persons with disability, stakeholders' participation in the design and development of AI systems, and diversity of the development teams. The Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI development, including on data access infrastructure, semantic and technical interoperability of different types of data.

Amendment

(81) The development of AI systems other than high-risk AI systems in ***a safe, trustworthy and ethical manner*** may lead to a larger uptake of trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should be encouraged to create ***voluntary market-based*** codes of conduct ***based on the*** requirements applicable to high-risk AI systems, ***adapted in light of the intended purpose of the systems and the lower risk involved.*** Providers should also be encouraged to apply on a voluntary basis additional requirements related, for example, to environmental sustainability, accessibility to persons with disability, stakeholders' participation in the design and development of AI systems, and diversity of the development teams. ***Compliance with the codes of conduct can be signaled through a label, where relevant. The Digital Europe Programme should support the development and uptake of these codes of conduct.*** The Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI development, including on data access infrastructure, semantic and technical interoperability of different types of data.

Or. en

Amendment 759

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituș

**Proposal for a regulation
Recital 81**

Text proposed by the Commission

(81) The development of AI systems other than high-risk AI systems in

Amendment

(81) The development of AI systems other than high-risk AI systems in

accordance with the requirements of this Regulation may lead to a larger uptake of trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should be encouraged to create codes of conduct intended to foster the voluntary application of the mandatory requirements applicable to high-risk AI systems. Providers should also be encouraged to apply on a voluntary basis additional requirements related, for example, to environmental sustainability, accessibility to persons with disability, stakeholders' participation in the design and development of AI systems, and diversity of the development teams. The Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI development, including on data access infrastructure, semantic and technical interoperability of different types of data.

accordance with the requirements of this Regulation may lead to a larger uptake of trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should be encouraged to create codes of conduct intended to foster the voluntary application of the mandatory requirements applicable to high-risk AI systems *or risk-appropriate codes of conduct that sufficiently increase trust in the underlying technology that is not high-risk*. Providers should also be encouraged to apply on a voluntary basis additional requirements related, for example, to environmental sustainability, accessibility to persons with disability, stakeholders' participation in the design and development of AI systems, and diversity of the development teams. The Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI development, including on data access infrastructure, semantic and technical interoperability of different types of data.

Or. en

Amendment 760

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

Proposal for a regulation

Recital 81

Text proposed by the Commission

(81) The development of AI systems other than high-risk AI systems in accordance with the requirements of this Regulation may lead to a larger uptake of trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should be encouraged to create codes of conduct intended to foster the voluntary application of the mandatory requirements applicable to high-risk AI

Amendment

(81) The development of AI systems other than high-risk AI systems in accordance with the requirements of this Regulation may lead to a larger uptake of trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should be encouraged to create codes of conduct intended to foster the voluntary application of the mandatory requirements applicable to high-risk AI

systems. Providers should also be encouraged to apply on a voluntary basis additional requirements related, for example, to environmental sustainability, accessibility to persons with disability, stakeholders' participation in the design and development of AI systems, and diversity of the development teams. The Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI development, including on data access infrastructure, semantic and technical interoperability of different types of data.

systems. Providers should also be encouraged to apply on a voluntary basis additional requirements related, for example, to **energy efficiency, resource use and waste production, and** environmental sustainability, accessibility to persons with disability, stakeholders' participation in the design and development of AI systems, and diversity, **equal representation and gender-balance** of the development teams. The Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI development, including on data access infrastructure, semantic and technical interoperability of different types of data.

Or. en

Amendment 761

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

Proposal for a regulation Recital 82

Text proposed by the Commission

(82) It is important that AI systems related to products that are not high-risk in accordance with this Regulation and thus are not required to comply with the requirements set out **herein** are nevertheless safe when placed on the market or put into service. To contribute to this objective, the Directive 2001/95/EC of the European Parliament and of the Council⁵⁷ would apply as a safety net.

Amendment

(82) It is important that AI systems related to products that are not high-risk in accordance with this Regulation and thus are not required to comply with the requirements set out **for high-risk AI systems** are nevertheless safe when placed on the market or put into service. To contribute to this objective, the Directive 2001/95/EC of the European Parliament and of the Council⁵⁷ would apply as a safety net.

⁵⁷ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).

⁵⁷ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).

Amendment 762

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

Proposal for a regulation

Recital 83

Text proposed by the Commission

(83) In order to ensure trustful and constructive cooperation of competent authorities on Union and national level, all parties involved in the application of this Regulation should respect the confidentiality of information and data obtained in carrying out their tasks.

Amendment

(83) In order to ensure trustful and constructive cooperation of competent authorities on Union and national level, all parties involved in the application of this Regulation should *aim for transparency and openness. Where necessary for individual cases and internal deliberations, they should also* respect the confidentiality of information and data obtained in carrying out their tasks.

Amendment 763

Axel Voss, Deirdre Clune

Proposal for a regulation

Recital 84

Text proposed by the Commission

(84) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement. For certain specific infringements, Member States should take into account the margins and criteria set out in this Regulation. The European Data Protection Supervisor should have the power to impose fines on Union institutions, agencies and bodies falling within the scope of this Regulation.

Amendment

(84) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement. For certain specific infringements, Member States should take into account the margins and criteria set out in this Regulation. The European Data Protection Supervisor should have the power to impose fines on Union institutions, agencies and bodies falling within the scope of this Regulation. *The penalties and litigation costs under*

this Regulation should not be subject to contractual clauses or any other arrangements.

Or. en

Amendment 764

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

Proposal for a regulation

Recital 84 a (new)

Text proposed by the Commission

Amendment

(84 a) In order to strengthen and harmonise administrative penalties for infringements of this Regulation, each national supervisory authority should have the power to impose administrative fines. This Regulation should indicate infringements and the upper limit for setting the related administrative fines, which should be determined by the national supervisory authority in each individual case, taking into account all relevant circumstances of the specific situation, with due regard in particular to the nature, gravity and duration of the infringement and of its consequences and the measures taken to ensure compliance with the obligations under this Regulation and to prevent or mitigate the consequences of the infringement.

Or. en

Amendment 765

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

Recital 84 a (new)

Text proposed by the Commission

Amendment

(84 a) An affected person should also have the right to mandate a not-for-profit body, organisation or association that has been properly constituted in accordance with the law of a Member State, to lodge the complaint on their behalf. To this end, Directive 2020/1828/EC on Representative Actions for the Protection of the Collective Interests of Consumers should be amended to include this Regulation among the provisions of Union law falling under its scope.

Or. en

Justification

Consistent with the new Articles 68 a and b.

Amendment 766

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 84 a (new)

Text proposed by the Commission

Amendment

(84 a) Union legislation on the protection of whistleblowers (Directive (EU) 2019/1937) has full application to academics, designers, developers, project contributors, auditors, product managers, engineers and economic operators acquiring information on breaches of Union law by a provider of AI system or its AI system, even if they are not explicitly mentioned in Article 4(1)a-4(1)d of that Directive.

Or. en

Amendment 767

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

Proposal for a regulation
Recital 84 b (new)

Text proposed by the Commission

Amendment

(84 b) Natural persons, affected by an AI system falling within the scope of this Regulation, should have the right to lodge a complaint against the providers or users of such AI system with a national supervisory authority, if they consider that their fundamental rights, health or safety have been breached. An affected person should also have the right to mandate a not-for-profit body, organisation or association that has been properly constituted in accordance with the law of a Member State, to lodge the complaint on their behalf.

Or. en

Amendment 768

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 84 b (new)

Text proposed by the Commission

Amendment

(84 b) Union legislation on consumer protection(notably Directives (EU) 2019/2161, 2005/29/EC,2011/83/EU) applies to AI systems to the extent determined in these legislations, regardless of whether these systems are categorized as high-risk.

Or. en

Amendment 769

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

Proposal for a regulation

Recital 85

Text proposed by the Commission

(85) Afin de garantir que le cadre réglementaire puisse être adapté si nécessaire, le pouvoir d'adopter des actes conformément à l'article 290 du TFUE devrait être délégué à la Commission pour lui permettre de modifier les techniques et les approches visées à l'annexe I pour définir les systèmes d'IA, les actes législatifs d'harmonisation de l'Union énumérés à l'annexe II, les systèmes d'IA à haut risque énumérés à l'annexe III, les dispositions relatives à la documentation technique énumérées à l'annexe IV, le contenu de la déclaration «UE» de conformité à l'annexe V, les dispositions relatives aux procédures d'évaluation de la conformité des annexes VI et VII et les dispositions établissant les systèmes d'IA à haut risque auxquels devrait s'appliquer la procédure d'évaluation de la conformité fondée sur l'évaluation du système de gestion de la qualité et l'évaluation de la documentation technique. Il importe particulièrement que la Commission procède aux consultations appropriées durant son travail préparatoire, y compris au niveau des experts, et que ces consultations soient menées conformément aux principes définis dans l'accord interinstitutionnel du 13 avril 2016 «Mieux légiférer»⁵⁸. En particulier, afin d'assurer une participation égale à la préparation des actes délégués, le Parlement européen et le Conseil reçoivent tous les documents en même temps que les experts des États membres, et leurs experts ont systématiquement accès aux réunions des groupes d'experts de la Commission participant à la préparation des actes délégués.

Amendment

(85) Afin de garantir que le cadre réglementaire puisse être adapté si nécessaire, le pouvoir d'adopter des actes conformément à l'article 290 du TFUE devrait être délégué à la Commission pour lui permettre de modifier les techniques et les approches visées à l'annexe I pour définir les systèmes d'IA, les actes législatifs d'harmonisation de l'Union énumérés à l'annexe II, les systèmes d'IA à haut risque énumérés à l'annexe III, les dispositions relatives à la documentation technique énumérées à l'annexe IV, le contenu de la déclaration «UE» de conformité à l'annexe V, les dispositions relatives aux procédures d'évaluation de la conformité des annexes VI et VII et les dispositions établissant les systèmes d'IA à haut risque auxquels devrait s'appliquer la procédure d'évaluation de la conformité fondée sur l'évaluation du système de gestion de la qualité et l'évaluation de la documentation technique. ***La délégation lui étant accordée dans le but d'adapter le présent règlement aux progrès de la technique, la Commission ne devrait pouvoir adopter de tels actes délégués que pour compléter par des ajouts ou des précisions non restrictives les listes figurant dans ces annexes, alors que les retraits, les précisions restrictives ou les modifications de la définition des entrées qui y figurent ne devraient résulter que de l'adoption de règlements modificatifs.*** Il importe particulièrement que la Commission procède aux consultations appropriées durant son travail préparatoire, y compris au niveau des experts, et que ces consultations soient menées conformément aux principes définis dans l'accord interinstitutionnel du 13 avril 2016 «Mieux légiférer»⁵⁸. En particulier, afin d'assurer une participation égale à la préparation des actes délégués, le Parlement européen et le Conseil reçoivent tous les documents en même temps que les experts des États

membres, et leurs experts ont systématiquement accès aux réunions des groupes d'experts de la Commission participant à la préparation des actes délégués.

⁵⁸ JO L 123 du 12.5.2016, p. 1.

⁵⁸ JO L 123 du 12.5.2016, p. 1.

Or. fr

Amendment 770

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Recital 85

Text proposed by the Commission

(85) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the techniques and approaches referred to in Annex I to define AI systems, the Union harmonisation legislation listed in Annex II, ***the high-risk AI systems listed in Annex III, the provisions regarding technical documentation listed in Annex IV***, the content of the EU declaration of conformity in Annex V, ***the provisions regarding the conformity assessment procedures in Annex VI and VII and the provisions establishing the high-risk AI systems to which the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation should apply***. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁵⁸. In

Amendment

(85) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the techniques and approaches referred to in Annex I to define AI systems, the Union harmonisation legislation listed in Annex II ***and*** the content of the EU declaration of conformity in Annex V. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁵⁸. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

⁵⁸ OJ L 123, 12.5.2016, p. 1.

⁵⁸ OJ L 123, 12.5.2016, p. 1.

Or. en

Justification

To create legal certainty for AI developers, it is important that the high-risk areas of application are clearly laid down and cannot be changed quickly and dramatically by means of delegated acts. All additions to the list of high risk AI systems should be subject to Parliament's approval.

Amendment 771

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

Proposal for a regulation Recital 85

Text proposed by the Commission

(85) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the techniques and approaches referred to in Annex I to define AI systems, the Union harmonisation legislation listed in Annex II, the high-risk AI systems listed in Annex III, the provisions regarding technical documentation listed in Annex IV, the content of the EU declaration of conformity in Annex V, the provisions regarding the conformity assessment procedures in Annex VI and VII and the provisions establishing the high-risk AI systems to which the conformity assessment procedure based on assessment

Amendment

(85) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the techniques and approaches referred to in Annex I to define AI systems, the Union harmonisation legislation listed in Annex II, the high-risk AI systems listed in Annex III, the provisions regarding technical documentation listed in Annex IV, the content of the EU declaration of conformity in Annex V, the provisions regarding the conformity assessment procedures in Annex VI and VII and the provisions establishing the high-risk AI systems to which the conformity assessment procedure based on assessment

of the quality management system and assessment of the technical documentation should apply. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁵⁸. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

of the quality management system and assessment of the technical documentation should apply. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁵⁸. **These consultations should involve the participation of a balanced selection of stakeholders, including consumer organisations, associations representing affected persons, businesses representatives from different sectors and sizes, as well as researchers and scientists.** In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

⁵⁸ OJ L 123, 12.5.2016, p. 1.

⁵⁸ OJ L 123, 12.5.2016, p. 1.

Or. en

Amendment 772

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 Recital 85

Text proposed by the Commission

(85) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend *the techniques and approaches referred to in Annex I to define AI systems*, the Union

Amendment

(85) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the Union harmonisation legislation listed in Annex II, the high-risk AI systems listed

harmonisation legislation listed in Annex II, the high-risk AI systems listed in Annex III, the provisions regarding technical documentation listed in Annex IV, the content of the EU declaration of conformity in Annex V, the provisions regarding the conformity assessment procedures in Annex VI and VII ***and the provisions establishing the high-risk AI systems to which the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation should apply.*** It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁵⁸. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

⁵⁸ OJ L 123, 12.5.2016, p. 1.

in Annex III, the provisions regarding technical documentation listed in Annex IV, the content of the EU declaration of conformity in Annex V ***and*** the provisions regarding the conformity assessment procedures in Annex VI and VII. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁵⁸. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

⁵⁸ OJ L 123, 12.5.2016, p. 1.

Or. en

Justification

Consistent with the deletion of Annex I and the changes in Article 43.

Amendment 773

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Andrus Ansip, Dita Charanzová, Morten Løkkegaard, Alin Mituță

Proposal for a regulation

Recital 85

Text proposed by the Commission

(85) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the techniques and approaches referred to in Annex I to define AI systems, the Union harmonisation legislation listed in Annex II, the high-risk AI systems listed in Annex III, the provisions regarding technical documentation listed in Annex IV, the content of the EU declaration of conformity in Annex V, the provisions regarding the conformity assessment procedures in Annex VI and VII and the provisions establishing the high-risk AI systems to which the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation should apply. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁵⁸. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Amendment

(85) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the techniques and approaches referred to in Annex I to define AI systems, the Union harmonisation legislation listed in Annex II, the high-risk AI systems listed in Annex III, the provisions regarding technical documentation listed in Annex IV, the content of the EU declaration of conformity in Annex V, the provisions regarding the conformity assessment procedures in Annex VI and VII and the provisions establishing the high-risk AI systems to which the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation should apply. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including **with industry, civil society, other stakeholders, and** at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁵⁸. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

⁵⁸ OJ L 123, 12.5.2016, p. 1.

⁵⁸ OJ L 123, 12.5.2016, p. 1.

Or. en



*Committee on the Internal Market and Consumer Protection
Committee on Civil Liberties, Justice and Home Affairs*

2021/0106(COD)

13.6.2022

AMENDMENTS

774 - 1189

Draft report
Brando Benifei, Drago 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))

AM_Com_LegReport

Amendment 774

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

Proposal for a regulation

Recital 86 a (new)

Text proposed by the Commission

Amendment

(86 a) Given the rapid technological developments and the required technical expertise in conducting the assessment of high-risk AI systems, the Commission should regularly review Annex III, at least every six months, while consulting with the relevant stakeholders, including ethics experts and anthropologists, sociologists, mental health specialists and any relevant scientists and researchers.

Or. en

Amendment 775

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

Proposal for a regulation

Recital 86 a (new)

Text proposed by the Commission

Amendment

(86 a) In order to ensure uniform conditions for the implementation of this Regulation, it should be accompanied by the publication of guidelines to help all stakeholders to interpret key concepts covered by the Regulation, such as prohibited or high-risk AI cases and the precise means and implementation rules of the Regulation by national competent authorities;

Or. en

Amendment 776

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

**Proposal for a regulation
Recital 86 b (new)**

Text proposed by the Commission

Amendment

(86 b) When adopting delegated or implementing acts concerning high-risk sectors of AI development, notably those raising concerns with respect to ethical principles or entailing risks to the health or safety of humans, animals or plants, or the protection of the environment, Member States should also assume greater responsibility in the decision-making process. In particular, the abstentions of Member States representatives' should be counted within a qualified majority, each Member State representative should give substantive reasons for votes and abstentions, each of their vote and abstention should be accompanied by a detailed justification, on the basis of Regulation XX/XX amending Regulation (EU) No 182/2011.

Or. en

Amendment 777

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

**Proposal for a regulation
Recital 87 a (new)**

Text proposed by the Commission

Amendment

(87 a) As reliable information on the resource and energy use, waste production and other environmental impact of AI systems and related ICT technology, including software, hardware and in particular data centres, is limited, the Commission should evaluate the impact and effectiveness of this Regulation regarding these criteria and

further evaluate bringing legislation for the sector to contribute to EU climate strategy and targets.

Or. en

Amendment 778

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

Proposal for a regulation

Recital 89

Text proposed by the Commission

(89) The European Data Protection Supervisor and the European Data Protection Board were consulted in accordance with Article 42(2) of Regulation (EU) 2018/1725 and delivered an opinion on [...].

Amendment

(89) The European Data Protection Supervisor and the European Data Protection Board were consulted in accordance with Article 42(2) of Regulation (EU) 2018/1725 and delivered an opinion on **18.6.2021**.

Or. en

Amendment 779

Sophia in 't Veld, Michal Šimek

Proposal for a regulation

Article 1 – title

Text proposed by the Commission

1 Subject matter

Amendment

1 **Aim and** subject matter

Or. en

Amendment 780

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 1 – paragraph -1 (new)

Text proposed by the Commission

Amendment

-1 The purpose of this Regulation is to ensure a high level of protection of health, safety, fundamental rights, the environment and the Union values enshrined in Article 2 TEU from harmful effects of artificial intelligence systems in the Union while promoting innovation.

Or. en

Amendment 781

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 1 – paragraph -1 (new)

Text proposed by the Commission

Amendment

-1 The purpose of this Regulation is to ensure a high level of protection of health, safety, fundamental rights and the environment, from harmful effects of artificial intelligence systems ("AI systems") in the Union, while enhancing innovation.

Or. en

Amendment 782

Sophia in 't Veld, Michal Šime ka

Proposal for a regulation

Article 1 – paragraph -1 (new)

Text proposed by the Commission

Amendment

-1 The purpose of this Regulation is to ensure a high level of protection of health, safety, and fundamental rights from harmful effects of artificial intelligence systems ("AI systems") in the Union, while enhancing innovation.

Or. en

Amendment 783

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

Proposal for a regulation

Article 1 – paragraph 1 – introductory part

Text proposed by the Commission

This Regulation lays down:

Amendment

1. The purpose of this Regulation is to ensure a high level of protection of public interests, such as health, safety, fundamental rights, the environment and democracy from harmful effects of artificial intelligence systems ("AI systems") in the Union, whether individual, societal or environmental, while enhancing innovation. Its provisions are underpinned by the precautionary principle.

This Regulation lays down:

Or. en

Amendment 784

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

Proposal for a regulation

Article 1 – paragraph 1 – introductory part

Text proposed by the Commission

This Regulation lays down:

Amendment

The purpose of this Regulation is to ensure a high level of protection of fundamental rights, health, safety and the environment from harmful effects of the use of artificial intelligence systems in the Union while enhancing innovation. This Regulation lays down:

Or. en

Amendment 785

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

Proposal for a regulation

Article premier – paragraph 1 – point a

Text proposed by the Commission

(a) des règles harmonisées concernant la mise sur le marché, la mise en service et l'utilisation de systèmes d'intelligence artificielle (ci-après dénommés «systèmes d'IA») **dans l'Union**;

Amendment

(a) des règles **minimales** harmonisées concernant **le développement d'une I.A. centrée sur l'humain dans l'Union au travers de** la mise sur le marché, la mise en service et l'utilisation de systèmes d'intelligence artificielle (ci-après dénommés «systèmes d'IA»);

Or. fr

Amendment 786

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

Proposal for a regulation

Article 1 – paragraph 1 – point a

Text proposed by the Commission

(a) harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems') in the Union;

Amendment

(a) harmonised rules for the placing on the market, the **development, the** putting into service, **the deployment** and the use of **human-centric and trustworthy** artificial intelligence systems ('AI systems') in the Union;

Or. en

Amendment 787

Marion Walsmann

Proposal for a regulation

Article 1 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems') in the Union;

(a) harmonised rules for the placing on the market, the putting into service and the use of **safe and trustworthy** artificial intelligence systems ('AI systems') in the Union;

Or. en

Amendment 788

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 1 – paragraph 1 – point a

Text proposed by the Commission

(a) harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems') in the Union;

Amendment

(a) harmonised rules for the **development**, placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems') in the Union;

Or. en

Amendment 789

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

Proposal for a regulation

Article 1 – paragraph 1 – point a

Text proposed by the Commission

(a) harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems') in the Union;

Amendment

(a) harmonised rules for the **development**, placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems') in the Union;

Or. en

Amendment 790

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 1 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) principles applicable to all AI systems;

Or. en

Justification

Consistent with new Article 4a.

Amendment 791

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 1 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) specific requirements for high-risk AI systems and obligations for operators of such systems;

(c) specific requirements for high-risk AI systems and obligations for operators of such systems, *unless these systems are already covered by sector-specific regulation*;

Or. en

Amendment 792

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 1 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) harmonised rules on high-risk AI systems to ensure a high level of trustworthiness and protection of fundamental rights, health and safety, the Union values enshrined in Article 2 TEU

and the environment;

Or. en

Amendment 793

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

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(c a) harmonised rules on high-risk AI systems to ensure a high level of trustworthiness and protection of fundamental rights, health and safety

Or. en

Amendment 794

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

Proposal for a regulation

Article 1 – paragraph 1 – point d

Text proposed by the Commission

Amendment

*(d) harmonised transparency rules for AI systems **intended to interact with natural persons, emotion recognition systems and biometric categorisation systems, and AI systems used to generate or manipulate image, audio or video content;***

(d) harmonised transparency rules for AI systems;

Or. en

Amendment 795

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

Proposal for a regulation
Article 1 – paragraph 1 – point d

Text proposed by the Commission

(d) harmonised transparency rules for AI systems *intended to interact with natural persons, emotion recognition systems and biometric categorisation systems, and AI systems used to generate or manipulate image, audio or video content;*

Amendment

(d) harmonised transparency rules for AI systems;

Or. en

Amendment 796

Svenja Hahn, Drago Tudorache, Nicola Beer, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation
Article 1 – paragraph 1 – point d

Text proposed by the Commission

(d) harmonised transparency rules for AI systems *intended to interact with natural persons, emotion recognition systems and biometric categorisation systems, and AI systems used to generate or manipulate image, audio or video content;*

Amendment

(d) harmonised transparency rules for *certain* AI systems;

Or. en

Amendment 797

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation
Article 1 – paragraph 1 – point e

Text proposed by the Commission

(e) rules on market monitoring *and* surveillance.

Amendment

(e) rules on market monitoring, *market surveillance and governance*;

Amendment 798

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

Proposal for a regulation

Article 1 – paragraph 1 – point e

Text proposed by the Commission

(e) rules on market monitoring *and* surveillance.

Amendment

(e) rules on market monitoring, ***market*** surveillance ***and enforcement***.

Amendment 799

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 1 – paragraph 1 – point e

Text proposed by the Commission

(e) rules on market monitoring *and* surveillance.

Amendment

(e) rules on market monitoring, ***market*** surveillance ***and governance***;

Amendment 800

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 1 – paragraph 1 – point e a (new)

Text proposed by the Commission

Amendment

(e a) measures in support of innovation with a particular focus on SMEs and start-ups, including but not limited to setting up regulatory sandboxes and targeted measures to reduce the compliance burden on SME's and start-

ups;

Or. en

Amendment 801
Marion Walsmann

Proposal for a regulation
Article 1 – paragraph 1 – point e a (new)

Text proposed by the Commission

Amendment

(e a) measures to support innovation and provide for a level playing field for European providers of AI systems on international level, in particular for small-scale providers like SMEs.

Or. en

Amendment 802
Svenja Hahn, Drago Tudorache, Nicola Beer, Dita Charanzová, Andrus Ansip, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Ondej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation
Article 1 – paragraph 1 – point e a (new)

Text proposed by the Commission

Amendment

(e a) measures in support of innovation with a particular focus on SMEs and start-ups, including the setting up of regulatory sandboxes and the reduction of regulatory burdens.

Or. en

Amendment 803
Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation
Article 1 – paragraph 1 – point e a (new)

Text proposed by the Commission

Amendment

(e a) rules for the establishment and functioning of the European Union Artificial Intelligence Office;

Or. en

Amendment 804

Karlo Ressler

Proposal for a regulation

Article 1 – paragraph 1 – point e a (new)

Text proposed by the Commission

Amendment

(e a) measures in support of innovation particularly focusing on SMEs and start-ups.

Or. en

Amendment 805

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituța, Michal Šime ka

Proposal for a regulation

Article 1 – paragraph 1 – point e b (new)

Text proposed by the Commission

Amendment

(e b) measures in support of innovation, including the setting up of regulatory sandboxes, and measures to reduce the regulatory burden on SMEs and start-ups.

Or. en

Amendment 806

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 1 – paragraph 1 – point e b (new)

Text proposed by the Commission

Amendment

(e b) the establishment of an independent ‘European Artificial Intelligence Board’ and its activities supporting the enforcement of this Regulation.

Or. en

Amendment 807

Sophia in 't Veld, Michal Šimek

Proposal for a regulation

Article 1 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

This Regulation is based on the principle that it is for developers, importers, distributors and users to ensure that they develop, place on the market or use AI systems that do not adversely affect health, safety, or fundamental rights. Its provisions are underpinned by the precautionary principle.

Or. en

Amendment 808

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 1 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

When justified by significant risks to fundamental rights of persons, including the protection of consumer rights, Member States may introduce regulatory solutions ensuring a higher level of

protection of persons than offered in this Regulation.

Or. en

Amendment 809

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 1 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The purpose of this Regulation is to ensure protection of health, safety, fundamental rights and the environment, from harmful effects of artificial intelligence systems in the Union, while supporting innovation.

Or. en

Amendment 810

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 1 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

These provisions shall apply to AI systems as a product, service or practice, or as part of a product, service or practice.

Or. en

Amendment 811

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 1 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

This Regulation shall be applied taking due account of the precautionary principle.

Or. en

Amendment 812

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 1 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

This Regulation is based on the principle that it is for developers, importers, distributors and downstream users to ensure that they develop, place on the market or use artificial intelligence that does not adversely affect health, safety, fundamental rights, and the environment. Its provisions are underpinned by the precautionary principle.

Or. en

Amendment 813

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 1 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

This Regulation is based on the principle that it is for developers, importers, distributors and downstream users to ensure that they develop, place on the market or use artificial intelligence that does not adversely affect health, safety, fundamental rights, or the environment. Its provisions are underpinned by the precautionary principle.

Or. en

Amendment 814

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 1 – paragraph 1 c (new)

Text proposed by the Commission

Amendment

Any processing of personal data for the purposes of this Regulation shall take place in accordance with Union legislation for the protection of personal data, in particular Regulation 2016/679, Directive 2016/680, Regulation 2018/1725 and Directive 2002/58.

Or. en

Amendment 815

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 2 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) providers placing on the market *or* putting into service AI systems in the Union, irrespective of whether those providers are established within the Union or in a third country;

(a) providers placing on the market, *developing*, putting into service *or deploying* AI systems in the Union, irrespective of whether those providers are established within the Union or in a third country;

Or. en

Amendment 816

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

Proposal for a regulation

Article 2 – paragraph 1 – point a

Text proposed by the Commission

- (a) ***providers*** placing on the market or putting into service AI systems in the Union, irrespective of whether those ***providers*** are established within the Union or in a third country;

Amendment

- (a) ***operators*** placing on the market or putting into service AI systems in the Union, irrespective of whether those ***operators*** are established within the Union or in a third country;

Or. en

Amendment 817

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 2 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

- (a a) providers of AI systems that have their main establishment in the EU;***

Or. en

Amendment 818

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 1 – point b

Text proposed by the Commission

Amendment

- (b) users of AI systems ***located*** within the Union;

- (b) users of AI systems *who are physically present or established* within the Union;***

Or. en

Amendment 819

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

Proposal for a regulation
Article 2 – paragraph 1 – point b

Text proposed by the Commission

(b) *users* of AI systems located within the Union;

Amendment

(b) *deployers* of AI systems located *or established* within the Union;

Or. en

Amendment 820

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

Proposal for a regulation
Article 2 – paragraph 1 – point b

Text proposed by the Commission

(b) users of AI systems *located* within the Union;

Amendment

(b) users of AI systems *who are established* within the Union;

Or. en

Amendment 821

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

Proposal for a regulation
Article 2 – paragraph 1 – point b

Text proposed by the Commission

(b) users of AI systems located within the Union;

Amendment

(b) users of AI systems *that are* located within the Union;

Or. en

Amendment 822

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

Proposal for a regulation
Article 2 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) users of AI systems **located within** the Union;

(b) users of AI systems **using the AI system in** the Union;

Or. en

Amendment 823

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 2 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(b a) natural persons affected by the use of AI systems;

Or. en

Amendment 824

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) providers and users of AI systems that are located in a third country, where the output produced by the system **is used** in the Union;

(c) providers and users of AI systems that are located in a third country, where the output, **meaning predictions, recommendations or decisions**, produced by the **AI system and influencing the environment it interacts with, is intended for use** in the Union **and puts at risk the health, safety or fundamental rights of natural persons physically present in the Union, insofar as the provider has permitted, is aware or can reasonably expect such use;**

Or. en

Amendment 825

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

Proposal for a regulation**Article 2 – paragraph 1 – point c***Text proposed by the Commission*

(c) providers and users of AI systems that are located in a third country, where the output produced by the system is used in the Union;

Amendment

(c) providers and users of AI systems that are located in a third country, where the output produced by the system is used in the Union *or affects natural persons within the Union*;

Or. en

Amendment 826

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

Proposal for a regulation**Article 2 – paragraph 1 – point c***Text proposed by the Commission*

(c) providers and users of AI systems that are located in a third country, where the output produced by the system is used in the Union;

Amendment

(c) providers and users of AI systems that are located in a third country, where the output produced by the system is used in the Union *or has effects in the Union*;

Or. en

Amendment 827

Svenja Hahn, Drago Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation**Article 2 – paragraph 1 – point c***Text proposed by the Commission*

(c) providers and users of AI systems *that are located* in a third country, where the output produced by the system is used

Amendment

(c) providers and users of AI systems *who are established* in a third country, where the output produced by the system is

in the Union;

used in the Union;

Or. en

Amendment 828

Sophia in 't Veld, Michal Šimek

Proposal for a regulation

Article 2 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) public authorities in a third country or to international organisations where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States.

Or. en

Amendment 829

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 2 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) importers, distributors, and authorised representatives of providers of AI systems;

Or. en

Amendment 830

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) importers, distributors and authorised representatives of providers of AI-systems.

Or. en

Amendment 831

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 2 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) natural persons, affected by the use of an AI system, who are in the Union;

Or. en

Amendment 832

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

Proposal for a regulation

Article 2 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) natural persons, affected by the use of an AI system, who are in the Union;

Or. en

Amendment 833

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

Proposal for a regulation
Article 2 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) importers and distributors of AI systems;

Or. en

Amendment 834

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

Proposal for a regulation
Article 2 – paragraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(c b) product placing on the market or putting into service an AI system together with their product and under their own name or trademark;

Or. en

Amendment 835

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

Proposal for a regulation
Article 2 – paragraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(c b) providers placing on the market or putting into service AI systems outside the Union where the provider is located within the Union;

Or. en

Amendment 836

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation
Article 2 – paragraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(c b) AI systems as a product, service or practice, or as part of a product, service or practice.

Or. en

Amendment 837

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

Proposal for a regulation
Article 2 – paragraph 1 – point c c (new)

Text proposed by the Commission

Amendment

(c c) authorised representatives of providers, which are established in the Union.

Or. en

Amendment 838

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 2 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

I a. providers placing on the market or putting into service AI systems in a third country where the provider or distributor of such AI systems originates from the Union;

Or. en

Amendment 839

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 2 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

I a. This Regulation shall also apply to Union institutions, offices and agencies where they develop, deploy or otherwise make use of AI systems.

Or. en

Amendment 840

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

Proposal for a regulation

Article 2 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

I a. This Regulation shall apply to Union institutions, offices, bodies and agencies when acting as an operator of an AI system.

Or. en

Amendment 841

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 2 – paragraph 2

Text proposed by the Commission

Amendment

2. For high-risk AI systems that are safety components of products or systems, or which are themselves products or systems, falling within the scope of the following acts, only Article 84 of this

deleted

Regulation shall apply:

- (a) Regulation (EC) 300/2008;
- (b) Regulation (EU) No 167/2013;
- (c) Regulation (EU) No 168/2013;
- (d) Directive 2014/90/EU;
- (e) Directive (EU) 2016/797;
- (f) Regulation (EU) 2018/858;
- (g) Regulation (EU) 2018/1139;
- (h) Regulation (EU) 2019/2144.

Or. en

Amendment 842

Marion Walsmann

Proposal for a regulation

Article 2 – paragraph 2 – introductory part

Text proposed by the Commission

2. For high-risk AI systems that are safety components of products or systems, or which are themselves products or systems, falling within the scope of the following acts, **only Article 84 of this Regulation shall apply**:

Amendment

2. **In order to ensure legal certainty, preserve the existing legislation and avoid duplication, only Article 84 of this Regulation shall apply** for high-risk AI systems that are safety components of products or systems, or which are themselves products or systems, falling within the scope of the following acts:

Or. en

Amendment 843

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 2 – introductory part

Text proposed by the Commission

2. For high-risk AI systems that are safety components of products or systems, or which are themselves products or systems, **falling** within the scope of the

Amendment

2. For high-risk AI systems that are safety components of products or systems, or which are themselves products or Systems **and that fall** within the scope of

following acts, only Article 84 of this Regulation shall apply:

the *listed Acts in Annex II - Section B*, only Article 84 of this Regulation shall apply.

Or. en

Amendment 844

Svenja Hahn, Drago Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 2 – paragraph 2 – introductory part

Text proposed by the Commission

2. For high-risk AI systems *that are safety components of products or systems, or which are themselves products or systems, falling within the scope of the following acts*, only Article 84 of this Regulation shall apply:

Amendment

2. For AI systems *classified as high-risk AI in accordance with Article 6 related to products covered by Union harmonisation legislation listed in Annex II, section B* only Article 84 of this Regulation shall apply.

Or. en

Amendment 845

Svenja Hahn, Drago Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 2 – paragraph 2 – point a

Text proposed by the Commission

(a) **Regulation (EC) 300/2008;**

Amendment

deleted

Or. en

Amendment 846

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 2 – point a

Text proposed by the Commission

Amendment

(a) **Regulation (EC) 300/2008;** *deleted*

Or. en

Amendment 847

Svenja Hahn, Drago Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 2 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) **Regulation (EU) No 167/2013;** *deleted*

Or. en

Amendment 848

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) **Regulation (EU) No 167/2013;** *deleted*

Or. en

Amendment 849

Svenja Hahn, Drago Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 2 – paragraph 2 – point c

Text proposed by the Commission

Amendment

(c) **Regulation (EU) No 168/2013;** *deleted*

Or. en

Amendment 850

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 2 – point c

Text proposed by the Commission

Amendment

(c) ***Regulation (EU) No 168/2013;*** *deleted*

Or. en

Amendment 851

Svenja Hahn, Drago Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 2 – paragraph 2 – point d

Text proposed by the Commission

Amendment

(d) ***Directive 2014/90/EU;*** *deleted*

Or. en

Amendment 852

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 2 – point d

Text proposed by the Commission

Amendment

(d) ***Directive 2014/90/EU;*** *deleted*

Or. en

Amendment 853

Svenja Hahn, Drago Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 2 – paragraph 2 – point e

Text proposed by the Commission

Amendment

(e) *Directive (EU) 2016/797;* *deleted*

Or. en

Amendment 854

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 2 – point e

Text proposed by the Commission

Amendment

(e) *Directive (EU) 2016/797;* *deleted*

Or. en

Amendment 855

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 2 – point f

Text proposed by the Commission

Amendment

(f) *Regulation (EU) 2018/858;* *deleted*

Or. en

Amendment 856

Svenja Hahn, Drago Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 2 – paragraph 2 – point f

Text proposed by the Commission

Amendment

(f) *Regulation (EU) 2018/858;* *deleted*

Or. en

Amendment 857

Svenja Hahn, Drago Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 2 – paragraph 2 – point g

Text proposed by the Commission

Amendment

(g) *Regulation (EU) 2018/1139;*

deleted

Or. en

Amendment 858

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 2 – point g

Text proposed by the Commission

Amendment

(g) *Regulation (EU) 2018/1139;*

deleted

Or. en

Amendment 859

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 2 – point h

Text proposed by the Commission

Amendment

(h) *Regulation (EU) 2019/2144.*

deleted

Or. en

Amendment 860

Svenja Hahn, Drago Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 2 – paragraph 2 – point h

Text proposed by the Commission

Amendment

(h) **Regulation (EU) 2019/2144.** *deleted*

Or. en

Amendment 861

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto ,
Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 2 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. *This Regulation shall not apply to AI systems, including their output, specifically developed and put into service for the sole purpose of scientific research and development.*

Or. en

Amendment 862

Milan Brglez, Hilde Vautmans, Catharina Rinzema

Proposal for a regulation

Article 2 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. *AI systems likely to interact with or impact on children shall be considered high-risk for this group;*

Or. en

Amendment 863

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto ,
Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 2 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2 b. This Regulation shall not apply to any research and development activity regarding AI systems in so far as such activity does not lead to or entail placing an AI system on the market or putting it into service.

Or. en

Amendment 864

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

Proposal for a regulation

Article 2 – paragraph 3

Text proposed by the Commission

Amendment

3. This Regulation shall not apply to AI systems developed or used exclusively for military purposes. *deleted*

Or. en

Amendment 865

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 2 – paragraph 3

Text proposed by the Commission

Amendment

3. This Regulation shall not apply to AI systems developed or used exclusively for military purposes. *deleted*

Or. en

Amendment 866

Pernando Barrena Arza, Cornelia Ernst

**Proposal for a regulation
Article 2 – paragraph 3**

Text proposed by the Commission

3. *This Regulation shall not apply to AI systems developed or used exclusively for military purposes.*

Amendment

deleted

Or. en

Amendment 867

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 2 – paragraph 3**

Text proposed by the Commission

3. This Regulation shall not apply to AI systems developed or used exclusively for military purposes.

Amendment

3. This Regulation shall not apply to AI systems developed or used exclusively for military purposes.

However, this Regulation shall apply to AI systems which are developed or used as dual-use items, as defined in Article 2, point (1) of Regulation (EU) 2021/821 of the European Parliament and of the Council^{1a}.

^{1a} *Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items (OJ L 206, 11.6.2021, p. 1).*

Or. en

Amendment 868

Sophia in 't Veld, Michal Šimeka

Proposal for a regulation
Article 2 – paragraph 3

Text proposed by the Commission

3. This Regulation shall not apply to AI systems developed or used exclusively for military purposes.

Amendment

3. This Regulation shall not apply to AI systems developed or used exclusively for military purposes, *unless the AI system is subsequently used for non-military purposes.*

Or. en

Amendment 869
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 2 – paragraph 3

Text proposed by the Commission

3. This Regulation shall not apply to AI systems developed or used exclusively for military purposes.

Amendment

3. This Regulation shall not apply to AI systems developed or used exclusively for military *or national security* purposes

Or. en

Amendment 870
Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan, Vincenzo Sofo

Proposal for a regulation
Article 2 – paragraph 3

Text proposed by the Commission

3. This Regulation shall not apply to AI systems developed or used exclusively for military purposes.

Amendment

3. This Regulation shall not apply to AI systems *designed, modified*, developed or used exclusively for military purposes.

Or. en

Amendment 871
Rob Rookens

on behalf of the ECR Group

**Proposal for a regulation
Article 2 – paragraph 3**

Text proposed by the Commission

3. This Regulation shall not apply to AI systems developed or used *exclusively* for military purposes.

Amendment

3. This Regulation shall not apply to AI systems developed or used for military purposes.

Or. en

Amendment 872

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

**Proposal for a regulation
Article 2 – paragraph 3 a (new)**

Text proposed by the Commission

Amendment

3 a. Union law on the protection of personal data, privacy and the confidentiality of communications applies to personal data processed in connection with the rights and obligations laid down in this Regulation. This Regulation shall not affect Regulations (EU) 2016/679, (EU) 2018/1725 or Directives 2002/58/EC and (EU) 2016/680.

Or. en

Amendment 873

Fernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Article 2 – paragraph 3 a (new)**

Text proposed by the Commission

Amendment

3 a. Any exemptions from the application of this Act to AI systems used exclusively by Member States for national security purposes will be without

prejudice to the application of Union law to any activity carried out by the Union or by a Member State that is subject to Union law.

Or. en

Amendment 874

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 2 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. This Regulation shall not apply to AI systems, including their output, specifically developed and put into service for the sole purpose of research and development.

Or. en

Amendment 875

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. Title III of this Regulation shall not apply to AI systems that are used in a business-to-business environment and do not directly impact natural persons.

Or. en

Amendment 876

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 2 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. This Regulation shall apply to Union institutions, offices, bodies and agencies when acting as an operator of an AI system.

Or. en

Amendment 877

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte

Proposal for a regulation

Article 2 – paragraph 4

Text proposed by the Commission

Amendment

4. Le présent règlement ne s'applique pas aux autorités publiques d'un pays tiers ni aux organisations internationales relevant du champ d'application du présent règlement en vertu du paragraphe 1, lorsque ces autorités ou organisations utilisent des systèmes d'IA dans le cadre d'accords internationaux de coopération des services répressifs et judiciaires avec l'Union ou avec un ou plusieurs États membres.

supprimé

Or. fr

Amendment 878

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 2 – paragraph 4

Text proposed by the Commission

Amendment

4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within

deleted

the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States.

Or. en

Amendment 879

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

Proposal for a regulation

Article 2 – paragraph 4

Text proposed by the Commission

Amendment

4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States.

Or. en

Amendment 880

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 2 – paragraph 4

Text proposed by the Commission

Amendment

4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or

organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States.

Or. en

Amendment 881

Sophia in 't Veld, Michal Šimek

**Proposal for a regulation
Article 2 – paragraph 4**

Text proposed by the Commission

Amendment

4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States.

deleted

Or. en

Amendment 882

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

**Proposal for a regulation
Article 2 – paragraph 4**

Text proposed by the Commission

Amendment

4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial

deleted

cooperation with the Union or with one or more Member States.

Or. en

Amendment 883

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Mituță, Ramona Strugariu, Drago Pîslaru, Lucia Šuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 2 – paragraph 4

Text proposed by the Commission

4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States.

Amendment

4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States *and are subject of a decision of the Commission adopted in accordance with Article 36 of Directive (EU)2016/680 or Article 45 of Regulation 2016/679 ('adequacy decision') or are part of an international agreement concluded between the Union and that third country or international organisation pursuant to Article 218 TFEU adducing adequate safeguards with respect to the protection of privacy and fundamental rights and freedoms of individuals;*

Or. en

Amendment 884

Kosma Złotowski, Patryk Jaki

Proposal for a regulation

Article 2 – paragraph 4

Text proposed by the Commission

4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States.

Amendment

4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international ***cooperation or*** agreements for law enforcement and judicial cooperation ***or in the context of border checks, asylum and immigration related activities*** with the Union or with one or more Member States.

Or. en

Amendment 885

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 2 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. *The use of any AI-system that is in line with this Regulation, should also continue to comply with the European Charter on Fundamental Rights, secondary Union law and national law. This Regulation shall not provide the legal ground for unlawful AI development, deployment or use.*

Or. en

Amendment 886

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 2 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. *An AI-system or practice that is in line with this Regulation, should also*

continue to comply with the European Charter on Fundamental Rights, existing and new secondary Union law and national law.

Or. en

Amendment 887

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Vincenzo Sofo, Adam Bielan

Proposal for a regulation

Article 2 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. This Regulation shall not apply to AI systems, including their output, specifically developed or used exclusively for scientific research and development purposes.

Or. en

Amendment 888

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. This Regulation shall not affect any research, testing and development activity regarding an AI system prior to this system being placed on the market or put into service.

Or. en

Amendment 889

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

Proposal for a regulation
Article 2 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. This Regulation shall not provide a legal basis for the development, deployment or use of AI systems that is unlawful under Union or national law;

Or. en

Amendment 890

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 2 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. This Regulation shall not affect community law on social policy.

Or. en

Amendment 891

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 2 – paragraph 5 b (new)

Text proposed by the Commission

Amendment

5 b. This Regulation shall not affect national labour law and practice or collective agreements, and it shall not preclude national legislation to ensure the protection of workers' rights in respect of the use of AI systems by employers, including where this implies introducing more stringent obligations than those laid down in this Regulation.

Or. en

Amendment 892

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 5 b (new)

Text proposed by the Commission

Amendment

5 b. This Regulation shall not apply to AI systems, including their output, specifically developed and put into service for the sole purpose of scientific research, testing and development. The Commission may adopt delegated acts that clarify this exemption.

Or. en

Amendment 893

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 2 – paragraph 5 b (new)

Text proposed by the Commission

Amendment

5 b. This Regulation is without prejudice to the rules laid down by other Union legal acts regulating the protection of personal data, in particular Regulation (EU) 2016/679, Directive (EU) 2016/680, Regulation (EU) 2018/1725, and Directive 2002/57/EC;

Or. en

Amendment 894

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 2 – paragraph 5 b (new)

Text proposed by the Commission

Amendment

5 b. Member States may adopt or maintain in force more stringent provisions, compatible with the Treaty in the field covered by this Directive, to ensure a higher level of protection of health, safety and fundamental rights.

Or. en

Amendment 895

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 2 – paragraph 5 b (new)

Text proposed by the Commission

Amendment

5 b. This Regulation shall not affect any research and development activity regarding AI systems in so far as such activity does not lead to placing an AI system on the market or putting it into service.

Or. en

Amendment 896

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 2 – paragraph 5 b (new)

Text proposed by the Commission

Amendment

5 b. This Regulation shall be without prejudice to Regulation (EU) 2016/679.

Or. en

Amendment 897

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

Proposal for a regulation

Article 2 – paragraph 5 c (new)

Text proposed by the Commission

Amendment

5 c. This Regulation is without prejudice to the rules laid down by other Union legal acts regulating other aspects of AI systems as well as the national rules aimed at enforcing or, as the case may be, implementing these acts, in particular Union law on consumer protection and product safety, including Regulation (EU)2017/2394, Regulation (EU) 2019/1020, Directive 2001/95/EC on general product safety and Directive 2013/11/EU.

Or. en

Amendment 898

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

Proposal for a regulation

Article 2 – paragraph 5 c (new)

Text proposed by the Commission

Amendment

5 c. This Regulation is without prejudice to the rules laid down by other Union legal acts relating to consumer protection and product safety, including Regulation (EU) 2017/2394, Regulation (EU) 2019/1020 and Directive 2001/95/EC on general product safety and Directive 2013/11/EU.

Or. en

Amendment 899

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 2 – paragraph 5 c (new)

Text proposed by the Commission

Amendment

5 c. This Regulation shall be without prejudice to Community law on social policy.

Or. en

Amendment 900

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 2 – paragraph 5 d (new)

Text proposed by the Commission

Amendment

5 d. This Regulation shall be without prejudice to national labour law and practice, that is any legal or contractual provision concerning employment conditions, working conditions, including health and safety at work and the relationship between employers and workers, including information, consultation and participation

Or. en

Amendment 901

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 2 – paragraph 5 e (new)

Text proposed by the Commission

Amendment

5 e. This Regulation shall not in any way affect the exercise of fundamental rights as recognised in the Member States and at Union level, including the right or freedom to strike or to take other action

covered by the specific industrial relations systems in Member States, in accordance with national law and/or practice. Nor does it affect the right to negotiate, to conclude and enforce collective agreements, or to take collective action in accordance with national law and/or practice.

Or. en

Amendment 902

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Mituță, Ramona Strugariu, Drago Pîslaru, Lucia Šuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 2 a (new)

Text proposed by the Commission

Amendment

Article 2 a

Metaverse environments

1. This regulation shall apply, mutatis mutandis, to operators of AI systems operating in virtual environments that can be accessed by natural persons in the Union that fulfil all the following criteria ('metaverse environments'):

- (i) they require natural persons to have a uniquely identifiable and permanent representation within the virtual environment that is legally and economically connected to them via an official identity document, a digital identity, a digital wallet, or equivalent;*
- (ii) they are built for social and economic interaction on a large scale;*
- (iii) they allow natural persons to behave and interact virtually in manners that are consistent with their real-world behaviours and interactions and that can be analysed to infer real-world characteristics, including personal data;*
- (iv) they allow natural persons to engage*

in real-world financial transactions, including through blockchain-backed digital currencies and non-fungible tokens;

(v) they allow for such interactions between natural persons as to make possible risks to the health, safety, or fundamental rights of natural persons or to bring prejudice to the values of the Union as enshrined in Article 2 TEU.

Or. en

Amendment 903

Rob Rooken

on behalf of the ECR Group

Proposal for a regulation

Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘artificial intelligence system’ (AI system) **means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;**

Amendment

(1) ‘artificial intelligence system’ (AI system) **refers to systems designed by humans that, given a complex goal, act in the physical or digital world by perceiving their environment, interpreting the collected structured or unstructured data, reasoning on the knowledge derived from this data and deciding the best action(s) to take (according to pre-defined parameters) to achieve the given goal. AI systems can also be designed to learn to adapt their behaviour by analysing how the environment is affected by their previous actions. As a scientific discipline, AI includes several approaches and techniques, such as machine learning (of which deep learning and reinforcement learning are specific examples), machine reasoning (which includes planning, scheduling, knowledge representation and reasoning, search, and optimization), and robotics (which includes control, perception, sensors and actuators, as well as the integration of all other techniques into cyber-physical systems);**

Amendment 904
Geoffroy Didier

Proposal for a regulation
Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘artificial intelligence system’ (AI system) means *software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;*

Amendment

(1) ‘artificial intelligence system’ (AI system) means *a system that combines these three criteria:*

- (i) receives machine and/or human-based data and inputs,*
- (ii) infers how to achieve a given set of human-defined objectives using learning, reasoning or modelling implemented with the techniques and approaches listed in Annex I, and*
- (iii) generates outputs in the form of content (generative AI systems), predictions, recommendations or decisions, which influence the environments it interacts with;*

Justification

At this point, the definition of AI (and AI techniques and approaches list of Annex I) is very broad in that they can include all types of systems or software applications, including software already on the market for decades, that do not involve the same risks. The inclusion of such systems or applications within the scope of the regulation would hampering innovation in technology companies, especially smaller ones. However, in a context of international competitiveness, it is essential to encourage technological development and not to prevent SMEs from accessing these markets.

Amendment 905

Proposal for a regulation

Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘artificial intelligence system’ (AI system) means software that is **developed with one or more of** the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;

Amendment

(1) ‘artificial intelligence system’ (AI system) means software that **display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals, which:**

(a) receives machine and/or human-based data and inputs;

(b) infers how to achieve a given set of human-defined objectives using data-driven models created through learning or reasoning implemented with the techniques and approaches listed in Annex I, and

(c) generates outputs in the form of content (generative AI systems), predictions, recommendations or decisions, which influence the environments it interacts with;

Or. en

Amendment 906

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘artificial intelligence system’ (AI system) means **software** that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions

Amendment

(1) ‘artificial intelligence system’ (AI system) means **a machine-based system** that is developed with one or more of the techniques and approaches listed in Annex I and is **capable of influencing the environment by producing an output**(predictions, recommendations, or

influencing the environments they interact with;

decisions) for a given set of objectives. It uses machine and/or human-based data and inputs to (i) perceive real and/or virtual environments; (ii) abstract these perceptions into models through analysis in an automated manner (e.g. with machine learning), or manually; and (iii) use model inference to formulate options for outcomes. AI systems are designed to operate with varying levels of autonomy;

Or. en

Justification

Unchanged OECD definition

Amendment 907

Morten Løkkegaard

Proposal for a regulation

Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘artificial intelligence system’ (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;

Amendment

(1) ‘artificial intelligence’ (AI) systems are software (and also hardware) systems designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal. AI systems can either use symbolic rules or learn a numeric model, and they can also adapt their behaviour by analysing how the environment is affected by their previous actions;

Or. en

Justification

A more technology neutral definition of AI, as proposed by the independent high-level expert group set up by the European Commission, should be supported instead of the current

proposal. The current proposal for the definition of AI is very technology centric, essentially based on a list of specific technologies in Annex I. The list in Annex I includes a lot of technologies which are usually not regarded as AI (such as logics, knowledge, statistics and optimization). Furthermore, it mentions terms such as deep learning, which is a very hyped term at the moment, but it lacks a clear definition.

Amendment 908

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘artificial intelligence system’ (AI system) means **software that is developed with one or more of** the techniques and approaches listed in Annex I **and can, for a given set of human-defined objectives, generate outputs such as** content, predictions, recommendations, or decisions **influencing** the environments **they interact with;**

Amendment

(1) ‘artificial intelligence system’ (AI system) means **a system that**

(I) receives machine and/or human-based data and inputs,

(II) infers how to achieve a given set of human-defined objectives using learning, reasoning or modelling implemented with the techniques and approaches listed in Annex I, **and**

(III) generates outputs in the form of content, predictions, recommendations or decisions, **which influence** the environments **it interacts with;**

Or. en

Justification

There is a need to distinguish AI systems from classic software systems and programming that the AI Act was never meant to target.

Amendment 909

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation
Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘artificial intelligence system’ (AI system) means *software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;*

Amendment

(1) ‘artificial intelligence (AI)’ means *computer systems that act in the physical or digital world and that, in an automated manner:*

- (i) decide on action(s) to take according to predefined parameters by perceiving their environment and analysing the collected structured or unstructured information from that environment; and/or*
- (ii) can adapt their decisions by analysing how the environment is affected by their previous actions.*

Or. en

Amendment 910
Andrea Caroppo, Salvatore De Meo

Proposal for a regulation
Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘artificial intelligence system’ (AI system) means *software that is developed with* one or more of the techniques and approaches listed in Annex I and can, for *a given set of* human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;

Amendment

(1) ‘artificial intelligence system’ (AI system) means *a system that operates with varying degrees of autonomy, uses* one or more of the techniques and approaches listed in Annex I and can, for human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with *and that cannot be fully predicted by the natural person developing the system;*

Or. en

Amendment 911
Carlo Fidanza

Proposal for a regulation
Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘artificial intelligence system’ (AI system) means *software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;*

Amendment

(1) ‘artificial intelligence system’ (AI system) means *a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions real or virtual environments*

Or. en

Justification

The development and uptake of AI applications and improved consumer confidence requires a more detailed definition of an AI system than the one proposed by the European Commission. In order for EU players to compete with their counterparts in other parts of the world, the OECD’s definition would serve as a good basis to reduce legal uncertainty and using the OECD’s definition may moreover inspire a common approach to AI at global level.

Amendment 912

Svenja Hahn, Nicola Beer, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation
Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘artificial intelligence system’ (AI system) means software that *is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;*

Amendment

(1) ‘artificial intelligence system’ (AI system) means software that *can, for a given set of human-defined objectives, generate outputs such as predictions, recommendations, or decisions influencing real or virtual environments; AI systems can be designed to operate with varying levels of autonomy and can be developed with one or more of the techniques and approaches listed in Annex*

I;

Or. en

Amendment 913

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

Proposal for a regulation

Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘artificial intelligence system’ (AI system) means **software that is developed with** one or more of the techniques and approaches listed in Annex I and **can, for a given set of human-defined objectives, generate** outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;

Amendment

(1) ‘artificial intelligence system’ (AI system) means **a system based on machine or human-based data and input that infers how to achieve a given set of human-defined objectives using** one or more of the techniques and approaches listed in Annex I and **generates** outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;

Or. en

Amendment 914

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

Proposal for a regulation

Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘artificial intelligence system’ (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;

Amendment

(1) ‘artificial intelligence system’ (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, **indispensably with some degree of autonomy**, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;

Amendment 915

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

Proposal for a regulation

Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) «système d'intelligence artificielle» (système d'IA), un logiciel qui est développé au moyen d'une ou plusieurs des techniques et approches énumérées à l'annexe I et qui peut, pour un ensemble donné d'objectifs *définis par l'homme*, générer des résultats tels que des contenus, des prédictions, des recommandations ou des décisions influençant les environnements avec lesquels il interagit;

Amendment

(1) «système d'intelligence artificielle» (système d'IA), un logiciel qui est développé au moyen d'une ou plusieurs des techniques et approches énumérées à l'annexe I et qui peut, pour un ensemble donné d'objectifs *ou de paramètres ayant pour origine la commande humaine*, générer des résultats tels que des contenus, des prédictions, des recommandations ou des décisions influençant les environnements avec lesquels il interagit;

Or. fr

Amendment 916

Marion Walsmann

Proposal for a regulation

Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘artificial intelligence system’ (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;

Amendment

(1) ‘artificial intelligence system’ (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives *and with varying levels of autonomy*, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;

Or. en

Amendment 917

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

Proposal for a regulation

Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘artificial intelligence system’ (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of **human-defined** objectives, generate outputs such as content, predictions, recommendations, or decisions **influencing the environments they interact with**;

Amendment

(1) ‘artificial intelligence system’ (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of **inputs and** objectives, generate outputs such as content, predictions, recommendations, or decisions;

Or. en

Amendment 918

Karlo Ressler

Proposal for a regulation

Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘artificial intelligence system’ (AI system) means **software that is developed with one or more of the techniques and approaches listed in Annex I and** can, for a given set of human-defined objectives, **generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with**;

Amendment

(1) ‘artificial intelligence system’ (AI system) means **a machine-based system that** can, for a given set of human-defined objectives, **make** predictions, recommendations, or decisions influencing **real or virtual environments and is designed to operate with varying levels of autonomy**;

Or. en

Amendment 919

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘artificial intelligence system’ (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, *for a given set of human-defined objectives*, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;

Amendment

(1) ‘artificial intelligence system’ (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;

Or. en

Amendment 920

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 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘artificial intelligence system’ (AI system) means software that *is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives*, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;

Amendment

(1) ‘artificial intelligence system’(AI system) means software that *can perceive, learn, reason or model based on machine and/or human based inputs, to generate outputs such as content, hypotheses, predictions, recommendations, or decisions influencing the real or virtual environments they interact with;*

Or. en

Amendment 921

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

Proposal for a regulation

Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘artificial intelligence system’ (AI system) means software that *is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives*, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;

Amendment

(1) ‘artificial intelligence system’ (AI system) means software that *can for example perceive, learn, reason or model based on machine and/or human based inputs, to generate outputs such as content, hypotheses, predictions, recommendations, or decisions influencing the real or virtual environments they interact with;*

Or. en

Amendment 922

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

Proposal for a regulation

Article 3 – paragraph 1 – point 1 a (new)

Text proposed by the Commission

Amendment

(1 bis) « I.A. centrée sur l'humain », une approche selon laquelle l'homme et les valeurs humaines sont centrales dans le développement, le déploiement, l'utilisation et la surveillance des systèmes d'I.A., en veillant au respect des droits fondamentaux, y compris ceux reconnus par les traités de l'Union européenne et la Charte des droits fondamentaux de l'Union européenne, qui se rejoignent dans un fondement commun ancré dans le respect de la dignité humaine, en vertu de laquelle tout être humain jouit d'un statut moral unique et inaliénable, ce qui implique également la prise en compte de l'environnement naturel et des autres êtres vivants qui font partie de l'écosystème humain, ainsi qu'une approche durable permettant l'épanouissement des générations à venir;

Or. fr

Justification

Définition tirée des Lignes directrices en matière d'éthique pour une I.A. digne de confiance de 2019 du Groupe d'experts indépendant de haut niveau sur l'intelligence artificielle constitué par la Commission européenne.

Amendment 923

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

Proposal for a regulation

Article 3 – paragraph 1 – point 1 a (new)

Text proposed by the Commission

Amendment

(1 a) 'autonomy' means that to some degree an AI system operates by interpreting certain input and by using a set of pre-determined objectives, without being limited to such instructions, even when the system's behaviour was initially constrained by, and targeted at, fulfilling the goal it was given and other relevant design choices made by its developer;

Or. en

Amendment 924

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 1 a (new)

Text proposed by the Commission

Amendment

(1 a) 'machine learning' means an AI system that gives computers the ability to find patterns in data without being explicitly programmed for a given task;

Or. en

Amendment 925

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 1 b (new)

Text proposed by the Commission

Amendment

(1 b) 'general purpose AI system' means an AI system that - irrespective of the modality in which it is placed on the market or put into service including as open source software - is able to perform generally applicable functions such as image or speech recognition, audio or video generation, pattern detection, question answering, translation or others; a general purpose AI system may be used in a plurality of contexts and may be integrated in a plurality of other AI systems;

Or. en

Amendment 926

Svenja Hahn, Nicola Beer, Vlad-Marius Boto , Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 3 – paragraph 1 – point 1 b (new)

Text proposed by the Commission

Amendment

(1 b) 'general purpose AI system' means an AI system that is able to perform generally applicable functions for multiple potential purposes, such as image or speech recognition, audio or video generation, pattern detection, question answering, and translation, is largely customizable and often open source software;

Or. en

Amendment 927

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 1 c (new)

Text proposed by the Commission

Amendment

(1 c) ‘autonomous’ means an AI-system that operates by interpreting certain input and results and by using a set of pre-determined objectives, without being limited to such instructions, despite the system’s behaviour being constrained by, and targeted at, fulfilling the goal it was given and other relevant design choices made by its provider;

Or. en

Justification

Unchanged definition from AI Whitepaper (Commission)

Amendment 928

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 1 d (new)

Text proposed by the Commission

Amendment

(1 d) ‘risk’ means the combination of the probability of occurrence of a harm and the severity of that harm;

Or. en

Amendment 929

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 1 e (new)

Text proposed by the Commission

Amendment

(1 e) ‘harm’ means an adverse impact affecting the health, safety or fundamental rights of a natural person;

Or. en

Amendment 930

**Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto ,
Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen**

Proposal for a regulation

Article 3 – paragraph 1 – point 2

Text proposed by the Commission

(2) ‘provider’ means a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed *with a view to placing* it on the market or *putting* it into service under its own name or trademark, whether for payment or free of charge;

Amendment

(2) ‘developer’ means a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed *and places* it on the market or *puts* it into service under its own name or trademark, whether for payment or free of charge *or that adapts general purpose AI systems to a specific intended purpose*;

Or. en

Justification

'Developer' is the a more accurate term and, moreover, used within the tech community. Therefore, the term “provider” should be replaced by “developer” throughout the entire text of the Regulation, even though the Renew Europe IMCO Shadow Rapporteur refrains from tabling separate amendments on all concerning passages for reasons of readability.

Amendment 931

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 2

Text proposed by the Commission

(2) ‘provider’ means a natural or legal person, public authority, agency or other body that *develops* an AI system *or that has an AI system developed with a view to placing it* on the market or *putting* it into service under its own name or trademark, whether for payment or free of charge;

Amendment

(2) ‘provider’ means a natural or legal person, public authority, agency or other body that *places* an AI system on the market or *puts* it into service under its own name or trademark, whether for payment or free of charge *or that adapts general purpose AI systems to an intended purpose*;

Or. en

Amendment 932**Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan****Proposal for a regulation****Article 3 – paragraph 1 – point 2***Text proposed by the Commission*

(2) ‘provider’ means a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed *with a view to placing it* on the market or *putting* it into service under its own name or trademark, whether for payment or free of charge;

Amendment

(2) ‘provider’ means a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed *and places that system* on the market or *puts* it into service under its own name or trademark, whether for payment or free of charge;

Or. en

Amendment 933**Andrea Caroppo, Salvatore De Meo****Proposal for a regulation****Article 3 – paragraph 1 – point 2***Text proposed by the Commission*

(2) ‘provider’ means a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed *with a view to placing it* on the market or *putting* it into service under its own name or trademark, whether for payment or free of charge;

Amendment

(2) ‘provider’ means a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed *and places that system* on the market or *puts* it into service under its own name or trademark, whether for payment or free of charge;

Or. en

Amendment 934**Axel Voss, Deirdre Clune, Eva Maydell****Proposal for a regulation****Article 3 – paragraph 1 – point 2 a (new)***Text proposed by the Commission**Amendment*

(2 a) ‘new provider’ means a natural or legal person that becomes provider for the purposes of this Regulation due to one of the circumstances referred to in Art 23a(1).

Or. en

Amendment 935

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 2 b (new)

Text proposed by the Commission

Amendment

(2 b) ‘former provider’ means a provider that initially placed the AI system on the market or put it into service but is according to Art 23a(2) no longer considered a provider for the purposes of this Regulation;

Or. en

Amendment 936

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 2 c (new)

Text proposed by the Commission

Amendment

(2 c) ‘original provider’ means a provider of a general purpose AI system, who has made available the AI system to a natural or legal person that itself became a provider by giving an intended purpose to the general purpose AI system;

Or. en

Amendment 937

Svenja Hahn, Drago Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Moritz

Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 3 – paragraph 1 – point 3

Text proposed by the Commission

Amendment

(3) ‘*small-scale provider*’ means a provider that is a micro or small enterprise within the meaning of Commission Recommendation 2003/361/EC⁶¹ ; *deleted*

⁶¹ *Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).*

Or. en

Amendment 938

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 3

Text proposed by the Commission

Amendment

(3) ‘*small-scale provider*’ means a provider that is a micro or small enterprise within the meaning of Commission Recommendation 2003/361/EC⁶¹ ; *deleted*

⁶¹ *Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).*

Or. en

Amendment 939

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation
Article 3 – paragraph 1 – point 3 a (new)

Text proposed by the Commission

Amendment

(3 a) ‘risk’ means the combination of the probability of occurrence of a harm and the severity of that harm;

Or. en

Amendment 940

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation
Article 3 – paragraph 1 – point 3 b (new)

Text proposed by the Commission

Amendment

(3 b) ‘significant harm’ means a material harm to a person’s life, health and safety or fundamental rights or entities or society at large whose severity is exceptional. The severity is in particular exceptional when the harm is hardly reversible, the outcome has a material adverse impact on health or safety of a person or the impacted person is dependent on the outcome;

Or. en

Amendment 941

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

Proposal for a regulation
Article 3 – paragraph 1 – point 4

Text proposed by the Commission

Amendment

(4) «utilisateur», toute personne physique ou morale, autorité publique, agence ou autre organisme utilisant sous sa

(4) «utilisateur», toute personne physique ou morale, autorité publique, agence ou autre organisme utilisant sous sa

propre autorité un système d'IA, *sauf lorsque ce système est utilisé dans le cadre d'une activité personnelle à caractère non professionnel;*

propre autorité un système d'IA;

Or. fr

Amendment 942

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 3 – paragraph 1 – point 4

Text proposed by the Commission

(4) ‘user’ means any natural or legal person, public authority, agency or other body using an AI system under its authority, *except where the AI system is used in the course of a personal non-professional activity;*

Amendment

(4) ‘user’ means any natural or legal person, public authority, agency or other body using an AI system under its authority;

Or. en

Amendment 943

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 4

Text proposed by the Commission

(4) ‘user’ means any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity;

Amendment

(4) ‘user’ means any natural or legal person, *data subject*, public authority, agency or other body using an AI system under its authority *and on its own responsibility*, except where the AI system is used in the course of a personal non-professional activity;

Or. en

Amendment 944

Kosma Złotowski, Patryk Jaki, Adam Bielan

Proposal for a regulation
Article 3 – paragraph 1 – point 4

Text proposed by the Commission

(4) ‘**user**’ means any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity;

Amendment

(4) ‘**deployer**’ means any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity;

Or. en

Amendment 945
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 3 – paragraph 1 – point 4

Text proposed by the Commission

(4) ‘**user**’ means any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity;

Amendment

(4) ‘**deployer**’ means any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity;

Or. en

Amendment 946
Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation
Article 3 – paragraph 1 – point 4

Text proposed by the Commission

(4) ‘**user**’ means any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is

Amendment

(4) ‘**deployer**’ means any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is

used in the course of a personal non-professional activity;

used in the course of a personal non-professional activity;

Or. en

Amendment 947

**Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto ,
Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen**

Proposal for a regulation

Article 3 – paragraph 1 – point 4

Text proposed by the Commission

(4) ‘**user**’ means any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity;

Amendment

(4) ‘**deployer**’ means any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity;

Or. en

Justification

'Deployer' is a more accurate term than “user” and used within the tech community. Moreover, the term 'user' would lead to legal overlaps and contradictions with other laws such as the GDPR. Therefore, the term “user” should be replaced by “deployer” throughout the entire text of the regulation, even though the Renew Europe IMCO Shadow Rapporteur refrains from tabling separate amendments on all concerning passages for reasons of readability.

Amendment 948

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

Proposal for a regulation

Article 3 – paragraph 1 – point 4 a (new)

Text proposed by the Commission

Amendment

(4 a) ‘AI subject’ means any natural or legal person that is subject to a decision based on or assisted by an AI system, or subject to interaction with an AI system or

treatment of data relating to them by an AI system, or otherwise subjected to analysis by an AI or otherwise impacted or affected by an AI system;

Or. en

Amendment 949

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 3 – paragraph 1 – point 4 a (new)

Text proposed by the Commission

Amendment

(4 a) ‘end user’ means any natural person who, in the context of employment or contractual agreement with the user, uses or deploys the AI system under the authority of the user;

Or. en

Amendment 950

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 3 – paragraph 1 – point 4 a (new)

Text proposed by the Commission

Amendment

(4 a) ‘End-user’ means any natural person who, in the framework of employment, contract or agreement with the deployer, uses the AI system under the authority of the deployer;

Or. en

Amendment 951

René Repasi, Marc Angel, Andreas Schieder, Maria-Manuel Leitão-Marques

Proposal for a regulation

Article 3 – paragraph 1 – point 4 a (new)

Text proposed by the Commission

Amendment

(4 a) ‘affected person’ means the natural or legal person who is ultimately directly or indirectly affected by the deployment of an AI system.

Or. en

Justification

The amendment intends to cover persons that are affected by the AI system without actively using it (users) nor subject to their personal data being used (data subject).

Amendment 952

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 5

Text proposed by the Commission

(5) ‘authorised representative’ means any natural or legal person established in the Union who has received a written mandate from a provider of an AI system to, respectively, perform and carry out on its behalf the obligations and procedures established by this Regulation;

Amendment

(5) ‘authorised representative’ means any natural or legal person **physically present or** established in the Union who has received **and accepted** a written mandate from a provider of an AI system to, respectively, perform and carry out on its behalf the obligations and procedures established by this Regulation;

Or. en

Amendment 953

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

Proposal for a regulation

Article 3 – paragraph 1 – point 5

Text proposed by the Commission

(5) ‘**authorised** representative’ means any natural or legal person established in the Union who has received a written mandate from a provider of an AI system

Amendment

(5) ‘**legal** representative’ means any natural or legal person established in the Union who has received a written mandate from a provider of an AI system to,

to, respectively, perform and carry out on its behalf the obligations and procedures established by this Regulation;

respectively, perform and carry out on its behalf *any of* the obligations and procedures established by this Regulation;

Or. en

Amendment 954

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 5 a (new)

Text proposed by the Commission

Amendment

(5 a) ‘product manufacturer’ means a manufacturer within the meaning of any of the Union harmonisation legislation listed in Annex II;

Or. en

Amendment 955

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 6

Text proposed by the Commission

Amendment

(6) ‘importer’ means any natural or legal person established in the Union that places on the market *or puts into service* an AI system that bears the name or trademark of a natural or legal person established outside the Union;

(6) ‘importer’ means any natural or legal person *physically present or* established in the Union that places on the market an AI system that bears the name or trademark of a natural or legal person established outside the Union;

Or. en

Amendment 956

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 7 a (new)

Text proposed by the Commission

Amendment

(7 a) ‘economic operator’ means the provider, the authorised representative, the importer and the distributor;

Or. en

Amendment 957

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 8

Text proposed by the Commission

Amendment

(8) ‘operator’ means the *provider*, the user, *the authorised representative, the importer and the distributor*;

(8) ‘operator’ means the *economic operator and the user*;

Or. en

Amendment 958

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 3 – paragraph 1 – point 8

Text proposed by the Commission

Amendment

(8) ‘operator’ means the provider, the user, the authorised representative, the importer and the distributor;

(8) ‘operator’ means the provider, the *deployer*, the authorised representative, the importer and the distributor;

Or. en

Amendment 959

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

Proposal for a regulation

Article 3 – paragraph 1 – point 8

Text proposed by the Commission

(8) ‘operator’ means the provider, the user, the **authorised** representative, the importer and the distributor;

Amendment

(8) ‘operator’ means the provider, the user, the **legal** representative, the importer and the distributor;

Or. en

Amendment 960

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

Proposal for a regulation

Article 3 – paragraph 1 – point 8 a (new)

Text proposed by the Commission

Amendment

(8 a) ‘affected person’ means any natural person or a group of persons who are subjects to or affected by an AI system

Or. en

Amendment 961

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 3 – paragraph 1 – point 8 a (new)

Text proposed by the Commission

Amendment

(8 a) ‘affected person’ means any natural person or group of persons who are subject to or affected by an AI system;

Or. en

Amendment 962

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 3 – paragraph 1 – point 11

Text proposed by the Commission

(11) ‘putting into service’ means the supply of an AI system for first use directly to the user or for own use on the Union market for its intended purpose;

Amendment

(11) ‘putting into service’ means the supply of an AI system for first use directly to the user or for own use on the Union market for its intended purpose **or reasonably foreseeable use** ;

Or. en

Amendment 963

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

Proposal for a regulation

Article 3 – paragraph 1 – point 11

Text proposed by the Commission

(11) ‘putting into service’ means the supply of an AI system for first use directly to the **user** or for own use on the Union market for its intended purpose;

Amendment

(11) ‘putting into service’ means the supply of an AI system for first use directly to the **deployer** or for own use on the Union market for its intended purpose;

Or. en

Amendment 964

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 3 – paragraph 1 – point 11

Text proposed by the Commission

(11) ‘putting into service’ means the supply of an AI system for first use directly to the user or for own use on the Union market for its **intended purpose**;

Amendment

(11) ‘putting into service’ means the supply of an AI system for first use directly to the user or for own use on the Union market for its **foreseeable uses**;

Or. en

Amendment 965
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 3 – paragraph 1 – point 11 a (new)

Text proposed by the Commission

Amendment

(11 bis) «essai», lorsque le système IA est mis à disposition d'un groupe limité et restreint d'utilisateurs avant mise sur le marché ou mise en service;

Or. fr

Amendment 966
Kosma Złotowski, Patryk Jaki, Adam Bielan

Proposal for a regulation
Article 3 – paragraph 1 – point 12

Text proposed by the Commission

Amendment

(12) ‘intended purpose’ means the use for which an AI system is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation;

(12) ‘intended purpose’ means the **specific** use for which an AI system is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation; **general purpose AI systems shall not be considered as having an intended purpose within the meaning of this Regulation;**

Or. en

Amendment 967
Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation
Article 3 – paragraph 1 – point 12

Text proposed by the Commission

Amendment

(12) ‘**intended purpose**’ means the use for which *an* AI system is intended *by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation;*

(12) ‘**foreseeable uses**’ means *uses that can reasonably be expected to be made of an AI system, including but not limited to* the use for which *the* AI system is intended *for consumers or the likely use by consumers under reasonably foreseeable conditions;*

Or. en

Justification

The AI Act as it stands does not address the uses other than the intended use that nevertheless can be reasonably expected of users. Most AI systems have multiple potential uses; some, like GPT3, could have hundreds of use cases. If a user does not follow the provider’s “intended purpose”, it becomes itself a provider and therefore needs to redo the whole compliance process. This is extremely inefficient, as it remains the same AI system (same underlying code). Requirements and registration could apply to the foreseeable use instead, to save time for national competent authorities, notified bodies and economic operators.

Amendment 968

René Repasi, Marc Angel, Andreas Schieder, Maria-Manuel Leitão-Marques

Proposal for a regulation

Article 3 – paragraph 1 – point 12

Text proposed by the Commission

(12) ‘**intended purpose**’ means the use for which an AI system is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation;

Amendment

(12) ‘**reasonably foreseeable** purpose’ means the use for which an AI system is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation;

Or. en

Justification

The amendment intends to cover a wider range of potential uses for the technology. Example: a system for ‘visual recognition’ could be intended to identify text and then be used to identify QR codes.

Amendment 969

Sophia in 't Veld, Michal Šimek

Proposal for a regulation

Article 3 – paragraph 1 – point 12 – point i (new)

Text proposed by the Commission

Amendment

i) *'Reasonably foreseeable use'*
means the use of an AI system in a way
that is or should be reasonably
foreseeable and that addresses the risks to
health, safety and fundamental rights that
it can cause.

Or. en

Amendment 970

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 12 a (new)

Text proposed by the Commission

Amendment

(12 a) *'foreseeable uses'* means uses that
can reasonably be expected to be made of
an AI system, including but not limited to
the use for which the AI system is
intended for consumers or the likely use
by consumers under reasonably
foreseeable conditions;

Or. en

Amendment 971

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 12 a (new)

Text proposed by the Commission

Amendment

(12 a) *'reasonably foreseeable use'*
means the use of an AI system in a way
that is or should be reasonably

foreseeable;

Or. en

Amendment 972
Marion Walsmann

Proposal for a regulation
Article 3 – paragraph 1 – point 13

Text proposed by the Commission

Amendment

(13) ‘*reasonably foreseeable misuse*’ means the use of an AI system in a way that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems;

deleted

Or. en

Amendment 973
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 3 – paragraph 1 – point 13

Text proposed by the Commission

Amendment

(13) ‘*reasonably foreseeable misuse*’ means the use of an AI system in a way that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems;

(13) ‘*reasonably foreseeable misuse*’ means the use of an AI system in a way that is not in accordance with its intended purpose *and with the specific context and conditions of use established by the provider*, but which may result from reasonably foreseeable human behaviour or interaction with other systems;

Or. en

Amendment 974
Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 3 – paragraph 1 – point 13

Text proposed by the Commission

(13) ‘reasonably foreseeable misuse’ means the use of an AI system *in a way that is not in accordance with* its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems;

Amendment

(13) ‘reasonably foreseeable misuse’ means the use of an AI system *within* its intended purpose, but *not in accordance with the specific context and conditions of use established by the provider and in a way* which may result from reasonably foreseeable human behaviour or interaction with other systems;

Or. en

Amendment 975

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 3 – paragraph 1 – point 13

Text proposed by the Commission

(13) ‘reasonably foreseeable misuse’ means the use of an AI system in a way that is not in accordance with its *intended* purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems;

Amendment

(13) ‘reasonably foreseeable misuse’ means the use of an AI system in a way that is not in accordance with its purpose *as indicated in instruction for use or technical specification*, but which may result from reasonably foreseeable human behaviour or interaction with other systems;

Or. en

Amendment 976

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 3 – paragraph 1 – point 13

Text proposed by the Commission

(13) ‘reasonably foreseeable misuse’ means the use of an AI system in a way

Amendment

(13) ‘reasonably foreseeable misuse’ means the use of an AI system in a way

that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems;

that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems, ***including other AI systems***;

Or. en

Amendment 977

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 3 – paragraph 1 – point 13

Text proposed by the Commission

(13) ‘reasonably foreseeable misuse’ means the use of an AI system in a way that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems;

Amendment

(13) ‘reasonably foreseeable misuse’ means the use of an AI system in a way that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems, ***and with other AI systems***;

Or. en

Amendment 978

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

Proposal for a regulation

Article 3 – paragraph 1 – point 13

Text proposed by the Commission

(13) ‘reasonably foreseeable misuse’ means the use of an AI system in a way that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems;

Amendment

(13) ‘reasonably foreseeable misuse’ means the use of an AI system in a way that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems, ***and with other AI systems***;

Or. en

Amendment 979
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 3 – paragraph 1 – point 13

Text proposed by the Commission

(13) «mauvaise utilisation raisonnablement prévisible», l'utilisation d'un système d'IA d'une manière qui n'est pas conforme à sa destination, mais qui peut résulter d'un comportement humain raisonnablement prévisible *ou d'une interaction raisonnablement prévisible avec d'autres systèmes*;

Amendment

(13) «mauvaise utilisation raisonnablement prévisible», l'utilisation d'un système d'IA d'une manière qui n'est pas conforme à sa destination, mais qui peut résulter d'un comportement humain raisonnablement prévisible *et connu* ;

Or. fr

Amendment 980
Karlo Ressler

Proposal for a regulation
Article 3 – paragraph 1 – point 13 a (new)

Text proposed by the Commission

Amendment

(13 a) ‘harmful subliminal technique’ means a measure whose existence and operation are entirely imperceptible by those on whom it is used, and which has the purpose and direct effect to induce actions leading to that person’s physical or psychological harm.

Or. en

Amendment 981
Andrea Caroppo, Salvatore De Meo

Proposal for a regulation
Article 3 – paragraph 1 – point 14

Text proposed by the Commission

Amendment

(14) ‘safety component of a product or

(14) ‘safety component of a product or

'system' means a component of a product or of a system which fulfils a safety function for that product or system or the failure or malfunctioning of which endangers the health and safety of persons or property;

'system' means a component of a product or of a system which fulfils a safety function for that product or system or the failure or malfunctioning of which endangers the health and safety of persons or property, *but which is not necessary in order for the product or system to function*;

Or. en

Amendment 982

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 14

Text proposed by the Commission

(14) 'safety component of a product or system' means a component of a product or of a system which fulfils a safety function for that product or system *or the failure or malfunctioning of which endangers* the health and safety of persons *or property*;

Amendment

(14) 'safety component of a product or system' means, *in line with the relevant Union harmonisation legislation listed in Annex II*, a component of a product or of a system which fulfils a *direct and critical* safety function for that product or system *so that its malfunction endangers* the health and safety of persons;

Or. en

Amendment 983

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

Proposal for a regulation

Article 3 – paragraph 1 – point 14

Text proposed by the Commission

(14) 'safety component of a product or system' means a component of a product or of a system which fulfils a safety function for that product or system or the failure or malfunctioning of which endangers the health *and* safety of persons *or* property;

Amendment

(14) 'safety component of a product or system' means a component of a product or of a system which fulfils a safety *or security* function for that product or system or the failure or malfunctioning of which endangers the *fundamental rights*, health *or* safety of persons, *or which damages* property *or the environment*;

Amendment 984

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 3 – paragraph 1 – point 14

Text proposed by the Commission

(14) ‘safety component of a product or system’ means a component of a product or of a system which fulfils a safety function for that product or system or the failure or malfunctioning of which endangers the health **and** safety of persons or property;

Amendment

(14) ‘safety component of a product or system’ means a component of a product or of a system which fulfils a safety **or security** function for that product or system or the failure or malfunctioning of which endangers the health, safety, **fundamental rights** of persons or **which damages** property, **or the environment**;

Amendment 985

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 14

Text proposed by the Commission

(14) ‘safety component of a product or system’ means a component of a product or of a system which fulfils a safety function for that product or system or the failure or malfunctioning of which endangers the health and safety of persons or property;

Amendment

(14) ‘safety component of a product or system’ means a component of a product or of a system which fulfils a **direct or indirect** safety function for that product or system or the failure or malfunctioning of which endangers the health and safety of persons or property;

Amendment 986

Marion Walsmann

Proposal for a regulation
Article 3 – paragraph 1 – point 14

Text proposed by the Commission

(14) ‘safety component of a product or system’ means a component of a product or of a system which fulfils a safety function for that product or system *or the failure or malfunctioning of which* endangers the health and safety of persons or property;

Amendment

(14) ‘safety component of a product or system’ means a component of a product or of a system which fulfils a safety function for that product or system *so that its malfunctioning endangers the health and safety of persons or property;*

Or. en

Amendment 987
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 3 – paragraph 1 – point 15

Text proposed by the Commission

(15) ‘instructions for use’ means the information provided by the provider to inform the user of in particular an AI system’s intended purpose and proper use, *inclusive of the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used;*

Amendment

(15) ‘instructions for use’ means the information provided by the provider to inform the user of in particular an AI system’s intended purpose and proper use,

Or. en

Amendment 988
Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation
Article 3 – paragraph 1 – point 15

Text proposed by the Commission

(15) ‘instructions for use’ means the information provided by the provider to inform the user of in particular an AI system’s intended purpose and proper use, inclusive of the specific geographical,

Amendment

(15) ‘instructions for use’ means the information provided by the provider to inform the user of in particular an AI system’s intended purpose *or reasonably foreseeable use* and proper use, inclusive

behavioural or functional setting within which the high-risk AI system is intended to be used;

of the specific geographical, behavioural or functional setting within which the high-risk AI system is intended *or foreseeable* to be used;

Or. en

Amendment 989

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

Proposal for a regulation

Article 3 – paragraph 1 – point 15

Text proposed by the Commission

(15) ‘instructions for use’ means the information provided by the provider to inform the *user* of in particular an AI system’s intended purpose and proper use, inclusive of the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used;

Amendment

(15) ‘instructions for use’ means the information provided by the provider to inform the *deployer* of in particular an AI system’s intended purpose and proper use, inclusive of the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used;

Or. en

Amendment 990

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 3 – paragraph 1 – point 15

Text proposed by the Commission

(15) ‘instructions for use’ means the information provided by the provider to inform the user of in particular an AI system’s *intended purpose* and proper use, inclusive of the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used;

Amendment

(15) ‘instructions for use’ means the information provided by the provider to inform the user of in particular an AI system’s *foreseeable uses* and proper use, inclusive of the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used;

Or. en

Amendment 991

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 16

Text proposed by the Commission

(16) ‘recall of an AI system’ means any measure aimed at achieving the return to the provider of an AI system made available to users;

Amendment

(16) ‘recall of an AI system’ means any measure aimed at achieving the return to the provider *or taking it out of service or disable the use* of an AI system made available to users;

Or. en

Amendment 992

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 3 – paragraph 1 – point 16

Text proposed by the Commission

(16) ‘recall of an AI system’ means any measure aimed at achieving the return to the provider of an AI system made available to *users*;

Amendment

(16) ‘recall of an AI system’ means any measure aimed at achieving the return to the provider of an AI system made available to *deployers*;

Or. en

Amendment 993

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 17

Text proposed by the Commission

(17) ‘withdrawal of an AI system’ means any measure aimed at preventing *the distribution, display and offer of* an AI

Amendment

(17) ‘withdrawal of an AI system’ means any measure aimed at preventing an AI system *in the supply chain being made*

system;

available on the market;

Or. en

Amendment 994

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 3 – paragraph 1 – point 18

Text proposed by the Commission

(18) ‘performance of an AI system’ means the ability of an AI system to achieve its intended purpose;

Amendment

(18) ‘performance of an AI system’ means the ability of an AI system to achieve its intended purpose *or reasonably foreseeable use* ;

Or. en

Amendment 995

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 3 – paragraph 1 – point 18

Text proposed by the Commission

(18) ‘performance of an AI system’ means the ability of an AI system to achieve its *intended purpose*;

Amendment

(18) ‘performance of an AI system’ means the ability of an AI system to achieve its *foreseeable uses*;

Or. en

Amendment 996

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

Proposal for a regulation

Article 3 – paragraph 1 – point 18 a (new)

Text proposed by the Commission

Amendment

(18 bis) « cycle de vie de l'I.A. », le processus de développement, de

déploiement et d'utilisation d'un système d'I.A., y compris les phases de recherche, de conception, d'approvisionnement en données, d'entraînement, de déploiement à échelle limitée, de mise en œuvre et de retrait;

Or. fr

Amendment 997

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

Proposal for a regulation

Article 3 – paragraph 1 – point 20

Text proposed by the Commission

(20) ‘conformity assessment’ means the process of *verifying* whether the requirements set out in Title III, Chapter 2 of this Regulation relating to an AI system have been fulfilled;

Amendment

(20) ‘conformity assessment’ means the process of *verification by an independent third party* whether the *principles and* requirements set out in Title III, Chapter 2 of this Regulation relating to an AI system have been fulfilled;

Or. en

Amendment 998

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 20

Text proposed by the Commission

(20) ‘conformity assessment’ means the process of *verifying* whether the requirements set out in Title III, Chapter 2 of this Regulation relating to an AI system have been fulfilled;

Amendment

(20) ‘conformity assessment’ means the process of *demonstrating* whether the requirements set out in Title III, Chapter 2 of this Regulation relating to an AI system have been fulfilled;

Or. en

Amendment 999

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

Proposal for a regulation**Article 3 – paragraph 1 – point 20***Text proposed by the Commission*

(20) ‘conformity assessment’ means the process of *verifying* whether the requirements set out in Title III, Chapter 2 of this Regulation relating to an AI system have been fulfilled;

Amendment

(20) ‘conformity assessment’ means the process of *demonstrating* whether the requirements set out in Title III, Chapter 2 of this Regulation relating to an AI system have been fulfilled;

Or. en

Amendment 1000

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation**Article 3 – paragraph 1 – point 22***Text proposed by the Commission*

(22) ‘notified body’ means a conformity assessment body *designated* in accordance with this Regulation and other relevant Union harmonisation legislation;

Amendment

(22) ‘notified body’ means a conformity assessment body *notified* in accordance with *Art 32 of* this Regulation and *with* other relevant Union harmonisation legislation;

Or. en

Amendment 1001

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation**Article 3 – paragraph 1 – point 23***Text proposed by the Commission*

(23) ‘substantial modification’ means a change to *the* AI system following its placing on the market or putting into service which affects the compliance of the

Amendment

(23) ‘substantial modification’ means a change to *a high-risk* AI system following its placing on the market or putting into service which affects the compliance of the

AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed;

AI system with the requirements set out in Title III, Chapter 2 of this Regulation *such as a new training with a completely different dataset with respect to the one used to begin with or the addition of a further AI module into the AI system* or results in a modification to the intended purpose for which the AI system has been assessed; *Supplementary and periodic training of an AI algorithm by the AI user or provider using their own data to ensure that the system remains accurate and/or is working as intended does not amount to a ‘substantial modification’ under this Regulation. The periodic retraining of models due to new data with same structure shall not constitute a substantial modification. 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 predetermined 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;*

Or. en

Amendment 1002

**Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto ,
Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen**

Proposal for a regulation

Article 3 – paragraph 1 – point 23

Text proposed by the Commission

(23) ‘substantial modification’ means a change to the AI system following its placing on the market or putting into service which *affects* the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation *or* results in a modification to the intended

Amendment

(23) ‘substantial modification’ means a change to the AI system following its placing on the market or putting into service, which *is not foreseen or planned by the provider and as a result of which* the compliance of the AI system with the requirements set out in Title III, Chapter 2

purpose for which the AI system has been assessed;

of this Regulation *is affected or which* results in a modification to the intended purpose for which the AI system has been assessed. *A substantial modification is given if the remaining risk is increased by the modification of the AI system under the application of all necessary protective measures;*

Or. en

Amendment 1003

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

Proposal for a regulation

Article 3 – paragraph 1 – point 23

Text proposed by the Commission

(23) ‘substantial modification’ means a change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed;

Amendment

(23) ‘substantial modification’ means a change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed *or to its performance, including modifications of the intended purpose of an AI system which is not classified as high-risk and is already placed on the market or put into service;*

Or. en

Amendment 1004

René Repasi, Marc Angel, Andreas Schieder, Maria-Manuel Leitão-Marques

Proposal for a regulation

Article 3 – paragraph 1 – point 23

Text proposed by the Commission

(23) ‘substantial modification’ means a

Amendment

(23) ‘substantial modification’ means a

change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed;

change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed ***including the use of an AI system beyond its reasonably foreseeable purpose;***

Or. en

Amendment 1005

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 3 – paragraph 1 – point 23

Text proposed by the Commission

(23) ‘substantial modification’ means a change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the ***intended purpose*** for which the AI system has been assessed;

Amendment

(23) ‘substantial modification’ means a change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the ***foreseeable uses*** for which the AI system has been assessed, ***health and safety requirements are to be covered;***

Or. en

Amendment 1006

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

Proposal for a regulation

Article 3 – paragraph 1 – point 23

Text proposed by the Commission

(23) «modification substantielle», une modification apportée au système d’IA à la suite de sa mise sur le marché ou de sa

Amendment

(23) «modification substantielle», une modification, ***y compris issue de l’« apprentissage »***, apportée au système d’IA

mise en service, qui a une incidence sur la conformité de ce système avec les exigences énoncées au titre III, chapitre 2, du présent règlement ou entraîne une modification de la destination pour laquelle le système d'IA a été évalué;

à la suite de sa mise sur le marché ou de sa mise en service, qui a une incidence sur la conformité de ce système avec les exigences énoncées au titre III, chapitre 2, du présent règlement ou entraîne une modification de la destination pour laquelle le système d'IA a été évalué;

Or. fr

Amendment 1007

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 23

Text proposed by the Commission

(23) ‘substantial modification’ means a change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed;

Amendment

(23) ‘substantial modification’ means a change to the AI system following its placing on the market or putting into service, ***not foreseen by the provider***, which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed;

Or. en

Amendment 1008

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 3 – paragraph 1 – point 23

Text proposed by the Commission

(23) ‘substantial modification’ means a change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended

Amendment

(23) ‘substantial modification’ means a change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended

purpose for which the AI system has been assessed;

purpose *or reasonably foreseeable use* for which the AI system has been assessed;

Or. en

Amendment 1009

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 3 – paragraph 1 – point 24

Text proposed by the Commission

(24) ‘CE marking of conformity’ (CE marking) means a marking by which a provider indicates that an AI system is in conformity with the requirements set out in Title III, Chapter 2 of this Regulation and other applicable Union legislation harmonising the conditions for the marketing of products (‘Union harmonisation legislation’) providing for its affixing;

Amendment

(24) ‘CE marking of conformity’ (CE marking) means a *physical or digital* marking by which a provider indicates that an *AI system or a product with an embedded* AI system is in conformity with the requirements set out in Title III, Chapter 2 of this Regulation and other applicable Union legislation harmonising the conditions for the marketing of products (‘Union harmonisation legislation’) providing for its affixing;

Or. en

Amendment 1010

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 24

Text proposed by the Commission

(24) ‘CE marking of conformity’ (CE marking) means a marking by which a provider indicates that an AI system is in conformity with the requirements set out in Title III, Chapter 2 of this Regulation and other applicable Union legislation harmonising the conditions for the marketing of products (‘Union harmonisation legislation’) providing for its affixing;

Amendment

(24) ‘CE marking of conformity’ (CE marking) means a *physical or electronic* marking by which a provider indicates that an AI system is in conformity with the requirements set out in Title III, Chapter 2 of this Regulation and other applicable Union legislation harmonising the conditions for the marketing of products (‘Union harmonisation legislation’) providing for its affixing *as well as the*

GDPR;

Or. en

Amendment 1011

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

Proposal for a regulation

Article 3 – paragraph 1 – point 25

Text proposed by the Commission

(25) «surveillance après commercialisation», l'ensemble des activités réalisées par les fournisseurs de systèmes d'IA pour recueillir et analyser de manière proactive les données issues de l'expérience d'utilisation des systèmes d'IA qu'ils mettent sur le marché ou mettent en service de manière à repérer toute nécessité d'appliquer immédiatement une mesure préventive ou corrective;

Amendment

(25) «surveillance après commercialisation», l'ensemble des activités réalisées par les fournisseurs de systèmes d'IA pour recueillir et analyser de manière proactive les données issues de l'expérience d'utilisation des systèmes d'IA qu'ils mettent sur le marché ou mettent en service de manière à repérer toute nécessité d'appliquer immédiatement une mesure préventive ou corrective, *sans que ces activités puissent consister en un envoi automatisé de données ou de rapports d'erreurs au fournisseur par le système d'I.A.;*

Or. fr

Amendment 1012

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 28

Text proposed by the Commission

(28) ‘common specifications’ means a document, other than a standard, **containing technical solutions** providing a means to, comply with certain requirements and obligations established under this Regulation;

Amendment

(28) ‘common specifications’ means a document **comprising a set of technical specifications**, other than a standard, providing a means to comply with certain requirements and obligations established under this Regulation;

Or. en

Amendment 1013

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

Proposal for a regulation

Article 3 – paragraph 1 – point 28 a (new)

Text proposed by the Commission

Amendment

(28 bis) « bac à sable », en matière de développement de systèmes d'I.A., un environnement d'exécution et d'expérimentation isolé permettant de réaliser certaines actions en utilisant un système d'I.A. tout en protégeant l'utilisateur de tout préjudice résultant de biais, de dommages ou de compromission informatique;

Or. fr

Amendment 1014

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 29

Text proposed by the Commission

Amendment

(29) ‘training data’ means data used for training an AI system *through fitting* its learnable parameters, *including the weights of a neural network*;

(29) ‘training data’ means data used for training an AI system *to fit* its learnable parameters;

Or. en

Amendment 1015

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

Proposal for a regulation

Article 3 – paragraph 1 – point 29

Text proposed by the Commission

(29) ‘training data’ means data used for training an AI system through fitting its learnable parameters, ***including the weights of a neural network;***

Amendment

(29) ‘training data’ means data used for training an AI system through fitting its learnable parameters;

Or. en

Amendment 1016

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 30

Text proposed by the Commission

(30) ‘validation data’ means data used for providing an evaluation of the trained AI system ***and for tuning its non-learnable parameters and its learning process, among other things, in order to prevent overfitting;*** whereas the validation dataset ***can*** be a separate dataset ***or part*** of the training dataset, ***either as a fixed or variable split;***

Amendment

(30) ‘validation data’ means data used for providing an evaluation of the trained AI system. ***The process evaluates whether the model is under-fitted or overfitted;*** The validation dataset ***should*** be a separate dataset of the training ***set for the evaluation to be unbiased.*** If there is only one available dataset, this is divided into two parts, a training set and a validation set. Both sets should still comply with Article 10(3) to ensure appropriate data governance and management practices.

Or. en

Amendment 1017

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

Proposal for a regulation

Article 3 – paragraph 1 – point 30

Text proposed by the Commission

(30) ‘validation data’ means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process, ***among***

Amendment

(30) ‘validation data’ means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process,

other things, in order to prevent overfitting; whereas the validation dataset can be a separate dataset or part of the training dataset, either as a fixed or variable split;

whereas the validation dataset can be a separate dataset or part of the training dataset, either as a fixed or variable split;

Or. en

Amendment 1018

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 30

Text proposed by the Commission

(30) ‘validation data’ means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process, among other things, in order to prevent overfitting; whereas the validation dataset can be a separate dataset or part of the training dataset, either as a fixed or variable split;

Amendment

(30) ‘**machine learning** validation data’ means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process, among other things, in order to prevent overfitting; whereas the validation dataset can be a separate dataset or part of the training dataset, either as a fixed or variable split;

Or. en

Amendment 1019

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 3 – paragraph 1 – point 30

Text proposed by the Commission

(30) ‘validation data’ means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process, among other things, in order to prevent overfitting; whereas the validation dataset **can be** a separate dataset or part of the training dataset, either as a fixed or variable split;

Amendment

(30) ‘validation data’ means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process, among other things, in order to prevent **underfitting or** overfitting; whereas the validation dataset **is** a separate dataset or part of the training dataset, either as a fixed

or variable split;

Or. en

Amendment 1020

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 31

Text proposed by the Commission

(31) ‘testing data’ means data used for providing an independent evaluation of the trained and validated AI system *in order* to confirm the expected performance of that system before its placing on the market or putting into service;

Amendment

(31) ‘testing data’ means data used for providing an independent evaluation of the trained and validated AI system to confirm the expected performance of that system before its placing on the market or putting into service. *Similar to Article 3(30), the testing dataset should be a separate dataset from the training set and validation set. This set should also comply with Article 10(3) to ensure appropriate data governance and management practices.*

Or. en

Amendment 1021

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 31

Text proposed by the Commission

(31) ‘testing data’ means data used for providing an independent evaluation of the trained and validated AI system in order to confirm the expected performance of that system before its placing on the market or putting into service;

Amendment

(31) ‘testing data’ means data used for providing an independent evaluation of the trained and validated AI system in order to confirm the expected performance of that system before its placing on the market or putting into service. *The testing data must be a separate dataset;*

Or. en

Amendment 1022

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

Proposal for a regulation**Article 3 – paragraph 1 – point 33***Text proposed by the Commission*

(33) ‘biometric data’ means personal data *resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images or dactyloscopic data;*

Amendment

(33) ‘biometric data’ means personal data *as defined in Article 4, point (14) of Regulation (EU) 2016/679;*

Or. en

Amendment 1023

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

Proposal for a regulation**Article 3 – paragraph 1 – point 33***Text proposed by the Commission*

(33) ‘biometric data’ means personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, *which allow or confirm the unique identification of that natural person*, such as facial images or dactyloscopic data;

Amendment

(33) ‘biometric data’ means personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, such as facial images or dactyloscopic data;

Or. en

Amendment 1024

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte

Proposal for a regulation**Article 3 – paragraph 1 – point 33**

Text proposed by the Commission

(33) «données biométriques», les données à caractère personnel résultant d'un traitement technique spécifique, relatives aux caractéristiques physiques, physiologiques *ou comportementales* d'une personne physique, qui permettent ou confirment son identification unique, telles que des images faciales ou des données dactyloscopiques;

Amendment

(33) «données biométriques», les données à caractère personnel résultant d'un traitement technique spécifique, relatives aux caractéristiques physiques *ou* physiologiques d'une personne physique, qui permettent ou confirment son identification unique, telles que des images faciales ou des données dactyloscopiques;

Or. fr

Amendment 1025

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 33 a (new)

Text proposed by the Commission

Amendment

(33 a) ‘biometrics-based data’ means data resulting from specific technical processing relating to physical, physiological or behavioural signals of a natural person which may or may not allow or confirm the unique identification of a natural person;

Or. en

Amendment 1026

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 33 a (new)

Text proposed by the Commission

Amendment

(33 a) ‘biometrics-based data’ means data resulting from specific technical processing relating to physical, physiological or behavioural signals of a natural person which may or may not

*allow or confirm the unique identification
of a natural person*

Or. en

Amendment 1027

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 3 – paragraph 1 – point 33 a (new)

Text proposed by the Commission

Amendment

*(33 a) ‘biometrics-based data’ means
data resulting from specific technical
processing relating to physical,
physiological, or behavioural features,
signals, or characteristics of a natural
person;*

Or. en

Amendment 1028

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța, Michal Šimečka

Proposal for a regulation

Article 3 – paragraph 1 – point 33 a (new)

Text proposed by the Commission

Amendment

*(33 a) ‘subliminal techniques’ means
techniques that use sensorial stimuli such
as images, text, or sounds, that are below
the limits of conscious human sensorial
perception;*

Or. en

Amendment 1029

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López

Aguilar, Paul Tang, Maria Grapini

Proposal for a regulation

Article 3 – paragraph 1 – point 33 a (new)

Text proposed by the Commission

Amendment

(33 a) “special categories of personal data” means the categories of personal data referred to in Article 9(1) of Regulation (EU)2016/679;

Or. en

Amendment 1030

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

Proposal for a regulation

Article 3 – paragraph 1 – point 33 b (new)

Text proposed by the Commission

Amendment

(33 b) ‘biometric identification’ means the use of AI-systems for the purpose of the automated recognition of physical, physiological, behavioural, and psychological human features such as the face, eye movement, facial expressions, body shape, voice, speech, gait, posture, heart rate, blood pressure, odour, keystrokes, psychological reactions (anger, distress, grief, etc.) for the purpose of verification of an individual’s identity by comparing biometric data of that individual to stored biometric data of individuals in a database (one-to-many identification);

Or. en

Amendment 1031

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 34

Text proposed by the Commission

(34) ‘emotion recognition system’ means an AI system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric data;

Amendment

(34) ‘emotion recognition system’ means an AI system for the purpose of identifying or inferring emotions, *thoughts, states of mind (such as ‘deception’, ‘trustworthiness’ or ‘truthfulness’)* or intentions of natural persons on the basis of their biometric data *or other biometrics-based data*;

Or. en

Amendment 1032

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 34

Text proposed by the Commission

(34) ‘emotion recognition system’ means an AI system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric data;

Amendment

(34) ‘emotion recognition system’ means an AI system for the purpose of identifying or inferring emotions, *thoughts, states of mind (such as ‘deception’, ‘trustworthiness’ or ‘truthfulness’)* or intentions of natural persons on the basis of their biometric data *or biometrics-based data*;

Or. en

Amendment 1033

Sophia in ’t Veld, Michal Šime ka

Proposal for a regulation

Article 3 – paragraph 1 – point 34

Text proposed by the Commission

(34) ‘emotion recognition system’ means an AI system *for the purpose* of identifying or inferring emotions or intentions of natural persons on the basis of their biometric data;

Amendment

(34) ‘emotion recognition system’ means an AI system *capable* of identifying, *categorizing* or inferring emotions, *thoughts, states of mind (such as ‘deception’, ‘trustworthiness’, or*

'trustfulness') or intentions of natural persons on the basis of their biometric data;

Or. en

Amendment 1034

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

Proposal for a regulation

Article 3 – paragraph 1 – point 34

Text proposed by the Commission

(34) «système de reconnaissance des émotions», un système d'IA permettant la reconnaissance ou la déduction des émotions ou des intentions de personnes physiques sur la base de leurs données biométriques;

Amendment

(34) «système de reconnaissance des émotions», un système d'IA permettant la reconnaissance ou la déduction des émotions ou des intentions de personnes physiques sur la base de leurs données biométriques *ou comportementales, ou au moyen d'implants biologiques ou cérébraux;*

Or. fr

Amendment 1035

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 3 – paragraph 1 – point 34

Text proposed by the Commission

(34) ‘emotion recognition system’ means an AI system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric *data*;

Amendment

(34) ‘emotion recognition system’ means an AI system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric *or other data obtained, read or interpreted from an individual*;

Or. en

Amendment 1036

Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina

Vollath, Tsvetelina Penkova, Paul Tang, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation

Article 3 – paragraph 1 – point 34

Text proposed by the Commission

(34) ‘emotion recognition system’ means an AI system for the purpose of identifying or inferring emotions or intentions of **natural persons** on the basis of their biometric data;

Amendment

(34) ‘emotion recognition system’ means an AI system for the purpose of identifying or inferring emotions **thoughts, states of mind** or intentions of **individuals or groups** on the basis of their biometric **and biometric-based** data;

Or. en

Amendment 1037

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard, Sandro Gozi, Ró a Thun und Hohenstein, Vlad-Marius Boto , Abir Al-Sahlani, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 3 – paragraph 1 – point 34

Text proposed by the Commission

(34) ‘emotion recognition system’ means an AI system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric data;

Amendment

(34) ‘emotion recognition system’ means an AI system for the purpose of identifying or inferring emotions, **thoughts** or intentions of natural persons on the basis of their biometric **or biometrics-based** data;

Or. en

Amendment 1038

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

Proposal for a regulation

Article 3 – paragraph 1 – point 34

Text proposed by the Commission

(34) ‘emotion recognition system’ means an AI system for the purpose of identifying or inferring emotions or intentions of natural persons *on the basis of their biometric data*;

Amendment

(34) ‘emotion recognition system’ means an AI system for the purpose of identifying or inferring emotions, *thoughts, states of mind* or intentions of natural persons;

Or. en

Amendment 1039

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

Proposal for a regulation

Article 3 – paragraph 1 – point 35

Text proposed by the Commission

(35) ‘biometric categorisation system’ means an AI system for the purpose of assigning natural persons to specific categories, such as sex, age, hair colour, eye colour, tattoos, ethnic origin or sexual or political orientation, on the basis of their biometric *data*;

Amendment

(35) ‘biometric categorisation system’ means an AI system for the purpose of assigning natural persons to specific categories, such as *gender*, sex, age, hair colour, eye colour, tattoos, ethnic *or social* origin, *health, mental or physical ability, behavioural or personality traits, language, religion, or membership of a national minority*, or sexual or political orientation, on the basis of their biometric *or biometric-based data, or which can be reasonably inferred from such data*.

Or. en

Amendment 1040

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Paul Tang

Proposal for a regulation

Article 3 – paragraph 1 – point 35

Text proposed by the Commission

(35) ‘biometric categorisation system’ means an AI system for the purpose of

Amendment

(35) ‘biometric categorisation system’ means an AI system for the purpose of

assigning natural persons to specific categories, such as sex, age, hair colour, eye colour, tattoos, ethnic origin or sexual or political orientation, on the basis of their biometric data;

assigning natural persons to specific categories, such as **gender**, sex, age, hair colour, eye colour, tattoos, ethnic **or social** origin, **health, mental or physical ability, behavioural or personality traits, language, religion, or membership of a national minority**, or sexual or political orientation, on the basis of their biometric **or biometric-based data, or which can be reasonably inferred from such data**;

Or. en

Amendment 1041

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

Proposal for a regulation

Article 3 – paragraph 1 – point 35

Text proposed by the Commission

(35) ‘biometric categorisation system’ means an AI system for the purpose of assigning natural persons to specific categories, such as sex, age, hair colour, eye colour, tattoos, ethnic origin or sexual or political orientation, on the basis of their biometric data;

Amendment

(35) ‘biometric categorisation system’ means an AI system for the purpose of assigning natural persons to specific categories, such as sex, age, hair colour, eye colour, **health, mental ability, personality traits**, tattoos, ethnic origin or sexual or political orientation, on the basis of their biometric data **or biometrics-based data**;

Or. en

Amendment 1042

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte

Proposal for a regulation

Article 3 – paragraph 1 – point 35

Text proposed by the Commission

(35) «système de catégorisation biométrique», un système d’IA destiné à affecter des personnes physiques à des

Amendment

(35) «système de catégorisation biométrique», un système d’IA destiné à affecter des personnes physiques à des

catégories spécifiques selon le sexe, l'âge, la couleur des cheveux, la couleur des yeux, les tatouages, l'origine ethnique ou l'orientation sexuelle ou politique, etc., sur la base de leurs données biométriques;

catégories spécifiques selon le sexe, l'âge, la couleur des cheveux, la couleur des yeux, les tatouages, *l'état de santé*, l'origine ethnique ou l'orientation sexuelle ou politique, etc., sur la base de leurs données biométriques;

Or. fr

Amendment 1043

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 35

Text proposed by the Commission

(35) ‘biometric categorisation system’ means an AI system for the purpose of assigning natural persons to specific categories, *such as sex, age, hair colour, eye colour, tattoos, ethnic origin or sexual or political orientation, on the basis of their biometric data*;

Amendment

(35) ‘biometric categorisation system’ means an AI system *that uses biometric or biometrics-based data* for the purpose of assigning natural persons to specific categories, *or inferring their characteristics and attributes* ;

Or. en

Amendment 1044

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard, Ró a Thun und Hohenstein, Vlad-Marius Boto , Abir Al-Sahlani, Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 3 – paragraph 1 – point 35

Text proposed by the Commission

(35) ‘biometric categorisation system’ means an AI system for the purpose of assigning natural persons to specific categories, *such as sex, age, hair colour, eye colour, tattoos, ethnic origin or sexual or political orientation*, on the basis of their biometric data;

Amendment

(35) ‘biometric categorisation system’ means an AI system for the purpose of assigning natural persons to specific categories *or inferring their characteristics and attributes* on the basis of their biometric *or biometrics-based* data;

Or. en

Amendment 1045

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation**Article 3 – paragraph 1 – point 35***Text proposed by the Commission*

(35) ‘biometric categorisation system’ means an AI system for the purpose of assigning natural persons to specific categories, *such as sex, age, hair colour, eye colour, tattoos, ethnic origin or sexual or political orientation*, on the basis of their biometric data;

Amendment

(35) ‘biometric categorisation system’ means an AI system for the purpose of assigning natural persons to specific categories *or inferring their characteristics and attributes* on the basis of their biometric data *or biometrics-based data*;

Or. en

Amendment 1046

Sophia in ’t Veld, Michal Šime ka, Ró a Thun und Hohenstein

Proposal for a regulation**Article 3 – paragraph 1 – point 35***Text proposed by the Commission*

(35) ‘biometric categorisation system’ means an AI system *for the purpose* of assigning natural persons to specific categories, *such as sex, age, hair colour, eye colour, tattoos, ethnic origin or sexual or political orientation, on the basis of* their *biometric data*;

Amendment

(35) ‘biometric categorisation system’ means an AI system *that uses biometric data, or other physical, physiological or behavioral data, capable* of assigning natural persons to specific categories *or inferring* their *characteristics and attributes*;

Or. en

Amendment 1047

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuťă, Ramona Strugariu, Drago Pîslaru, Sophia in ’t Veld, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation**Article 3 – paragraph 1 – point 35 a (new)**

Text proposed by the Commission

Amendment

(35 a) ‘remote biometric categorisation system’ means a biometric categorisation system capable of categorising natural persons at a distance;

Or. en

Amendment 1048

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 3 – paragraph 1 – point 36

Text proposed by the Commission

(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons at a distance through the comparison of a person’s biometric data with the biometric data contained in a reference database, and without prior knowledge of the user of the AI system whether the person will be present and can be identified ;

Amendment

(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons at a distance through the comparison of a person’s biometric data with the biometric data contained in a reference database, and without prior knowledge of the user of the AI system whether the person will be present and can be identified; *this does not include biometric identification systems used for remote customer onboarding as proscribed under Article 13(1) of Directive (EU) 2018/843 of the European Parliament and of the Council, nor the use for authentication as defined under Articles 4(29) & 4(30) of Directive (EU) 2015/2366 of the European Parliament and of the Council;*

Or. en

Amendment 1049

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

Proposal for a regulation

Article 3 – paragraph 1 – point 36

Text proposed by the Commission

(36) ‘**remote** biometric identification system’ means an AI system for the purpose of identifying natural persons at a distance through the comparison of a person’s biometric data with the biometric data contained in a reference **database**, and without prior knowledge of the user of the AI system whether the person will be present and can be identified ;

Amendment

(36) ‘biometric identification system’ means an AI system, **including remote biometric identification**, for the purpose of identifying natural persons **including** at a distance through the comparison of a person’s biometric data with the biometric data contained in a reference **data repository, excluding verification/authentication systems whose sole purpose is to confirm that a specific natural person is the person he or she claims to be, and systems that are used to confirm the identity of a natural person for the sole purpose of having access to a service, a device or premises;**, and without prior knowledge of the user of the AI system whether the person will be present and can be identified;

Or. en

Amendment 1050

Kosma Złotowski, Patryk Jaki, Eugen Jurzyca

Proposal for a regulation

Article 3 – paragraph 1 – point 36

Text proposed by the Commission

(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons **at a** distance through the comparison of a person’s biometric data with the biometric data contained in a reference **database**, and without prior knowledge of the user of the AI system whether the person will be present and can be identified ;

Amendment

(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons, **at a physical** distance through the comparison of a person’s biometric data with the biometric data contained in a reference **data repository, excluding verification/authentication systems whose sole purpose is to confirm that a specific natural person is the person he or she claims to be, and systems that are used to confirm the identity of a natural person for the sole purpose of having access to a service, a device or premises;** and without prior knowledge of the user of the AI system whether the person will be present and can be identified;

Amendment 1051

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituța, Michal Šimečka

Proposal for a regulation

Article 3 – paragraph 1 – point 36

Text proposed by the Commission

(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons at a distance through the comparison of a person’s biometric data with the biometric data contained in a reference database, and without prior knowledge of the user of the AI system whether the person will be present and can be identified ;

Amendment

(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons at a distance through the comparison of a person’s biometric data with the biometric data contained in a reference database, and without prior knowledge of the user of the AI system whether the person will be present and can be identified, , *excluding authentication and verification systems whose sole purpose is to confirm, based on prior consent, that a specific natural person is the person he or she claims to be or to confirm the identity of a natural person for the sole purpose of having access to a service, a device or premises;*

Amendment 1052

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard, Vlad-Marius Boto , Abir Al-Sahlani, Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 3 – paragraph 1 – point 36

Text proposed by the Commission

(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons at a distance through the comparison of a person’s biometric data with the biometric

Amendment

(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons at a distance through the comparison of a person’s biometric data with the biometric

data contained in a reference database, and without prior knowledge of the user of the AI system whether the person will be present and can be identified ;

data contained in a reference database, and without prior knowledge of the user of the AI system whether the person will be present and can be identified, *excluding verification/authentification systems whose sole purpose is to confirm that a specific natural person is the person he or she claims to be, and systems that are used to confirm the identity of a natural person for the sole purpose of having access to a service, a device or premises;*

Or. en

Amendment 1053
Jorge Buxadé Villalba

Proposal for a regulation
Article 3 – paragraph 1 – point 36

Text proposed by the Commission

36) «Sistema de identificación biométrica remota»: un sistema de IA destinado a identificar a personas físicas a distancia comparando sus datos biométricos con los que figuran en una base de datos de referencia, *y sin que el usuario del sistema de IA sepa de antemano si la persona en cuestión se encontrará en dicha base de datos y podrá ser identificada.*

Amendment

36) «Sistema de identificación biométrica remota»: un sistema de IA destinado a identificar a personas físicas a distancia comparando sus datos biométricos con los que figuran en una base de datos de referencia.

Or. es

Amendment 1054
Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 3 – paragraph 1 – point 36

Text proposed by the Commission

(36) ‘remote biometric identification system’ means an AI system *for the purpose* of identifying natural persons at a

Amendment

(36) ‘remote biometric identification system’ means an AI system *capable* of identifying natural persons at a distance

distance through the comparison of a person's biometric data with the biometric data contained in a reference database, ***and without prior knowledge of the user of the AI system whether the person will be present and can be identified*** ;

through the comparison of a person's biometric data with the biometric data contained in a reference database;

Or. en

Amendment 1055

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

Proposal for a regulation

Article 3 – paragraph 1 – point 36

Text proposed by the Commission

(36) ‘remote biometric identification system’ means an AI system ***for the purpose*** of identifying natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database, ***and without prior knowledge of the user of the AI system whether the person will be present and can be identified*** ;

Amendment

(36) ‘remote biometric identification system’ means an AI system ***capable*** of identifying natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database;

Or. en

Amendment 1056

Rob Rooken
on behalf of the ECR Group

Proposal for a regulation

Article 3 – paragraph 1 – point 36

Text proposed by the Commission

(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database, ***and***

Amendment

(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database;

without prior knowledge of the user of the AI system whether the person will be present and can be identified ;

Or. en

Amendment 1057

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

Proposal for a regulation

Article 3 – paragraph 1 – point 36

Text proposed by the Commission

(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons at a distance through the comparison of a person’s biometric data with the biometric data contained in a reference database, *and without prior knowledge of the user of the AI system whether the person will be present and can be identified* ;

Amendment

(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons at a distance through the comparison of a person’s biometric data with the biometric data contained in a reference database;

Or. en

Amendment 1058

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 36

Text proposed by the Commission

(36) ‘remote biometric identification system’ means an AI system *for the purpose* of identifying natural persons at a distance through the comparison of a person’s biometric data with the biometric data contained in a reference database, *and without prior knowledge of the user of the AI system whether the person will be present and can be identified* ;

Amendment

(36) ‘remote biometric identification system’ means an AI system *capable* of identifying natural persons at a distance through the comparison of a person’s biometric data with the biometric data contained in a reference database *or data repository*;

Or. en

Amendment 1059

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 3 – paragraph 1 – point 36

Text proposed by the Commission

(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons at a distance through *the comparison of a person’s biometric data with the biometric data contained in a reference database, and without prior knowledge of the user of the AI system whether the person will be present and can be identified* ;

Amendment

(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons at a *physical* distance through *a “one to many” comparison where the persons identified do not claim to have a particular identity but where the identity is otherwise established - without the conscious cooperation of these persons - by matching live templates with templates stored in a template database*;

Or. en

Amendment 1060

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

Proposal for a regulation

Article 3 – paragraph 1 – point 36

Text proposed by the Commission

(36) «système d’identification biométrique à distance», un système d’IA destiné à identifier des personnes physiques à distance en comparant les données biométriques d’une personne avec celles qui figurent dans une base de données de référence, *et sans que l’utilisateur du système d’IA ne sache au préalable si la personne sera présente et pourra être identifiée*;

Amendment

(36) «système d’identification biométrique à distance», un système d’IA destiné, *au terme d’un processus unique*, à identifier des personnes physiques à distance en comparant les données biométriques d’une personne avec celles qui figurent dans une base de données de référence;

Or. fr

Amendment 1061

Sophia in 't Veld, Michal Šimek, Róza Thun und Hohenstein

Proposal for a regulation

Article 3 – paragraph 1 – point 36

Text proposed by the Commission

(36) ‘remote biometric identification system’ means an AI system *for the purpose of identifying* natural persons at a distance through the comparison of a person’s biometric data *with the biometric* data contained in a reference database, *and without prior knowledge of the user of the AI system whether the person will be present and can be identified* ;

Amendment

(36) ‘remote biometric identification system’ means an AI system *capable of categorizing* natural persons at a distance through the comparison of a person’s biometric data *or other physical, physiological or behavioral data, with this* data contained in a reference database;

Or. en

Amendment 1062

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 3 – paragraph 1 – point 36 a (new)

Text proposed by the Commission

Amendment

(36 a) ‘at a distance’ means *the process of identification, verification or authentication in physical distance with indirect interaction with the data subject or without*;

Or. en

Amendment 1063

Patrick Breyer

Proposal for a regulation

Article 3 – paragraph 1 – point 37

Text proposed by the Commission

Amendment

(37) ‘real-time’ remote biometric identification system’ means a remote

deleted

biometric identification system whereby the capturing of biometric data, the comparison and the identification all occur without a significant delay. This comprises not only instant identification, but also limited short delays in order to avoid circumvention.

Or. en

Amendment 1064

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

Proposal for a regulation

Article 3 – paragraph 1 – point 37

Text proposed by the Commission

(37) ‘**real-time**’ remote biometric identification system’ means a remote biometric identification system whereby the capturing of biometric data, the comparison and the identification *all* occur without *a significant delay*. This comprises not only instant identification, but also limited short delays in order to avoid circumvention.

Amendment

(37) biometric identification system’ means a remote biometric identification system whereby the capturing of biometric data, the comparison and the identification occur *on a continuous or large-scale basis over a period of time and without limitation to a particular past incident*.

Or. en

Amendment 1065

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

Proposal for a regulation

Article 3 – paragraph 1 – point 38

Text proposed by the Commission

(38) ‘**post**’ remote biometric identification system’ means a remote biometric identification system other than a ‘**real-time**’ remote biometric

Amendment

deleted

identification system;

Or. en

Amendment 1066

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

Proposal for a regulation

Article 3 – paragraph 1 – point 38

Text proposed by the Commission

(38) «système d’identification biométrique à distance “a posteriori”, un système d’identification biométrique à distance autre qu’un système d’identification biométrique à distance «en temps réel»;

Amendment

(38) «système d’identification biométrique à distance “a posteriori”, un système d’identification biométrique à distance autre qu’un système d’identification biométrique à distance «en temps réel», *que les données acquises soient ou non hébergées sur un système distinct préalablement à la comparaison et à l’identification;*

Or. fr

Amendment 1067

Rob Rooken

on behalf of the ECR Group

Proposal for a regulation

Article 3 – paragraph 1 – point 38 a (new)

Text proposed by the Commission

Amendment

(38 a) 'deepfakes' means manipulated or synthetic audio or video which appears to be authentic, and which feature people, without their consent/awareness, or events that are false and/or misleading, produced using artificial intelligence techniques, including machine learning and deep learning;

Or. en

Amendment 1068
Axel Voss, Deirdre Clune

Proposal for a regulation
Article 3 – paragraph 1 – point 39

Text proposed by the Commission

(39) ‘publicly accessible space’ means any physical place accessible to *the public*, regardless of whether certain conditions for access *may apply*;

Amendment

(39) ‘publicly accessible space’ means any *publicly or privately owned* physical place accessible to *an undetermined number of natural persons*, regardless of whether certain conditions *or circumstances* for access *have been predetermined, and regardless of the potential capacity restrictions*;

Or. en

Amendment 1069
Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation
Article 3 – paragraph 1 – point 39

Text proposed by the Commission

(39) ‘publicly accessible space’ means any *physical* place accessible to the public, regardless of whether certain conditions for access may apply;

Amendment

(39) ‘publicly accessible space’ means any place accessible to the public, *or fulfilling a public function*, regardless of whether certain conditions for access may apply;

Or. en

Amendment 1070
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Article 3 – paragraph 1 – point 40 – introductory part

Text proposed by the Commission

Amendment

(40) «autorités répressives»,

(40) «autorités répressives», *toute autorité publique compétente pour la prévention et la détection des infractions pénales, les enquêtes et les poursuites en la matière ou l'exécution de sanctions pénales, y compris la protection contre les menaces pour la sécurité publique et la prévention de telles menaces;*

Or. fr

Amendment 1071

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

Proposal for a regulation

Article 3 – paragraph 1 – point 40 – point a

Text proposed by the Commission

Amendment

(a) toute autorité publique compétente pour la prévention et la détection des infractions pénales, les enquêtes et les poursuites en la matière ou l'exécution de sanctions pénales, y compris la protection contre les menaces pour la sécurité publique et la prévention de telles menaces; ou

supprimé

Or. fr

Justification

Le sous-paragraphe b) étant supprimé, l'existence d'un sous-paragraphe a) ne se justifie plus, dans texte étant directement réintégré au sein du paragraphe 40.

Amendment 1072

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 40 – point a a (new)

Text proposed by the Commission

Amendment

(a a) any other authority competent for law enforcement, including courts and the

judiciary;

Or. en

Amendment 1073

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte

Proposal for a regulation

Article 3 – paragraph 1 – point 40 – point b

Text proposed by the Commission

Amendment

(b) *tout autre organisme ou entité à qui le droit d'un État membre confie l'exercice de l'autorité publique et des prérogatives de puissance publique à des fins de prévention et de détection des infractions pénales, d'enquêtes et de poursuites en la matière ou d'exécution de sanctions pénales, y compris la protection contre les menaces pour la sécurité publique et la prévention de telles menaces;*

supprimé

Or. fr

Amendment 1074

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 41

Text proposed by the Commission

Amendment

(41) ‘law enforcement’ means activities carried out by law enforcement authorities for 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;

(41) ‘law enforcement’ means

i) activities carried out by law enforcement authorities for 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; **and**

ii) activities carried out by any other authority that is part of the criminal justice system, including the judiciary;

Or. en

Amendment 1075

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 3 – paragraph 1 – point 41

Text proposed by the Commission

(41) ‘law enforcement’ means activities carried out by law enforcement authorities for 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;

Amendment

(41) ‘law enforcement’ means activities carried out by law enforcement authorities **or on their behalf** for 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;

Or. en

Amendment 1076

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

Proposal for a regulation

Article 3 – paragraph 1 – point 41

Text proposed by the Commission

(41) ‘law enforcement’ means activities carried out by law enforcement authorities for 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;

Amendment

(41) ‘law enforcement’ means activities carried out by law enforcement authorities **solely** for 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;

Amendment 1077

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

Proposal for a regulation

Article 3 – paragraph 1 – point 42

Text proposed by the Commission

(42) ‘national supervisory authority’ means **the** authority to which a Member State assigns the responsibility for the implementation and application of this Regulation, for coordinating the activities entrusted to that Member State, for acting as the single contact point for the Commission, and for representing the Member State at the European Artificial Intelligence Board;

Amendment

(42) ‘national supervisory authority’ means **an independent public** authority to which a Member State assigns the responsibility for the implementation and application of this Regulation, for coordinating the activities entrusted to that Member State, for acting as the single contact point for the Commission, and for representing the Member State at the European Artificial Intelligence Board;

Amendment 1078

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Nută, Ramona Strugariu, Drago Pîslaru, Lucia Šuriš Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation

Article 3 – paragraph 1 – point 42

Text proposed by the Commission

(42) ‘national supervisory authority’ means the authority to which a Member State assigns the responsibility for the implementation and application of this Regulation, for coordinating the activities entrusted to that Member State, for acting as the single contact point for the Commission, and for representing the Member State **at the European Artificial Intelligence Board**;

Amendment

(42) ‘national supervisory authority’ means the authority to which a Member State assigns the responsibility for the implementation and application of this Regulation, for coordinating the activities entrusted to that Member State, for acting as the single contact point for the Commission, and for representing the Member State **in the management board of the AI Office**;

Amendment 1079

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 43

Text proposed by the Commission

Amendment

(43) ‘***national competent authority***’ means ***the national supervisory authority, the notifying authority and the market surveillance authority;***

deleted

Or. en

Amendment 1080

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

Proposal for a regulation

Article 3 – paragraph 1 – point 43

Text proposed by the Commission

Amendment

(43) ‘***national competent authority***’ means ***the national supervisory authority, the notifying authority and the market surveillance authority;***

(43) ‘***national competent authority***’ means the notifying authority and the market surveillance authority;

Or. en

Amendment 1081

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 3 – paragraph 1 – point 43

Text proposed by the Commission

Amendment

(43) ‘***national*** competent authority’ means the national supervisory authority, the notifying authority and the market

(43) ‘competent authority’ means ***the EDPS, the national supervisory authority, the notifying authority and the market***

surveillance authority;

surveillance authority;

Or. en

Amendment 1082

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

Proposal for a regulation

Article 3 – paragraph 1 – point 44 – introductory part

Text proposed by the Commission

(44) «incident grave», tout incident entraînant directement ou indirectement, susceptible d'avoir entraîné ou susceptible d'entraîner:

Amendment

(44) «incident grave», tout incident **ou dysfonctionnement** entraînant directement ou indirectement, susceptible d'avoir entraîné ou susceptible d'entraîner:

Or. fr

Amendment 1083

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 44 – introductory part

Text proposed by the Commission

(44) ‘serious incident’ means any incident that directly or indirectly leads, **might have led or might lead** to any of the following:

Amendment

(44) ‘serious incident’ means any incident that directly or indirectly leads to any of the following:

Or. en

Amendment 1084

Marion Walsmann

Proposal for a regulation

Article 3 – paragraph 1 – point 44 – introductory part

Text proposed by the Commission

(44) ‘serious incident’ means any

Amendment

(44) ‘serious incident’ means any

incident that directly or indirectly leads, *might have led or might lead* to any of the following:

incident that directly or indirectly leads to any of the following:

Or. en

Amendment 1085

Rob Rooken

on behalf of the ECR Group

Proposal for a regulation

Article 3 – paragraph 1 – point 44 – point a

Text proposed by the Commission

(a) the death of a person or serious damage to a person's health, to property or the environment,

Amendment

(a) the death of a person or serious damage to a person's *physical* health, *mental health or wellbeing*, to property or the environment,

Or. en

Amendment 1086

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 44 – point a

Text proposed by the Commission

(a) the death of a person or serious damage to a person's health, to property or the environment,

Amendment

(a) the death of a person or serious damage to a person's *physical* health, *mental health or wellbeing*, to property or the environment

Or. en

Amendment 1087

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

Proposal for a regulation

Article 3 – paragraph 1 – point 44 – point a

Text proposed by the Commission

(a) le décès d'une personne ou une atteinte **grave** à la santé d'une personne, à des biens ou à l'environnement,

Amendment

(a) le décès d'une personne ou une atteinte à la santé d'une personne, **à son patrimoine**, à des biens ou à l'environnement,

Or. fr

Amendment 1088

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 44 – point a

Text proposed by the Commission

(a) the death of a person or serious damage to a person's health, **to property or the environment**,

Amendment

(a) the death of a person or serious damage to a person's health,

Or. en

Amendment 1089

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 3 – paragraph 1 – point 44 – point a

Text proposed by the Commission

(a) the death of a person or **serious** damage to a person's health, to property or the environment,

Amendment

(a) the death of a person or damage to a person's health, to property or the environment,

Or. en

Amendment 1090

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 44 – point a a (new)

Text proposed by the Commission

Amendment

(a a) a breach of fundamental rights defined by The Charter of Fundamental Rights of the European Union;

Or. en

Amendment 1091

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 44 – point a b (new)

Text proposed by the Commission

Amendment

(a b) systematic, mass or serious breach of other rights;

Or. en

Amendment 1092

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 44 – point a c (new)

Text proposed by the Commission

Amendment

(a c) damage to democracy, the rule of law or the environment

Or. en

Amendment 1093

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

Proposal for a regulation

Article 3 – paragraph 1 – point 44 – point b

Text proposed by the Commission

Amendment

(b) une perturbation grave *et*

(b) une perturbation grave de la gestion

irréversible de la gestion et du fonctionnement d'infrastructures critiques.

et du fonctionnement d'infrastructures critiques,

Or. fr

Amendment 1094

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

Proposal for a regulation

Article 3 – paragraph 1 – point 44 – point b a (new)

Text proposed by the Commission

Amendment

(b bis) une violation des obligations au titre du droit national ou du droit de l'Union visant à protéger les droits fondamentaux.

Or. fr

Amendment 1095

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 3 – paragraph 1 – point 44 – point b a (new)

Text proposed by the Commission

Amendment

(b a) a breach of obligations under Union law intended to protect fundamental rights;

Or. en

Amendment 1096

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 44 – point b a (new)

Text proposed by the Commission

Amendment

(b a) breach of obligations under Union law intended to protect personal data

Or. en

Amendment 1097

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 3 – paragraph 1 – point 44 – point b a (new)

Text proposed by the Commission

Amendment

(b a) a serious violation of an individual's fundamental rights;

Or. en

Amendment 1098

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 3 – paragraph 1 – point 44 a (new)

Text proposed by the Commission

Amendment

(44 a) ‘AI systems presenting a risk’ means an AI system having the potential to affect adversely fundamental rights, health and safety of persons in general, including in the workplace, protection of consumers, the environment, public security, the values enshrined in Article 2 TEU and other public interests, that are protected by the applicable Union harmonisation legislation, to a degree which goes beyond that considered reasonable and acceptable in relation to its intended purpose or under the normal or reasonably foreseeable conditions of

use of the system concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements.

Or. en

Amendment 1099

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 44 a (new)

Text proposed by the Commission

Amendment

(44 a) ‘regulatory sandbox’ means a framework which, by providing a structured context for experimentation, enable where appropriate in a real-world or digital environment the testing of innovative technologies, products, services or approaches for a limited time and in a limited part of a sector or area under regulatory supervision ensuring that appropriate safeguards are in place;

Or. en

Amendment 1100

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 3 – paragraph 1 – point 44 a (new)

Text proposed by the Commission

Amendment

(44 a) ‘Recommender system’ means a fully or partially automated system used by an online platform to suggest or prioritise in its online interface specific information to recipients of the service, including as a result of a search initiated by the recipient of the service or otherwise determining the relative order or

prominence of information displayed.

Or. en

Amendment 1101

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 3 – paragraph 1 – point 44 a (new)

Text proposed by the Commission

Amendment

(44 a) 'critical infrastructure' means an asset, system or part thereof which is necessary for the delivery of a service that is essential for the maintenance of vital societal functions or economic activities within the meaning of Article 2(4) and (5) of Directive (...) on the resilience of critical entities;

Or. en

Amendment 1102

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte

Proposal for a regulation

Article 3 – paragraph 1 – point 44 a (new)

Text proposed by the Commission

Amendment

(44 bis) « biais », toute inclination au préjugé envers ou contre une personne, un objet ou un point de vue, volontaire ou non, susceptible d'apparaître en raison de la conception, l'approvisionnement en données, les interactions, la personnalisation ou le paramétrage d'un système d'I.A.;

Or. fr

Justification

Définition tirée des Lignes directrices en matière d'éthique pour une I.A. digne de confiance de 2019 du Groupe d'experts indépendant de haut niveau sur l'intelligence artificielle

constitué par la Commission européenne.

Amendment 1103

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ondej Kováčik, Jan-Christoph Oetjen

Proposal for a regulation

Article 3 – paragraph 1 – point 44 a (new)

Text proposed by the Commission

Amendment

(44 a) ‘regulatory sandbox’ means a facility that provides 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;

Or. en

Amendment 1104

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 3 – paragraph 1 – point 44 a (new)

Text proposed by the Commission

Amendment

(44 a) ‘unfair bias’ means an inclination of prejudice towards or against a natural person that can result in discriminatory and/or unfair treatment of some natural persons with respect to others;

Or. en

Amendment 1105

Kateina Konevá, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 44 a (new)

Text proposed by the Commission

Amendment

(44 a) 'scientific research and development' means any scientific development, experimentation, analysis, testing or validation carried out under controlled conditions.

Or. en

Amendment 1106

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 44 a (new)

Text proposed by the Commission

Amendment

(44 a) scientific research and development means: any scientific development, experimentation, analysis, testing or validation carried out under controlled conditions.

Or. en

Amendment 1107

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

Proposal for a regulation

Article 3 – paragraph 1 – point 44 a (new)

Text proposed by the Commission

Amendment

(44 a) 'near miss' means any incident that, if the circumstances were slightly different, would have resulted in a 'serious incident';

Or. en

Amendment 1108

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 44 b (new)

Text proposed by the Commission

Amendment

(44 b) ‘social scoring’ means the evaluation or categorisation of EU citizens based on their behavior or (personality) characteristics, where one or more of the following conditions apply:

- (i) the information is not reasonably relevant for the evaluation or categorisation;*
- (ii) the information is generated or collected in another domain than that of the evaluation or categorisation;*
- (iii) the information is not necessary for or proportionate to the evaluation or categorisation;*
- (iv) the information contains or reveals special categories of personal data.*

Or. en

Amendment 1109

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 44 b (new)

Text proposed by the Commission

Amendment

(44 b) ‘social scoring’ means the evaluation or categorisation of persons based on their behaviour or (personality) characteristics, where one or more of the following conditions apply:

- (i) the information is not reasonably relevant for the evaluation or categorisation;*
- (ii) the information is generated or collected in another domain than that of the evaluation or categorisation;*
- (iii) the information is not necessary for*

or proportionate to the evaluation or categorisation;

(iv) the information contains or reveals special categories of personal data.

Or. en

Amendment 1110

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 44 b (new)

Text proposed by the Commission

Amendment

(44 b) ‘deep fake’ means manipulated or synthetic audio, image or video content that would falsely appear to be authentic or truthful, and which features depictions of persons appearing to say or do things they did not say or do, without their consent, produced using AI techniques, including machine learning and deep learning;

Or. en

Amendment 1111

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 3 – paragraph 1 – point 44 b (new)

Text proposed by the Commission

Amendment

(44 b) ‘deep fake’ means 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.

Or. en

Amendment 1112

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

Proposal for a regulation

Article 3 – paragraph 1 – point 44 b (new)

Text proposed by the Commission

Amendment

(44 b) ‘artificial intelligence system with indeterminate uses’ means an artificial intelligence system without specific and limited provider-defined purposes;

Or. en

Amendment 1113

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

Proposal for a regulation

Article 3 – paragraph 1 – point 44 b (new)

Text proposed by the Commission

Amendment

(44 ter) « auditabilité », la capacité d'un système d'I.A. à subir une évaluation de ses algorithmes, de ses données et de ses processus de conception;

Or. fr

Justification

Définition tirée des Lignes directrices en matière d'éthique pour une I.A. digne de confiance de 2019 du Groupe d'experts indépendant de haut niveau sur l'intelligence artificielle constitué par la Commission européenne.

Amendment 1114

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 3 – paragraph 1 – point 44 b (new)

Text proposed by the Commission

Amendment

(44 b) ‘child’ means any person below the age of 18 years.

Or. en

Amendment 1115

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

Proposal for a regulation

Article 3 – paragraph 1 – point 44 c (new)

Text proposed by the Commission

Amendment

(44 quater) « Reproductibilité », la capacité d'un système d'I.A. à démontrer expérimentalement un comportement identique lors d'une exécution dans des conditions identiques;

Or. fr

Justification

Définition tirée des Lignes directrices en matière d'éthique pour une I.A. digne de confiance de 2019 du Groupe d'experts indépendant de haut niveau sur l'intelligence artificielle constitué par la Commission européenne.

Amendment 1116

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 44 c (new)

Text proposed by the Commission

Amendment

(44 c) ‘affectee(s)’ mean(s) any natural or legal person or group of natural or legal persons affected by the use or outcomes of, or a combination of, AI system(s);

Or. en

Amendment 1117

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

Proposal for a regulation

Article 3 – paragraph 1 – point 44 c (new)

Text proposed by the Commission

Amendment

(44 c) ‘profiling’ means any form of automated processing of personal data as defined point (4) of Article 4 of Regulation (EU) 2016/679;

Or. en

Amendment 1118

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 44 c (new)

Text proposed by the Commission

Amendment

(44 c) ‘incident’ means a faulty operation of an AI system;

Or. en

Amendment 1119

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 44 c (new)

Text proposed by the Commission

Amendment

(44 c) “child” is any person under the age of 18.

Or. en

Amendment 1120

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 44 d (new)

Text proposed by the Commission

Amendment

(44 d) ‘artificial intelligence system within determinate uses’ means an artificial intelligence system without specific and limited provider-defined purposes;

Or. en

Amendment 1121

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 44 d (new)

Text proposed by the Commission

Amendment

(44 d) ‘personal data’ means data as defined in point (1) of Article 4 of Regulation (EU) 2016/679;

Or. en

Amendment 1122

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 44 e (new)

Text proposed by the Commission

Amendment

(44 e) ‘deep fake’ means generated or manipulated image, audio or video content produced by an AI system that appreciably resembles existing persons, objects, places or other entities or events and falsely appears to a person to be authentic or truthful;

Or. en

Amendment 1123

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 44 e (new)

Text proposed by the Commission

Amendment

(44 e) ‘non-personal data’ means data other than personal data as defined in point (1) of Article 4 of Regulation (EU) 2016/679;

Or. en

Amendment 1124

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 44 f (new)

Text proposed by the Commission

Amendment

(44 f) ‘critical infrastructure’ means an asset, system or part thereof which is necessary for the delivery of a service that is essential for the maintenance of vital societal functions or economic activities within the meaning of Article 2 (4) and (5) of Directive of the European Parliament and of the Council on the resilience of critical entities (2020/0365 (COD));

Or. en

Amendment 1125

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 3 – paragraph 1 – point 44 f (new)

Text proposed by the Commission

Amendment

(44f) 'redress by design' means technical mechanisms and/or operational procedures, established from the design phase, in order to be able to effectively detect, audit, rectify the consequences and implications of wrong predictions by an AI system and improve it.

Or. en

Amendment 1126

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 44 g (new)

Text proposed by the Commission

Amendment

(44 g) 'harmful subliminal technique' means a measure whose existence and operation is entirely imperceptible by a natural person on whom it is used, and which has the purpose and direct effect to induce actions leading to that persons physical or psychological harm;

Or. en

Amendment 1127

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 44 h (new)

Text proposed by the Commission

Amendment

(44 h) 'unfair bias' means an inclination of prejudice towards or against a natural person that can result in discriminatory and/or unfair treatment of some natural persons with respect to others.

Or. en

Amendment 1128

Sophia in 't Veld, Michal Šimeka

Proposal for a regulation

Article 3 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

'Social scoring' means the evaluation or categorization of an individual natural person, or a group, based on their behaviour or (personality) characteristics, where one or more of the following conditions apply: (1) the information is not reasonably relevant, necessary for, or proportionate to the evaluation or categorization; (2) the information is generated or collected in another domain than that of the evaluation or categorization; (3) the information contains or reveals special categories.

Or. en

Amendment 1129

Svenja Hahn, Nicola Beer, Vlad-Marius Boto, Moritz Körner, Ondřej Kováčík, Jan-Christoph Oetjen

Proposal for a regulation

Article 3 a (new)

Text proposed by the Commission

Amendment

Article 3 a

General Purpose AI

1. General purpose AI applications shall not be considered as having an intended purpose within the meaning of this Regulation unless those systems have been adapted to a specific intended purpose that falls within the scope of this Regulation.

2. Any natural or legal person that adapts a general purpose AI application to a specific intended purpose and places it on

the market or puts it into service shall be considered the provider and be subject to the obligations laid down in this Regulation.

3. The initial provider of a general purpose AI application shall comply with Article 15 of this Regulation at all times. After placing it on the market or putting it to service, and without compromising its own intellectual property rights or trade secrets, provide the new provider referred to in paragraph 2 with all essential, relevant and reasonably expected information that is necessary to comply with the obligations set out in this Regulation.

4. The initial provider of a general purpose AI application shall only be responsible for the accuracy of the provided information and compliance with Article 15 of this Regulation towards the natural or legal person that adapts the general purpose AI application to a specific intended purpose.

Or. en

Amendment 1130

Sergey Lagodinsky

on behalf of the Verts/ALE Group

Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 4

Text proposed by the Commission

Amendment

Article 4

deleted

Amendments to Annex I

The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and approaches listed in Annex I, in order to update that list to market and technological developments on the basis of characteristics that are similar to the

techniques and approaches listed therein.

Or. en

Amendment 1131

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

Proposal for a regulation

Article 4

Text proposed by the Commission

Amendment

Article 4

deleted

Amendments to Annex I

The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and approaches listed in Annex I, in order to update that list to market and technological developments on the basis of characteristics that are similar to the techniques and approaches listed therein.

Or. en

Amendment 1132

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 4

Text proposed by the Commission

Amendment

Article 4

deleted

Amendments to Annex I

The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and approaches listed in Annex I, in order to update that list to market and technological developments on the basis

of characteristics that are similar to the techniques and approaches listed therein.

Or. en

Justification

It is appropriate to delete Annex I, in order to ensure future-proofness and enable legal certainty. Therefore, Article 4 is not needed anymore.

Amendment 1133

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 4

Text proposed by the Commission

Amendment

Article 4

deleted

Amendments to Annex I

The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and approaches listed in Annex I, in order to update that list to market and technological developments on the basis of characteristics that are similar to the techniques and approaches listed therein.

Or. en

Justification

Our modified definition of AI in Art 3 makes this Article and Annex I obsolete.

Amendment 1134

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 4 – paragraph 1

Text proposed by the Commission

Amendment

The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and

deleted

approaches listed in Annex I, in order to update that list to market and technological developments on the basis of characteristics that are similar to the techniques and approaches listed therein.

Or. en

Justification

To create legal certainty for AI developers, it is important that the definition of AI systems is clearly laid down and cannot be changed quickly and dramatically by means of delegated acts. All changes in this regard should be subject to Parliament's approval.

Amendment 1135

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 4 – paragraph 1

Text proposed by the Commission

The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and approaches listed in Annex I, in order to update that list to market and technological developments on the basis of ***characteristics that are similar to the*** techniques and approaches listed ***therein***.

Amendment

The Commission is empowered to adopt delegated acts in accordance with Article 73, ***after ensuring adequate consultation with relevant stakeholders***, to amend the list of techniques and approaches listed in Annex I ***within the scope of the definition of an AI system as provided for in Article 3(1)***, in order to update that list to market and technological developments on the basis of ***transparent criteria***.

Every time the list of techniques and approaches listed in Annex I is amended, providers and users of AI systems, which become in scope of the Regulation shall have 24 months to apply the relevant requirements and obligations. Article 83 shall apply for AI systems already placed on the market before delegated acts are published.

Or. en

Amendment 1136

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto ,

Moritz Körner, Ondřej Kováčík, Jan-Christoph Oetjen

**Proposal for a regulation
Article 4 – paragraph 1**

Text proposed by the Commission

The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and approaches listed in Annex I, in order to update that list to market and technological developments on the basis of characteristics ***that are similar to the techniques and approaches listed therein.***

Amendment

The Commission is empowered to adopt delegated acts in accordance with Article 73, ***after an adequate and transparent consultation process involving the relevant stakeholders,*** to amend the list of techniques and approaches listed in Annex I ***within the scope of the definition of an AI system as provided for in Article 3(1),*** in order to update that list to market and technological developments on the basis of ***transparent*** characteristics. ***Providers and users of AI systems should be given 24 months to comply with any amendment to Annex I.***

Or. en

Amendment 1137

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

**Proposal for a regulation
Article 4 – paragraph 1**

Text proposed by the Commission

The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and approaches listed in Annex I, in order to update that list to market and technological developments on the basis of characteristics that are similar to the techniques and approaches listed therein.

Amendment

The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and approaches listed in Annex I, ***within the scope of the definition of an AI system as provided for in Article 3(1),*** in order to update that list to market and technological developments on the basis of characteristics ***and hazards*** that are similar to the techniques and approaches listed therein.

Or. en

Amendment 1138**Barbara Thaler, Lukas Mandl, Axel Voss, Deirdre Clune****Proposal for a regulation****Article 4 – paragraph 1***Text proposed by the Commission*

The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and approaches listed in Annex I, in order to update that list to market and technological developments on the basis of characteristics that are similar to the techniques and approaches listed therein.

Amendment

The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and approaches listed in Annex I, in order to update that list to market and technological developments on the basis of characteristics that are similar to the techniques and approaches listed therein.
As an adequate transitional period, two years shall be applied to each amendment.

Or. en

Amendment 1139**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud****Proposal for a regulation****Article 4 – paragraph 1***Text proposed by the Commission*

La Commission est habilitée à adopter des actes délégués conformément à l'article 73 afin de modifier la liste des techniques et approches énumérées à l'annexe I, en vue de mettre cette liste à jour en fonction de l'évolution du marché et des technologies sur la base de caractéristiques similaires aux techniques et approches qui y sont énumérées.

Amendment

La Commission est habilitée à adopter des actes délégués conformément à l'article 73 afin de modifier la liste des techniques et approches énumérées à l'annexe I, en vue de mettre cette liste à jour en fonction de l'évolution du marché et des technologies *par des ajouts ou des précisions non restrictives* sur la base de caractéristiques *descriptives* similaires aux techniques et approches qui y sont énumérées.

Or. fr

Amendment 1140**Marion Walsmann**

Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission

The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and approaches listed in Annex I, in order to update that list to market and technological developments on the basis of characteristics that are similar to the techniques and approaches listed therein.

Amendment

The Commission is empowered to adopt delegated acts in accordance with Article 73 **after consulting relevant stakeholders** to amend the list of techniques and approaches listed in Annex I, in order to update that list to market and technological developments on the basis of characteristics that are similar to the techniques and approaches listed therein.

Or. en

Amendment 1141
Bettina Vollath

Proposal for a regulation
Article 4 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Article 4 a

Principles applicable to all AI systems

All operators of AI systems shall respect the following principles:

1. Operators of AI systems shall respect fundamental rights and the Union values, as enshrined in Article 2 TEU,

throughout the AI system lifecycle. To ensure this, operators shall implement mechanisms and safeguards that are appropriate to the context and consistent with the state of art ('fairness')

2. Operators shall be accountable for the proper functioning of AI systems and for the respect of the fairness principle, based on their roles, the context, and consistent with the state of art. Operators shall ensure the proper functioning,

throughout their lifecycle, of the AI systems that they design, develop, operate or deploy, in accordance with their role

and applicable regulatory framework, and by demonstrating this through their actions and decision-making processes ('accountability')

3. Operators shall commit to transparency and responsible disclosure regarding AI systems. To this end, they shall provide meaningful information, appropriate to the context, and consistent with the state of art:

- (a) to foster a general understanding of AI systems,*
- (b) to make affected persons aware that they are interacting with an AI system and an explanation thereof,*
- (c) to enable those affected by an AI system to understand the outcome, and*
- (d) to enable those adversely affected by an AI system to challenge its outcome based on plain and easy-to-understand information on the factors, and the logic that served as the basis for the prediction, recommendation or decision ('transparency and explainability')*

4. Operators shall ensure that AI systems are robust, secure and safe throughout their entire lifecycle so that, in conditions of normal use, foreseeable use or misuse, or other adverse conditions, they function appropriately and do not pose unreasonable risk. Operators shall ensure, based on their roles and the context, traceability including in relation to datasets, processes and decisions made during the AI system lifecycle, to enable the analysis of the outcomes of the AI system and responses to inquiry, appropriate to the context and consistent with the state of art.

Operators shall, based on their roles, the context, and their ability to act, apply a systematic risk management approach to each phase of the AI system lifecycle on a continuous basis to address the risks related to AI systems, including privacy, protection of personal data, digital security, safety and bias ('privacy and

security’)

5. Operators shall proactively engage in pursuit of beneficial outcomes for people, societies and the planet, such as advancing inclusion, reducing economic, social, gender and other inequalities, and protecting natural environments, therefore invigorating inclusive growth, sustainable development and well-being (‘social benefit’)

6. Operators should be motivated to follow a human-centric approach. AI available in the Union market or otherwise affecting people in the Union should be designed human centered, so that people can trust that the technology is used in a way that is safe and compliant with the law, including the respect of fundamental rights what requires a shift towards a Human Centered AI Engineering, also in research and education.

Or. en

Amendment 1142

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

Proposal for a regulation

Article 4 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Les techniques et approches énumérées à l'annexe I ne peuvent être modifiées que par un règlement modificatif si la modification concerne un retrait, une précision restrictive ou une modification de la définition desdites techniques et approches.

Or. fr

Amendment 1143

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 4 a (new)

Text proposed by the Commission

Amendment

Article 4 a

Principles applicable to all AI systems

All operators of AI systems shall respect the following principles:

1. Operators of AI systems shall respect fundamental rights and the Union values, as enshrined in Article 2 TEU, throughout the AI system lifecycle. To ensure this, operators shall implement mechanisms and safeguards that are appropriate to the context and consistent with the state of art ('fairness')

2. Operators shall be accountable for the proper functioning of AI systems and for the respect of the fairness principle, based on their roles, the context, and consistent with the state of art. Operators shall ensure the proper functioning, throughout their lifecycle, of the AI systems that they design, develop, operate or use, in accordance with their role and applicable regulatory framework, and by demonstrating this through their actions and decision-making processes ('accountability')

3. Operators shall commit to transparency and responsible disclosure regarding AI systems. To this end, they shall provide meaningful information, appropriate to the context, and consistent with the state of the art:

(a) to foster a general understanding of AI systems,

(b) to make affected persons aware that they are interacting with an AI system and an explanation thereof,

(c) to make affected persons aware about their rights conferred in this Regulation,

(d) to enable those affected by an AI system to understand the outcome, and
(e) to enable those adversely affected by an AI system to challenge its outcome based on plain and easy-to-understand information on the factors, and the logic that served as the basis for the prediction, recommendation or decision ('transparency and explainability').

4. Operators shall ensure that AI systems are robust, secure and safe throughout their entire lifecycle so that, in conditions of normal use, foreseeable use or misuse, or other adverse conditions, they function appropriately and do not pose unreasonable risk. Operators shall ensure, based on their roles and the context, traceability including in relation to datasets, processes and decisions made during the AI system lifecycle, to enable the analysis of the outcomes of the AI system and responses to inquiry, appropriate to the context and consistent with the state of the art. Operators shall, based on their roles, the context, and their ability to act, apply a systematic risk management approach to each phase of the AI system lifecycle on a continuous basis to address the risks related to AI systems, including privacy, protection of personal data, digital security, safety and bias ('privacy and security')

5. Operators shall proactively engage in pursuit of beneficial outcomes for people, societies and the planet, such as advancing inclusion, reducing economic, social, gender and other inequalities, and protecting natural environments, therefore invigorating inclusive growth, sustainable development and well-being ('social benefit').

Or. en

Amendment 1144
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 4 a (new)

Text proposed by the Commission

Amendment

Article 4 a

Trustworthy AI systems

1. The principles set out in this Article establish a high-level framework for a coherent and coordinated human-centric European approach on trustworthy AI systems that respect and promote the values on which the Union is founded. This Regulation takes those principles into account by establishing certain requirements for high-risk AI systems listed in Article 8 to 15.

- ‘human agency and oversight’ means that AI systems shall be developed and used as a tool that serves people, respects human dignity and personal autonomy, and that is functioning in a way that can be controlled and overseen by humans in a manner that is appropriate to the circumstances of the case.***
- ‘technical robustness and safety’ means that AI systems shall be developed and used in a way to minimize unintended and unexpected harm as well as being robust in case of problems and being resilient against attempts to alter the use or performance of the AI system by malicious third parties.***
- ‘privacy and data governance’ means that AI systems shall be developed and used in compliance with existing privacy and data protection rules, while processing data that meets high standards in terms of quality and integrity.***
- ‘transparency’ means that AI systems shall be developed and used in a way that allows appropriate traceability and explainability, while making humans aware that they communicate or interact with an AI system as well as duly informing users of the capabilities and***

limitations of that AI system.

- ‘*diversity, non-discrimination and fairness*’ means that AI systems shall be developed and used in a way that includes diverse actors and promotes equal access, while avoiding discriminatory impacts that are prohibited by Union or Member States law.
- ‘*social and environmental well-being*’ means that AI systems shall be developed and used in a sustainable and environmentally friendly manner as well as in a way to benefit all human beings, while monitoring and assessing the long-term impacts on the individual, society and democracy.
- ‘*accountability*’ means that AI systems shall be developed or used in a way that facilitates auditability and accountability pursuant to applicable Union and Member States law, while making clear who is legally responsible in case the AI system causes negative impacts.

2. Paragraph 1 is without prejudice to obligations set up by existing Union and Member States legislation and does not create any additional obligations for providers or users.

3. European Standardisation
Organisations shall understand the principles referred to in paragraph 1 as outcome-based objectives when developing the appropriate harmonised standards for high risk AI systems as referred to in Article 40(2b). For all other AI systems, the voluntary application on the basis of harmonised standards, technical specifications and codes of conduct as referred to in Article 69(1a) is encouraged.

Or. en

Amendment 1145

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López

Aguilar

Proposal for a regulation Article 4 a (new)

Text proposed by the Commission

Amendment

Article 4 a

Principles applicable to all AI systems

All operators of AI systems shall respect the following principles:

- 1. Operators of AI systems shall respect fundamental rights and the Union values, as enshrined in Article 2 TEU, throughout the AI system lifecycle. To ensure this, operators shall implement mechanisms and safeguards that are appropriate to the context and consistent with the state of art ('fairness')*
- 2. Operators shall be accountable for the proper functioning of AI systems and for the respect of the fairness principle, based on their roles, the context, and consistent with the state of art. Operators shall ensure the proper functioning, throughout their lifecycle, of the AI systems that they design, develop, operate or deploy, in accordance with their role and applicable regulatory framework, and by demonstrating this through their actions and decision-making processes ('accountability')*
- 3. Operators shall commit to transparency and responsible disclosure regarding AI systems. To this end, they shall provide meaningful information, appropriate to the context, and consistent with the state of art:
 - (a) to foster a general understanding of AI systems,*
 - (b) to make affected persons aware that they are interacting with an AI system and an explanation thereof,*
 - (c) to enable those affected by an AI system to understand the outcome, and*
 - (d) to enable those adversely affected by**

an AI system to challenge its outcome based on plain and easy-to-understand information on the factors, and the logic that served as the basis for the prediction, recommendation or decision ('transparency and explainability')

4. Operators shall ensure that AI systems are robust, secure and safe throughout their entire lifecycle so that, in conditions of normal use, foreseeable use or misuse, or other adverse conditions, they function appropriately and do not pose unreasonable risk. Operators shall ensure, based on their roles and the context, traceability including in relation to datasets, processes and decisions made during the AI system lifecycle, to enable the analysis of the outcomes of the AI system and responses to inquiry, appropriate to the context and consistent with the state of art.

Operators shall, based on their roles, the context, and their ability to act, apply a systematic risk management approach to each phase of the AI system lifecycle on a continuous basis to address the risks related to AI systems, including privacy, protection of personal data, digital security, safety and bias ('privacy and security')

5. Operators shall proactively engage in pursuit of beneficial outcomes for people, societies and the planet, such as advancing inclusion, reducing economic, social, gender and other inequalities, and protecting natural environments, therefore invigorating inclusive growth, sustainable development and well-being ('social benefit')

Or. en

Justification

Articles 4a and 4b to be part of new Title Ia Principles applicable to all AI systems

Amendment 1146

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

Proposal for a regulation
Article 4 a (new)

Text proposed by the Commission

Amendment

Article 4 a

Transparency Rights

- 1. Providers and deployers of 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 AI system.*
- 2. The information referred to in paragraph 1 shall include a clear and concise indication about the provider or deployer and the purpose of the 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 AI system can be found, in particular the relevant entry in the EU database referred to in Article 60, if applicable.*
- 3. This information shall be presented in a concise, intelligible and easily accessible form, including for persons with disabilities.*
- 4. 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].*
- 5. AI subjects will have the right not to be subject to a high-risk AI system.*

Or. en

Amendment 1147

Kosma Złotowski, Patryk Jaki, Vincenzo Sofo, Adam Bielan

Proposal for a regulation

Article 4 a (new)

Text proposed by the Commission

Amendment

Article 4 a

Notification about the use of an AI system

1. Users of 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 AI system.

2. The information referred to in paragraph 1 shall include a clear and concise indication of the user and the purpose of the 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 AI system can be found, in particular the relevant entry in the EU database referred to in Article 60, if applicable.

3. This information shall be presented in a concise, intelligible and easily accessible form, including for persons with disabilities.

4. This obligation shall be without prejudice to other Union or Member State laws, in particular Regulation 2016/679, Directive 2016/680, Regulation 2022/XXX.

Or. en

Amendment 1148

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 4 b (new)

Text proposed by the Commission

Amendment

Article 4 b

***Accessibility Requirements for providers
and users of AI systems***

- 1. Providers of AI systems shall ensure that their systems are accessible in accordance with the accessibility requirements set out in Section I, Section II, Section VI, and Section VII of Annex I of Directive (EU) 2019/882 prior to those systems being placed on the market or put into service.***
- 2. Users of AI systems shall use such systems in accordance with the accessibility requirements set out in Section III, Section IV, Section VI, and Section VII of Annex I of Directive (EU) 2019/882.***
- 3. Users of AI systems shall prepare the necessary information in accordance with Annex V of Directive (EU) 2019/882. Without prejudice to Annex VIII of this Regulation, the information shall be made available to the public in an accessible manner for persons with disabilities and be kept for as long as the AI system is in use.***
- 4. Without prejudice to the rights of affected persons to information about the use and functioning of AI systems, transparency obligations for providers and users of AI, obligations to ensure consistent and meaningful public transparency under this Regulation, providers and users of AI systems shall ensure that information, forms and measures provided pursuant to this Regulation are made available in such a manner that they are easy to find, easy to understand, and accessible in accordance***

with Annex I to Directive 2019/882.

5. Users of AI systems shall ensure that procedures are in place so that the use of AI systems remains in conformity with the applicable accessibility requirements.

Changes in the characteristics of the use, changes in applicable accessibility requirements and changes in the harmonised standards or in technical specifications by reference to which use of an AI system is declared to meet the accessibility requirements shall be adequately taken into account by the user.

6. In the case of non-conformity, users of AI systems shall take the corrective measures necessary to conform with the applicable accessibility requirements.

When necessary, and at the request of the user, the provider of the AI system in question shall cooperate with the user to bring the use of the AI system into compliance with applicable accessibility requirements.

7. Furthermore, where the use of an AI system is not compliant with applicable accessibility requirements, the user shall immediately inform the competent national authorities of the Member States in which the system is being used, to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken. They shall cooperate with the authority, at the request of that authority, on any action taken to bring the use of the AI system into compliance with applicable accessibility requirements.

8. AI systems and the use of thereof, which are in conformity with harmonised technical standards or parts thereof derived from Directive (EU) 2019/882 the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the accessibility requirements of this Regulation in so far as those standards or parts thereof cover those requirements.

9. AI systems and use of thereof, which are in conformity with the technical specifications or parts thereof adopted for the Directive (EU) 2019/882 shall be presumed to be in conformity with the accessibility requirements of this Regulation in so far as those technical specifications or parts thereof cover those requirements.

Or. en

Amendment 1149

Kosma Złotowski, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 4 b (new)

Text proposed by the Commission

Amendment

Article 4 b

Explanation of individual decision-making

1. A decision made by or with the assistance of a high risk AI system which produces legal effects concerning a person, or which similarly significantly affects that person, shall be accompanied by a meaningful, relevant explanation of at least:

- (a) the role of the AI system in the decision-making process;*
- (b) the input data relating to the affected person, including the indication of his or her personal data on the basis of which the decision was made;*
- (c) for high-risk AI systems, the link to the entry in the EU database referred to in Article 60;*
- (d) the information about the person's rights under this Regulation, including the right to lodge a complaint with the national supervisory authority.*

For information on input data under point b) to be meaningful it must include

an easily understandable description of inferences drawn from other data.

2. Paragraph 1 shall not apply to the use of AI systems:

(a) that are authorised by law to detect, prevent, investigate and prosecute criminal offences or other unlawful behaviour under the conditions laid down in Article 3(41) and Article 52 of this Regulation, if not explaining the decision is necessary and proportionate for detection, prevention, investigation and prosecution of a specific offence;

(b) for which exceptions from, or restrictions to, the obligation under paragraph 1 follow from Union or Member State law, which lays down appropriate other safeguards for the affected person's rights and freedoms and legitimate interests.

3. The explanation within the meaning of paragraph 1 shall be provided at the time when the decision is communicated to the affected person and shall be provided in a clear, easily understandable, and intelligible way, accessible for persons with disabilities.

4. If the affected person believes that the decision produced legal effects or similarly significantly affects him or her, but the deployer has not provided the explanation, he or she may request it. The deployer shall inform the affected person within 7 days about how he assessed the request and if it is accepted, the explanation shall be provided without undue delay. If the request is refused, the deployer shall inform the affected person of the right to complain to the national supervisory authority.

Or. en

Amendment 1150

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

**Proposal for a regulation
Article 4 b (new)**

Text proposed by the Commission

Amendment

Article 4 b

Principles applicable to all AI systems

1. Providers and deployers of AI systems shall respect the following principles:

- (a) AI systems must be used in a fair and transparent manner in relation to AI subjects;***
- (b) AI subjects shall have a right to automatically receive an explanation in accordance with Article 4c;***
- (c) AI subjects shall have the right to object to a decision taken solely by an AI system, or relying to a significant degree on the output of an AI system, which produces legal effects concerning him or her, or similarly significantly affects him or her. This paragraph is without prejudice to Article 22 of Regulation 2016/679;***
- (d) AI systems shall not be used to exploit power and information asymmetries to the detriment of AI subjects, regardless of whether such asymmetries already exist or may be created or aggravated by the use of AI systems themselves. In particular, AI systems may not be used to discriminate against AI subjects on the basis of the characteristics listed in Article 21 of the European Charter of Fundamental Rights, on the basis of biometrics-based data, as well as on the basis of economic factors;***
- (e) AI systems must be safe and secure, ensuring a performance that is reliable, accurate, and robust throughout their lifecycle;***
- (f) AI systems intended to interact with AI subjects shall be designed and developed***

in such a way that natural individuals are informed that they are interacting with an AI system, especially where its outputs or behaviour may be reasonably mistaken for that of a human being;

- 2. Providers of AI systems shall be responsible for, and be able to demonstrate compliance with, the principles established in paragraph 1. This requirement shall apply accordingly to deployers where they have substantially influenced the intended purpose or the manner of operation of the AI system;*
- 3. The functioning of AI systems shall be regularly monitored and assessed to ensure they respect the rights and obligations set out in Union law;*
- 4. These principles shall apply without prejudice to existing obligations relating to transparency, explanation or motivation of decision-making under Member State or Union law.*

Or. en

Amendment 1151

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

Proposal for a regulation

Article 4 b (new)

Text proposed by the Commission

Amendment

Article 4 b

A right to explanation of individual decision-making

1. A decision which is taken by the user on the basis of the output from an AI system and which produces legal effects on an affected person, or which similarly significantly affects that person, shall be accompanied by a meaningful explanation of:

(a) the role of the AI system in the

decision-making process;
(b) the logic involved, the main parameters of the decision-making, and their relative weight; and
(c) the input data relating to the affected person and each of the main parameters on the basis of which the decision was made.

For information on input data under point c) to be meaningful, it must include an easily understandable description of inferences drawn from other data, if it is the inference that relates to the main parameter.

- 2. For the purpose of Paragraph 1, it shall be prohibited for the law enforcement authorities or the judiciary in the Union to use AI systems that are considered closed or labelled as proprietary by the providers or the distributors;*
- 3. The explanation within the meaning of paragraph 1 shall be provided at the time when the decision is communicated to the affected person.*

Or. en

Amendment 1152

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

Proposal for a regulation

Article 4 c (new)

Text proposed by the Commission

Amendment

Article 4 c
Explanation of individual decision-making

1. A decision made by or with the assistance of an AI system which produces legal effects concerning an AI subject, or which similarly significantly affects an AI subject, shall be

accompanied by a meaningful, relevant explanation of at least:

- (a) the role of the AI system in the decision-making process and the extent to which the output produced by the AI system influenced the decision in this case;*
- (b) the logic involved, the main parameters of decision-making, and their relative weight;*
- (c) the input data relating to the AI subject, including the indication of his or her personal data, and each of the parameters on the basis of which the decision was made. For the information on input data to be meaningful it must include an easily understandable description of inferences drawn from other data;*
- (d) if applicable, the category or group into which the AI subject has been classified;*
- (e) whether the same decision was taken in relation to other persons in similar circumstances and if not – an explanation why the AI subject was treated differently, without prejudice to the protection of personal data;*
- (f) for high-risk AI systems, the link to the entry in the EU database referred to in Article 60;*
- (g) the information about the person's rights under this Regulation, including the right to lodge a complaint with a supervisory authority;*

2. Paragraph 1 shall not apply to the use of AI systems:

- (a) that are authorised by law to detect, prevent, investigate and prosecute criminal offences or other unlawful behaviour under the conditions laid down in Article 3(41) and Article 52 of this Regulation, if not explaining the decision is necessary and proportionate for detection, prevention, investigation and*

prosecution of a specific offence;

(b) for which exceptions from, or restrictions to, the obligation under paragraph 1 follow from Union or Member State law, which lays down appropriate other safeguards for the affected person's rights and freedoms and legitimate interests;

3. The explanation within the meaning of paragraph 1 shall be provided by default at the same time when the decision is communicated to the AI subject and shall be provided in a clear, easily understandable, and intelligible way, accessible for persons with disabilities;

4. If an AI subject has not received an explanation by default, AI subjects have the right to request it. The deployer shall inform the affected person within 7 days. If the request is refused, the deployer shall inform the AI subject of the right to complain to the national supervisory authority.

Or. en

Amendment 1153

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 4 c (new)**

Text proposed by the Commission

Amendment

Article 4 c

Right to receive an explanation of individual decision-making

1. A decision which is taken by the user on the basis of the output from an AI system and which produces legal effects on an affected person, or which similarly significantly affects that person, shall be accompanied by a meaningful

explanation of

- (a) the role of the AI system in the decision-making process;*
- (b) the logic involved, the main parameters of the decision-making, and their relative weight; and*
- (c) the input data relating to the affected person and each of the main parameters on the basis of which the decision was made.*

For information on input data under point c) to be meaningful, it must include an easily understandable description of inferences drawn from other data, if it is the inference that relates to the main parameter.

- 2. For the purpose of Paragraph 1, it shall be prohibited for the law enforcement authorities or the judiciary in the Union to use AI systems that are considered closed or labelled as proprietary by the providers or the distributors;*
- 3. The explanation within the meaning of paragraph 1 shall be provided at the time when the decision is communicated to the affected person.*

Or. en

Amendment 1154

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 4 d (new)

Text proposed by the Commission

Amendment

Article 4 d

Right not to be subject to non-compliant AI systems

Natural persons shall have the right not to be subject to AI systems that:

- (a) pose an unacceptable risk pursuant to Article 5, or
- (b) otherwise do not comply with the requirements of this Regulation.

Or. en

Amendment 1155

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

Proposal for a regulation

Article 5 – title

Text proposed by the Commission

5

5 -1. Any practices related to artificial intelligence and AI systems whose development, deployment or use, or reasonably foreseeable misuse, that adversely affect, or are likely to adversely affect, the essence of any fundamental right shall be prohibited.

Amendment

Or. en

Amendment 1156

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

Proposal for a regulation

Article 5 – paragraph 1 – introductory part

Text proposed by the Commission

1. The following artificial intelligence practices shall be prohibited:

Amendment

1. *In addition to paragraph -1, the following artificial intelligence practices shall be prohibited:*

Or. en

Amendment 1157

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 5 – paragraph 1 – point a

Text proposed by the Commission

(a) the placing on the market, putting into service or use of an AI system that deploys *subliminal* techniques *beyond a person's consciousness in order to* materially *distort* a person's behaviour in a manner that causes or is likely to cause that person or another person physical *or* psychological harm;

Amendment

(a) the placing on the market, putting into service or use of an AI system that deploys techniques *with the effect or likely effect of* materially *distorting* a person's behaviour *by appreciably impairing the persons' ability to make an informed decision, thereby causing the person to take a decision that they would not have taken otherwise*, in a manner that causes or is likely to cause that person or another person, *or a group of persons material or non-material harm, including* physical, psychological *or economic* harm;

Or. en

Amendment 1158

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä, Sylwia Spurek

Proposal for a regulation

Article 5 – paragraph 1 – point a

Text proposed by the Commission

(a) the placing on the market, putting into service or use of an AI system that deploys *subliminal* techniques *beyond a person's consciousness in order to* materially *distort* a person's behaviour in a manner that causes or is likely to cause *that* person or *another person* physical or psychological harm;

Amendment

(a) *the development*, the placing on the market, putting into service, *deployment* or use of an AI system that deploys techniques *with the effect or likely effect of* materially *distorting* a person's *or a group's* behaviour, *including by impairing the person's ability to make an informed decision, thereby causing the person to take a decision that they would not otherwise have taken*, in a manner that causes or is likely to cause *any* person or *society at large* physical, *economic* or psychological harm;

Amendment 1159

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point a

Text proposed by the Commission

(a) the placing on the market, putting into service or use of an AI system ***that deploys subliminal techniques beyond a person's consciousness in order to materially distort*** a person's behaviour in a manner that causes or is likely to cause ***that person or*** another ***person*** physical or psychological ***harm***;

Amendment

(a) the placing on the market, putting into service or use of an AI system ***deployed, aimed at, or used for manipulation, deception or distorting a person's behaviour or exploit a person's characteristics***, in a manner that causes, or is likely to cause, ***harm to***:

(i) ***that person's, another person's or group of persons' fundamental rights, including their physical or psychological health and safety, and/or***

(ii) ***democracy, the rule of law, or society at large;***

Amendment 1160

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

Proposal for a regulation

Article 5 – paragraph 1 – point a

Text proposed by the Commission

(a) the placing on the market, putting into service or use of an AI system that deploys ***subliminal techniques beyond a person's consciousness in order to materially distort a person's behaviour*** in a manner that causes or is likely to cause that person or ***another person*** physical or psychological harm;

Amendment

(a) the placing on the market, putting into service or use of an AI system that deploys techniques ***with the effect or the likely effect of materially distorting the behaviour of a person by impairing their ability to make an autonomous decision, thereby causing them to take a decision that they would not have taken otherwise,*** in a manner that causes or is likely to cause that person or ***other persons material or***

non-material harm, including physical, psychological or economic harm;

Or. en

Amendment 1161

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

Proposal for a regulation

Article 5 – paragraph 1 – point a

Text proposed by the Commission

(a) la mise sur le marché, la mise en service ou l'utilisation d'un système d'IA qui a recours à des techniques subliminales au-dessous du seuil de conscience d'une personne pour altérer *substantiellement* son comportement *d'une manière qui cause ou est susceptible de causer un préjudice physique ou psychologique à cette personne ou à un tiers*;

Amendment

(a) la mise sur le marché, la mise en service ou l'utilisation d'un système d'IA qui a recours à des techniques subliminales au-dessous du seuil de conscience d'une personne pour altérer son comportement ;

Or. fr

Amendment 1162

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point a

Text proposed by the Commission

(a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness *in order to materially distort a person's behaviour in a manner that causes or is likely to cause that person or another person physical or psychological harm*;

Amendment

(a) the placing on the market, putting into service or use of an AI system that deploys *manipulative, including* subliminal, techniques beyond a person's consciousness;

Or. en

Amendment 1163

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Mituță, Ramona Strugariu, Drago Pîslaru, Lucia Šuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 5 – paragraph 1 – point a

Text proposed by the Commission

(a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques *beyond a person's consciousness in order to materially distort a person's behaviour in a manner that causes or is likely to cause that person or another person physical or psychological harm;*

Amendment

(a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques, *with the exception of AI systems using such techniques for scientific research and for approved therapeutical purposes on the basis of explicit consent of the natural persons that are exposed to them, which systems shall be classified as high risk for the purposes of this Regulation;*

Or. en

Amendment 1164

Sophia in 't Veld, Michal Šimek

Proposal for a regulation

Article 5 – paragraph 1 – point a

Text proposed by the Commission

(a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness in order to materially distort a person's behaviour *in a manner that causes or is likely to cause that person or another person physical or psychological harm;*

Amendment

(a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness in order to materially distort a person's behaviour;

Or. en

Amendment 1165

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

Proposal for a regulation
Article 5 – paragraph 1 – point a

Text proposed by the Commission

- (a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness in order to materially distort a person's behaviour in a manner that causes or is likely to cause that person or another person physical or psychological harm;

Amendment

- (a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness in order to materially distort a person's behaviour in a manner that causes or is likely to cause that person or another person physical or psychological harm *that could be predicted with due diligence*;

Or. en

Amendment 1166
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 5 – paragraph 1 – point a

Text proposed by the Commission

- (a) the placing on the market, putting into service or use of an AI system *that deploys subliminal techniques beyond a person's consciousness in order to materially distort* a person's behaviour *in a manner that causes or is likely to cause* that person or another person *physical or psychological* harm;

Amendment

- (a) the placing on the market, putting into service or use of an AI system *with the objective to significantly and materially distorting* a person's behaviour *or directly causing* that person or another person *significant* harm;

Or. en

Amendment 1167
Karlo Ressler

Proposal for a regulation
Article 5 – paragraph 1 – point a

Text proposed by the Commission

- (a) the placing on the market, putting into service or use of an AI system that

Amendment

- (a) the placing on the market, putting into service, or use of an AI system that

deploys subliminal techniques beyond a person's consciousness *in order* to materially distort a person's *behaviour* in a manner that causes or *is likely to* cause that person or another person physical or psychological harm;

deploys **harmful** subliminal techniques beyond a person's consciousness *with the objective* to materially distort a person's *behavior* in a manner that causes or, *that foreseeably may* cause that person or another person **material**, physical or psychological harm;

Or. en

Amendment 1168

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 5 – paragraph 1 – point a

Text proposed by the Commission

(a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness in order to materially distort a person's behaviour in a manner that causes or is likely to cause that person or another person physical or psychological harm;

Amendment

(a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness in order to materially distort a person's behaviour in a manner *intended* that causes or is likely to cause that person or another person physical or psychological harm;

Or. en

Amendment 1169

Svenja Hahn, Nicola Beer, Karen Melchior, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Abir Al-Sahlani, Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 5 – paragraph 1 – point a

Text proposed by the Commission

(a) the placing on the market, putting into service or use of an AI system *that deploys subliminal techniques beyond a person's consciousness in order to* materially *distort* a person's behaviour in a manner that causes or is likely to cause that person or another person physical or psychological harm;

Amendment

(a) the placing on the market, putting into service or use of an AI system *with the objective to or the effect of* materially *distorting* a person's behaviour in a manner that causes or is *reasonably* likely to cause that person or another person physical or psychological harm;

Amendment 1170

René Repasi, Marc Angel, Andreas Schieder, Maria-Manuel Leitão-Marques

Proposal for a regulation

Article 5 – paragraph 1 – point a

Text proposed by the Commission

- (a) the placing on the market, putting into service or use of an AI system that deploys **subliminal** techniques beyond a person's consciousness in order to materially distort a person's behaviour in a manner that causes or is likely to cause that person or another person physical or psychological harm;

Amendment

- (a) the placing on the market, putting into service or use of an AI system that deploys techniques beyond a person's consciousness in order to materially distort a person's behaviour in a manner that causes or is likely to cause that person or another person physical or psychological harm;

Amendment 1171

Marion Walsmann

Proposal for a regulation

Article 5 – paragraph 1 – point a

Text proposed by the Commission

- (a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness in order to materially distort a person's behaviour in a manner that causes **or is likely to cause** that person or another person physical or psychological harm;

Amendment

- (a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness in order to materially distort a person's behaviour in a manner that causes that person or another person physical or psychological harm;

Amendment 1172

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Mituță, Ramona Strugariu, Drago Pîslaru, Sophia in 't Veld, Lucia Šuriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Alin Mituță, Michal Šimečka

Proposal for a regulation

Article 5 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) The placing on the market, putting into service or use of an AI system that deploys purposefully manipulative or deceptive techniques in order to materially distort a person's behaviour in a manner that causes or is likely to cause that person or another person physical or psychological harm, infringe on that person's or another person's fundamental rights, or contravene the Union values enshrined in Article 2 TEU;

Or. en

Amendment 1173

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 5 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques.

Or. en

Amendment 1174

**Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group**

Alexandra Geese, Alviina Alametsä, Sylwia Spurek

Proposal for a regulation

Article 5 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) the placing on the market, putting into service or use of an AI system that exploits any of the **vulnerabilities** of a specific group of persons *due to their age, physical or mental disability, in order to* materially **distort** the behaviour of **a person pertaining to** that group in a manner that causes or is likely to cause **that person or another person** physical or psychological harm;

(b) the **development**, placing on the market, putting into service, **deployment** or use of an AI system that exploits **or may be reasonably foreseen to exploit** any of the **characteristics of one or more individuals, or** a specific group of persons, **including those characteristic of known, inferred or predicted personality traits, orientations, or social or economic situation, with the effect or likely effect of** materially **distorting** the behaviour of **one or more persons that are part of** that group in a manner that causes or is likely to cause **any person material or non-material harm, including** physical, **economic** or psychological harm **or affecting democracy or society at large**;

Or. en

Amendment 1175

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point b

Text proposed by the Commission

(b) the placing on the market, putting into service or use of an AI system that exploits any of the **vulnerabilities** of a specific group of persons due to their age, **physical or mental** disability, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical **or** psychological harm;

Amendment

(b) the placing on the market, putting into service or use of an AI system that exploits any of the **characteristics** of a specific group of persons due to their age, **gender, ethnic origin, sexual orientation, disability, or any other biological, physical, physiological, behavioural or social characteristics that results in a detrimental, unfavourable, or discriminatory treatment vis-à-vis persons without those characteristics, or that is used** in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical, psychological **or material** harm;

Or. en

Justification

The proposed text of the Commission is very limiting and does not sufficiently protect individuals, especially belonging to marginalised groups, from AI-based exploitation. The AI Act should go beyond the paternalistic approach of seeing certain groups of society as inherently ‘vulnerable’ and instead should appreciate that this vulnerability is caused by unfavourable treatment and socio-economic or other barriers individuals belonging to marginalised groups experience. Therefore, the AI Act should ensure the full protection of individuals and prohibit exploitation of any sensitive characteristic that would result in unfavourable or discriminatory treatment of persons with given characteristics. Finally, the provision needs to consider harms beyond those of psychical or psychological, and include material harm.

Amendment 1176

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 5 – paragraph 1 – point b

Text proposed by the Commission

(b) the placing on the market, putting into service or use of an AI system that exploits **any of the** vulnerabilities of a specific group of persons due to their age, physical or mental **disability, in order to** materially **distort** the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical **or** psychological harm;

Amendment

(b) the placing on the market, putting into service or use of an AI system that exploits **or may be reasonably foreseen to exploit** vulnerabilities of **children or characteristics of a person or** a specific group of persons due to their age, physical or mental **ability, gender, sexual orientation, ethnicity, race, origin, and religion or social or economic situation, with the effect or likely effect of** materially **distorting** the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person **material or non-material harm, including** physical, psychological **or economic** harm;

Or. en

Amendment 1177

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

Proposal for a regulation
Article 5 – paragraph 1 – point b

Text proposed by the Commission

(b) the placing on the market, putting into service or use of an AI system that exploits *any of* the vulnerabilities of a specific group of persons due to their age, physical or mental *disability, in order to* materially *distort* the behaviour of a person *pertaining to that group* in a manner that causes or is likely to cause that person or *another person* physical *or* psychological harm;

Amendment

(b) the placing on the market, putting into service or use of an AI system that exploits *or may be reasonably foreseen to exploit* the vulnerabilities of a specific group of persons due to their age, physical or mental *ability, sex, gender, sexual orientation, ethnic or social origin, race, religion or belief, or social or economic situation, with the effect or the likely effect of* materially *distorting* the behaviour of a person in a manner that causes or is likely to cause that person or *other persons material or non-material harm, including* physical, psychological *or* economic harm;

Or. en

Amendment 1178

Rob Rooken

on behalf of the ECR Group

Proposal for a regulation
Article 5 – paragraph 1 – point b

Text proposed by the Commission

(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a *specific* group of persons *due to* their age, *physical or mental* disability, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm;

Amendment

(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a *person or a* group of persons *based on any characteristic or a combination thereof, including but not limited to:* their age, *race, sex, colour, health status, social and economic status, disability, political or other opinion*, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm;

Or. en

Amendment 1179

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

Proposal for a regulation

Article 5 – paragraph 1 – point b

Text proposed by the Commission

(b) la mise sur le marché, la mise en service ou l'utilisation d'un système d'IA qui exploite les éventuelles vulnérabilités *dues à l'âge ou au handicap physique ou mental d'un groupe de personnes donné pour altérer substantiellement le comportement d'un membre de ce groupe d'une manière qui cause ou est susceptible de causer un préjudice physique ou psychologique à cette personne ou à un tiers;*

Amendment

(b) la mise sur le marché, la mise en service ou l'utilisation d'un système d'IA qui exploite les éventuelles vulnérabilités *d'une personne ou d'un groupe de personnes donnés, telles que l'âge ou le handicap physique ou mental ;*

Or. fr

Amendment 1180

Sophia in 't Veld, Michal Šimek

Proposal for a regulation

Article 5 – paragraph 1 – point b

Text proposed by the Commission

(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a *specific* group of persons *due to their age, physical or mental disability, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm;*

Amendment

(b) the placing on the market, putting into service or use of an AI system that exploits, *intentionally or not*, any of the vulnerabilities of a *person or group of persons based on any sensitive or protected characteristic, including but not limited to age, gender and gender identity, racial or ethnic origin, health status, sexual orientation, sex characteristics, social or economic status, worker status, migration status, or disability in accordance with Article 21 of the Charter of Fundamental Rights;*

Or. en

Amendment 1181

Svenja Hahn, Nicola Beer, Karen Melchior, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Abir Al-Sahlani, Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 5 – paragraph 1 – point b

Text proposed by the Commission

(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, **physical or mental** disability, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm;

Amendment

(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of ***an individual, including characteristics of such individual's known or predicted personality or social or economic situation***, a specific group of persons due to their age **or** disability, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm;

Or. en

Amendment 1182

René Repasi, Marc Angel, Andreas Schieder, Paul Tang, Maria-Manuel Leitão-Marques

Proposal for a regulation

Article 5 – paragraph 1 – point b

Text proposed by the Commission

(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, physical or mental disability, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm;

Amendment

(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of ***an individual or*** a specific group of persons due to their age, physical or mental disability, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm, ***material or economic damage***;

Justification

The use of biometrics for categorisation and emotion recognition should be prohibited. Assigning a stigmatising category to a person, such as "criminal offender", can in itself severely affect a person's private life and could lead to discrimination.

Amendment 1183

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

Proposal for a regulation

Article 5 – paragraph 1 – point b

Text proposed by the Commission

(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, physical or mental disability, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm;

Amendment

(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, physical or mental disability, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm ***that could be predicted with due diligence***;

Amendment 1184

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 5 – paragraph 1 – point b

Text proposed by the Commission

(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, physical or mental disability, ***in order to*** materially ***distort*** the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or

Amendment

(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, physical or mental disability, ***with the objective to or the effect of*** materially ***distorting*** the behaviour of a person pertaining to that group in a manner that

another person ***physical or psychological*** harm;

causes or is likely to ***directly*** cause that person or another person ***significant*** harm;

Or. en

Amendment 1185

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuťă, Ramona Strugariu, Drago Pîslaru, Sophia in 't Veld, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Alin Mituťa, Michal Šimečka

Proposal for a regulation

Article 5 – paragraph 1 – point b

Text proposed by the Commission

(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons ***due to their age, physical or mental disability***, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm;

Amendment

(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm;

Or. en

Amendment 1186

Marion Walsmann

Proposal for a regulation

Article 5 – paragraph 1 – point b

Text proposed by the Commission

(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, physical or mental disability, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes ***or is likely to cause*** that person or another person physical or psychological harm;

Amendment

(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, physical or mental disability, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes that person or another person physical or psychological harm;

Amendment 1187

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point c – introductory part

Text proposed by the Commission

(c) the placing on the market, putting into service or use of AI systems by public authorities or *on their behalf* for the *evaluation or classification of the trustworthiness of natural persons over a certain period of time based on their social behaviour or known or predicted personal or personality characteristics, with the social score leading to either or both of the following:*

Amendment

(c) The placing on the market, putting into service or use of AI systems by *or on behalf of* public authorities or *by private actors* for the *purpose of social scoring.*

Amendment 1188

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

Proposal for a regulation

Article 5 – paragraph 1 – point c – introductory part

Text proposed by the Commission

(c) la mise sur le marché, la mise en service ou l'utilisation, *par les pouvoirs publics ou pour leur compte*, de systèmes d'IA destinés à évaluer ou à établir un classement de la fiabilité de personnes physiques au cours d'une période donnée en fonction de leur comportement social ou de caractéristiques personnelles ou de personnalité connues ou prédictes, *la note sociale conduisant à l'une ou l'autre des situations suivantes, ou aux deux:*

Amendment

(c) la mise sur le marché, la mise en service ou l'utilisation de systèmes d'IA destinés à évaluer ou à établir un classement de la fiabilité de personnes physiques au cours d'une période donnée en fonction de leur comportement social ou de caractéristiques personnelles ou de personnalité connues ou prédictes;

Justification

Nous interdisons la notation sociale par I.A. en toutes circonstances, et pas seulement par les autorités publiques ou dans le cas où elle cause un préjudice.

Amendment 1189

Vincenzo Sofo

Proposal for a regulation

Article 5 – paragraph 1 – point c – introductory part

Text proposed by the Commission

(c) the placing on the market, putting into service or use of AI systems by public authorities or on their behalf for the evaluation or classification of the trustworthiness of natural persons over a certain period of time based on their social behaviour or known or predicted personal or personality characteristics, with the social score leading to either or both of the following:

Amendment

(c) the placing on the market, putting into service or use of AI systems by public authorities or on their behalf *as well as private companies, including social media and cloud service providers*, for the evaluation or classification of the trustworthiness of natural persons over a certain period of time based on their social behaviour or known or predicted personal or personality characteristics, with the social score leading to either or both of the following:

Or. en



*Committee on the Internal Market and Consumer Protection
Committee on Civil Liberties, Justice and Home Affairs*

2021/0106(COD)

13.6.2022

AMENDMENTS

1190 - 1580

Draft report
Brando Benifei, Drago 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))

AM_Com_LegReport

Amendment 1190
Jorge Buxadé Villalba

Proposal for a regulation
Article 5 – paragraph 1 – point c – introductory part

Text proposed by the Commission

c) La introducción en el mercado, la puesta en servicio o la utilización de sistemas de IA por parte de las autoridades públicas o en su representación con el fin de evaluar o clasificar la fiabilidad de personas físicas durante un período determinado de tiempo atendiendo a su conducta social o a características personales o de su personalidad conocidas o predichas, *de forma que la clasificación social resultante provoque una o varias de las situaciones siguientes:*

Amendment

c) La introducción en el mercado, la puesta en servicio o la utilización de sistemas de IA por parte de las autoridades públicas o en su representación con el fin de evaluar o clasificar la fiabilidad de personas físicas durante un período determinado de tiempo atendiendo a su conducta social o a características personales o de su personalidad conocidas o predichas.

Or. es

Amendment 1191
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar

Proposal for a regulation
Article 5 – paragraph 1 – point c – introductory part

Text proposed by the Commission

(c) the placing on the market, putting into service or use of AI systems *by public authorities or on their behalf* for the evaluation or classification of *the trustworthiness of natural persons over a certain period of time based on* their social behaviour *or known or predicted personal or personality characteristics, with the social score leading to either or both of the following:*

Amendment

(c) the placing on the market, putting into service or use of AI systems for the *scoring, evaluation or classification of natural persons or groups related to* their *education, employment, housing, socioeconomic situation, health, reliability, social behaviour, location or movements;*

Or. en

Amendment 1192

Brando Benifei, 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 5 – paragraph 1 – point c – introductory part

Text proposed by the Commission

(c) the placing on the market, putting into service or use of AI systems by public authorities or on their behalf for the evaluation or classification of the trustworthiness of natural persons *over a certain period of time* based on their social behaviour or known or predicted personal or personality characteristics, *with the social score leading to either or both of the following:*

Amendment

(c) the placing on the market, putting into service or use of AI systems by *private actors or* public authorities or on their behalf for the evaluation or classification of the trustworthiness of natural persons based on their social behaviour or known or predicted personal or personality characteristics;

Or. en

Amendment 1193

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point c – introductory part

Text proposed by the Commission

(c) the placing on the market, putting into service or use of AI systems *by public authorities or on their behalf* for the evaluation or classification of the trustworthiness of natural persons *over a certain period of time based on* their social behaviour *or known or predicted personal or personality characteristics, with the social score leading to either or both of the following:*

Amendment

(c) the placing on the market, putting into service or use of AI systems for the evaluation or classification of the trustworthiness of natural persons *or groups thereof relating to* their *education, employment, housing, socio-economic situation, health, reliability, social behaviour, location or movements.*

Or. en

Justification

The text of the proposal does not sufficiently protect inherent dignity and privacy of individuals. AI-based techniques to evaluate or classify individuals as trustworthy does not

have a place in a democratic society no matter if the outcomes are harmful or not for individuals. It is also important to note that if an outcome for evaluation is beneficial for one individual it means that other individuals automatically get pushed back in the ‘trustworthiness line.’ So, indirectly people, especially people who are already marginalized, will be harmed even if they are not the ones being directly evaluated or classified.

Amendment 1194

Sophia in 't Veld, Michal Šimek

Proposal for a regulation

Article 5 – paragraph 1 – point c – introductory part

Text proposed by the Commission

(c) the placing on the market, putting into service or use of AI systems **by public authorities or on their behalf** for the evaluation or classification of **the trustworthiness of natural persons over a certain period of time** based on their social behaviour or known or predicted personal or personality characteristics, **with the social score leading to either or both of the following:**

Amendment

(c) the placing on the market, putting into service or use of AI systems **for calculation or establishment of a 'social score' resulting from** the evaluation or classification of natural persons based on their **physical attributes**, social behaviour or known or predicted personal or personality characteristics.

Or. en

Amendment 1195

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä, Sylwia Spurek

Proposal for a regulation

Article 5 – paragraph 1 – point c – introductory part

Text proposed by the Commission

(c) the placing on the market, putting into service or use of AI systems **by public authorities or on their behalf** for the evaluation or classification of the trustworthiness of natural persons over a certain period of time based on their social behaviour or known or predicted personal or personality characteristics, **with the social score leading to either or both of**

Amendment

(c) the **development**, placing on the market, putting into service, **deployment** or use of AI systems for the evaluation or classification of the trustworthiness **or social standing** of natural persons over a certain period of time based on their social behaviour or known, **inferred** or predicted personal or personality characteristics, **potentially leading to detrimental or**

the following:

unfavourable treatment of persons or whole groups;

Or. en

Amendment 1196

Rob Rooken

on behalf of the ECR Group

Proposal for a regulation

Article 5 – paragraph 1 – point c – introductory part

Text proposed by the Commission

(c) the placing on the market, putting into service or use of AI systems **by public authorities or on their behalf** for the evaluation or classification of **the trustworthiness of natural persons over a certain period of time based on** their social behaviour or known or predicted personal or personality characteristics, **with the social score leading to either or both of** the following:

Amendment

(c) the placing on the market, putting into service or use of AI systems for the **scoring**, evaluation or classification of natural persons **or groups thereof relating to** their social behaviour or known or predicted personal or personality characteristics, **where the score or assessment leads to any** of the following:

Or. en

Amendment 1197

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituță

Proposal for a regulation

Article 5 – paragraph 1 – point c – introductory part

Text proposed by the Commission

(c) the placing on the market, putting into service or use of AI systems by public authorities or on their behalf for the evaluation or classification of **the trustworthiness of natural persons over a certain period of time based on** their social behaviour or known or predicted personal or personality characteristics, with the social score leading to either **or both** of the

Amendment

(c) the placing on the market, putting into service or use of AI systems by public authorities or on their behalf for the evaluation or classification of natural persons over **an extended** period of time based on their social behaviour or known or predicted personal or personality characteristics (**social scoring**), with the social score leading to either of the

following:

following:

Or. en

Amendment 1198

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

Proposal for a regulation

Article 5 – paragraph 1 – point c – point i

Text proposed by the Commission

Amendment

- i) *le traitement préjudiciable ou défavorable de certaines personnes physiques ou de groupes entiers de personnes physiques dans des contextes sociaux dissociés du contexte dans lequel les données ont été générées ou collectées à l'origine;* *supprimé*

Or. fr

Justification

Nous interdisons la notation sociale par I.A. en toutes circonstances, et pas seulement dans le cas où elle cause un préjudice.

Amendment 1199

Jorge Buxadé Villalba

Proposal for a regulation

Article 5 – paragraph 1 – point c – point i

Text proposed by the Commission

Amendment

- i) *un trato perjudicial o desfavorable hacia determinadas personas físicas o colectivos enteros en contextos sociales que no guarden relación con los contextos donde se generaron o recabaron los datos originalmente;* *suprimido*

Or. es

Amendment 1200

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 5 – paragraph 1 – point c – point i

Text proposed by the Commission

Amendment

(i) *detrimental or unfavourable treatment of certain natural persons or whole groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected;* *deleted*

Or. en

Justification

covered by our definition of social scoring

Amendment 1201

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

Proposal for a regulation

Article 5 – paragraph 1 – point c – point i

Text proposed by the Commission

Amendment

(i) *detrimental or unfavourable treatment of certain natural persons or whole groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected;* *deleted*

Or. en

Amendment 1202

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

Proposal for a regulation

Article 5 – paragraph 1 – point c – point i

Text proposed by the Commission

Amendment

(i) *detrimental or unfavourable treatment of certain natural persons or whole groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected;*

deleted

Or. en

Amendment 1203

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

Proposal for a regulation

Article 5 – paragraph 1 – point c – point i

Text proposed by the Commission

Amendment

(i) *detrimental or unfavourable treatment of certain natural persons or whole groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected;*

deleted

Or. en

Amendment 1204

Sophia in 't Veld, Michal Šimek

Proposal for a regulation

Article 5 – paragraph 1 – point c – point i

Text proposed by the Commission

Amendment

(i) *detrimental or unfavourable treatment of certain natural persons or whole groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected;*

deleted

Or. en

Amendment 1205

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point c – point i

Text proposed by the Commission

Amendment

- (i) *detrimental or unfavourable treatment of certain natural persons or whole groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected;* *deleted*

Or. en

Amendment 1206

Rob Rooken

on behalf of the ECR Group

Proposal for a regulation

Article 5 – paragraph 1 – point c – point i

Text proposed by the Commission

Amendment

- (i) detrimental or unfavourable treatment of certain natural persons or whole groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected;

- (i) detrimental or unfavourable treatment *affecting the fundamental rights* of certain natural persons or whole groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected;

Or. en

Amendment 1207

Kosma Złotowski, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 5 – paragraph 1 – point c – point i

Text proposed by the Commission

Amendment

- (i) detrimental or unfavourable treatment of certain natural persons or

- (i) *preferential*, detrimental or unfavourable treatment of certain natural

whole groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected;

persons or whole groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected;

Or. en

Amendment 1208

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Andrus Ansip, Dita Charanzová, Morten Løkkegaard, Alin Mituța

Proposal for a regulation

Article 5 – paragraph 1 – point c – point i

Text proposed by the Commission

(i) detrimental or unfavourable treatment of certain natural persons or whole groups thereof in social contexts **which** are unrelated to the contexts in which the data was originally generated or collected;

Amendment

(i) detrimental or unfavourable treatment of certain natural persons or whole groups thereof in social contexts **that** are unrelated to the contexts in which the data was originally generated or collected;

Or. en

Amendment 1209

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 5 – paragraph 1 – point c – point i

Text proposed by the Commission

(i) detrimental or unfavourable treatment of certain natural persons or **whole** groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected;

Amendment

(i) detrimental or unfavourable treatment of certain natural persons or groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected;

Or. en

Amendment 1210

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

Proposal for a regulation

Article 5 – paragraph 1 – point c – point ii

Text proposed by the Commission

Amendment

ii) le traitement préjudiciable ou défavorable de certaines personnes physiques ou de groupes entiers de personnes physiques, qui est injustifié ou disproportionné par rapport à leur comportement social ou à la gravité de celui-ci;

Or. fr

Justification

Nous interdisons la notation sociale par I.A. en toutes circonstances, et pas seulement dans le cas où elle cause un préjudice.

Amendment 1211

Jorge Buxadé Villalba

Proposal for a regulation

Article 5 – paragraph 1 – point c – point ii

Text proposed by the Commission

Amendment

ii) un trato perjudicial o desfavorable hacia determinadas personas físicas o colectivos enteros que es injustificado o desproporcionado con respecto a su comportamiento social o la gravedad de este.

Or. es

Amendment 1212

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

Proposal for a regulation

Article 5 – paragraph 1 – point c – point ii

Text proposed by the Commission

Amendment

(ii) *detrimental or unfavourable treatment of certain natural persons or whole groups thereof that is unjustified or disproportionate to their social behaviour or its gravity;*

deleted

Or. en

Amendment 1213

Sophia in 't Veld, Michal Šimek

Proposal for a regulation

Article 5 – paragraph 1 – point c – point ii

Text proposed by the Commission

Amendment

(ii) *detrimental or unfavourable treatment of certain natural persons or whole groups thereof that is unjustified or disproportionate to their social behaviour or its gravity;*

deleted

Or. en

Amendment 1214

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 5 – paragraph 1 – point c – point ii

Text proposed by the Commission

Amendment

(ii) *detrimental or unfavourable treatment of certain natural persons or whole groups thereof that is unjustified or disproportionate to their social behaviour or its gravity;*

deleted

Or. en

Amendment 1215

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 5 – paragraph 1 – point c – point ii

Text proposed by the Commission

Amendment

(ii) *detrimental or unfavourable treatment of certain natural persons or whole groups thereof that is unjustified or disproportionate to their social behaviour or its gravity;* *deleted*

Or. en

Justification

covered by our definition of social scoring

Amendment 1216

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point c – point ii

Text proposed by the Commission

Amendment

(ii) *detrimental or unfavourable treatment of certain natural persons or whole groups thereof that is unjustified or disproportionate to their social behaviour or its gravity;* *deleted*

Or. en

Amendment 1217

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

Proposal for a regulation

Article 5 – paragraph 1 – point c – point ii

Text proposed by the Commission

Amendment

(ii) *detrimental or unfavourable treatment of certain natural persons or whole groups thereof that is unjustified or disproportionate to their social behaviour or its gravity;* *deleted*

Or. en

Amendment 1218

Kosma Złotowski, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 5 – paragraph 1 – point c – point ii

Text proposed by the Commission

(ii) detrimental or unfavourable treatment of certain natural persons or whole groups thereof that is unjustified or disproportionate to their social behaviour or its gravity;

Amendment

(ii) *preferential*, detrimental or unfavourable treatment of certain natural persons or whole groups thereof that is unjustified or disproportionate to their social behaviour or its gravity;

Or. en

Amendment 1219

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 5 – paragraph 1 – point c – point ii

Text proposed by the Commission

(ii) detrimental or unfavourable treatment of certain natural persons or **whole** groups thereof that is unjustified or disproportionate to their social behaviour or its gravity;

Amendment

(ii) detrimental or unfavourable treatment of certain natural persons or groups thereof that is unjustified or disproportionate to their social behaviour or its gravity;

Or. en

Amendment 1220

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia uríš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituță

Proposal for a regulation

Article 5 – paragraph 1 – point c – point ii a (new)

Text proposed by the Commission

Amendment

(ii a) privileged treatment of certain natural persons or whole groups thereof in social contexts that are unrelated to the contexts in which the data was originally generated or collected;

Or. en

Amendment 1221

Rob Rooken

on behalf of the ECR Group

Proposal for a regulation

Article 5 – paragraph 1 – point c – point ii a (new)

Text proposed by the Commission

Amendment

(ii a) treatment of certain natural persons or whole groups thereof otherwise amounting to an unnecessary or disproportionate restriction on fundamental rights.

Or. en

Amendment 1222

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

Proposal for a regulation

Article 5 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) the placing on the market, putting into service or use of an AI system for making individual or place-based risk assessments of natural persons in order to assess the risk of a natural person for

offending or reoffending or for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of a natural person or on assessing personality traits and characteristics or past criminal behaviour of natural persons or groups of natural persons;

Or. en

Amendment 1223

Svenja Hahn, Drago Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Abir Al-Sahlani, Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 5 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) the placing on the market, putting into service or use of an AI system for making individual risk assessments of natural persons in order to assess the risk of a natural person for offending or reoffending or for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of a natural person or on assessing personality traits and characteristics or past criminal behaviour of natural persons or groups of natural persons;

Or. en

Amendment 1224

Jean-Lin Lacapelle, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 5 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c bis) la mise sur le marché, la mise en

service ou l'utilisation d'un système d'IA qui prend des décisions pour envoyer ou établir des priorités dans l'envoi des services d'intervention d'urgence dont dépend la vie des personnes secourues;

Or. fr

Justification

Nous précisons que cette interdiction s'applique aux systèmes d'I.A. qui prennent des décisions, et non à ceux qui émettent de simples recommandations.

Amendment 1225

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Paul Tang

Proposal for a regulation

Article 5 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) the placing on the market, putting into service, or use of AI systems intended to be used as polygraphs and similar tools to detect the emotional state, trustworthiness or related characteristics of a natural person;

Or. en

Amendment 1226

Jean-Lin Lacapelle, Markus Buchheit, Hélène Laporte

Proposal for a regulation

Article 5 – paragraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(c ter) la mise sur le marché, la mise en service ou l'utilisation d'un système d'IA qui réalise des évaluations individuelles des risques, qui sert de polygraphes ou d'outils similaires, ou qui analyse l'état émotionnel de personnes physiques, ou qui prédit la survenance ou la répétition

d'une infraction pénale réelle ou potentielle sur la base du profilage de personnes physiques ou de groupes, ou qui évalue les traits de personnalité de personnes physiques ou de groupes à des fins de profilage dans le cadre d'activités de détection, d'enquête ou de poursuite relatives à des infractions pénales;

Or. fr

Amendment 1227

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte

Proposal for a regulation

Article 5 – paragraph 1 – point c c (new)

Text proposed by the Commission

Amendment

(c quater) la mise sur le marché, la mise en service ou l'utilisation d'un système d'IA destiné à l'administration de la justice et aux processus démocratiques, qui aide les autorités judiciaires à rechercher et à interpréter les faits et la loi, et à appliquer la loi à un ensemble concrets de faits, à l'exception des activités administratives purement accessoires qui n'ont aucune incidence sur l'administration réelle de la justice dans les cas individuels;

Or. fr

Amendment 1228

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

Proposal for a regulation

Article 5 – paragraph 1 – point c d (new)

Text proposed by the Commission

Amendment

(c quinques) la mise sur le marché, la mise en service ou l'utilisation d'un système d'IA opérant des analyses

*génomiques, physiologiques,
psychologiques ou comportementales
d'une personne physique dans le but
d'opérer un profilage de celle-ci;*

Or. fr

Amendment 1229

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

Proposal for a regulation

Article 5 – paragraph 1 – point c e (new)

Text proposed by the Commission

Amendment

*(c sexies) la mise sur le marché, la
mise en service ou l'utilisation d'un
système d'IA susceptible d'agir sur
l'intégrité cognitive ou la personnalité
d'une personne physique, avec ou sans le
support d'implants physiques;*

Or. fr

Amendment 1230

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 5 – paragraph 1 – point d

Text proposed by the Commission

Amendment

*(d) the use of 'real-time' remote
biometric identification systems in
publicly accessible spaces for the purpose
of law enforcement, unless and in as far
as such use is strictly necessary for one of
the following objectives:*

- (i) the targeted search for specific
potential victims of crime, including
missing children;*
- (ii) the prevention of a specific,
substantial and imminent threat to the life
or physical safety of natural persons or of*

a terrorist attack;

(iii) the detection, localisation, identification or prosecution of a perpetrator or suspect of a criminal offence referred to in Article 2(2) of Council Framework Decision 2002/584/JHA⁶² and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, as determined by the law of that Member State.

⁶² *Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).*

Or. en

Justification

Instead of blanketly banning the law enforcement's use of facial recognition AI, these systems should be incorporated in the list of high-risk AI systems and subject to strict control. Such modern AI software can process information and images at lightning speed and with great precision - tasks that would take days for a human law enforcement agent to go through. Also with much less risk of bias, when the programs are diligently designed. Using such technology can help law enforcement not only prevent crimes, but also react rapidly when they occur, and provide a very powerful tool to investigate serious crimes.

Amendment 1231

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte

Proposal for a regulation

Article 5 – paragraph 1 – point d – introductory part

Text proposed by the Commission

(d) l'utilisation de systèmes d'identification biométrique à *distance «en temps réel» dans des espaces accessibles au public à des fins répressives, sauf* si et dans la mesure où cette utilisation est strictement nécessaire eu égard à l'un des objectifs suivants:

Amendment

(d) l'utilisation de systèmes d'identification biométrique, *sauf ceux strictement utilisés pour l'authentification individuelle d'accès à des espaces ou systèmes protégés, ceux utilisés pour l'accomplissement des procédures administratives par les autorités fiscales et douanières, et sauf par les autorités*

répressives si et dans la mesure où cette utilisation est strictement nécessaire eu égard à l'un des objectifs suivants:

Or. fr

Amendment 1232

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 5 – paragraph 1 – point d – introductory part

Text proposed by the Commission

(d) the use of ‘*real-time*’ remote biometric identification systems in publicly accessible spaces *for the purpose of law enforcement, unless and in as far as such use is strictly necessary for one of the following objectives:*

Amendment

(d) *putting into service, by public and private entities or on their behalf, of remote biometric identification systems that are or may be used in publicly-accessible, including online, spaces; and the use of remote biometric identification systems in publicly accessible, including online, spaces, but without affecting employees who work in publicy accessible spaces.*

Or. en

Amendment 1233

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Ró a Thun und Hohenstein, Alin Mituță

Proposal for a regulation

Article 5 – paragraph 1 – point d – introductory part

Text proposed by the Commission

(d) the use of ‘*real-time*’ remote biometric identification systems in publicly accessible spaces *for the purpose of law enforcement, unless and in as far as such use is strictly necessary for one of the following objectives:*

Amendment

(d) the use of ‘*real-time*’ remote biometric identification systems in publicly accessible spaces

Or. en

Amendment 1234

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Ró a Thun und Hohenstein, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 5 – paragraph 1 – point d – introductory part

Text proposed by the Commission

(d) the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces *for the purpose of law enforcement, unless and in as far as such use is strictly necessary for one of the following objectives:*

Amendment

(d) the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces.

Or. en

Amendment 1235

Sophia in ’t Veld, Michal Šimeka, Ró a Thun und Hohenstein

Proposal for a regulation

Article 5 – paragraph 1 – point d – introductory part

Text proposed by the Commission

(d) the use of ‘*real-time*’ *remote biometric identification systems* in publicly accessible spaces *for the purpose of law enforcement, unless and in as far as such use is strictly necessary for one of the following objectives:*

Amendment

(d) The *placing on the market, putting into service or use of AI for an automated recognition of human features* in publicly accessible spaces - *such as of faces but also of gait, fingerprints, DNA, voice, keystrokes and other biometric or behavioral signals - for any purpose, including law enforcement.*

Or. en

Amendment 1236

Rob Rookens

on behalf of the ECR Group

Proposal for a regulation

Article 5 – paragraph 1 – point d – introductory part

Text proposed by the Commission

(d) the use of '**real-time**' remote biometric identification systems in publicly accessible spaces *for the purpose of law enforcement, unless and in as far as such use is strictly necessary for one of the following objectives:*

Amendment

(d) the **placing on the market and** use of remote biometric identification systems in publicly accessible spaces;

Or. en

Amendment 1237

Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Marc Angel

Proposal for a regulation

Article 5 – paragraph 1 – point d – introductory part

Text proposed by the Commission

(d) the use of '**real-time**' remote biometric identification systems in publicly accessible spaces *for the purpose of law enforcement, unless and in as far as such use is strictly necessary for one of the following objectives:*

Amendment

(d) the use of remote biometric identification systems in publicly **or privately** accessible spaces, **both online and offline.**

Or. en

Amendment 1238

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d – introductory part

Text proposed by the Commission

(d) the use of '**real-time**' remote biometric identification systems in publicly accessible spaces *for the purpose of law enforcement, unless and in as far as such use is strictly necessary for one of the following objectives:*

Amendment

(d) **the placing or making available on the market or putting into service of remote biometric identification systems that are or may be used in publicly-accessible spaces, as well as online spaces, and** the use of remote biometric identification systems in publicly accessible spaces;

Amendment 1239

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Article 5 – paragraph 1 – point d – introductory part

Text proposed by the Commission

(d) the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement, *unless and in as far as such use is strictly necessary for one of the following objectives:*

Amendment

(d) the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement;

Amendment 1240

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 5 – paragraph 1 – point d – introductory part

Text proposed by the Commission

(d) the use of ‘real-time’ remote biometric identification *systems* in publicly accessible spaces *for the purpose of* law enforcement, unless and in as far as such use is strictly necessary for one of the following objectives:

Amendment

(d) the use of ‘real-time’ remote biometric identification *function of an AI system* in publicly accessible spaces *by* law enforcement *or on their behalf*, unless and in as far as such use is strictly necessary *used* for one of the following objectives:

Amendment 1241

Jorge Buxadé Villalba

Proposal for a regulation

Article 5 – paragraph 1 – point d – introductory part

Text proposed by the Commission

d) El uso de sistemas de identificación

Amendment

d) El uso *e instalación* de sistemas de

biométrica remota «en tiempo real» en espacios de acceso público con fines de aplicación de la ley, salvo *y en la medida en que dicho uso sea estrictamente necesario para alcanzar uno o varios de los objetivos siguientes:*

identificación biométrica remota «en tiempo real» *o en «diferido»* en espacios de acceso público con fines de aplicación de la ley, salvo *para lo referido al control de fronteras y en el marco de la lucha antiterrorista:*

Or. es

Amendment 1242

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

Proposal for a regulation

Article 5 – paragraph 1 – point d – introductory part

Text proposed by the Commission

(d) *the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces **for the purpose of law enforcement, unless and in as far as such use is strictly necessary for one of the following objectives:***

Amendment

(d) *the development, placing on the market, putting into service, deployment or use of remote biometric identification systems **or biometrics-based** in publicly accessible spaces, **including online accessible spaces;***

Or. en

Amendment 1243

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

Proposal for a regulation

Article 5 – paragraph 1 – point d – introductory part

Text proposed by the Commission

(d) *the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces **for the purpose of law enforcement, unless and in as far as such use is strictly necessary for one of the following objectives:***

Amendment

(d) *the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces, unless and in as far as such use **by law enforcement** is strictly necessary for one of the following objectives:*

Or. en

Amendment 1244

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Paul Tang

Proposal for a regulation

Article 5 – paragraph 1 – point d – introductory part

Text proposed by the Commission

(d) the use of ‘*real-time*’ remote biometric identification systems in publicly accessible spaces *for the purpose of law enforcement, unless and in as far as such use is strictly necessary for one of the following objectives:*

Amendment

(d) the *placing or making available on the market, the putting into service or* use of remote biometric identification systems *that are or maybe used* in publicly or privately accessible spaces, *as well as online spaces;*

Or. en

Amendment 1245

Jorge Buxadé Villalba

Proposal for a regulation

Article 5 – paragraph 1 – point d – point i

Text proposed by the Commission

i) *la búsqueda selectiva de posibles víctimas concretas de un delito, incluidos menores desaparecidos;*

Amendment

suprimido

Or. es

Amendment 1246

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

Proposal for a regulation

Article 5 – paragraph 1 – point d – point i

Text proposed by the Commission

(i) *the targeted search for specific potential victims of crime, including missing children;*

Amendment

deleted

Or. en

Amendment 1247

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 5 – paragraph 1 – point d – point i

Text proposed by the Commission

Amendment

(i) *the targeted search for specific potential victims of crime, including missing children;* *deleted*

Or. en

Amendment 1248

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 5 – paragraph 1 – point d – point i

Text proposed by the Commission

Amendment

(i) *the targeted search for specific potential victims of crime, including missing children;* *deleted*

Or. en

Amendment 1249

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 5 – paragraph 1 – point d – point i

Text proposed by the Commission

Amendment

(i) *the targeted search for specific potential victims of crime, including missing children;* *deleted*

Or. en

Amendment 1250

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Article 5 – paragraph 1 – point d – point i

Text proposed by the Commission

Amendment

(i) *the targeted search for specific potential victims of crime, including missing children;* *deleted*

Or. en

Amendment 1251

Rob Rooken

on behalf of the ECR Group

Proposal for a regulation

Article 5 – paragraph 1 – point d – point i

Text proposed by the Commission

Amendment

(i) *the targeted search for specific potential victims of crime, including missing children;* *deleted*

Or. en

Amendment 1252

Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López

Proposal for a regulation

Article 5 – paragraph 1 – point d – point i

Text proposed by the Commission

Amendment

(i) *the targeted search for specific potential victims of crime, including missing children;* *deleted*

Amendment 1253

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Sophia in 't Veld, Lucia ūriš Nicholsonová, Irena Joveva, Karen Melchior, Svenja Hahn, Ró a Thun und Hohenstein, Alin Mituța

Proposal for a regulation

Article 5 – paragraph 1 – point d – point i

Text proposed by the Commission

Amendment

(i) *the targeted search for specific potential victims of crime, including missing children;* *deleted*

Amendment 1254

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Abir Al-Sahlani, Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 5 – paragraph 1 – point d – point i

Text proposed by the Commission

Amendment

(i) *the targeted search for specific potential victims of crime, including missing children;* *deleted*

Amendment 1255

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 5 – paragraph 1 – point d – point i

Text proposed by the Commission

Amendment

(i) the targeted search for specific potential victims of crime, ***including*** (i) the targeted search for specific potential victims of crime;

missing children;

Or. en

Amendment 1256

Jorge Buxadé Villalba

Proposal for a regulation

Article 5 – paragraph 1 – point d – point ii

Text proposed by the Commission

Amendment

*ii) la prevención de una amenaza
específica, importante e inminente para la
vida o la seguridad física de las personas
físicas o de un atentado terrorista;*

suprimido

Or. es

Amendment 1257

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

Proposal for a regulation

Article 5 – paragraph 1 – point d – point ii

Text proposed by the Commission

Amendment

*(ii) the prevention of a specific,
substantial and imminent threat to the life
or physical safety of natural persons or of
a terrorist attack;*

deleted

Or. en

Amendment 1258

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 5 – paragraph 1 – point d – point ii

Text proposed by the Commission

Amendment

(ii) the prevention of a specific,

deleted

*substantial and imminent threat to the life
or physical safety of natural persons or of
a terrorist attack;*

Or. en

Amendment 1259

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

Proposal for a regulation

Article 5 – paragraph 1 – point d – point ii

Text proposed by the Commission

Amendment

*(ii) the prevention of a specific,
substantial and imminent threat to the life
or physical safety of natural persons or of
a terrorist attack;* *deleted*

Or. en

Amendment 1260

**Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Vlad-Marius Boto ,
Samira Rafaela, Monica Semedo, Salima Yenbou, Abir Al-Sahlani, Sophia in 't Veld,
Moritz Körner, Jan-Christoph Oetjen**

Proposal for a regulation

Article 5 – paragraph 1 – point d – point ii

Text proposed by the Commission

Amendment

*(ii) the prevention of a specific,
substantial and imminent threat to the life
or physical safety of natural persons or of
a terrorist attack;* *deleted*

Or. en

Amendment 1261

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Article 5 – paragraph 1 – point d – point ii

Text proposed by the Commission

Amendment

(ii) the prevention of a specific, substantial and imminent threat to the life or physical safety of natural persons or of a terrorist attack; *deleted*

Or. en

Amendment 1262

Rob Rooken

on behalf of the ECR Group

Proposal for a regulation

Article 5 – paragraph 1 – point d – point ii

Text proposed by the Commission

Amendment

(ii) the prevention of a specific, substantial and imminent threat to the life or physical safety of natural persons or of a terrorist attack; *deleted*

Or. en

Amendment 1263

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Sophia in 't Veld, Lucia ūriš Nicholsonová, Irena Joveva, Karen Melchior, Svenja Hahn, Ró a Thun und Hohenstein, Alin Mituță

Proposal for a regulation

Article 5 – paragraph 1 – point d – point ii

Text proposed by the Commission

Amendment

(ii) the prevention of a specific, substantial and imminent threat to the life or physical safety of natural persons or of a terrorist attack; *deleted*

Or. en

Amendment 1264

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 5 – paragraph 1 – point d – point ii

Text proposed by the Commission

Amendment

(ii) the prevention of a specific, substantial and imminent threat to the life or physical safety of natural persons or of a terrorist attack;

deleted

Or. en

Amendment 1265

Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López

Proposal for a regulation

Article 5 – paragraph 1 – point d – point ii

Text proposed by the Commission

Amendment

(ii) the prevention of a specific, substantial and imminent threat to the life or physical safety of natural persons or of a terrorist attack;

deleted

Or. en

Amendment 1266

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 5 – paragraph 1 – point d – point ii

Text proposed by the Commission

Amendment

*(ii) the prevention of a specific, substantial **and imminent** threat to the **life** or physical safety of natural persons or of a terrorist attack;*

*(ii) the prevention of a specific **and** substantial threat to the **critical infrastructure, life, health** or physical safety of natural persons or of a terrorist attack;*

Or. en

Amendment 1267

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

Proposal for a regulation

Article 5 – paragraph 1 – point d – point ii

Text proposed by the Commission

(ii) the prevention of a *specific, substantial and imminent* threat to the life or physical safety of natural persons or of a terrorist attack;

Amendment

(ii) the prevention of a threat to the life or physical safety of natural persons or of a terrorist attack;

Or. en

Amendment 1268

Jorge Buxadé Villalba

Proposal for a regulation

Article 5 – paragraph 1 – point d – point iii

Text proposed by the Commission

iii) la detección, la localización, la identificación o el enjuiciamiento de la persona que ha cometido o se sospecha que ha cometido alguno de los delitos mencionados en el artículo 2, apartado 2, de la Decisión Marco 2002/584/JAI del Consejo⁶², para el que la normativa en vigor en el Estado miembro implicado imponga una pena o una medida de seguridad privativas de libertad cuya duración máxima sea al menos de tres años, según determine el Derecho de dicho Estado miembro.

Amendment

suprimido

⁶² *Decisión Marco 2002/584/JAI del Consejo, de 13 de junio de 2002, relativa a la orden de detención europea y a los procedimientos de entrega entre Estados miembros (DO L 190 de 18.7.2002, p. 1).*

Or. es

Amendment 1269

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Article 5 – paragraph 1 – point d – point iii

Text proposed by the Commission

Amendment

(iii) the detection, localisation, identification or prosecution of a perpetrator or suspect of a criminal offence referred to in Article 2(2) of Council Framework Decision 2002/584/JHA⁶² and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, as determined by the law of that Member State.

⁶² *Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).*

Or. en

Amendment 1270

Rob Rooken

on behalf of the ECR Group

Proposal for a regulation

Article 5 – paragraph 1 – point d – point iii

Text proposed by the Commission

Amendment

(iii) the detection, localisation, identification or prosecution of a perpetrator or suspect of a criminal offence referred to in Article 2(2) of Council Framework Decision 2002/584/JHA⁶² and punishable in the Member State concerned by a custodial sentence or a detention order for a

maximum period of at least three years, as determined by the law of that Member State.

⁶² Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).

Or. en

Amendment 1271

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 5 – paragraph 1 – point d – point iii

Text proposed by the Commission

Amendment

(iii) the detection, localisation, identification or prosecution of a perpetrator or suspect of a criminal offence referred to in Article 2(2) of Council Framework Decision 2002/584/JHA⁶² and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, as determined by the law of that Member State.

deleted

⁶² Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).

Or. en

Amendment 1272

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

Proposal for a regulation
Article 5 – paragraph 1 – point d – point iii

Text proposed by the Commission

Amendment

(iii) *the detection, localisation, identification or prosecution of a perpetrator or suspect of a criminal offence referred to in Article 2(2) of Council Framework Decision 2002/584/JHA⁶² and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, as determined by the law of that Member State.*

⁶² *Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).*

Or. en

Amendment 1273

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tefnută, Ramona Strugariu, Drago Pîslaru, Sophia in 't Veld, Lucia ūriš Nicholsonová, Irena Joveva, Karen Melchior, Svenja Hahn, Alin Mituță

Proposal for a regulation
Article 5 – paragraph 1 – point d – point iii

Text proposed by the Commission

Amendment

(iii) *the detection, localisation, identification or prosecution of a perpetrator or suspect of a criminal offence referred to in Article 2(2) of Council Framework Decision 2002/584/JHA⁶² and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, as determined by the law of that Member State.*

*⁶² Council Framework Decision
2002/584/JHA of 13 June 2002 on the
European arrest warrant and the
surrender procedures between Member
States (OJ L 190, 18.7.2002, p. 1).*

Or. en

Amendment 1274

**Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Vlad-Marius Boto ,
Samira Rafaela, Monica Semedo, Salima Yenbou, Abir Al-Sahlani, Sophia in 't Veld,
Moritz Körner, Jan-Christoph Oetjen**

Proposal for a regulation

Article 5 – paragraph 1 – point d – point iii

Text proposed by the Commission

Amendment

*(iii) the detection, localisation,
identification or prosecution of a
perpetrator or suspect of a criminal
offence referred to in Article 2(2) of
Council Framework Decision
2002/584/JHA⁶² and punishable in the
Member State concerned by a custodial
sentence or a detention order for a
maximum period of at least three years, as
determined by the law of that Member
State.*

deleted

*⁶² Council Framework Decision
2002/584/JHA of 13 June 2002 on the
European arrest warrant and the
surrender procedures between Member
States (OJ L 190, 18.7.2002, p. 1).*

Or. en

Amendment 1275

Vincenzo Sofo, Kosma Złotowski

Proposal for a regulation

Article 5 – paragraph 1 – point d – point iii

Text proposed by the Commission

Amendment

(iii) *the detection, localisation, identification or prosecution of a perpetrator or suspect of a criminal offence referred to in Article 2(2) of Council Framework Decision 2002/584/JHA⁶² and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, as determined by the law of that Member State.*

⁶² Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).

Or. en

Amendment 1276

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d – point iii

Text proposed by the Commission

Amendment

(iii) *the detection, localisation, identification or prosecution of a perpetrator or suspect of a criminal offence referred to in Article 2(2) of Council Framework Decision 2002/584/JHA⁶² and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, as determined by the law of that Member State.*

⁶² Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member

States (OJ L 190, 18.7.2002, p. 1).

Or. en

Amendment 1277

Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López

Proposal for a regulation

Article 5 – paragraph 1 – point d – point iii

Text proposed by the Commission

Amendment

(iii) the detection, localisation, identification or prosecution of a perpetrator or suspect of a criminal offence referred to in Article 2(2) of Council Framework Decision 2002/584/JHA⁶² and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, as determined by the law of that Member State.

deleted

⁶² *Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).*

Or. en

Amendment 1278

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d – point iii

Text proposed by the Commission

Amendment

(iii) the detection, localisation, identification or prosecution of a perpetrator or suspect of a criminal offence referred to in Article 2(2) of

deleted

Council Framework Decision
2002/584/JHA⁶² and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, as determined by the law of that Member State.

⁶² **Council Framework Decision**
2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).

Or. en

Amendment 1279

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

Proposal for a regulation

Article 5 – paragraph 1 – point d – point iii

Text proposed by the Commission

Amendment

(iii) *the detection, localisation, identification or prosecution of a perpetrator or suspect of a criminal offence referred to in Article 2(2) of Council Framework Decision*
2002/584/JHA⁶² and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, as determined by the law of that Member State.

deleted

⁶² **Council Framework Decision**
2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).

Or. en

Amendment 1280
Axel Voss, Deirdre Clune

Proposal for a regulation
Article 5 – paragraph 1 – point d – point iii

Text proposed by the Commission

(iii) the **detection**, localisation, identification **or** prosecution of a **perpetrator or suspect of a criminal offence** referred to in Article 2(2) of Council Framework Decision 2002/584/JHA⁶² and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, as determined by the law of that Member State.

Amendment

(iii) the localisation **or** identification of a **natural person for the purpose of conducting a criminal investigation**, prosecution **or executing** a criminal **penalty for offences** referred to in Article 2(2) of Council Framework Decision 2002/584/JHA⁶² and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, **or other specific offences punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least five years** as determined by the law of that Member State.

⁶² Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).

⁶² Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).

Or. en

Amendment 1281
Jean-Lin Lacapelle, Markus Buchheit, Hélène Laporte

Proposal for a regulation
Article 5 – paragraph 1 – point d – point iii

Text proposed by the Commission

iii) la détection, la localisation, l'identification ou les poursuites à l'encontre de l'auteur ou du suspect d'une infraction pénale *visée à l'article 2*,

Amendment

iii) la détection, la localisation, l'identification ou les poursuites à l'encontre de l'auteur ou du suspect d'une infraction pénale punissable dans l'État

paragraphe 2, de la décision-cadre 2002/584/JAI du Conseil⁶² et punissable dans l'État membre concerné d'une peine ou d'une mesure de sûreté privatives de liberté d'une durée maximale d'au moins trois ans, déterminées par le droit de cet État membre.

⁶² *Décision-cadre 2002/584/JAI du Conseil du 13 juin 2002 relative au mandat d'arrêt européen et aux procédures de remise entre États membres (JO L 190 du 18.7.2002, p. 1).*

membre concerné d'une peine ou d'une mesure de sûreté privatives de liberté d'une durée maximale d'au moins *dix* ans, déterminées par le droit de cet État membre.

Or. fr

Amendment 1282

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 5 – paragraph 1 – point d – point iii a (new)

Text proposed by the Commission

Amendment

(iii a) searching for missing persons, especially those who are minors or have medical conditions that affect memory, communication, or independent decision-making skills;

Or. en

Amendment 1283

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(d a) the placing on the market, putting into service or use of:

(i) AI systems intended to be used for the purpose of determining access or assigning natural persons to educational

- and vocational training institutions;*
- (ii) AI systems intended to be used for the purpose of assessing students in educational and vocational training institutions.*
- (iii) AI systems intended to be used for recruitment or selection of natural persons, notably for advertising vacancies, screening or filtering applications, evaluating candidates in the course of interviews or tests;*
- (iv) AI systems intended to be used for making decisions on promotion and termination of work-related contractual relationships, for task allocation and for monitoring and evaluating performance and behavior of persons in such relationships.*
- (v) AI systems intended to be used by public authorities, private entities or on their behalf to evaluate the eligibility of natural persons for public assistance benefits and services, essential private services, as well as to grant, reduce, revoke, or reclaim such benefits and services;*
- (vi) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems put into service by small scale providers for their own use;*
- (vii) AI systems intended to be used by competent authorities for migration, asylum and border control management to assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;*
- (viii) AI systems intended to be used by public authorities, including competent authorities for migration, asylum and border control management, as polygraphs and similar tools or to detect the emotional state of a natural person;*

Amendment 1284

Maria-Manuel Leitão-Marques, Eva Kaili

Proposal for a regulation

Article 5 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(d a) the placing on the market, putting into service, or use of an AI system for the specific technical processing of brain or brain-generated data in order to access, infer, influence, or manipulate a person's thoughts, emotions, memories, intentions, beliefs, or other mental states against that person's will or in a manner that causes or is likely to cause that person or another person physical or psychological harm.

Amendment 1285

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(d a) AI systems intended to be used by law enforcement authorities for making individual risk assessments of natural persons in order to assess the risk of a natural person for offending or reoffending or the risk for potential victims of criminal offences;

Amendment 1286

Svenja Hahn, Nicola Beer, Moritz Körner, Jan-Christoph Oetjen, Karen Melchior, Morten Løkkegaard, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima

Yenbou, Abir Al-Sahlani, Sophia in 't Veld

Proposal for a regulation

Article 5 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(d a) the use of an AI system for the general monitoring, detection and interpretation of private content in interpersonal communication services, including all measures that would undermine end-to-end encryption..

Or. en

Justification

Fundamental rights in the digital sphere have to be guaranteed to the same extent as in the offline world. The right to privacy needs to be ensured, amongst others through end-to-end encryption in private online communication and the protection of private content against any kind of general or targeted surveillance, be it by public or private actors. Therefore, the use of AI systems violating the right to privacy in online communication services shall be prohibited.

Amendment 1287

Sophia in 't Veld, Michal Šimečka, Róza Thun und Hohenstein

Proposal for a regulation

Article 5 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(d a) The creation or expansion of facial recognition or other biometric databases through the untargeted scraping of biometric data from social media profiles or CCTV footage or equivalent methods;

Or. en

Amendment 1288

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

Proposal for a regulation
Article 5 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(d a) the creation or expansion of biometric databases through the untargeted or generalised scraping of biometric data from social media profiles or CCTV footage, or equivalent methods;

Or. en

Amendment 1289

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

Proposal for a regulation
Article 5 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(d a) the development, placing on the market, putting into service, deployment or use of biometric categorisation systems;

Or. en

Amendment 1290

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation
Article 5 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(d a) The use of predictive, profiling and risk assessment AI systems in law enforcement and criminal justice;

Or. en

Amendment 1291

Rob Rooken

on behalf of the ECR Group

Proposal for a regulation

Article 5 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(d a) The use of private biometric databases for the purpose of law enforcement;

Or. en

Amendment 1292

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Article 5 – paragraph 1 – point d b (new)

Text proposed by the Commission

Amendment

(d b) The use of predictive, profiling and risk assessment AI system by or on behalf of competent authorities in migration, asylum or border control management, to profile an individual or assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered the territory of a Member State, on the basis of personal or sensitive data, known or predicted, except for the sole purpose of identifying specific care and support needs;

Or. en

Amendment 1293

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d b (new)

Text proposed by the Commission

Amendment

(d b) the placing on the market, putting into service or use of AI systems to infer emotions of a natural person, except for health or research purposes or other exceptional purposes, and subject to full regulatory review and with full and informed consent at all times.

Or. en

Amendment 1294

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d b (new)

Text proposed by the Commission

Amendment

(d b) AI systems intended to be used by law enforcement authorities or other competent public authorities as polygraphs and similar tools or to detect the emotional state of a natural person;

Or. en

Amendment 1295

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä, Marcel Kolaja, Patrick Breyer

Proposal for a regulation

Article 5 – paragraph 1 – point d b (new)

Text proposed by the Commission

Amendment

(d b) the placing on the market, putting into service, deployment or use of of emotion recognition systems other than for the personal use of natural persons as an assistive technology;

Or. en

Amendment 1296

Sophia in 't Veld, Michal Šimek, Róza Thun und Hohenstein

Proposal for a regulation

Article 5 – paragraph 1 – point d b (new)

Text proposed by the Commission

Amendment

(d b) The use of private facial recognition or other private biometric databases for the purpose of law enforcement

Or. en

Amendment 1297

Rob Rooken

on behalf of the ECR Group

Proposal for a regulation

Article 5 – paragraph 1 – point d b (new)

Text proposed by the Commission

Amendment

(d b) The placing on the market, putting into service or use of ‘emotion recognition systems’;

Or. en

Amendment 1298

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

Proposal for a regulation

Article 5 – paragraph 1 – point d b (new)

Text proposed by the Commission

Amendment

(d b) the use of remote biometric categorisation systems in publicly accessible spaces;

Or. en

Amendment 1299

Sophia in 't Veld, Michal Šimek, Róza Thun und Hohenstein

Proposal for a regulation

Article 5 – paragraph 1 – point d c (new)

Text proposed by the Commission

Amendment

(d c) The placing on the market, putting into service or use of 'emotion recognition systems', unless for health purposes, which would be considered high risk.

Emotion recognition systems for health purposes shall be limited to their intended purpose, subject to all applicable data protection conditions and limits, and:

(i) undergo strict testing to ensure scientific and clinical validity;

(ii) contain clear advice to anyone that may procure or use them about the limitations of such technologies and their potential risks, including of flawed or potentially harmful outcomes;

(iii) be developed with the active participation and input of the groups they are intended to benefit, as well as those with expertise in the range of fundamental rights that could be deliberately or inadvertently impacted;

(iv) be developed and deployed in a manner that respects the rights of all persons likely to be affected by them;

(v) be subject to an opinion of the Health Security Committee and the Fundamental Rights Agency.

Or. en

Amendment 1300

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

Proposal for a regulation

Article 5 – paragraph 1 – point d c (new)

Text proposed by the Commission

Amendment

(d c) the placing on the market, putting into service or use of biometric categorisation systems, or other AI systems, that categorise natural persons according to sensitive or protected attributes or characteristics, or infer those attributes or characteristics. Sensitive attributes or characteristics include, but are not limited to:

- (i) Gender & gender identity*
- (ii) Race*
- (iii) Ethnic origin*
- (iv) Migration or citizenship status*
- (v) Political orientation*
- (vi) Sexual orientation*
- (vii) Religion*
- (viii) Disability*
- (ix) Or any other grounds on which discrimination is prohibited under Article 21 of the EU Charter of Fundamental Rights as well as under Article 9 of the Regulation (EU) 2016/679;*

Or. en

Amendment 1301

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d c (new)

Text proposed by the Commission

Amendment

(d c) the use of AI systems by or on behalf of competent authorities in migration, asylum or border control management, to profile an individual or assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered the

territory of a Member State, on the basis of personal or sensitive data, known or predicted, except for the sole purpose of identifying specific care and support needs;

Or. en

Amendment 1302

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d c (new)

Text proposed by the Commission

Amendment

(d c) AI systems intended to be used by law enforcement authorities for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 or assessing personality traits and characteristics or past criminal behaviour of natural persons, groups, or locations;

Or. en

Amendment 1303

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Article 5 – paragraph 1 – point d c (new)

Text proposed by the Commission

Amendment

(d c) the placing on the market, putting into service, or use of AI systems by law enforcement authorities or by competent authorities in migration, asylum and border control management, such as polygraphs and similar tools to detect deception, trustworthiness or related characteristics;

Or. en

Amendment 1304

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

Proposal for a regulation

Article 5 – paragraph 1 – point d c (new)

Text proposed by the Commission

Amendment

(d c) the development, placing on the market, putting into service, deployment or use of AI systems for automated monitoring and analysis of human behaviour in publicly accessible spaces, including online;

Or. en

Amendment 1305

Rob Rooken
on behalf of the ECR Group

Proposal for a regulation

Article 5 – paragraph 1 – point d c (new)

Text proposed by the Commission

Amendment

(d c) The use of biometric categorisation systems;

Or. en

Amendment 1306

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

Proposal for a regulation

Article 5 – paragraph 1 – point d d (new)

Text proposed by the Commission

Amendment

(d d) the development, placing on the market, putting into service, deployment or use of an AI system that can reasonably foreseeably be used for constant monitoring of an individual's behaviour to identify, predict or deter rule-breaking or fraud in a relationship of power, such as at work or in education, in particular where this constant monitoring has potential punitive or detrimental consequences for individuals;

Or. en

Amendment 1307

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

Proposal for a regulation

Article 5 – paragraph 1 – point d d (new)

Text proposed by the Commission

Amendment

(d d) the placing on the market, putting into service or use of an AI system for making predictions, profiles or risk assessments based on data analysis or profiling of natural persons, groups or locations, for the purpose of predicting the occurrence or reoccurrence of an actual or potential criminal offence(s) or other criminalised social behaviour;

Or. en

Amendment 1308

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Article 5 – paragraph 1 – point d d (new)

Text proposed by the Commission

Amendment

(d d) the use of AI systems by or on behalf of competent authorities in migration, asylum and border control

management, to forecast or predict individual or collective movement for the purpose of, or in any way reasonably foreseeably leading to, the interdicting, curtailing or preventing migration or border crossings;

Or. en

Amendment 1309

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d d (new)

Text proposed by the Commission

Amendment

(d d) The creation or expansion of facial recognition or other biometric databases through the untargeted or generalised scraping of biometric data from social media profiles or closed circuit television (CCTV) footage, or equivalent methods;

Or. en

Amendment 1310

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d d (new)

Text proposed by the Commission

Amendment

(d d) AI systems intended to be used by law enforcement authorities for profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of detection, investigation or prosecution of criminal offences;

Or. en

Amendment 1311

Sophia in 't Veld, Michal Šimeška, Róza Thun und Hohenstein

Proposal for a regulation

Article 5 – paragraph 1 – point d d (new)

Text proposed by the Commission

Amendment

(d d) AI systems intended to be used by law enforcement authorities as polygraphs and similar tools or to detect the emotional state of a natural person;

Or. en

Amendment 1312

Kate iná Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d d (new)

Text proposed by the Commission

Amendment

(d d) The use of private facial recognition or other private biometric databases for the purpose of law enforcement;

Or. en

Amendment 1313

Sophia in 't Veld, Michal Šimeška

Proposal for a regulation

Article 5 – paragraph 1 – point d e (new)

Text proposed by the Commission

Amendment

(d e) The placing on the market, putting into service or use of AI systems including, but not limited to polygraphs and similar tools to detect deception, trustworthiness or related characteristics, by or on behalf of competent authorities in migration, asylum or border control management, to profile an individual or

assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered the territory of a Member state, on the basis of personal or sensitive data, known or predicted, except for the sole purpose of identifying specific care and support needs;

Or. en

Amendment 1314

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d e (new)

Text proposed by the Commission

Amendment

(d e) AI systems intended to be used for crime analytics regarding natural persons, allowing law enforcement authorities to search complex related and unrelated large data sets available in different data sources or in different data formats in order to identify unknown patterns or discover hidden relationships in the data.

Or. en

Amendment 1315

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

Proposal for a regulation

Article 5 – paragraph 1 – point d e (new)

Text proposed by the Commission

Amendment

(d e) the placing on the market, putting into service, deployment or use of recommender systems aimed at generating interaction that systematically

suggest disinformation or illegal content;

Or. en

Amendment 1316

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Paul Tang, Maria Grapini, Brando Benifei

Proposal for a regulation

Article 5 – paragraph 1 – point d e (new)

Text proposed by the Commission

Amendment

(d e) the use of private facial recognition or other private biometric databases for the purpose of law enforcement;

Or. en

Amendment 1317

Sophia in 't Veld, Michal Šimečka, Róza Thun und Hohenstein

Proposal for a regulation

Article 5 – paragraph 1 – point d f (new)

Text proposed by the Commission

Amendment

(d f) the placing on the market, putting into service or use of AI systems that use physiological, behavioural or biometric data to infer attributes or characteristics of persons or groups which are not solely determined by such data or are not externally observable or whose complexity is not possible to fully capture in data, including but not limited to gender, race, colour, ethnic or social origin, as well as political or sexual orientation, or other grounds for discrimination prohibited under Article 21 of the Charter.

Or. en

Amendment 1318

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Tineke Strik, Alexandra Geese, Alviina Alametsä, Marcel Kolaja, Patrick Breyer

Proposal for a regulation

Article 5 – paragraph 1 – point d f (new)

Text proposed by the Commission

Amendment

(d f) the use of AI systems by law enforcement authorities, criminal justice authorities, migration, asylum and border-control authorities, or other public authorities to make predictions, profiles or risk assessments based on data analysis or profiling of natural persons as referred to in Article 3(4) of Directive EU 2016/680, groups or locations, for the purpose of predicting the occurrence or recurrence of an actual or potential criminal offence(s) or other offences, or rule-breaking;

Or. en

Amendment 1319

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

Proposal for a regulation

Article 5 – paragraph 1 – point d f (new)

Text proposed by the Commission

Amendment

(d f) the placing on the market, putting into service, or use of AI systems that are aimed at automating judicial or similarly intrusive binding decisions by state actors;

Or. en

Amendment 1320

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d f (new)

Text proposed by the Commission

Amendment

(d f) The use of remote biometric identification in migration management, border surveillance and humanitarian aid.

Or. en

Amendment 1321

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d f (new)

Text proposed by the Commission

Amendment

(d f) the placing on the market, putting into service or use of ‘emotion recognition systems’

Or. en

Amendment 1322

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

Proposal for a regulation

Article 5 – paragraph 1 – point d g (new)

Text proposed by the Commission

Amendment

(d g) the placing on the market, putting into service or the use of AI systems by or on behalf of competent authorities in migration, asylum or border control management, to profile an individual or assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered the territory of a Member State, on the basis of personal or sensitive data, known or predicted, except for the sole purpose of

identifying specific care and support needs;

Or. en

Amendment 1323

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä, Tineke Strik, Marcel Kolaja, Patrick Breyer

Proposal for a regulation

Article 5 – paragraph 1 – point d g (new)

Text proposed by the Commission

Amendment

(d g) the use of AI systems by or on behalf of competent authorities, or third parties acting on their behalf, in migration, asylum or border control management, to profile an individual or assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person on the basis of personal or sensitive data, known or predicted, except for the sole purpose of identifying specific care and support needs;

Or. en

Amendment 1324

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d g (new)

Text proposed by the Commission

Amendment

(d g) the use of AI systems, by or on behalf of competent authorities in migration, asylum and border control management, to forecast or predict individual or collective movement for the purpose of, or in any way reasonably foreseeable leading to, the interdicting, curtailing or preventing migration or

border crossings;

Or. en

Amendment 1325

Sophia in 't Veld, Michal Šimečka, Róza Thun und Hohenstein

Proposal for a regulation

Article 5 – paragraph 1 – point d g (new)

Text proposed by the Commission

Amendment

(d g) AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for public assistance benefits and services, as well as to grant, reduce, revoke, or reclaim such benefits and services;

Or. en

Amendment 1326

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

Proposal for a regulation

Article 5 – paragraph 1 – point d g (new)

Text proposed by the Commission

Amendment

(d g) the use of biometric categorisation systems in publicly-accessible spaces, workplaces (including in hiring processes), and educational settings;

Or. en

Amendment 1327

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

Proposal for a regulation

Article 5 – paragraph 1 – point d h (new)

Text proposed by the Commission

Amendment

(d h) the placing on the market, putting into service or use of biometric categorisation systems, or other AI systems, that categorise natural persons according to sensitive or protected attributes or characteristics, or infer those attributes or characteristics, including:

Sex

Gender & gender identity

Race

Ethnic origin

Membership of a national minority

Migration or citizenship status

Political orientation

Social origin or class

Language or dialect

Trade union membership

Sexual orientation

Religion or philosophical orientation

Disability

Or any other grounds on which discrimination is prohibited under Article 21 of the EU Charter of Fundamental Rights as well as under Article 9 of the General Data Protection Regulation

Or. en

Amendment 1328

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

Proposal for a regulation

Article 5 – paragraph 1 – point d h (new)

Text proposed by the Commission

Amendment

(d h) the placing on the market, putting into service or the use of AI systems, by or on behalf of competent authorities in

migration, asylum and border control management, to forecast or predict individual or collective movement for the purpose of, or in any way reasonably foreseeable leading to, the prohibiting, curtailing or preventing migration or border crossings;

Or. en

Amendment 1329

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä, Tineke Strik, Marcel Kolaja, Patrick Breyer

Proposal for a regulation

Article 5 – paragraph 1 – point d h (new)

Text proposed by the Commission

Amendment

(d h) the placing on the market, putting into service, or use of AI systems by law enforcement authorities, or by competent authorities in migration, asylum and border control management, as polygraphs and similar tools to detect deception, trustworthiness or related characteristics

Or. en

Amendment 1330

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d h (new)

Text proposed by the Commission

Amendment

(d h) The use of private facial recognition or other private biometric databases for the purpose of law enforcement;

Or. en

Amendment 1331

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d i (new)

Text proposed by the Commission

Amendment

(d i) the use of AI systems by law enforcement authorities, criminal justice authorities, or other public authorities in conjunction with law enforcement and criminal justice authorities, to make predictions, profiles or risk assessments based on data analysis or profiling of natural persons [as referred to in Article 3(4) of Directive EU)2016/680], groups or locations, for the purpose of predicting the occurrence or reoccurrence of an actual or potential criminal offence(s) or other criminalised social behaviour.”

Or. en

Amendment 1332

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

Proposal for a regulation

Article 5 – paragraph 1 – point d i (new)

Text proposed by the Commission

Amendment

(d i) the placing on the market, putting into service or the use of AI systems intended to assist competent authorities for the examination of application for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status;

Or. en

Amendment 1333

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d i (new)

Text proposed by the Commission

Amendment

(d i) The creation or expansion of facial recognition or other biometric databases through the untargeted or generalised scraping of biometric data from social media profiles or CCTV footage, or equivalent methods;

Or. en

Amendment 1334

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä, Marcel Kolaja, Patrick Breyer

Proposal for a regulation

Article 5 – paragraph 1 – point d i (new)

Text proposed by the Commission

Amendment

(d i) The development of private facial recognition or other private biometric databases and the use of such databases for the purpose of law enforcement;

Or. en

Amendment 1335

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d j (new)

Text proposed by the Commission

Amendment

(d j) the use of AI systems, by or on behalf of competent authorities in migration, asylum and border control management, to forecast or predict

individual or collective movement for the purpose of, or in any way reasonably foreseeably leading to, the interdicting, curtailing or preventing migration or border crossings;

Or. en

Amendment 1336

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä, Marcel Kolaja, Patrick Breyer

Proposal for a regulation

Article 5 – paragraph 1 – point d j (new)

Text proposed by the Commission

Amendment

(d j) The creation or expansion of facial recognition or other biometric databases through the untargeted or generalised scraping of biometric data from social media profiles or CCTV footage, or equivalent methods;

Or. en

Amendment 1337

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d j (new)

Text proposed by the Commission

Amendment

(d j) the placing on the market, putting into service or use of ‘emotion recognition systems’;

Or. en

Amendment 1338

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 5 – paragraph 1 – point d k (new)

Text proposed by the Commission

Amendment

(d k) The use of AI systems by law enforcement and criminal justice authorities to make predictions, profiles or risk assessments for the purpose of predicting crime.

Or. en

Amendment 1339

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 5 – paragraph 1 – point d k (new)

Text proposed by the Commission

Amendment

(d k) the use of biometric categorisation systems in publicly-accessible spaces, workplaces (including in hiring processes), and educational settings;

Or. en

Amendment 1340

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä, Tineke Strik, Marcel Kolaja, Patrick Breyer

Proposal for a regulation
Article 5 – paragraph 1 – point d k (new)

Text proposed by the Commission

Amendment

(d k) The use of remote biometric identification for the purpose of migration management, border surveillance and humanitarian aid;

Or. en

Amendment 1341

Fernando Barrena Arza, Kateina Konevá, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 – paragraph 1 – point d 1 (new)

Text proposed by the Commission

Amendment

(d 1) the placing on the market, putting into service or use of:

- (i) AI systems intended to be used for the purpose of determining access or assigning natural persons to educational and vocational training institutions;*
- (ii) AI systems intended to be used for the purpose of assessing students in educational and vocational training institutions.*
- (iii) AI systems intended to be used for recruitment or selection of natural persons, notably for advertising vacancies, screening or filtering applications, evaluating candidates in the course of interviews or tests;*
- (iv) AI systems intended to be used for making decisions on promotion and termination of work-related contractual relationships, for task allocation and for monitoring and evaluating performance and behaviour of persons in such relationships;*
- (v) AI systems intended to be used by public authorities, private entities or on their behalf to evaluate the eligibility of natural persons for public assistance benefits and services, essential private services, as well as to grant, reduce, revoke, or reclaim such benefits and services;*
- (vi) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score;*

Or. en

Amendment 1342

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä, Marcel Kolaja, Patrick Breyer

Proposal for a regulation

Article 5 – paragraph 1 – point d l (new)

Text proposed by the Commission

Amendment

(d l) the use of AI systems for indiscriminate surveillance applied in a generalised manner to a large number of natural persons without differentiation;

Or. en

Amendment 1343

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä, Marcel Kolaja, Patrick Breyer

Proposal for a regulation

Article 5 – paragraph 1 – point d m (new)

Text proposed by the Commission

Amendment

(d m) The collection or generation of data for practices and AI systems listed in paragraphs -1 and 1 shall also be prohibited throughout their lifecycle, including training, validation and testing;

Or. en

Amendment 1344

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä, Marcel Kolaja, Patrick Breyer

Proposal for a regulation

Article 5 – paragraph 1 – point d n (new)

Text proposed by the Commission

Amendment

(d n) The placing on the market, putting

into use or deployment of AI systems built on, designed, trained, validated or tested with data that was collected, processed or generated illegally;

Or. en

Amendment 1345

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä, Marcel Kolaja, Patrick Breyer

Proposal for a regulation

Article 5 – paragraph 1 – point d o (new)

Text proposed by the Commission

Amendment

(d o) The Union shall not fund research into and development of AI systems which are likely to be used for indiscriminate surveillance of publicly accessible spaces applied in a generalised manner to a large number of natural persons without differentiation.

Or. en

Amendment 1346

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä, Marcel Kolaja, Patrick Breyer

Proposal for a regulation

Article 5 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. In Accordance with Article 73, the Commission is empowered to amend paragraph 1 of this Article by means of a delegated act by adding systems that adversely affect, or are likely to adversely affect, the essence of fundamental rights. In doing so the Commission shall consult civil society and human rights experts annually to reflect state-of-the-art

knowledge regarding the potential impacts of technology on fundamental rights.

Or. en

Amendment 1347

René Repasi, Marc Angel, Andreas Schieder, Paul Tang, Maria-Manuel Leitão-Marques

Proposal for a regulation

Article 5 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

I a. the placing on the market, putting into service or use of an AI system that analyses and understands human non-verbal signs such as facial expressions, body language, gestures and voice tones to assess their emotional state or perform biometric categorisation.

Or. en

Amendment 1348

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Sophia in 't Veld, Irena Joveva, Karen Melchior, Svenja Hahn, Alin Mituță

Proposal for a regulation

Article 5 – paragraph 2

Text proposed by the Commission

Amendment

2. The use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall take into account the following elements:

deleted

(a) the nature of the situation giving rise to the possible use, in particular the seriousness, probability and scale of the harm caused in the absence of the use of

the system;

(b) the consequences of the use of the system for the rights and freedoms of all persons concerned, in particular the seriousness, probability and scale of those consequences.

In addition, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall comply with necessary and proportionate safeguards and conditions in relation to the use, in particular as regards the temporal, geographic and personal limitations.

Or. en

Amendment 1349

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 5 – paragraph 2

Text proposed by the Commission

Amendment

2. The use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall take into account the following elements:

deleted

(a) the nature of the situation giving rise to the possible use, in particular the seriousness, probability and scale of the harm caused in the absence of the use of the system;

(b) the consequences of the use of the system for the rights and freedoms of all persons concerned, in particular the seriousness, probability and scale of those consequences.

In addition, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall comply with necessary and proportionate safeguards and conditions in relation to the use, in particular as regards the temporal, geographic and personal limitations.

Or. en

Amendment 1350

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Paul Tang

**Proposal for a regulation
Article 5 – paragraph 2**

Text proposed by the Commission

Amendment

2. *The use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall take into account the following elements:*

- (a) the nature of the situation giving rise to the possible use, in particular the seriousness, probability and scale of the harm caused in the absence of the use of the system;*
- (b) the consequences of the use of the system for the rights and freedoms of all persons concerned, in particular the seriousness, probability and scale of those consequences.*

In addition, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall comply with necessary and proportionate safeguards and conditions in relation to the use, in particular as

regards the temporal, geographic and personal limitations.

Or. en

Amendment 1351

Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Paul Tang, René Repasi, Birgit Sippel, Maria Grapini

Proposal for a regulation

Article 5 – paragraph 2

Text proposed by the Commission

Amendment

2. *The use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall take into account the following elements:*

(a) the nature of the situation giving rise to the possible use, in particular the seriousness, probability and scale of the harm caused in the absence of the use of the system;

(b) the consequences of the use of the system for the rights and freedoms of all persons concerned, in particular the seriousness, probability and scale of those consequences.

In addition, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall comply with necessary and proportionate safeguards and conditions in relation to the use, in particular as regards the temporal, geographic and personal limitations.

Or. en

Amendment 1352

Rob Rooken

**Proposal for a regulation
Article 5 – paragraph 2**

Text proposed by the Commission

Amendment

2. *The use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall take into account the following elements:*

deleted

(a) the nature of the situation giving rise to the possible use, in particular the seriousness, probability and scale of the harm caused in the absence of the use of the system;

(b) the consequences of the use of the system for the rights and freedoms of all persons concerned, in particular the seriousness, probability and scale of those consequences.

In addition, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall comply with necessary and proportionate safeguards and conditions in relation to the use, in particular as regards the temporal, geographic and personal limitations.

Or. en

Amendment 1353

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

**Proposal for a regulation
Article 5 – paragraph 2**

Text proposed by the Commission

Amendment

2. *The use of ‘real-time’ remote biometric identification systems in*

deleted

publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall take into account the following elements:

- (a) the nature of the situation giving rise to the possible use, in particular the seriousness, probability and scale of the harm caused in the absence of the use of the system;*
- (b) the consequences of the use of the system for the rights and freedoms of all persons concerned, in particular the seriousness, probability and scale of those consequences.*

In addition, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall comply with necessary and proportionate safeguards and conditions in relation to the use, in particular as regards the temporal, geographic and personal limitations.

Or. en

Amendment 1354

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Ró a Thun und Hohenstein, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Abir Al-Sahlani, Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation Article 5 – paragraph 2

Text proposed by the Commission

Amendment

2. The use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall take into account the following elements:

- (a) the nature of the situation giving rise*

to the possible use, in particular the seriousness, probability and scale of the harm caused in the absence of the use of the system;

(b) the consequences of the use of the system for the rights and freedoms of all persons concerned, in particular the seriousness, probability and scale of those consequences.

In addition, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall comply with necessary and proportionate safeguards and conditions in relation to the use, in particular as regards the temporal, geographic and personal limitations.

Or. en

Amendment 1355

Jörgen Warborn, Arba Kokalari, Tomas Tobé

**Proposal for a regulation
Article 5 – paragraph 2**

Text proposed by the Commission

Amendment

2. The use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall take into account the following elements:

(a) the nature of the situation giving rise to the possible use, in particular the seriousness, probability and scale of the harm caused in the absence of the use of the system;

(b) the consequences of the use of the system for the rights and freedoms of all persons concerned, in particular the seriousness, probability and scale of those

deleted

consequences.

In addition, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall comply with necessary and proportionate safeguards and conditions in relation to the use, in particular as regards the temporal, geographic and personal limitations.

Or. en

Justification

Instead of blanketly banning the law enforcement's use of facial recognition AI, these systems should be incorporated in the list of high-risk AI systems and subject to strict control. Such modern AI software can process information and images at lightning speed and with great precision - tasks that would take days for a human law enforcement agent to go through. Also with much less risk of bias, when the programs are diligently designed. Using such technology can help law enforcement not only prevent crimes, but also react rapidly when they occur, and provide a very powerful tool to investigate serious crimes.

Amendment 1356

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Ró a Thun und Hohenstein, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Abir Al-Sahlani, Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 5 – paragraph 2 – point a

Text proposed by the Commission

Amendment

(a) the nature of the situation giving rise to the possible use, in particular the seriousness, probability and scale of the harm caused in the absence of the use of the system; *deleted*

Or. en

Amendment 1357

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Sophia in 't Veld, Lucia ūriš Nicholsonová, Irena Joveva, Karen Melchior, Svenja Hahn, Alin Mituță

Proposal for a regulation
Article 5 – paragraph 2 – point a

Text proposed by the Commission

Amendment

(a) the nature of the situation giving rise to the possible use, in particular the seriousness, probability and scale of the harm caused in the absence of the use of the system; *deleted*

Or. en

Amendment 1358

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Róza Thun und Hohenstein, Vlad-Marius Botoș, Samira Rafaela, Monica Semedo, Salima Yenbou, Abir Al-Sahlani, Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation
Article 5 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) the consequences of the use of the system for the rights and freedoms of all persons concerned, in particular the seriousness, probability and scale of those consequences. *deleted*

Or. en

Amendment 1359

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tefnută, Ramona Strugariu, Drago Pîslaru, Sophia in 't Veld, Lucia Ťuriš Nicholsonová, Irena Joveva, Karen Melchior, Svenja Hahn, Alin Mituță

Proposal for a regulation
Article 5 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) the consequences of the use of the system for the rights and freedoms of all persons concerned, in particular the seriousness, probability and scale of those consequences. *deleted*

consequences.

Or. en

Amendment 1360

Vincenzo Sofo, Kosma Złotowski

Proposal for a regulation

Article 5 – paragraph 2 – point b a (new)

Text proposed by the Commission

Amendment

(b a) the full respect of fundamental rights and freedoms in conformity with Union values, the Universal Declaration of Human Rights, the European Convention of Human Rights and the Charter of Fundamental Rights of the EU.

Or. en

Amendment 1361

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Róza Thun und Hohenstein, Vlad-Marius Botoș, Samira Rafaela, Monica Semedo, Salima Yenbou, Abir Al-Sahlani, Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 5 – paragraph 2 – subparagraph 1

Text proposed by the Commission

Amendment

In addition, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall comply with necessary and proportionate safeguards and conditions in relation to the use, in particular as regards the temporal, geographic and personal limitations.

deleted

Or. en

Amendment 1362

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tefnută, Ramona Strugariu, Drago Pîslaru, Sophia in 't Veld, Irena Joveva, Karen Melchior, Svenja Hahn, Alin Mituța

Proposal for a regulation**Article 5 – paragraph 2 – subparagraph 1***Text proposed by the Commission**Amendment*

In addition, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall comply with necessary and proportionate safeguards and conditions in relation to the use, in particular as regards the temporal, geographic and personal limitations.

deleted

Or. en

Amendment 1363

Jorge Buxadé Villalba

Proposal for a regulation**Article 5 – paragraph 2 – subparagraph 1***Text proposed by the Commission**Amendment*

Además, el uso de sistemas de identificación biométrica remota «en tiempo real» en espacios de acceso público con fines de aplicación de la ley para cualquiera de los objetivos mencionados en el apartado 1, letra d), cumplirá salvaguardias y condiciones necesarias y proporcionadas en relación con el uso, *en particular en lo que respecta a las limitaciones temporales, geográficas y personales*.

Además, el uso de sistemas de identificación biométrica remota «en tiempo real» o «en diferido» en espacios de acceso público con fines de aplicación de la ley para cualquiera de los objetivos mencionados en el apartado 1, letra d), cumplirá salvaguardias y condiciones necesarias y proporcionadas en relación con el uso.

Or. es

Justification

Limitando su uso al control de fronteras y la lucha antiterrorista, no es necesario limitar

personal, geográficamente o temporalmente su utilización.

Amendment 1364

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Sophia in 't Veld, Irena Joveva, Karen Melchior, Svenja Hahn, Alin Mituța

Proposal for a regulation

Article 5 – paragraph 3

Text proposed by the Commission

Amendment

3. *As regards paragraphs 1, point (d) and 2, each individual use for the purpose of law enforcement of a ‘real-time’ remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent administrative authority of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation and the authorisation may be requested only during or after the use.*

The competent judicial or administrative authority shall only grant the authorisation where it is satisfied, based on objective evidence or clear indications presented to it, that the use of the ‘real-time’ remote biometric identification system at issue is necessary for and proportionate to achieving one of the objectives specified in paragraph 1, point (d), as identified in the request. In deciding on the request, the competent judicial or administrative authority shall take into account the elements referred to in paragraph 2.

deleted

Or. en

Amendment 1365

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 5 – paragraph 3

Text proposed by the Commission

Amendment

3. *As regards paragraphs 1, point (d) and 2, each individual use for the purpose of law enforcement of a ‘real-time’ remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent administrative authority of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation and the authorisation may be requested only during or after the use.*

The competent judicial or administrative authority shall only grant the authorisation where it is satisfied, based on objective evidence or clear indications presented to it, that the use of the ‘real-time’ remote biometric identification system at issue is necessary for and proportionate to achieving one of the objectives specified in paragraph 1, point (d), as identified in the request. In deciding on the request, the competent judicial or administrative authority shall take into account the elements referred to in paragraph 2.

Or. en

Justification

Instead of blanketly banning the law enforcement's use of facial recognition AI, these systems should be incorporated in the list of high-risk AI systems and subject to strict control. Such modern AI software can process information and images at lightning speed and with great precision - tasks that would take days for a human law enforcement agent to go through. Also with much less risk of bias, when the programs are diligently designed. Using such

technology can help law enforcement not only prevent crimes, but also react rapidly when they occur, and provide a very powerful tool to investigate serious crimes.

Amendment 1366

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 5 – paragraph 3

Text proposed by the Commission

Amendment

3. *As regards paragraphs 1, point (d) and 2, each individual use for the purpose of law enforcement of a ‘real-time’ remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent administrative authority of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation and the authorisation may be requested only during or after the use.*

deleted

The competent judicial or administrative authority shall only grant the authorisation where it is satisfied, based on objective evidence or clear indications presented to it, that the use of the ‘real-time’ remote biometric identification system at issue is necessary for and proportionate to achieving one of the objectives specified in paragraph 1, point (d), as identified in the request. In deciding on the request, the competent judicial or administrative authority shall take into account the elements referred to in paragraph 2.

Or. en

Amendment 1367

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Ró a Thun und Hohenstein, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Abir Al-Sahlani, Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 5 – paragraph 3

Text proposed by the Commission

Amendment

3. *As regards paragraphs 1, point (d) and 2, each individual use for the purpose of law enforcement of a ‘real-time’ remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent administrative authority of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation and the authorisation may be requested only during or after the use.*

The competent judicial or administrative authority shall only grant the authorisation where it is satisfied, based on objective evidence or clear indications presented to it, that the use of the ‘real-time’ remote biometric identification system at issue is necessary for and proportionate to achieving one of the objectives specified in paragraph 1, point (d), as identified in the request. In deciding on the request, the competent judicial or administrative authority shall take into account the elements referred to in paragraph 2.

Or. en

Amendment 1368

Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Paul Tang, René Repasi, Birgit Sippel, Maria Grapini

Proposal for a regulation
Article 5 – paragraph 3

Text proposed by the Commission

Amendment

3. *As regards paragraphs 1, point (d) and 2, each individual use for the purpose of law enforcement of a ‘real-time’ remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent administrative authority of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation and the authorisation may be requested only during or after the use.*

The competent judicial or administrative authority shall only grant the authorisation where it is satisfied, based on objective evidence or clear indications presented to it, that the use of the ‘real-time’ remote biometric identification system at issue is necessary for and proportionate to achieving one of the objectives specified in paragraph 1, point (d), as identified in the request. In deciding on the request, the competent judicial or administrative authority shall take into account the elements referred to in paragraph 2.

Or. en

Amendment 1369
Rob Rooken

Proposal for a regulation
Article 5 – paragraph 3

Text proposed by the Commission

Amendment

3. As regards paragraphs 1, point (d) and 2, each individual use for the purpose of law enforcement of a ‘real-time’ remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent administrative authority of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation and the authorisation may be requested only during or after the use.

The competent judicial or administrative authority shall only grant the authorisation where it is satisfied, based on objective evidence or clear indications presented to it, that the use of the ‘real-time’ remote biometric identification system at issue is necessary for and proportionate to achieving one of the objectives specified in paragraph 1, point (d), as identified in the request. In deciding on the request, the competent judicial or administrative authority shall take into account the elements referred to in paragraph 2.

Or. en

Amendment 1370

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Paul Tang

**Proposal for a regulation
Article 5 – paragraph 3**

Text proposed by the Commission

Amendment

3. As regards paragraphs 1, point (d) and 2, each individual use for the purpose of law enforcement of a ‘real-time’ remote biometric identification system in

publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent administrative authority of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation and the authorisation may be requested only during or after the use.

The competent judicial or administrative authority shall only grant the authorisation where it is satisfied, based on objective evidence or clear indications presented to it, that the use of the ‘real-time’ remote biometric identification system at issue is necessary for and proportionate to achieving one of the objectives specified in paragraph 1, point (d), as identified in the request. In deciding on the request, the competent judicial or administrative authority shall take into account the elements referred to in paragraph 2.

Or. en

Amendment 1371

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

**Proposal for a regulation
Article 5 – paragraph 3**

Text proposed by the Commission

Amendment

3. *As regards paragraphs 1, point (d) and 2, each individual use for the purpose of law enforcement of a ‘real-time’ remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent administrative authority of the Member State in which the use is to take place,* *deleted*

issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation and the authorisation may be requested only during or after the use.

The competent judicial or administrative authority shall only grant the authorisation where it is satisfied, based on objective evidence or clear indications presented to it, that the use of the ‘real-time’ remote biometric identification system at issue is necessary for and proportionate to achieving one of the objectives specified in paragraph 1, point (d), as identified in the request. In deciding on the request, the competent judicial or administrative authority shall take into account the elements referred to in paragraph 2.

Or. en

Amendment 1372
Jorge Buxadé Villalba

Proposal for a regulation
Article 5 – paragraph 3 – introductory part

Text proposed by the Commission

3. Con respecto al apartado 1, letra d), y el apartado 2, cualquier uso concreto de un sistema de identificación biométrica remota «en tiempo real» en un espacio de acceso público con fines de aplicación de la ley estará supeditado a la concesión de una autorización previa por parte de una autoridad judicial o una autoridad administrativa independiente del Estado miembro donde vaya a utilizarse dicho sistema, que la otorgarán previa solicitud motivada y de conformidad con las normas detalladas del Derecho interno mencionadas en el apartado 4. No obstante,

Amendment

3. Con respecto al apartado 1, letra d), y el apartado 2, cualquier uso concreto de un sistema de identificación biométrica remota «en tiempo real» *o «en diferido»* en un espacio de acceso público con fines de aplicación de la ley estará supeditado a la concesión de una autorización previa por parte de una autoridad judicial o una autoridad administrativa independiente del Estado miembro donde vaya a utilizarse dicho sistema, que la otorgarán previa solicitud motivada y de conformidad con las normas detalladas del Derecho interno mencionadas en el apartado 4. No obstante,

en una situación de urgencia debidamente justificada, se podrá empezar a utilizar el sistema antes de obtener la autorización correspondiente, que podrá solicitarse durante el uso o después de este.

en una situación de urgencia debidamente justificada, se podrá empezar a utilizar el sistema antes de obtener la autorización correspondiente, que podrá solicitarse durante el uso o después de este. *Si la justificación previa no se ajusta a los principios de necesidad y de proporcionalidad, no podrán utilizarse los resultados obtenidos por la utilización de esta tecnología con fines de aplicación de la ley.*

Or. es

Amendment 1373
Axel Voss, Deirdre Clune

Proposal for a regulation
Article 5 – paragraph 3 – introductory part

Text proposed by the Commission

3. As regards paragraphs 1, point (d) and 2, each **individual** use for the purpose of law enforcement of a ‘real-time’ remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent administrative authority of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation **and the authorisation *may be* requested *only during or after the use*.**

Amendment

3. As regards paragraphs 1, point (d) and 2, each use for the purpose of law enforcement of a ‘real-time’ remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent administrative authority of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation **if such authorisation is requested *without undue delay, and, if such authorisation is rejected, the system’s use is stopped with immediate effect.***

Or. en

Amendment 1374
Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 5 – paragraph 3 – introductory part

Text proposed by the Commission

3. As regards paragraphs 1, point (d) and 2, each individual use for the purpose of law enforcement of a ‘real-time’ remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent administrative authority of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation and the authorisation may be requested only during or after the use.

Amendment

3. As regards paragraphs 1, point (d) and 2, each individual use for the purpose of law enforcement of a ‘real-time’ remote biometric identification system in publicly accessible **or online** spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent administrative authority of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation and the authorisation may be requested only during or after the use.

Or. en

Amendment 1375

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Ró a Thun und Hohenstein, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Abir Al-Sahlani, Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation
Article 5 – paragraph 3 – subparagraph 1

Text proposed by the Commission

The competent judicial or administrative authority shall only grant the authorisation where it is satisfied, based on objective evidence or clear indications presented to it, that the use of the ‘real-time’ remote biometric identification system at issue is necessary for and proportionate to achieving one of the objectives specified in paragraph 1, point (d), as identified in the request. In deciding on the request, the competent judicial or administrative authority shall

Amendment

deleted

take into account the elements referred to in paragraph 2.

Or. en

Amendment 1376

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Sophia in 't Veld, Irena Joveva, Karen Melchior, Svenja Hahn, Alin Mituță

Proposal for a regulation

Article 5 – paragraph 3 – subparagraph 1

Text proposed by the Commission

Amendment

The competent judicial or administrative authority shall only grant the authorisation where it is satisfied, based on objective evidence or clear indications presented to it, that the use of the ‘real-time’ remote biometric identification system at issue is necessary for and proportionate to achieving one of the objectives specified in paragraph 1, point (d), as identified in the request. In deciding on the request, the competent judicial or administrative authority shall take into account the elements referred to in paragraph 2.

deleted

Or. en

Amendment 1377

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

Proposal for a regulation

Article 5 – paragraph 3 – subparagraph 1

Text proposed by the Commission

Amendment

The competent judicial or administrative authority shall only grant the authorisation where it is satisfied, based on objective evidence or clear indications

deleted

presented to it, that the use of the ‘real-time’ remote biometric identification system at issue is necessary for and proportionate to achieving one of the objectives specified in paragraph 1, point (d), as identified in the request. In deciding on the request, the competent judicial or administrative authority shall take into account the elements referred to in paragraph 2.

Or. en

Amendment 1378

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

Proposal for a regulation

Article 5 – paragraph 3 – subparagraph 1

Text proposed by the Commission

L’autorité judiciaire ou administrative compétente n’accorde l’autorisation que si elle estime, sur la base d’éléments objectifs ou d’indications claires qui lui sont présentés, que l’utilisation du système d’identification biométrique à distance «en temps réel» en cause est nécessaire et proportionnée à la réalisation de l’un des objectifs énumérés au paragraphe 1, point d), tels qu’indiqués dans la demande. Lorsqu’elle statue sur la demande, l’autorité judiciaire ou administrative compétente tient compte des éléments visés au paragraphe 2.

Amendment

L’autorité judiciaire ou administrative compétente n’accorde l’autorisation que si elle estime, sur la base d’éléments objectifs ou d’indications claires qui lui sont présentés, que l’utilisation du système d’identification biométrique à distance «en temps réel» en cause est nécessaire et proportionnée à la réalisation de l’un des objectifs énumérés au paragraphe 1, point d), tels qu’indiqués dans la demande. Lorsqu’elle statue sur la demande, l’autorité judiciaire ou administrative compétente tient compte des éléments visés au paragraphe 2. *Elle accorde l’autorisation pour une durée et un périmètre limités. Tout renouvellement ou modification de l’autorisation est soumis à la présentation d’une nouvelle demande auprès de l’autorité judiciaire ou administrative compétente.*

Or. fr

Amendment 1379

Jorge Buxadé Villalba

Proposal for a regulation

Article 5 – paragraph 3 – subparagraph 1

Text proposed by the Commission

La autoridad judicial o administrativa competente únicamente concederá la autorización cuando esté convencida, atendiendo a las pruebas objetivas o a los indicios claros que se le presenten, de que el uso del sistema de identificación biométrica remota «en tiempo real» es necesario y proporcionado para alcanzar alguno de los objetivos que figuran en el apartado 1, letra d), el cual se indicará en la solicitud. Al pronunciarse al respecto, la autoridad judicial o administrativa competente tendrá en cuenta los aspectos mencionados en el apartado 2.

Amendment

La autoridad judicial o administrativa competente únicamente concederá la autorización cuando esté convencida, atendiendo a las pruebas objetivas o a los indicios claros que se le presenten, de que el uso del sistema de identificación biométrica remota «en tiempo real» *o «en diferido»* es necesario y proporcionado para alcanzar alguno de los objetivos que figuran en el apartado 1, letra d), el cual se indicará en la solicitud. Al pronunciarse al respecto, la autoridad judicial o administrativa competente tendrá en cuenta los aspectos mencionados en el apartado 2.

Or. es

Amendment 1380

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

Proposal for a regulation

Article 5 – paragraph 3 – subparagraph 1 – point 1 (new)

Text proposed by the Commission

Amendment

(1) The placing on the market, putting into service or use of biometric categorisation systems, or other AI systems, that categorise natural persons or groups of persons according to sensitive or protected attributes or characteristics, or infer those attributes or characteristics. Sensitive attributes or characteristics include, but are not limited to: gender and gender identity, race, ethnic origin, migration or citizenship status, political orientation, sexual orientation, religion, disability or any other grounds on which discrimination is

*prohibited under Article 21 of the EU
Charter of Fundamental Rights as well as
under Article 9 of the Regulation (EU)
2016/679.*

Or. en

Amendment 1381

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Sophia in 't Veld, Irena Joveva, Karen Melchior, Svenja Hahn, Alin Mituța

Proposal for a regulation

Article 5 – paragraph 4

Text proposed by the Commission

Amendment

4. A Member State may decide to provide for the possibility to fully or partially authorise the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.

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Or. en

Amendment 1382

Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Paul Tang, René Repasi, Birgit Sippel, Maria Grapini

Proposal for a regulation

Article 5 – paragraph 4

Text proposed by the Commission

Amendment

4. A Member State may decide to provide for the possibility to fully or partially authorise the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.

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Or. en

Amendment 1383

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 5 – paragraph 4

Text proposed by the Commission

Amendment

4. A Member State may decide to provide for the possibility to fully or partially authorise the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of

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the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.

Or. en

Justification

Instead of blanketly banning the law enforcement's use of facial recognition AI, these systems should be incorporated in the list of high-risk AI systems and subject to strict control. Such modern AI software can process information and images at lightning speed and with great precision - tasks that would take days for a human law enforcement agent to go through. Also with much less risk of bias, when the programs are diligently designed. Using such technology can help law enforcement not only prevent crimes, but also react rapidly when they occur, and provide a very powerful tool to investigate serious crimes.

Amendment 1384

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Article 5 – paragraph 4

Text proposed by the Commission

Amendment

4. A Member State may decide to provide for the possibility to fully or partially authorise the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.

Amendment 1385

Rob Rooken

Proposal for a regulation

Article 5 – paragraph 4

Text proposed by the Commission

Amendment

4. A Member State may decide to provide for the possibility to fully or partially authorise the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.

Amendment 1386

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Paul Tang

Proposal for a regulation

Article 5 – paragraph 4

Text proposed by the Commission

Amendment

4. A Member State may decide to provide for the possibility to fully or partially authorise the use of ‘real-time’ remote biometric identification systems in

publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.

Or. en

Amendment 1387

Svenja Hahn, Drago Tudorache, Nicola Beer, Ró a Thun und Hohenstein, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Abir Al-Sahlani, Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

**Proposal for a regulation
Article 5 – paragraph 4**

Text proposed by the Commission

Amendment

4. A Member State may decide to provide for the possibility to fully or partially authorise the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the

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purpose of law enforcement.

Or. en

Amendment 1388

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

Proposal for a regulation

Article 5 – paragraph 4

Text proposed by the Commission

Amendment

4. A Member State may decide to provide for the possibility to fully or partially authorise the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.

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Or. en

Amendment 1389

Vincenzo Sofo, Kosma Złotowski

Proposal for a regulation

Article 5 – paragraph 4

Text proposed by the Commission

Amendment

4. A Member State may decide to

4. A Member State may decide to

provide for the possibility to fully or partially authorise the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision relating to, the authorisations referred to in paragraph 3. Those rules shall **also** specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.

provide for the possibility to fully or partially authorise the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision relating to, the authorisations referred to in paragraph 3. Those rules shall **fully comply with EU values, the Universal Declaration of Human Rights, the European Convention of Human Rights and the Charter of Fundamental Rights of the EU and shall** specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.

Or. en

Amendment 1390
Jorge Buxadé Villalba

Proposal for a regulation
Article 5 – paragraph 4

Text proposed by the Commission

4. Los Estados miembros podrán decidir contemplar la posibilidad de autorizar, ya sea total o parcialmente, el uso de sistemas de identificación biométrica remota «en tiempo real» en espacios de acceso público con fines de aplicación de la ley dentro de los límites y en las condiciones que se indican en el apartado 1, letra d), y los apartados 2 y 3. A tal fin, tendrán que establecer en sus respectivos Derechos internos las normas detalladas necesarias aplicables a la solicitud, la concesión y el ejercicio de las autorizaciones a que se refiere el apartado

Amendment

4. Los Estados miembros podrán decidir contemplar la posibilidad de autorizar, ya sea total o parcialmente, el uso de sistemas de identificación biométrica remota «en tiempo real» **o «en diferido»** en espacios de acceso público con fines de aplicación de la ley dentro de los límites y en las condiciones que se indican en el apartado 1, letra d), y los apartados 2 y 3. A tal fin, tendrán que establecer en sus respectivos Derechos internos las normas detalladas necesarias aplicables a la solicitud, la concesión y el ejercicio de las autorizaciones a que se

3, así como a la supervisión de estas. Dichas normas especificarán también para cuáles de los objetivos enumerados en el apartado 1, letra d), *y en su caso en relación con cuáles de los delitos indicados en su inciso iii)*, se podrá autorizar que las autoridades competentes utilicen esos sistemas con fines de aplicación de la ley.

refiere el apartado 3, así como a la supervisión de estas. Dichas normas especificarán también para cuáles de los objetivos enumerados en el apartado 1, letra d), se podrá autorizar que las autoridades competentes utilicen esos sistemas con fines de aplicación de la ley.

Or. es

Amendment 1391
Axel Voss, Deirdre Clune

Proposal for a regulation
Article 5 – paragraph 4

Text proposed by the Commission

4. A Member State may decide to provide for the possibility to fully or partially authorise the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.

Amendment

4. A Member State may decide to provide for the possibility to fully or partially authorise the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision **and reporting** relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.

Or. en

Amendment 1392
Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 5 – paragraph 4

Text proposed by the Commission

4. A Member State may decide to provide for the possibility to fully or partially authorise the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.

Amendment

4. A Member State may decide to provide for the possibility to fully or partially authorise the use of ‘real-time’ remote biometric identification systems in publicly accessible **or online** spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.

Or. en

Amendment 1393
Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation
Article 5 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. *When assessing for the purposes of paragraph 1 whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on worker’s rights that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall seek and take into account the opinion of social partners.*

Or. en

Amendment 1394

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

Proposal for a regulation

Article 5 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. This Article shall not affect the restrictions, prohibitions or enforcement that apply where an artificial intelligence practice infringes another EU law, including EU acquis on data protection, privacy, or the confidentiality of communications, on non discrimination, consumer protection or on competition.

Or. en

Amendment 1395

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

Proposal for a regulation

Article 5 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. The placing on the market, putting into service or use of AI systems intended to be used as polygraphs, emotion recognition systems or similar tools to detect the emotional state, trustworthiness or related characteristics of a natural person.

Or. en

Justification

Emotion recognition systems hold a particularly high risk of discrimination and lack scientific accuracy. They should therefore be prohibited.

Amendment 1396

René Repasi, Marc Angel, Andreas Schieder, Maria-Manuel Leitão-Marques

Proposal for a regulation

Article 5 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. In order to increase public transparency and oversight every decision about the deployment or marketing of any AI system that is categorised as posing an unacceptable risk shall be made public.

Or. en

Amendment 1397

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 5 – paragraph 4 b (new)

Text proposed by the Commission

Amendment

4 b. Member States may, by law or collective agreement, decide to prohibit or to limit the use of AI systems or provide more specific provisions for this purpose to ensure the protection of the rights of workers in the employment context, in particular for the purposes of the recruitment, the performance of the contract of employment, including discharge of obligations laid down by law or by collective agreements, management, planning and organisation of work, equality and diversity in the workplace, health and safety at work, protection of employer's or customer's property and for the purposes of the exercise and enjoyment, on an individual or collective basis, of rights and benefits related to employment, and for the purpose of the termination of the employment relationship.

Or. en

Amendment 1398

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 5 – paragraph 4 b (new)

Text proposed by the Commission

Amendment

4 b. *Member States may, by law or collective agreements, decide to prohibit or to limit the use of AI systems to ensure the protection of the rights of workers in the employment context, in particular for the purposes of the recruitment, the performance of the contract of employment, including discharge obligations laid down by law or by collective agreements, management, planning and organization of work, equality and diversity at the workplace, health and safety at work, protection of employers or customers' property and for the purposes of the exercise and enjoyment, on an individual or collective basis, of rights and benefits related to employment, and for the purpose of the termination of the employment relationship.*

Or. en

Amendment 1399

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

Proposal for a regulation

Article 5 – paragraph 4 c (new)

Text proposed by the Commission

Amendment

4 c. *the placing on the market, putting into service or the use of AI systems by or on behalf of competent authorities in*

migration, asylum or border control management, to profile an individual or assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered the territory of a Member State, on the basis of personal or sensitive data, known or predicted, except for the sole purpose of identifying specific care and support needs;

Or. en

Amendment 1400

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

Proposal for a regulation

Article 5 – paragraph 4 d (new)

Text proposed by the Commission

Amendment

4 d. the placing on the market, putting into service or use of AI systems by competent authorities or on their behalf in migration, asylum and border control management, to forecast or predict individual or collective movement for the purpose of, or in any way reasonably foreseeably leading to, the prohibiting, curtailing or preventing migration or border crossings;

Or. en

Amendment 1401

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

Proposal for a regulation

Article 5 – paragraph 4 e (new)

Text proposed by the Commission

Amendment

4 e. the placing on the market, putting into service or the use of AI systems intended to assist competent authorities for the examination of application for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status;

Or. en

Amendment 1402

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 5 – paragraph 4 f (new)

Text proposed by the Commission

Amendment

4 f. the placing on the market, putting into service, or use of an AI system for the specific technical processing of brain or brain-generated data in order to access, infer, influence, or manipulate a person's thoughts, emotions, memories, intentions, beliefs, or other mental states against that person's will or in a manner that causes or is likely to cause that person or another person physical or psychological harm;

Or. en

Amendment 1403

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 5 a (new)

Text proposed by the Commission

Amendment

Article 5 a

***Accessibility Requirements for providers
and users of AI systems***

- 1. Providers of AI systems shall ensure that their systems are accessible in accordance with the accessibility requirements set out in Section I, Section II, Section VI, and Section VII of Annex I of Directive (EU) 2019/882 prior to those systems being placed on the market or put into service.***
- 2. Users of AI systems shall use such systems in accordance with the accessibility requirements set out in Section III, Section IV, Section VI, and Section VII of Annex I of Directive (EU) 2019/882.***
- 3. Users of AI systems shall prepare the necessary information in accordance with Annex V of Directive (EU) 2019/882. Without prejudice to Annex VIII of this Regulation, the information shall be made available to the public in an accessible manner for persons with disabilities and be kept for as long as the AI system is in use.***
- 4. Without prejudice to right of affected persons to information about the use and functioning of AI systems, transparency obligations for providers and users of AI, obligations to ensure consistent and meaningful public transparency under this Regulation, providers and users of AI systems shall ensure that information, forms and measures provided pursuant to this Regulation are made available in a manner that they are easy to find, easy to understand, and accessible in accordance with Annex I to Directive 2019/882.***
- 5. Users of AI systems shall ensure that procedures are in place so that the use of AI systems remains in conformity with the applicable accessibility requirements. Changes in the characteristics of the use, changes in applicable accessibility requirements and changes in the harmonised standards or in technical specifications by reference to which use of an AI system is declared to meet the***

accessibility requirements shall be adequately taken into account by the user.

6. In the case of non-conformity, users of AI systems shall take the corrective measures necessary to conform with the applicable accessibility requirements. When necessary, and at the request of the user, the provider of the AI system in question shall cooperate with the user to bring the use of the AI system into compliance with applicable accessibility requirements.

7. Furthermore, where the use of an AI system is not compliant with applicable accessibility requirements, the user shall immediately inform the competent national authorities of the Member States in which the system is being used, to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken. They shall cooperate with the authority, at the request of that authority, on any action taken to bring the use of the AI system into compliance with applicable accessibility requirements.

8. AI systems and the use of thereof, which are in conformity with harmonised technical standards or parts thereof derived from Directive (EU) 2019/882 the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the accessibility requirements of this Regulation in so far as those standards or parts thereof cover those requirements.

9. AI systems and use of thereof, which are in conformity with the technical specifications or parts thereof adopted for the Directive (EU) 2019/882 shall be presumed to be in conformity with the accessibility requirements of this Regulation in so far as those technical specifications or parts thereof cover those requirements.

Or. en

Amendment 1404
Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 5 a (new)

Text proposed by the Commission

Amendment

Article 5 a

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list of prohibited artificial intelligence practices referred to in Article 5 by adding AI systems that pose an unacceptable risk of harm to health and safety, or an unacceptable risk of adverse impact on fundamental rights.

2. When assessing for the purposes of paragraph 1 whether an AI system poses an unacceptable risk of harm to health and safety, or an unacceptable risk of adverse impact on fundamental rights, the Commission shall take into account the following non-cumulative criteria:

a) the extent to which the intended purpose of the AI system, or the reasonably foreseeable consequences of its use, conflict with the essence of the rights and freedoms established by the Charter, such that these rights and freedoms would lose their value either for the rights holder or for society as a whole;

b) the extent to which the risks posed by an AI system cannot be sufficiently mitigated, including by the obligations imposed upon high-risk AI systems under this Regulation;

c) the extent to which an AI system violates human dignity;

d) the extent to which the use of an AI system has already caused harm to the health and safety of persons or disproportionate impact on their 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;

e) 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;

f) 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;

g) 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;

h) the extent to which the outcome produced with an AI system is easily reversible, whereby outcomes having an impact on the health or safety of persons or on their fundamental rights shall not be considered as easily reversible;

i) the extent to which existing Union legislation lacks:

1) effective measures of redress in relation to the risks posed by an AI system, with the exclusion of claims for damages;

2) effective measures to prevent those risks.

Or. en

Amendment 1405

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

**Proposal for a regulation
Article 5 a (new)**

Text proposed by the Commission

Amendment

Article 5 a

Amendments to Article 5

The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list of AI systems and practices prohibited under Article 5 of the present regulation, according to the latest development in technology and to the assessment of increased or newly emerged risks to fundamental rights.

Or. en

Amendment 1406

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Article 5 b (new)**

Text proposed by the Commission

Amendment

Article 5 b

Delegated acts to update the list of prohibited AI practices

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list of prohibited artificial intelligence practices referred to in Article 5 by adding AI systems that pose an unacceptable risk of harm to health and safety, or an unacceptable risk of adverse impact on fundamental rights. 2. When assessing for the purposes of paragraph 1 whether an AI system poses an unacceptable risk of harm to health and safety, or an unacceptable risk of adverse impact on fundamental rights, the Commission shall take into account the following non-cumulative criteria:

a) the extent to which the intended purpose of the AI system, or the

reasonably foreseeable consequences of its use, conflict with the essence of the rights and freedoms established by the Charter, such that these rights and freedoms would lose their value either for the rights holder or for society as a whole;

b) the extent to which the risks posed by an AI system cannot be sufficiently mitigated, including by the obligations imposed upon high-risk AI systems under this Regulation;

c) the extent to which an AI system violates human dignity;

d) the extent to which the use of an AI system has already caused harm to the health and safety of persons or disproportionate impact on their 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;

e) 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;

f) 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;

g) 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;

h) the extent to which the outcome produced with an AI system is easily reversible, whereby outcomes having an

impact on the health or safety of persons or on their fundamental rights shall not be considered as easily reversible;

i) 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 those risks.

Or. en

Amendment 1407

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Title II a (new)**

Text proposed by the Commission

Amendment

Horizontal Requirements for all AI systems

Title for a new Article -Accessibility Requirements for providers and users of AI systems

1. Providers of AI systems shall ensure that their systems are accessible in accordance with the accessibility requirements set out in Section I, Section II, Section VI, and Section VII of Annex I of Directive (EU) 2019/882 prior to those systems being placed on the market or put into service.

2. Users of AI systems shall use such systems in accordance with the accessibility requirements set out in Section III, Section IV, Section VI, and Section VII of Annex I of Directive (EU) 2019/882.

3. Users of AI systems shall prepare the necessary information in accordance with Annex V of Directive (EU) 2019/882. Without prejudice to Annex VIII of this Regulation, the information shall be made available to the public in an accessible manner for persons with disabilities and be kept for as long as the AI system is in

use.

4. Without prejudice to right of affected persons to information about the use and functioning of AI systems, transparency obligations for providers and users of AI, obligations to ensure consistent and meaningful public transparency under this Regulation , providers and users of AI systems shall ensure that information, forms and measures provided pursuant to this Regulation are made available in a manner that they are easy to find, easy to understand, and accessible in accordance with Annex I to Directive 2019/882.

5. Users of AI systems shall ensure that procedures are in place 6 so that the use of AI systems remains in conformity with the applicable accessibility requirements. Changes in the characteristics of the use, changes in applicable accessibility requirements and changes in the harmonised standards or in technical specifications by reference to which use of an AI system is declared to meet the accessibility requirements shall be adequately taken into account by the user.

6. In the case of non-conformity, users of AI systems shall take the corrective measures necessary to conform with the applicable accessibility requirements. When necessary, and at the request of the user, the provider of the AI system in question shall cooperate with the user to bring the use of the AI system into compliance with applicable accessibility requirements.

7. Furthermore, where the use of an AI system is not compliant with applicable accessibility requirements, the user shall immediately inform the competent national authorities of the Member States in which the system is being used, to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken. They shall cooperate with the authority, at the request of that authority, on any action taken to bring the use of the AI system into compliance with applicable accessibility requirements.

8. AI systems and the use of thereof,

which are in conformity with harmonised technical standards or parts thereof derived from Directive (EU) 2019/882 the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the accessibility requirements of this Regulation in so far as those standards or parts thereof cover those requirements.

9. AI systems and use of thereof, which are in conformity with the technical specifications or parts thereof adopted for the Directive(EU) 2019/882 shall be presumed to be in conformity with the accessibility requirements of this Regulation in so far as those technical specifications or parts thereof cover those requirements.

Or. en

Amendment 1408
Geoffroy Didier

Proposal for a regulation
Title III

Text proposed by the Commission

HIGH-RISK AI SYSTEMS

Amendment

HIGH-RISK **USES OF** AI SYSTEMS

Or. en

Amendment 1409
Geoffroy Didier

Proposal for a regulation
Title III – Chapter 1 – title

Text proposed by the Commission

1 CLASSIFICATION OF AI SYSTEMS AS **HIGH-RISK**

Amendment

1 CLASSIFICATION OF AI SYSTEMS AS **WITH HIGH-RISK USES**

Or. en

Amendment 1410

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

Proposal for a regulation

Article 6 – title

Text proposed by the Commission

Classification rules for high-risk AI systems

Amendment

Classification rules for high-risk AI systems

-1. AI systems shall be classified as high-risk where they pose a significant risk of harm to the health and safety of individuals, a significant risk of adverse impact on fundamental rights, environment, society, rule of law or democracy, or a significant risk of economic harm or to consumer protection, that is, in respect of its severity, intensity, probability of occurrence, duration of its effects and its ability to affect an individual, a plurality of persons or to affect a particular group of persons disproportionately;

Or. en

Amendment 1411

Geoffroy Didier

Proposal for a regulation

Article 6 – title

Text proposed by the Commission

Classification rules for high-risk AI systems

Amendment

Classification rules for high-risk *uses of* AI systems

Or. en

Amendment 1412

Krzysztof Hetman, Adam Jarubas, Andrzej Halicki, Jerzy Buzek, Janusz Lewandowski,

Radosław Sikorski

**Proposal for a regulation
Article 6 – paragraph -1 (new)**

Text proposed by the Commission

Amendment

-1. The AI system shall be considered high-risk where it meets the following two cumulative criteria: •

(a) the AI system is used or applied in a sector where, given the characteristics of the activities typically undertaken, significant risks of harm to the health and safety or a risk of adverse impact on fundamental rights of users, as outlined in Article 7(2) can be expected to occur.

(b) the AI system application in the sector in question is used in such a manner that significant risks of harm to the health and safety or a risk of adverse impact on fundamental rights of users, as outlined in Article 7(2) are likely to arise.

Or. en

Amendment 1413

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 6 – paragraph -1 (new)**

Text proposed by the Commission

Amendment

-1. AI systems referred to in Annex III shall be considered high-risk for the purposes of this Regulation.

Or. en

Amendment 1414

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 6 – paragraph 1 – introductory part

Text proposed by the Commission

1. *Irrespective of whether an AI system is placed on the market or put into service independently from the products referred to in points (a) and (b), that AI system shall be considered high-risk where both of the following conditions are fulfilled:*

Amendment

1. An AI system *that is itself a product* shall be considered *as high risk AI system if, under the applicable Union harmonisation legislation listed in Annex II, it is classified as high-risk AI system or an equivalent thereof and has to undergo a third-party conformity assessment for meeting essential safety requirements prior to placing it on the market or putting it into service.*

An AI system intended to be used as a core and essential safety component of a product under the applicable Union harmonisation legislation listed in Annex II, shall be considered as high risk if such Union harmonisation legislation classifies it as high-risk or an equivalent thereof and requires it to undergo a third-party conformity assessment for meeting essential safety requirements with a view to placing it on the market or putting it into service.

The high-risk classification set in paragraph 1 shall not impact or determine the outcome of other risk classification procedures established in Union harmonisation legislation listed in Annex II

Or. en

Amendment 1415
Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation
Article 6 – paragraph 1 – introductory part

Text proposed by the Commission

1. Irrespective of whether an AI

Amendment

1. Irrespective of whether an AI

system is placed on the market or put into service independently from the products referred to in *points (a) and (b)*, that AI system shall be considered high-risk where *both of the following conditions are fulfilled*:

system is placed on the market or put into service independently from the products referred to in *point (a)*, that AI system shall be considered high-risk where:

Or. en

Amendment 1416

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 6 – paragraph 1 – introductory part

Text proposed by the Commission

1. Irrespective of whether an AI system is placed on the market or put into service independently from the products referred to in points (a) and (b), that AI system shall be considered high-risk where *both* of the following conditions are fulfilled:

Amendment

1. Irrespective of whether an AI system is placed on the market or put into service independently from the products referred to in points (a) and (b), that AI system shall be considered high-risk where *one* of the following conditions are fulfilled:

Or. en

Amendment 1417

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 6 – paragraph 1 – point a

Text proposed by the Commission

(a) the AI system is intended to be used as a safety component of a product, or is itself a product, covered by the Union harmonisation legislation listed in Annex II;

Amendment

deleted

Or. en

Amendment 1418

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

Proposal for a regulation

Article 6 – paragraph 1 – point a

Text proposed by the Commission

(a) the AI system is intended to be used as a safety component of a product, or is itself a product, *covered by* the Union harmonisation legislation listed in Annex II;

Amendment

(a) the AI system is intended to be used as a safety component of a product, or is itself a product *or it is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to* the Union harmonisation legislation listed in Annex II;

Or. en

Amendment 1419

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

Proposal for a regulation

Article 6 – paragraph 1 – point a

Text proposed by the Commission

(a) the AI system is intended to be used as a safety component of a product, or is itself a product, covered by the Union harmonisation legislation listed in Annex II;

Amendment

(a) the AI system *has a self-evolving behaviour, the failure of which results in an immediate hazardous condition in a specific domain, and* is intended to be used as a safety component of a product, or is itself a product, covered by the Union harmonisation legislation listed in Annex II;

Or. en

Amendment 1420

Sophia in 't Veld, Michal Šimečka, Róza Thun und Hohenstein

Proposal for a regulation

Article 6 – paragraph 1 – point a

Text proposed by the Commission

(a) the AI system is intended to be used as a safety component of a product, or is itself a product, covered by the Union harmonisation legislation listed in Annex II;

Amendment

(a) the AI system is intended to be ***used or reasonably foreseeable*** used as a safety component of a product, or is itself a product, covered by the Union harmonisation legislation listed in Annex II;

Or. en

Amendment 1421

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 6 – paragraph 1 – point a

Text proposed by the Commission

(a) the AI system is intended to be used as a **safety** component of a product, or is itself a product, **covered by the Union harmonisation legislation listed in Annex II;**

Amendment

(a) the AI system is intended to be used as a component of a product, or is itself a product, ***the failure or malfunctioning of which endangers the health, safety or fundamental rights of persons;***

Or. en

Amendment 1422

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 6 – paragraph 1 – point a

Text proposed by the Commission

(a) the AI system is intended to be used as a safety component of a product, or is itself a product, covered by the Union harmonisation legislation listed in Annex II;

Amendment

(a) the AI system is intended to be used as a safety component of a product, or is itself a product ***involving significant risks,*** covered by the Union harmonisation legislation listed in Annex II;

Or. en

Amendment 1423

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

Proposal for a regulation

Article 6 – paragraph 1 – point a

Text proposed by the Commission

(a) the AI system is intended to be used as a safety component of a product, or is itself a product, covered by the Union harmonisation legislation listed in Annex II;

Amendment

(a) the AI system is intended to be used as a **main** safety component of a product, or is itself a product, covered by the Union harmonisation legislation listed in Annex II;

Or. en

Amendment 1424

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

Proposal for a regulation

Article 6 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

*(a a) its uses are undetermined or
indeterminate;*

Or. en

Amendment 1425

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

Proposal for a regulation

Article 6 – paragraph 1 – point a b (new)

Text proposed by the Commission

Amendment

*(a b) in the course of the self-
assessment pursuant to Article 6 a of this
Regulation, the AI system or its operation
is found to result in a high risk to the
rights and freedoms of natural persons;*

or

Or. en

Amendment 1426

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

Proposal for a regulation

Article 6 – paragraph 1 – point a c (new)

Text proposed by the Commission

Amendment

(a c) it is listed in Annex III.

Or. en

Amendment 1427

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

Proposal for a regulation

Article 6 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) the product whose safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.

deleted

Or. en

Justification

Moved up

Amendment 1428
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 6 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) *the product whose safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.*

deleted

Or. en

Amendment 1429
Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation
Article 6 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) the product whose safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.

(b) the product whose **main** safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment **in order to ensure compliance with essential safety requirements** with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.

Or. en

Amendment 1430
Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 6 – paragraph 1 – point b

Text proposed by the Commission

(b) the product whose safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.

Amendment

(b) the product whose safety component **as meant under (a)** is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service **or use** of that product pursuant to the Union harmonisation legislation listed in Annex II.

Or. en

Amendment 1431

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 6 – paragraph 1 – point b

Text proposed by the Commission

(b) the product whose safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.

Amendment

(b) the product whose safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment **related to safety** with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.

Or. en

Amendment 1432

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 6 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(b a) the AI system is used by a public authority.

Amendment 1433

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 6 – paragraph 2

Text proposed by the Commission

Amendment

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk.

deleted

Justification

moved up as new paragraph 1.

Amendment 1434

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 6 – paragraph 2

Text proposed by the Commission

Amendment

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems **referred to in Annex III shall also be considered high-risk.**

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems *identified as posing a risk to fundamental human rights as defined in the EU Charter of Fundamental Rights, in relation to a specific intended use* shall also be considered high-risk. *Such risk is to be determined by completion of a Human Rights Impact Assessment by the user of the AI in relation to the specific use intended for the AI system, with records of such assessment retained for regulatory inspection.*

The provider shall apply a precautionary principle and, in case of uncertainty over

the AI system's classification, shall consider the AI system high-risk.

Or. en

Amendment 1435

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Mituță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 6 – paragraph 2

Text proposed by the Commission

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk.

Amendment

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk, *with the exception of those AI systems that are not safety components of a product and that fulfil both of the following conditions:*

- (a) they are not developed with and do not use biometric data, biometrics-based data, or personal data as inputs;*
- (b) they are not intended to influence decisions of natural persons or to make decisions or to assist in the making of decisions affecting natural persons.*

Or. en

Amendment 1436

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 6 – paragraph 2

Text proposed by the Commission

2. In addition to the high-risk AI systems referred to in paragraph 1, *AI systems* referred to in Annex III shall also be considered high-risk.

Amendment

2. In addition to the high-risk AI systems referred to in paragraph 1, *each AI system with an intended purpose - as specified in its instruction to use in accordance with Art 3(12) and Art 13(2) -*

that means that it will be deployed in a way that falls under one of the critical use cases referred to in Annex III shall also be considered high-risk if that AI system will make a final decision that puts significantly at risk the health, safety or fundamental rights of natural persons.

Or. en

Amendment 1437

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 6 – paragraph 2

Text proposed by the Commission

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems *referred to in Annex III* shall also be considered high-risk.

Amendment

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems shall also be considered high-risk *in the meaning of this regulation, if they will be deployed in a critical area referred to in Annex III and an individual assessment of the specific application carried out in accordance with Art. 6a showed that a significant harm is likely to arise.*

Or. en

Amendment 1438

Marion Walsmann

Proposal for a regulation

Article 6 – paragraph 2

Text proposed by the Commission

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk.

Amendment

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk *if they pose a risk of harm to the health and safety or a risk of adverse impact on fundamental rights.*

Amendment 1439
Geoffroy Didier

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk.

Amendment

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk, *if they pose a risk of harm to either physical health and safety or fundamental human rights, or both.*

Justification

It is important to clarify that the classification of high-risk, also for those uses listed in Annex III, is linked clearly to the risk of harm to physical health and safety or to fundamental rights. This could usefully restrict applications that could be considered high-risk.

Amendment 1440
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission

2. Outre les systèmes d'IA à haut risque visés au paragraphe 1, les systèmes d'IA visés à l'annexe III sont également considérés comme à haut risque.

Amendment

2. Outre les systèmes d'IA à haut risque visés au paragraphe 1, les systèmes d'IA visés à l'annexe III sont également considérés comme à haut risque, *s'ils représentent une menace pour la santé humaine, la sécurité ou les droits fondamentaux*

Amendment 1441

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Vincenzo Sofo, Adam Bielan

**Proposal for a regulation
Article 6 – paragraph 2**

Text proposed by the Commission

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk.

Amendment

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk, *if they pose a risk of harm to either physical health and safety or human rights, or both.*

Or. en

Amendment 1442

Andrea Caroppo, Salvatore De Meo

**Proposal for a regulation
Article 6 – paragraph 2**

Text proposed by the Commission

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk.

Amendment

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk *when no internal risk-mitigation mechanisms embedded in the AI system apply.*

Or. en

Amendment 1443

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

**Proposal for a regulation
Article 6 – paragraph 2**

Text proposed by the Commission

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk.

Amendment

2. In addition to the high-risk AI systems referred to in paragraph 1 *and in accordance with Article 6– paragraph -1a,* AI systems referred to in Annex III shall

also be considered high-risk.

Or. en

Amendment 1444

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 6 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The classification as high-risk as a consequence of Article 6(1) and 6(2) shall be disregarded for AI systems whose intended purpose demonstrates that the generated output is a recommendation requiring a human intervention to convert this recommendation into a decision and for AI systems which do not lead to autonomous decisions or actions of the overall system.

Or. en

Amendment 1445

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 6 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The assessment by the provider of whether an AI system puts at risk the health, safety or fundamental rights of natural persons shall also take into account the factors enumerated in Article 7(2).

Or. en

Amendment 1446

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation
Article 6 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The assessment referred to in paragraph 2 shall be conducted by the Commission annually and under the consultation conditions laid down in this regulation, notably in Article 73;

Or. en

Amendment 1447

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

Proposal for a regulation
Article 6 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. An artificial intelligence system with indeterminate uses shall also be considered high risk if so identified per Article 9, paragraph 2, point (a).

Or. en

Amendment 1448

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 6 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk.

Or. en

Amendment 1449

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

Proposal for a regulation

Article 6 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2 b. Where the Commission finds in the course of the assessment pursuant to paragraphs 1 and 2 that an AI system or an area of AI systems must be considered "high risk" or can no longer be considered "high risk", including due to improvements in technology or to social or legal safeguards put in place, it is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by adding or removing AI systems and areas of AI systems.

Or. en

Amendment 1450

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 6 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2 b. In addition to the high-risk AI systems referred to in paragraphs 1, AI systems that have over 20 million EU citizens across the EU or 50% of any given Member States' population as active monthly users, or whose users have cumulatively over 20 million customers or beneficiaries in the EU affected by it shall be considered high-risk, unless these are placed onto the market.

Or. en

Amendment 1451

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 6 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2 b. When assessing an AI system for the purposes of paragraph 1 of Article 6, a safety component shall be assessed against the essential health and safety requirements of the relevant EU harmonisation legislation listed in Annex II.

Or. en

Amendment 1452

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

Proposal for a regulation

Article 6 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2 b. In addition to the high-risk AI systems referred to in paragraph 1 and paragraph 2, AI systems that create foreseeable high-risks when combined shall also be considered high-risk.

Or. en

Amendment 1453

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 6 – paragraph 2 c (new)

Text proposed by the Commission

Amendment

2 c. In addition to the high-risk AI systems referred to in paragraph 1, AI

systems affecting employees in the employment relationship or in matters of training or further education shall be considered high risk.

Or. en

Amendment 1454

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 6 – paragraph 2 d (new)

Text proposed by the Commission

Amendment

2 d. In addition to the high-risk AI systems referred to in paragraph 1, AI systems likely to interact with children shall be considered high-risk.

Or. en

Amendment 1455

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 6 – paragraph 2 e (new)

Text proposed by the Commission

Amendment

2 e. In addition to the high-risk AI systems referred to in paragraph 1, an artificial intelligence system with indeterminate uses shall also be considered high risk.

Or. en

Amendment 1456

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Catharina Rinzema, Samira Rafaela, Monica Semedo, Salima Yenbou, Sophia in 't Veld, Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 6 a (new)

Text proposed by the Commission

Amendment

Article 6 a

Risk assessment

1. In order to determine the level of risk of AI systems, the provider of an AI system with an intended purpose in the areas referred to in Annex III has to conduct a risk assessment.

2. The risk assessment has to contain the following elements:

a) name all possible harms to life, health and safety or fundamental rights of potentially impacted persons or entities or society at large;

b) asses the likelihood and severity these harms might materialise;

c) name the potential benefits of such system for the potentially impacted persons and society at large;

d) name possible and taken measures to address, prevent, minimise or mitigate the identified harms with a high probability to materialise;

e) asses the possibilities to reverse these negative outcome;

f) the extent to which decision-making of the system is autonomous and outside of human influence.

3. If the risk assessment showed a significant harm is likely to materialise the provider has to comply with Chapter 2 in a way that is appropriate and proportionate to the identified risks.

Or. en

Justification

To determine whether or not an AI system is to be considered high-risk, a use-case specific risk assessment that contains all relevant aspects should be conducted. An operation in one of the areas listed in Annex III alone is not sufficient to determine the risk level of an AI system. Only when the sector as well as the intended use of the AI system involves significant risks, the AI system shall be considered as high risk. The amendments to Art. 6 and the new Art. 6a

make sure that only those AI systems are categorized as “high risk” that fulfil clear and transparent criteria.

Amendment 1457

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 6 a (new)

Text proposed by the Commission

Amendment

Article 6 a

Preliminary self-assessment

1. Before the conformity assessment procedure foreseen in Articles 43 for high-risk AI systems and 51a for other than high-risk AI system, the provider of the AI system shall carry out a preliminary self-assessment to determine whether:

(a) the intended purpose, potential use, or reasonably foreseeable misuse of the AI system constitute a prohibited practice pursuant to Article 5; or

(b) the AI system is classified as ‘high-risk’ pursuant to Article 6.

2. The provider of the AI system shall keep a detailed record, including all relevant documentation, of that self-assessment at the disposal of the national competent authorities during the lifespan of the AI system concerned.

3. Where the preliminary self-assessment indicates non-compliance of the AI system with this Regulation, in particular due to it falling within the scope of Article 5, the provider shall, without delay, take measures to ensure compliance of the concerned AI system with this Regulation, or immediately desist from placing it on the market.

Or. en

Amendment 1458
Sophia in 't Veld, Michal Šimeka

Proposal for a regulation
Article 6 a (new)

Text proposed by the Commission

Amendment

Article 6 a

Risk assessment

The European Artificial Intelligence Board shall develop guidance for the risk assessment.

Or. en

Justification

This provision should be seen as an addition to the Renew Europe IMCO shadow's amendment on a risk assessment to determine the level of risk of AI systems.

Amendment 1459
Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation
Article 7

Text proposed by the Commission

Amendment

[...]

deleted

Or. en

Justification

To create legal certainty for AI developers, it is important that the high-risk areas of application are clearly laid down and cannot be changed quickly and dramatically by means of delegated acts. All additions to the list of high risk AI systems should be subject to Parliament's approval.

Amendment 1460
Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 7 – paragraph 1

Text proposed by the Commission

Amendment

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by adding high-risk AI systems where both of the following conditions are fulfilled:

(a) the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III;

(b) the AI systems pose a risk of harm to the health and safety, or a risk of adverse impact on fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.

Or. en

Justification

To create legal certainty for AI developers, it is important that the high-risk areas of application are clearly laid down and cannot be changed quickly and dramatically by means of delegated acts. All additions to the list of high risk AI systems should be subject to Parliament's approval.

Amendment 1461

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 7 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by adding high-risk AI systems where **both of the following **conditions are** fulfilled:**

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by adding high-risk AI systems where the following **condition is fulfilled: **the AI systems pose a risk of harm to 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 associated with the high-risk AI systems already referred to in Annex III. Where an AI system is not intended to be used in any of the areas listed in points 1 to 8 of Annex III, the Commission is empowered to update the list of areas in Annex III by including new areas or extending the scope of existing areas.

Or. en

Amendment 1462

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 7 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update *the list in* Annex III by adding high-risk AI systems *where both of the following conditions are fulfilled:*

Amendment

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update Annex III, *including* by adding *new areas of high-risk AI systems, where a type of AI system poses a risk of harm to the health and safety, a risk of adverse impact on fundamental rights, on climate change mitigation and adaptation, the environment, or a risk of contravention of the Union values enshrined in Article 2 TEU, and that risk is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems in use in the areas listed in Annex III.*

Or. en

Amendment 1463

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

Proposal for a regulation
Article 7 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by adding high-risk AI systems where **both** of the **following conditions are fulfilled:**

Amendment

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update **or amend** the list in Annex III by adding **areas of high-risk AI systems where the AI systems pose a risk of harm to the health and safety, or a risk of adverse impact on fundamental rights, a risk of breach of the Union values enshrined in Article 2 TEU or a risk of adverse impact on the society and the environment.**

Or. en

Amendment 1464

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

Proposal for a regulation
Article 7 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by adding high-risk AI systems where both of the following conditions are fulfilled:

Amendment

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by adding high-risk AI systems where both of the following conditions are fulfilled **and areas of high-risk systems that pose a risk of harm to health and safety, or a risk of adverse impact on fundamental rights, environment, society, rule of law or democracy, a risk of economic harm or to consumer protection that is, in respect of its severity or probability of occurrence;**

Or. en

Amendment 1465

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

Garraud

Proposal for a regulation

Article 7 – paragraph 1 – introductory part

Text proposed by the Commission

1. La Commission est habilitée à adopter des actes délégués conformément à l’article 73 afin de mettre à jour la liste figurant à l’annexe III en y ajoutant des systèmes d’IA à haut risque *lorsque les deux conditions suivantes sont remplies:*

Amendment

1. La Commission est habilitée à adopter des actes délégués conformément à l’article 73 afin de mettre à jour la liste figurant à l’annexe III en y ajoutant des *domaines de* systèmes d’IA à haut risque *lorsqu’ils présentent un risque de préjudice pour la santé et la sécurité ou un risque d’incidence négative sur les droits fondamentaux qui, eu égard à sa gravité et à sa probabilité d’occurrence, est équivalent ou supérieur au risque de préjudice ou d’incidence négative que présentent les systèmes d’IA à haut risque déjà visés à l’annexe III.*

Or. fr

Amendment 1466

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Samira Rafaela, Monica Semedo, Salima Yenbou, Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 7 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by adding *high-risk AI systems where* both of the following conditions *are* fulfilled:

Amendment

1. The Commission is empowered to adopt delegated acts in accordance with Article 73, *after an adequate and transparent consultation process involving the relevant stakeholders*, to update the list in Annex III by *withdrawing areas from that list or by* adding *critical areas. For additions* both of the following conditions *need to be* fulfilled:

Or. en

Amendment 1467**Axel Voss, Deirdre Clune, Eva Maydell****Proposal for a regulation****Article 7 – paragraph 1 – introductory part***Text proposed by the Commission*

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by adding high-risk AI systems where both of the following conditions are fulfilled:

Amendment

1. The Commission is empowered to adopt delegated acts in accordance with Article 73, *after ensuring adequate consultation with relevant stakeholders*, to update the list in Annex III by adding high-risk AI systems where both of the following conditions are fulfilled:

Or. en

Amendment 1468**Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák****Proposal for a regulation****Article 7 – paragraph 1 – introductory part***Text proposed by the Commission*

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by adding high-risk AI systems where both of the following conditions are fulfilled:

Amendment

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by adding *new area headings and* high-risk AI systems where both of the following conditions are fulfilled:

Or. en

Amendment 1469**Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura****Proposal for a regulation****Article 7 – paragraph 1 – introductory part***Text proposed by the Commission*

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by

Amendment

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by

adding high-risk AI systems *where both of the following conditions are fulfilled:*

adding high-risk AI systems.

Or. en

Amendment 1470

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 7 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by adding high-risk AI systems where **both** of the following conditions **are** fulfilled:

Amendment

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by adding high-risk AI systems where **either** of the following conditions **is** fulfilled:

Or. en

Amendment 1471

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

Proposal for a regulation

Article 7 – paragraph 1 – point a

Text proposed by the Commission

(a) *les systèmes d'IA sont destinés à être utilisés dans l'un des domaines énumérés à l'annexe III, points 1 à 8;*

supprimé

Amendment

Or. fr

Justification

Cette précision limite les domaines dans lesquels un système d'I.A. est susceptible de présenter des risques et doit donc être supprimée pour ne pas présumer que les nouvelles technologies poseront à l'avenir des risques dans ces domaines seulement et non dans d'autres.

Amendment 1472

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 7 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III; *deleted*

Or. en

Amendment 1473

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 7 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III; *deleted*

Or. en

Amendment 1474

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

Proposal for a regulation

Article 7 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III; *deleted*

Or. en

Amendment 1475

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

Proposal for a regulation

Article 7 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) *the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III;* *deleted*

Or. en

Amendment 1476

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Article 7 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III;

(a) the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III *or in the newly identified area headings;*

Or. en

Amendment 1477

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

Proposal for a regulation

Article 7 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) *les systèmes d'IA présentent un risque de préjudice pour la santé et la sécurité, ou un risque d'incidence négative sur les droits fondamentaux, qui, eu égard à sa gravité et à sa probabilité d'occurrence, est équivalent ou supérieur au risque de préjudice ou d'incidence* *supprimé*

négative que présentent les systèmes d'IA à haut risque déjà visés à l'annexe III.

Or. fr

Justification

Le sous-paragraphe a) étant supprimé, l'existence d'un b) ne se justifie plus et le texte est directement intégré au corps du paragraphe.

Amendment 1478

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 7 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) the AI systems pose a risk of harm to the health and safety, or a risk of adverse impact on fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III. *deleted*

Or. en

Amendment 1479

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

Proposal for a regulation

Article 7 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) the AI systems pose a risk of harm to the health and safety, or a risk of adverse impact on fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III. *deleted*

Amendment 1480

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

Proposal for a regulation

Article 7 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) *the AI systems pose a risk of harm to the health and safety, or a risk of adverse impact on fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.* *deleted*

Justification

Moved up in paragraph 1

Amendment 1481

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 7 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) *the AI systems pose a risk of harm to the health and safety, or a risk of adverse impact on fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.* *deleted*

Amendment 1482

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 7 – paragraph 1 – point b

Text proposed by the Commission

(b) the AI systems pose a risk of harm to the health and safety, or a risk of adverse impact on fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.

Amendment

(b) the AI systems pose a risk of ***economic harm, negative societal impacts or*** harm to the ***environment***, health and safety, or a risk of adverse impact on fundamental rights, ***democracy and the rule of law***, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.

Amendment 1483

Kosma Złotowski, Patryk Jaki, Vincenzo Sofo, Adam Bielan

Proposal for a regulation

Article 7 – paragraph 1 – point b

Text proposed by the Commission

(b) the AI systems pose a risk of harm to the health and safety, or a risk of adverse impact on fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.

Amendment

(b) the AI systems pose a risk of harm to the health, ***natural environment*** and safety, or a risk of adverse impact on fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.

Amendment 1484

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 1 – point b

Text proposed by the Commission

(b) the AI systems pose a risk of harm to the health and safety, or a risk of adverse impact on fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact *posed by the high-risk AI systems already referred to in Annex III.*

Amendment

(b) the AI systems pose a *serious* risk of harm to the health and safety, or a *serious* risk of adverse impact on fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact.

Or. en

Amendment 1485

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 7 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(b a) the AI systems pose a risk of harm to occupational health and safety, including psychosocial risks.

Or. en

Amendment 1486

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 7 – paragraph 2

Text proposed by the Commission

Amendment

2. *When assessing for the purposes of paragraph 1 whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights that is equivalent to or greater than the risk of harm posed by the*

deleted

high-risk AI systems already referred to in Annex III, the Commission shall take into account the following criteria:

- (a) the intended purpose of the AI system;*
- (b) the extent to which an AI system has been used or is likely to be used;*
- (c) the extent to which the use of an AI system has already caused harm to the health and safety or adverse impact on the fundamental rights or has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by reports or documented allegations submitted to national competent authorities;*
- (d) the potential extent of such harm or such adverse impact, in particular in terms of its intensity and its ability to affect a plurality of persons;*
- (e) 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;*
- (f) 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, or age;*
- (g) the extent to which the outcome produced with an AI system is easily reversible, whereby outcomes having an impact on the health or safety of persons shall not be considered as easily reversible;*
- (h) the extent to which existing Union legislation provides for:*
 - (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

Justification

To create legal certainty for AI developers, it is important that the high-risk areas of application are clearly laid down and cannot be changed quickly and dramatically by means of delegated acts. All additions to the list of high risk AI systems should be subject to Parliament's approval.

Amendment 1487

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

Proposal for a regulation

Article 7 – paragraph 2 – introductory part

Text proposed by the Commission

2. Lorsqu'elle évalue, aux fins du paragraphe 1, *si un système d'IA présente un risque de préjudice pour la santé et la sécurité ou un risque d'incidence négative sur les droits fondamentaux équivalent ou supérieur au risque de préjudice que présentent les systèmes d'IA à haut risque déjà visés à l'annexe III*, la Commission tient compte des critères suivants:

Amendment

2. Lorsqu'elle évalue *un système d'IA* aux fins du paragraphe 1, la Commission tient compte des critères suivants:

Or. fr

Amendment 1488

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

Proposal for a regulation

Article 7 – paragraph 2 – introductory part

Text proposed by the Commission

2. When assessing for the purposes of paragraph 1 *whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights that is equivalent to or greater than*

Amendment

2. When assessing for the purposes of paragraph 1, the Commission shall take into account the following criteria:

the risk of harm posed by the high-risk AI systems already referred to in Annex III,
the Commission shall take into account the following criteria:

Or. en

Amendment 1489

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

Proposal for a regulation

Article 7 – paragraph 2 – introductory part

Text proposed by the Commission

2. When assessing for the purposes of paragraph 1 *whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III*, the Commission shall take into account the following criteria:

Amendment

2. When assessing for the purposes of paragraph 1 the Commission shall take into account the following *non-cumulative* criteria:

Or. en

Amendment 1490

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 7 – paragraph 2 – introductory part

Text proposed by the Commission

2. When assessing for the purposes of paragraph 1 whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall take into account the following criteria:

Amendment

2. When assessing for the purposes of paragraph 1 whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights *or on the environment, democracy and rule of law* that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall *consult*

social partners and civil society and take into account, *including but not limited to*, the following *non-cumulative* criteria:

Or. en

Amendment 1491

Sophia in 't Veld, Michal Šimeka

Proposal for a regulation

Article 7 – paragraph 2 – introductory part

Text proposed by the Commission

2. When assessing for the purposes of paragraph 1 whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall take into account the following criteria:

Amendment

2. When assessing for the purposes of paragraph 1 whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall take into account, *including but not limited to*, the following criteria:

Or. en

Amendment 1492

Kosma Złotowski, Patryk Jaki, Vincenzo Sofo, Adam Bielan

Proposal for a regulation

Article 7 – paragraph 2 – introductory part

Text proposed by the Commission

2. When assessing for the purposes of paragraph 1 whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall take into account the following criteria:

Amendment

2. When assessing for the purposes of paragraph 1 whether an AI system poses a risk of harm to the health, *natural environment* and safety or a risk of adverse impact on fundamental rights that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall take into account the following criteria:

Amendment 1493

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

Proposal for a regulation

Article 7 – paragraph 2 – point a

Text proposed by the Commission

- (a) the intended purpose of the AI system;

Amendment

- (a) *a description of the AI system, including the intended purpose, the concrete use and context, complexity and autonomy of the AI system, the potential persons impacted, the extent to which the AI system has been used or is likely to be used, the extent to which any outcomes produced are subject to human review or intervention;*

Amendment 1494

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 7 – paragraph 2 – point a

Text proposed by the Commission

- (a) the intended purpose of the AI system;

Amendment

- (a) the intended purpose of the AI system, *or the reasonably foreseeable consequences of its use;*

Amendment 1495

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

Proposal for a regulation

Article 7 – paragraph 2 – point a

Text proposed by the Commission

(a) the intended purpose of the AI system;

Amendment

(a) the intended purpose of the AI system, *potential use, or reasonably foreseeable misuse*;

Or. en

Amendment 1496

Sophia in 't Veld, Michal Šimek

Proposal for a regulation

Article 7 – paragraph 2 – point a

Text proposed by the Commission

(a) the intended purpose of the AI system;

Amendment

(a) the intended purpose *or the reasonably foreseeable use* of the AI system;

Or. en

Justification

This amendment applies throughout the entire text. "or the reasonably foreseeable use" should be consistently added after "the intended purpose"

Amendment 1497

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 – point a a (new)

Text proposed by the Commission

Amendment

(a a) the general capabilities and functionalities of the AI system independent of its intended purpose;

Or. en

Amendment 1498

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

Proposal for a regulation
Article 7 – paragraph 2 – point b

Text proposed by the Commission

- (b) *the extent to which an AI system has been used or is likely to be used;*

Amendment

- (b) *an assessment of the potential benefits provided by the use of the AI system, as well as reticence risk and/or opportunity costs of not using the AI for individuals, groups of individuals, or society at large. This includes weighing the benefits of deploying the AI system against keeping the status quo;*

Or. en

Amendment 1499

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

Proposal for a regulation
Article 7 – paragraph 2 – point b

Text proposed by the Commission

- (b) the extent to which an AI system has been used or is likely to be used;

Amendment

- (b) the extent to which an AI system has been used or is likely to be used, *including its reasonably foreseeable misuse*;

Or. en

Amendment 1500

Vincenzo Sofo, Kosma Złotowski

Proposal for a regulation
Article 7 – paragraph 2 – point b

Text proposed by the Commission

- (b) the extent to which an AI system has been used or is likely to be used;

Amendment

- (b) the extent to which an AI system has been used or is likely to be used *and misused*;

Or. en

Amendment 1501

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 – point b a (new)

Text proposed by the Commission

Amendment

(b a) the extent to which the AI system acts with a certain level of autonomy;

Or. en

Amendment 1502

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

Proposal for a regulation

Article 7 – paragraph 2 – point b a (new)

Text proposed by the Commission

Amendment

(b a) the type and nature of the data processed and used by the AI system;

Or. en

Amendment 1503

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Moritz Körner, Ondřej Kovářík, Jan-Christoph Oetjen

Proposal for a regulation

Article 7 – paragraph 2 – point b a (new)

Text proposed by the Commission

Amendment

(b a) the extent to which the AI system acts autonomously;

Or. en

Amendment 1504

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

Proposal for a regulation

Article 7 – paragraph 2 – point b b (new)

Text proposed by the Commission

Amendment

(b b) the extent to which the AI system respects the principles of Article 4a;

Or. en

Amendment 1505

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

Proposal for a regulation

Article 7 – paragraph 2 – point c

Text proposed by the Commission

Amendment

(c) the extent to which the use of an AI system has already caused harm to the health and safety or adverse impact on the fundamental rights or has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by reports or documented allegations submitted to national competent authorities;

(c) an assessment of the probability of worst-case scenario, likelihood and severity of harm, to the health and safety or fundamental rights of potentially impacted persons and its irreversibility, including:

(i) the extent to which the AI system has already been evaluated and proven to have caused material harm as demonstrated by studies or reports published by the national competent authorities;

(ii) the extent to which potentially impacted persons are dependent on the outcome produced from the AI system, in particular because of practical or legal reasons it is not reasonably possible to opt-out from that outcome;

(iii) the extent to which the outcome produced by the AI system is easily

reversible;

(iv) the extent to which potentially impacted persons are in a vulnerable position in relation to the user of the AI system, in particular due to an imbalance of power, knowledge, economic or social circumstances, or age.

Or. en

Amendment 1506

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

Proposal for a regulation

Article 7 – paragraph 2 – point c

Text proposed by the Commission

(c) the extent to which the use of an AI system has already caused harm to the health and safety or adverse impact on the fundamental rights or has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by reports or documented allegations submitted to national competent authorities;

Amendment

(c) the extent to which the use of an AI system has already caused harm to **natural persons, has breached the Union values enshrined in Article 2 TEU, has caused harm to** the health and safety or **has had an** adverse impact on the fundamental rights, **on the environment or the society** or has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by reports or documented allegations submitted to **the national supervisory authority, to the** national competent authorities, **to the Commission, to the Board, to the EDPS or to the European Union Agency for Fundamental Rights (FRA);**

Or. en

Amendment 1507

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 7 – paragraph 2 – point c

Text proposed by the Commission

(c) the extent to which the use of an AI system has already caused harm to the health and safety or adverse impact on the fundamental rights or has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by reports or documented allegations submitted to national competent authorities;

Amendment

(c) the extent to which the use of an AI system has already caused harm to ***natural persons, has contravened the Union values enshrined in Article 2 TEU, has caused harm to*** the health and safety or ***has had an*** adverse impact on the fundamental rights, ***on the environment or society***, or has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by reports or documented allegations submitted to national competent authorities, ***to the Commission, to the Board, to the EDPS or to the European Union Agency for Fundamental Rights (FRA);***

Or. en

Amendment 1508

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 7 – paragraph 2 – point c

Text proposed by the Commission

(c) the extent to which the use of an AI system has already caused harm to the health and safety or ***adverse impact on the*** fundamental rights or has given rise to ***significant*** concerns in relation to the ***materialisation*** of such harm or adverse impact, ***as demonstrated by reports or documented allegations submitted to national competent authorities;***

Amendment

(c) the extent to which the use of an AI system has already caused harm to the health and safety or ***adversely impacted*** fundamental rights, ***environment, society, rule of law or democracy, consumer protection or caused economic harm*** or has given rise to ***reasonable*** concerns in relation to the ***likelihood*** of such harm or adverse impact;

Or. en

Amendment 1509

Kosma Złotowski, Patryk Jaki, Vincenzo Sofo, Adam Bielan

Proposal for a regulation

Article 7 – paragraph 2 – point c

Text proposed by the Commission

(c) the extent to which the use of an AI system has already caused harm to the health and safety or adverse impact on the fundamental rights or has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by reports or documented allegations submitted to national competent authorities;

Amendment

(c) the extent to which the use of an AI system has already caused harm to the health, **natural environment** and safety or adverse impact on the fundamental rights or has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by reports or documented allegations submitted to national competent authorities;

Or. en

Amendment 1510

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 7 – paragraph 2 – point c

Text proposed by the Commission

(c) the extent to which the use of an AI system has already caused harm to the health and safety or adverse impact on the fundamental rights **or** has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by reports or documented allegations **submitted to national competent authorities**;

Amendment

(c) the extent to which the use of an AI system has already caused harm to the health and safety or adverse impact on the fundamental rights, **democracy, rule of law and the environment** has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by **available** reports or documented allegations;

Or. en

Amendment 1511

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

Proposal for a regulation

Article 7 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(c a) the AI systems pose a risk of harm to occupational health and safety, including psychosocial risks and mental health;

Or. en

Amendment 1512

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

Proposal for a regulation

Article 7 – paragraph 2 – point d

Text proposed by the Commission

(d) the potential extent of such harm or such adverse impact, in particular in terms of its intensity and its ability to affect a plurality of persons;

Amendment

(d) measures taken to address or mitigate the identified risks, including to the extent existing Union legislation provides for:

- (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 1513

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 7 – paragraph 2 – point d

Text proposed by the Commission

(d) the potential extent of such harm or such adverse impact, in particular in terms of its intensity and its ability to affect a plurality of persons;

Amendment

*(d) the potential extent of such harm or such adverse impact, in particular in terms of its intensity and its ability to affect a plurality of persons **or on the environment or to affect a particular group of persons***

disproportionately;

Or. en

Amendment 1514

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

Proposal for a regulation

Article 7 – paragraph 2 – point d

Text proposed by the Commission

(d) the potential extent of such harm or such adverse impact, *in particular in terms of its intensity and its ability to affect a plurality of persons*;

Amendment

(d) the potential extent of such harm or such adverse impact;

Or. en

Amendment 1515

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

Proposal for a regulation

Article 7 – paragraph 2 – point e

Text proposed by the Commission

(e) 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;

Amendment

deleted

Or. en

Amendment 1516

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 – point e

Text proposed by the Commission

(e) 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;

Amendment

(e) the extent to which potentially harmed or adversely impacted persons are dependent on the outcome produced with an AI system ***with a distinction to be made between an AI system used in an advisory capacity or one used directly to make a decision***, in particular because for practical or legal reasons it is not reasonably possible to opt-out from that outcome;

Or. en

Amendment 1517

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 7 – paragraph 2 – point e

Text proposed by the Commission

(e) 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;

Amendment

(e) the extent to which potentially harmed or adversely impacted persons are dependent on the outcome produced ***by a process involving*** an AI system, in particular because for practical or legal reasons it is not reasonably possible to opt-out ***of*** that outcome;

Or. en

Amendment 1518

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 7 – paragraph 2 – point e

Text proposed by the Commission

(e) the extent to which potentially harmed or adversely impacted persons are

Amendment

(e) 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;

dependent on the outcome produced **involving** an AI system, in particular because for practical or legal reasons it is not reasonably possible to opt-out from that outcome;

Or. en

Amendment 1519

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Article 7 – paragraph 2 – point e

Text proposed by the Commission

(e) 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;

Amendment

(e) 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. en

Amendment 1520

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Moritz Körner, Ondej Kováč, Jan-Christoph Oetjen

Proposal for a regulation

Article 7 – paragraph 2 – point e a (new)

Text proposed by the Commission

Amendment

(e a) the potential misuse and malicious use of the AI system and of the technology underpinning it;

Or. en

Amendment 1521
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 7 – paragraph 2 – point e a (new)

Text proposed by the Commission

Amendment

(e a) the potential misuse and malicious use of the AI system and of the technology underpinning it;

Or. en

Amendment 1522
Alessandra Basso, Marco Campomenosi, Isabella Tovaglieri, Mara Bizzotto, Silvia Sardone, Annalisa Tardino

Proposal for a regulation
Article 7 – paragraph 2 – point f

Text proposed by the Commission

Amendment

(f) 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, or age;

deleted

Or. en

Amendment 1523
Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation
Article 7 – paragraph 2 – point f

Text proposed by the Commission

Amendment

(f) 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

(f) the extent to which ***there is an imbalance of power, or the*** potentially harmed or adversely impacted persons are in a vulnerable position in relation to the

an imbalance of power, knowledge, economic or social circumstances, or age;

user of an AI system, in particular due to *status, authority*, knowledge, economic or social circumstances, or age;

Or. en

Amendment 1524

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

Proposal for a regulation

Article 7 – paragraph 2 – point g

Text proposed by the Commission

Amendment

(g) *the extent to which the outcome produced with an AI system is easily reversible, whereby outcomes having an impact on the health or safety of persons shall not be considered as easily reversible;*

deleted

Or. en

Amendment 1525

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

Proposal for a regulation

Article 7 – paragraph 2 – point g

Text proposed by the Commission

Amendment

(g) the extent to which the outcome produced with an AI system is easily reversible, whereby outcomes having an impact on the health or safety of persons shall not be considered as easily reversible;

(g) the extent to which the outcome produced with an AI system is easily reversible, whereby outcomes having an impact on the *fundamental rights of persons, the environment or the society, the health or safety of persons, or on the Union values enshrined in Article 2 TEU*, shall not be considered as easily reversible;

Or. en

Amendment 1526

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 7 – paragraph 2 – point g**

Text proposed by the Commission

(g) the extent to which the outcome produced with an AI system is easily reversible, whereby outcomes having an impact on the health or safety of persons shall not be considered as easily reversible;

Amendment

(g) the extent to which the outcome produced with an AI system is easily reversible, whereby outcomes having an impact on the health or safety of persons, *the fundamental rights of persons, the environment or society, or on the Union values enshrined in Article 2 TEU* shall not be considered as easily reversible;

Or. en

Amendment 1527

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

Proposal for a regulation**Article 7 – paragraph 2 – point g**

Text proposed by the Commission

(g) the extent to which the outcome produced *with* an AI system is easily reversible, *whereby* outcomes having an impact on the health or safety of persons shall not be considered as easily reversible;

Amendment

(g) the extent to which the outcome produced *involving* an AI system is easily reversible *and can effectively be appealed by AI subjects*. Outcomes having an impact on the *fundamental rights or* health or safety of persons shall not be considered as easily reversible;

Or. en

Amendment 1528

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation**Article 7 – paragraph 2 – point g**

Text proposed by the Commission

(g) the extent to which the outcome produced with an AI system is easily reversible, whereby outcomes having an impact on the health or safety of persons shall not be considered as easily reversible;

Amendment

(g) 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 **or on their fundamental rights** shall not be considered as easily reversible;

Or. en

Amendment 1529

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 – point g

Text proposed by the Commission

(g) the extent to which the outcome produced with an AI system is easily reversible, whereby outcomes having an impact on the health or safety of persons shall not be considered as easily reversible;

Amendment

(g) the extent to which the outcome produced with an AI system is **not** easily reversible **or remedied**, whereby outcomes having an impact on the health or safety of persons shall not be considered as easily reversible;

Or. en

Amendment 1530

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 – point g a (new)

Text proposed by the Commission

Amendment

(g a) the extent of the availability and use of demonstrated technical solutions and mechanisms for the control, reliability and corrigibility of the AI system;

Or. en

Amendment 1531

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 7 – paragraph 2 – point g a (new)

Text proposed by the Commission

Amendment

(g a) magnitude and likelihood of benefit of the deployment of the AI system for individuals, groups, or society at large;

Or. en

Amendment 1532

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 – point g b (new)

Text proposed by the Commission

Amendment

(g b) the extent of human oversight and the possibility for a human to intercede in order to override a decision or recommendations that may lead to potential harm;

Or. en

Amendment 1533

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 – point g c (new)

Text proposed by the Commission

Amendment

(g c) the magnitude and likelihood of benefit of the deployment of the AI system for industry, individuals, or society at large;

Or. en

Amendment 1534

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 – point g d (new)

Text proposed by the Commission

Amendment

(g d) the reticence risk and/or opportunity costs of not using the AI system for industry, individuals, or society at large;

Or. en

Amendment 1535

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 – point g e (new)

Text proposed by the Commission

Amendment

(g e) the amount and nature of data processed;

Or. en

Amendment 1536

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 – point g f (new)

Text proposed by the Commission

Amendment

(g f) the benefits provided by the use of the AI system, including making products safer;

Or. en

Amendment 1537

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

Proposal for a regulation

Article 7 – paragraph 2 – point h

Text proposed by the Commission

Amendment

(h) the extent to which existing Union legislation provides for: *deleted*

(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 1538

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Moritz Körner, Ondej Kováčik, Jan-Christoph Oetjen

Proposal for a regulation

Article 7 – paragraph 2 – point h – introductory part

Text proposed by the Commission

Amendment

(h) the extent to which existing Union legislation provides for:

(h) the extent to which existing Union legislation, *in particular the GDPR*, provides for:

Or. en

Amendment 1539

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 7 – paragraph 2 – point h – introductory part

Text proposed by the Commission

Amendment

(h) the extent to which existing Union legislation provides for:

(h) the extent to which existing Union legislation, *in particular GDPR*, provides for:

Or. en

Amendment 1540

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 7 – paragraph 2 – point h – introductory part

Text proposed by the Commission

(h) the extent to which existing Union legislation *provides for*:

Amendment

(h) the extent to which existing Union legislation *lacks*:

Or. en

Amendment 1541

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 7 – paragraph 2 – point h – point i

Text proposed by the Commission

(i) effective measures of redress in relation to the risks posed by an AI system, *with the exclusion of* claims for damages;

Amendment

(i) effective measures of redress, *the availability of redress-by-design mechanisms and procedures* in relation to the risks posed by an AI system, *including* claims for *material and non-material* damages;

Or. en

Amendment 1542

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

Proposal for a regulation

Article 7 – paragraph 2 – point h – point i

Text proposed by the Commission

(i) effective measures of redress in relation to the ***risks posed*** by an AI system, with the exclusion of claims for damages;

Amendment

(i) effective measures of redress in relation to the ***damage caused*** by an AI system, with the exclusion of claims for ***direct or indirect*** damages;

Or. en

Amendment 1543

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 7 – paragraph 2 – point h a (new)

Text proposed by the Commission

Amendment

(h a) The general capabilities and functionalities of the AI system independent of its foreseeable use;

Or. en

Amendment 1544

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 7 – paragraph 2 – point h b (new)

Text proposed by the Commission

Amendment

(h b) The extent of the availability and use of demonstrated technical solutions and mechanisms for the control, reliability and corrigibility of the AI system;

Or. en

Amendment 1545

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 7 – paragraph 2 – point h c (new)

Text proposed by the Commission

Amendment

(h c) The potential misuse and malicious use of the AI system and of the technology underpinning it.

Or. en

Amendment 1546

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

Proposal for a regulation

Article 7 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 bis. Lorsqu'elle évalue un système d'I.A. aux fins du paragraphe 1, la Commission consulte, le cas échéant, des autorités et organismes nationaux et européens, des représentants des groupes concernés par ledit système d'I.A., des professionnels du secteur, des experts indépendants et des organisations de la société civile. La Commission est à cet égard tenue d'organiser des consultations publiques.

Or. fr

Amendment 1547

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

Proposal for a regulation

Article 7 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. When carrying out the assessment referred to in paragraph 1 the Commission shall consult, where relevant, representatives of groups on which an AI system has an impact, stakeholders,

independent experts and civil society organisations. The Commission shall organise public consultations in this regard.

Or. en

Amendment 1548

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The Commission may remove AI systems from the list in Annex III if the conditions referred to in paragraph 1 are no longer met.

Or. en

Amendment 1549

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ondej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 7 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The Commission shall provide a transitional period of at least 24 months following each update of Annex III.

Or. en

Amendment 1550

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2 b. The Board, notified bodies and other actors may request the Commission to reassess an AI system. The AI system shall then be reviewed for reassessment and may be re-categorized. The Commission shall give reasons for its decision and publish the reasons. The details of the application procedure shall be laid down by the Commission by means of delegated acts in accordance with Article 73.

Or. en

Amendment 1551

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

Proposal for a regulation

Article 7 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2 ter. La Commission publie un rapport détaillé sur l'évaluation visée au paragraphe 2.

Or. fr

Amendment 1552

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

Proposal for a regulation

Article 7 – paragraph 2 c (new)

Text proposed by the Commission

Amendment

2 quater. La Commission consulte le Comité avant d'adopter des actes délégués conformément au paragraphe 1.

Or. fr

Amendment 1553

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

Proposal for a regulation

Article 8 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall comply with the requirements established in this Chapter.

Amendment

1. High-risk AI systems shall comply with the requirements established in this Chapter *throughout the entire lifecycle of the AI system. This includes their placing on the market as well as their deployment and use. Providers and deployers of AI systems shall ensure compliance by establishing technical and operational measures in line with this Chapter.*

Or. en

Amendment 1554

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

Proposal for a regulation

Article 8 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall comply with the requirements established in this Chapter.

Amendment

1. High-risk AI systems shall comply with the requirements established in this Chapter, *taking into account the generally acknowledged state of the art and industry standards, including as reflected in relevant harmonised standards or common specifications.*

Or. en

Amendment 1555

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova įk, Jan-Christoph Oetjen

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall comply with the requirements established in this Chapter.

Amendment

1. High-risk AI systems shall comply with the requirements established in this Chapter, *taking into account the generally acknowledged state of the art, including as reflected in relevant harmonised standards or common specifications.*

Or. en

Amendment 1556
Geoffroy Didier

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall comply with the requirements established in this Chapter.

Amendment

1. High-risk AI systems shall comply with the requirements established in this Chapter, *taking into account the generally acknowledged state of the art and industry standards, including as reflected in relevant harmonised standards or common specifications.*

Or. en

Justification

The above language has been suggested by the French Presidency and would better reflect the constant development of best practices and industry standards in the field of AI.

Moreover, it is important to clarify that the compliance with the requirements of the Draft Regulation should build upon the risk-based approach of the proposal itself, therefore the compliance obligations and risk assessment should be modulated on the basis of the specific high-risk AI use case and risk posed.

Amendment 1557
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall comply with the requirements established in this Chapter.

Amendment

1. High-risk AI systems shall comply with the *essential* requirements established in this Chapter, *taking into account the generally acknowledged state of the art, including as reflected in relevant industry and harmonised standards.*

Or. en

Amendment 1558

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituța, Michal Šimečka

Proposal for a regulation

Article 8 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall comply with the requirements established in this Chapter.

Amendment

1. ***1. Operators*** of high-risk AI systems shall comply with the requirements established in this Chapter.

Or. en

Amendment 1559

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituța

Proposal for a regulation

Article 8 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

I a. In complying with the requirements established in this Chapter, operators of high-risk AI systems shall take into account the generally-acknowledged state of the art, including as reflected in the relevant harmonised standards and common specifications referenced in Articles 40 and 41.

Or. en

Amendment 1560

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

Proposal for a regulation

Article 8 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

I a. Where a deployer discovers non-compliance of a high-risk AI system with this regulation during reasonably foreseeable use, the deployer shall have the right to obtain the necessary modifications from the provider to the high-risk AI system.

Or. en

Amendment 1561

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

Proposal for a regulation

Article 8 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

I b. Prospective deployers of high-risk AI systems shall have certified third parties assess and confirm the conformity of the AI system and its use with this Regulation and relevant applicable Union legislation before putting it into use. The conformity certificate shall be uploaded to the database pursuant to Article 60.

Or. en

Amendment 1562

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

Proposal for a regulation
Article 8 – paragraph 1 c (new)

Text proposed by the Commission

Amendment

I c. Where personal data is processed or is expected to be processed in the use of a high-risk AI system, this shall be understood as constituting a high risk in the meaning of Article 35 of Regulation (EU) 2016/679.

Or. en

Amendment 1563
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission

Amendment

2. The intended purpose of the high-risk AI system and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.

2. The intended purpose of the high-risk AI system, *the foreseeable uses and foreseeable misuses of AI systems with indeterminate uses* and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.

Or. en

Amendment 1564
Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission

Amendment

2. The *intended purpose* of the high-risk AI system and the risk management system referred to in Article 9 shall be taken into account when ensuring

2. The *foreseeable uses and foreseeable misuses of AI systems with indeterminate uses* of the high-risk AI system and the risk management system

compliance with those requirements.

referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.

Or. en

Amendment 1565

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

Proposal for a regulation

Article 8 – paragraph 2

Text proposed by the Commission

2. The intended purpose of the high-risk AI system and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.

Amendment

2. The intended purpose, *the potential or reasonably foreseeable use or misuse* of the high-risk AI system and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.

Or. en

Amendment 1566

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 8 – paragraph 2

Text proposed by the Commission

2. The intended purpose of the high-risk AI system and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.

Amendment

2. The intended purpose, *reasonably foreseeable uses and foreseeable misuses* of the high-risk AI system and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.

Or. en

Amendment 1567

Geoffroy Didier

Proposal for a regulation Article 8 – paragraph 2

Text proposed by the Commission

2. The intended purpose of the high-risk AI system and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with **those** requirements.

Amendment

2. The intended purpose of the high-risk AI system and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with **the relevant** requirements **depending on the type of risks posed.**

Or. en

Justification

The above language has been suggested by the French Presidency and would better reflect the constant development of best practices and industry standards in the field of AI. Moreover, it is important to clarify that the compliance with the requirements of the Draft Regulation should build upon the risk-based approach of the proposal itself, therefore the compliance obligations and risk assessment should be modulated on the basis of the specific high-risk AI use case and risk posed.

Amendment 1568

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation Article 8 – paragraph 2

Text proposed by the Commission

2. The intended purpose of the high-risk AI system and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.

Amendment

2. The intended purpose **or** **reasonably foreseeable use** of the high-risk AI system and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.

Or. en

Amendment 1569

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 8 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. AI systems referred to in Article 6 may be wholly or partially exempted from fulfilling the requirements referred to in Articles 8-15 if risks posed by the AI systems are sufficiently eliminated or mitigated through appropriate operational countermeasures or built-in fail-safe systems.

Or. en

Amendment 1570

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 8 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. This article shall not apply where the content forms part of an evidently artistic, creative, satirical, fictional or analogous work or programme.

Or. en

Amendment 1571

Morten Løkkegaard

Proposal for a regulation

Article 8 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. This article shall not apply where the content forms part of an evidently artistic, creative, satirical, fictional and analogous work or programme.

Or. en

Amendment 1572

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tefnută, Ramona Strugariu, Drago Pîslaru, Lucia Ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation**Article 9 – paragraph 1**

Text proposed by the Commission

1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.

Amendment

1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems. *The risk management system can be integrated into, or a part of, already existing risk management procedures insofar as it fulfils the requirements of this article.*

Or. en

Amendment 1573

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation**Article 9 – paragraph 1**

Text proposed by the Commission

1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.

Amendment

1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems, *unless the AI system is covered by New Legislative Framework (NLF) legislation.*

Or. en

Amendment 1574

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation**Article 9 – paragraph 1**

Text proposed by the Commission

Amendment

1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.

1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems *if this system poses a risk of harm to health and safety or a risk of adverse impacts on fundamental rights.*

Or. en

Amendment 1575

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ondej Kováčik, Jan-Christoph Oetjen

Proposal for a regulation Article 9 – paragraph 1

Text proposed by the Commission

1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.

Amendment

1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems *and its risks identified in the risk assessment referred to in Art. 6a.*

Or. en

Amendment 1576

Marion Walsmann

Proposal for a regulation Article 9 – paragraph 1

Text proposed by the Commission

1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.

Amendment

1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems *or be included in existing risk management procedures.*

Or. en

Amendment 1577

Kateina Konevá, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission

1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.

Amendment

1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems, ***throughout the entire lifecycle of the AI system.***

Or. en

Amendment 1578

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

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission

1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.

Amendment

1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems ***throughout the entire lifecycle of the AI system.***

Or. en

Amendment 1579

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 9 – paragraph 2 – introductory part

Text proposed by the Commission

2. The risk management system shall consist of a continuous iterative process run throughout the entire *lifecycle* of a high-risk AI system, requiring regular ***systematic updating***. It shall comprise the following steps:

Amendment

2. The risk management system shall consist of a continuous iterative process run throughout the entire *lifetime* of a high-risk AI system, requiring regular ***review of the suitability of the risk management process to ensure its continuing effectiveness, and documentation of any***

decisions and actions taken. It shall comprise the following steps *and all of these steps shall be integrated into already existing risk management procedures relating to the relevant Union sectoral legislation to avoid unnecessary bureaucracy:*

Or. en

Amendment 1580

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 9 – paragraph 2 – introductory part

Text proposed by the Commission

2. The risk management system shall consist of a continuous iterative process run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic updating. It shall comprise the following steps:

Amendment

2. The risk management system shall consist of a continuous iterative process run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic *review and updating, including when the high-risk AI system is subject to significant changes in its design or purpose.* It shall comprise the following steps:

Or. en



*Committee on the Internal Market and Consumer Protection
Committee on Civil Liberties, Justice and Home Affairs*

2021/0106(COD)

13.6.2022

AMENDMENTS

1581 - 2005

Draft report
Brando Benifei, Drago 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))

AM_Com_LegReport

Amendment 1581

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

Proposal for a regulation**Article 9 – paragraph 2 – introductory part***Text proposed by the Commission*

2. The risk management system shall consist of a continuous iterative process run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic updating. It shall comprise the following steps:

Amendment

2. The risk management system shall consist of a continuous iterative process run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic ***review and*** updating. It shall comprise the following steps:

Or. en

Amendment 1582

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation**Article 9 – paragraph 2 – point a***Text proposed by the Commission*

(a) identification and analysis of the known and foreseeable risks ***associated with each*** high-risk AI system;

Amendment

(a) identification and analysis of the known and ***the reasonably*** foreseeable risks ***that the*** high-risk AI system, ***and AI systems with indeterminate uses can pose to:***

- (i) the health or safety of natural persons;***
- (ii) the legal rights or legal status of natural persons;***
- (iii) the fundamental rights of natural persons;***
- (iv) the equal access to services and opportunities of natural persons;***
- (v) the Union values enshrined in Article 2 TEU;***
- (vi) society at large and the environment.***

Or. en

Amendment 1583

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

Proposal for a regulation

Article 9 – paragraph 2 – point a

Text proposed by the Commission

(a) identification and analysis of the known and foreseeable risks *associated with each* high-risk AI system;

Amendment

(a) identification and analysis of the known and *the reasonably* foreseeable risks *that the* high-risk AI system, *and AI systems with indeterminate uses, can pose to:*

- (i) the health or safety of natural persons;*
- (ii) the legal rights or legal status of natural persons;*
- (iii) the fundamental rights;*
- (iv) the equal access to services and opportunities of natural persons;*
- (v) the Union values enshrined in Article 2 TEU.*

Or. en

Amendment 1584

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Mituță, Ramona Strugariu, Drago Pîslaru, Lucia Šuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 9 – paragraph 2 – point a

Text proposed by the Commission

(a) identification and analysis of the known and foreseeable risks associated with each high-risk AI system;

Amendment

(a) identification and analysis of the known and *reasonably* foreseeable risks associated with each high-risk AI system *with respect to health, safety, fundamental rights, and the values of the Union as enshrined in Article 2 TEU;*

Or. en

Amendment 1585

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 2 – point a

Text proposed by the Commission

- (a) identification and analysis of the known and foreseeable risks *associated with each* high-risk AI system;

Amendment

- (a) identification and analysis of the known and *reasonable* foreseeable risks *of harms most likely to occur to the health, safety or fundamental rights in view of the intended purpose of the* high-risk AI system;

Or. en

Amendment 1586

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

Proposal for a regulation

Article 9 – paragraph 2 – point a

Text proposed by the Commission

- (a) identification and analysis of the known and foreseeable risks associated with each high-risk AI system;

Amendment

- (a) identification and analysis of the known and foreseeable risks associated with each high-risk AI system, *including by means of a fundamental rights impact assessment as provided for in Article 9a;*

Or. en

Amendment 1587

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

Proposal for a regulation

Article 9 – paragraph 2 – point a

Text proposed by the Commission

- (a) identification and analysis of the known and foreseeable risks *associated with each* high-risk AI system;

Amendment

- (a) identification and analysis of the known and foreseeable risks *most likely to occur to health, safety and fundamental*

rights in view of the intended purpose of the high-risk AI system;

Or. en

Amendment 1588

Marion Walsmann

Proposal for a regulation

Article 9 – paragraph 2 – point a

Text proposed by the Commission

- (a) identification and analysis of the known and foreseeable risks associated with each high-risk AI system;

Amendment

- (a) identification and analysis of the known and foreseeable risks ***to the health and safety or fundamental rights of a person*** associated with each high-risk AI system;

Or. en

Amendment 1589

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

Proposal for a regulation

Article 9 – paragraph 2 – point a a (new)

Text proposed by the Commission

Amendment

(a bis) Les risques, les préjudices et les dommages effectivement réalisés dans le passé par le système d'I.A. à haut risque, qu'ils soient résultés de l'utilisation du système d'I.A. à haut risque conformément à sa destination ou d'une autre utilisation;

Or. fr

Amendment 1590

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

Proposal for a regulation
Article 9 – paragraph 2 – point a a (new)

Text proposed by the Commission

Amendment

(a a) evaluation of how the principles of Article 4a are adhered to;

Or. en

Amendment 1591

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ondej Kováčik, Jan-Christoph Oetjen

Proposal for a regulation
Article 9 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse;

deleted

Or. en

Amendment 1592

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 9 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse;

deleted

Or. en

Amendment 1593

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 9 – paragraph 2 – point b

Text proposed by the Commission

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse;

Amendment

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose ***or reasonably foreseeable use*** and under conditions of reasonably foreseeable misuse;

Or. en

Amendment 1594

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 9 – paragraph 2 – point b

Text proposed by the Commission

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse;

Amendment

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose ***or reasonably foreseeable use*** and under conditions of reasonably foreseeable misuse;

Or. en

Amendment 1595

Marion Walsmann

Proposal for a regulation

Article 9 – paragraph 2 – point b

Text proposed by the Commission

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its

Amendment

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its

intended purpose *and under conditions of reasonably foreseeable misuse*;

intended purpose;

Or. en

Amendment 1596

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

Proposal for a regulation

Article 9 – paragraph 2 – point b

Text proposed by the Commission

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse;

Amendment

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable *use or* misuse;

Or. en

Amendment 1597

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 2 – point c

Text proposed by the Commission

(c) evaluation of *other possibly arising* risks based on the analysis of data gathered from the post-market monitoring system referred to in Article 61;

Amendment

(c) evaluation of *new risks consistent with those described in paragraph (2a) of this Article and identified* based on the analysis of data gathered from the post-market monitoring system referred to in Article 61;

Or. en

Amendment 1598

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

Proposal for a regulation

Article 9 – paragraph 2 – point c

Text proposed by the Commission

(c) evaluation of **other possibly** arising risks based on the analysis of data gathered from the post-market monitoring system referred to in Article 61;

Amendment

(c) evaluation of **new** arising **significant** risks based on the analysis of data gathered from the post-market monitoring system referred to in Article 61;

Or. en

Amendment 1599

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

Proposal for a regulation

Article 9 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(c bis) L'expérimentation en bac à sable du fonctionnement des systèmes d'I.A.;

Or. fr

Amendment 1600

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 2 – point d

Text proposed by the Commission

Amendment

(d) adoption of **suitable** risk management measures in accordance with the provisions of the following paragraphs.

(d) adoption of **appropriate and targeted** risk management measures **designed to address identified known and foreseeable risks to health and safety or fundamental rights**, in accordance with the provisions of the following paragraphs.

Or. en

Amendment 1601

**Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto ,
Moritz Körner, Jan-Christoph Oetjen**

Proposal for a regulation

Article 9 – paragraph 2 – point d

Text proposed by the Commission

(d) adoption of *suitable* risk management measures in accordance with the provisions of the following paragraphs.

Amendment

(d) adoption of *appropriate and targeted* risk management measures *to address identified significant risks* in accordance with the provisions of the following paragraphs.

Or. en

Amendment 1602

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

Proposal for a regulation

Article 9 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The risks referred to in paragraph 2 shall concern only those which may be reasonably mitigated or eliminated through the development or design of the high-risk AI system, or the provision of adequate technical information.

Or. en

Amendment 1603

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 3

Text proposed by the Commission

Amendment

3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible interactions resulting from the

3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible interactions resulting from the

combined application of the requirements set out in this Chapter 2. They shall take into account the generally acknowledged state of the art, including as reflected in relevant harmonised standards *or common specifications*.

combined application of the requirements set out in this Chapter 2, *with a view to treating risks effectively while ensuring an appropriate and proportionate implementation of the requirements*. They shall take into account the generally acknowledged state of the art, including as reflected in relevant harmonised standards.

Or. en

Amendment 1604

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

Proposal for a regulation

Article 9 – paragraph 3

Text proposed by the Commission

3. Les mesures de gestion des risques visées au paragraphe 2, point d), tiennent dûment compte des effets et des interactions possibles résultant de l’application combinée des exigences énoncées dans le présent chapitre 2. Elles prennent en considération l’état de la technique généralement reconnu, notamment tel qu’il ressort des normes harmonisées *ou des spécifications communes* pertinentes.

Amendment

3. Les mesures de gestion des risques visées au paragraphe 2, point d), tiennent dûment compte des effets et des interactions possibles résultant de l’application combinée des exigences énoncées dans le présent chapitre 2. Elles prennent en considération l’état de la technique généralement reconnu, notamment tel qu’il ressort des *spécifications techniques communes adoptées par la Commission ou des normes harmonisées* pertinentes.

Or. fr

Amendment 1605

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

Proposal for a regulation

Article 9 – paragraph 3

Text proposed by the Commission

3. The risk management measures referred to in paragraph 2, point (d) shall

Amendment

3. The risk management measures referred to in paragraph 2, point (d) shall

give due consideration to the effects and possible interactions resulting from the combined application of the requirements set out in this Chapter 2. ***They shall take into account the generally acknowledged state of the art, including as reflected in relevant harmonised standards or common specifications.***

give due consideration to the effects and possible interactions resulting from the combined application of the requirements set out in this Chapter 2, ***with a view to minimising risks more effectively while achieving an appropriate balance in implementing the measures to fulfil those requirements.***

Or. en

Amendment 1606

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

Proposal for a regulation

Article 9 – paragraph 3

Text proposed by the Commission

3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible interactions resulting from the combined application of the requirements set out in this Chapter 2. They shall take into account the ***generally acknowledged*** state of the art, including as reflected in relevant harmonised standards or common specifications.

Amendment

3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible interactions resulting from the combined application of the requirements set out in this Chapter 2. They shall take into account the state of the art, including as reflected in relevant harmonised standards or common specifications.

Or. en

Amendment 1607

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan, Vincenzo Sofo

Proposal for a regulation

Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. The risk management measures referred to in paragraph 2, point (d) shall be such that ***any residual risk associated with each hazard as well as*** the overall residual risk of the high-risk AI systems is

Amendment

4. The risk management measures referred to in paragraph 2, point (d) shall be such that the overall residual risk of the high-risk AI systems is ***reasonably judged to be acceptable, having regard to the***

judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user.

benefits that the high-risk AI system is reasonably expected to deliver and, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, subject to terms, conditions as made available by the provider, and contractual and license restrictions. Those residual risks shall be communicated to the user.

Or. en

Amendment 1608

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

Proposal for a regulation

Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. Les mesures de gestion des risques visées au paragraphe 2, point d), sont telles que tout risque résiduel associé à chaque danger ainsi que le risque résiduel global lié aux systèmes d'IA à haut risque sont *jugés acceptables, à condition que le système d'IA à haut risque soit utilisé conformément à sa destination ou dans des conditions de mauvaise utilisation raisonnablement prévisible. L'utilisateur est informé de ces risques résiduels.*

Amendment

4. Les mesures de gestion des risques visées au paragraphe 2, point d), sont telles que tout risque résiduel associé à chaque danger ainsi que le risque résiduel global lié aux systèmes d'IA à haut risque sont :

Or. fr

Amendment 1609

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ondej Kováč, Jan-Christoph Oetjen

Proposal for a regulation

Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. The risk management measures

Amendment

4. The risk management measures

referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user.

referred to in paragraph 2, point (d) shall be such that any residual **significant** risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is **reasonably judged to be** acceptable, **having regard to the benefits that the high-risk AI system is reasonably expected to deliver and** provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual **significant** risks shall be communicated to the user.

Or. en

Amendment 1610

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

Proposal for a regulation

Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the *user*.

Amendment

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks **and the reasoned judgements made** shall be communicated to the **deployer and made available to AI subjects**.

Or. en

Amendment 1611

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any **residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems** is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. **Those** residual risks shall be communicated to the user.

Amendment

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any **significant** residual risk of the high-risk AI systems is **reasonably judged to be** acceptable, **having regards to the benefits that the high-risk AI system is reasonably expected to deliver and** provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. **Significant** residual risks shall be communicated to the user.

Or. en

Amendment 1612

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user.

Amendment

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or **reasonably foreseeable use or** under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user.

Or. en

Amendment 1613

Marion Walsmann

Proposal for a regulation

Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose *or under conditions of reasonably foreseeable misuse*. Those residual risks shall be communicated to the user.

Amendment

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose. Those residual risks shall be communicated to the user.

Or. en

Amendment 1614

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tefnută, Ramona Strugariu, Drago Pîslaru, Lucia Ūriš Nicholsonová, Irena Joveva, Malik Azmani, Andrus Ansip, Dita Charanzová, Alin Mituță

Proposal for a regulation

Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user.

Amendment

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any *relevant* residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user.

Or. en

Amendment 1615

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 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user.

Amendment

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable **use or** misuse. Those residual risks shall be communicated to the user.

Or. en

Amendment 1616

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – introductory part

Text proposed by the Commission

In identifying the most appropriate risk management measures, the following shall be **ensured**:

Amendment

In identifying the most appropriate risk management measures, the following shall be **taken into account**:

Or. en

Amendment 1617

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – introductory part

Text proposed by the Commission

In identifying **the most** appropriate risk management measures, the following shall be **ensured**:

Amendment

In identifying appropriate risk management measures, the following **outcomes** shall be **pursued**:

Or. en

Amendment 1618

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point a

Text proposed by the Commission

- (a) ***elimination or*** reduction of risks as far as possible through adequate design and development;

Amendment

- (a) reduction of ***identified and evaluated*** risks as far as ***proportionate and technologically possible in light of the generally acknowledged state of the art and industry standards***, through adequate design and development ***of the high risk AI system in question***;

Or. en

Amendment 1619

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point a

Text proposed by the Commission

- (a) elimination or reduction of risks as far as possible through adequate design and development;

Amendment

- (a) elimination or reduction of risks as far as possible through adequate design and development ***involving relevant domain and other experts and internal and external stakeholders, including but not limited to representative bodies and the social partners***;

Or. en

Amendment 1620

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point a

Text proposed by the Commission

- (a) elimination or reduction of risks as

Amendment

- (a) elimination or reduction of risks as

far as **possible** through **adequate** design and development;

far as **commercially reasonable and technologically feasible in light of the generally acknowledged state of the art**, through **appropriate** design and development **measures**;

Or. en

Amendment 1621

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point a

Text proposed by the Commission

(a) elimination or reduction of risks as far as **possible** through adequate design and development;

Amendment

(a) elimination or reduction of **identified and evaluated** risks as far as **economically and technologically feasible** through adequate design and development **of the high-risk AI system**;

Or. en

Amendment 1622

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

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point a

Text proposed by the Commission

(a) **elimination or** reduction of risks as far as **possible** through adequate design and development;

Amendment

(a) reduction of **identified and evaluated** risks as far as **commercially reasonable and technologically feasable** through adequate design and development;

Or. en

Amendment 1623

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

Proposal for a regulation
Article 9 – paragraph 4 – subparagraph 1 – point b

Text proposed by the Commission

Amendment

(b) *where appropriate, implementation of adequate mitigation and control measures in relation to risks that cannot be eliminated;* *deleted*

Or. en

Amendment 1624

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation
Article 9 – paragraph 4 – subparagraph 1 – point b

Text proposed by the Commission

Amendment

(b) where appropriate, implementation of adequate mitigation and control measures in relation to risks that cannot be eliminated;

(b) where appropriate, implementation of adequate mitigation and control measures in relation to *significant* risks that cannot be eliminated;

Or. en

Amendment 1625

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

Proposal for a regulation
Article 9 – paragraph 4 – subparagraph 1 – point b

Text proposed by the Commission

Amendment

(b) where appropriate, implementation of adequate mitigation and control measures *in relation to* risks that cannot be eliminated;

(b) where appropriate, implementation of adequate mitigation and control measures *addressing* risks that cannot be eliminated;

Or. en

Amendment 1626

Vincenzo Sofo, Kosma Złotowski

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point c

Text proposed by the Commission

(c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point (b) of this Article, and, where appropriate, training **to users**.

Amendment

(c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point (b) of this Article, and, where appropriate, **and relevant information on necessary competence training and authority for natural persons exercising such oversight**.

Or. en

Amendment 1627

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point c

Text proposed by the Commission

(c) provision of adequate information pursuant to Article 13, **in particular as regards the risks referred to in paragraph 2, point (b) of this Article**, and, where appropriate, training to users.

Amendment

(c) provision of adequate information pursuant to Article 13 and, where appropriate, training to users.

Or. en

Amendment 1628

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point c

Text proposed by the Commission

(c) provision of adequate information pursuant to Article 13, **in particular as**

Amendment

(c) provision of **the required** adequate information pursuant to Article 13 of this

regards the risks referred to in paragraph 2, point (b) of this Article, and, where appropriate, training to users.

Article, and, where appropriate, training to users.

Or. en

Amendment 1629

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point c

Text proposed by the Commission

(c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point (b) of this Article, and, where appropriate, training to users.

Amendment

(c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point (a) *and* (b) of this Article, and, where appropriate, training to users.

Or. en

Amendment 1630

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

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point c

Text proposed by the Commission

(c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point (b) of this Article, and, where appropriate, training to *users*.

Amendment

(c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point (b) of this Article, and, where appropriate, training to *deployers*.

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

Or. en

Amendment 1631

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

Proposal for a regulation**Article 9 – paragraph 4 – subparagraph 1 – point c a (new)**

Text proposed by the Commission

Amendment

(c a) the governance structures to mitigate risks.

Or. en

Amendment 1632

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

Proposal for a regulation**Article 9 – paragraph 4 – subparagraph 2**

Text proposed by the Commission

Amendment

In eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, training to be expected by the ***user and the environment*** in which the system is intended to be used.

In eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, training to be expected by the ***deployer, to the socio-technical context*** in which the system is intended to be used, ***and to reasonably foreseeable use or misuse.***

Or. en

Amendment 1633

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 9 – paragraph 4 – subparagraph 2**

Text proposed by the Commission

Amendment

In eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, training to be expected by the user and the environment in which the system is intended to be used.

In eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, training to be expected by the user and the environment in which the system is intended *or reasonably foreseeable* to be used.

Or. en

Amendment 1634

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 2

Text proposed by the Commission

In *eliminating or reducing* risks related to the use of the high-risk AI system, due consideration *shall be given to* the technical knowledge, experience, education, training *to be expected by* the user *and* the environment in which the system is intended to be used.

Amendment

In *seeking to reduce* risks related to the use of the high-risk AI system, *providers shall take into* due consideration the technical knowledge, experience, education, training the user *may need, including in relation to* the environment in which the system is intended to be used.

Or. en

Amendment 1635

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 2

Text proposed by the Commission

In *eliminating or reducing* risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, training to be expected by the user and the environment in which the system is intended to be used.

Amendment

In *seeking to eliminate or reduce* risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, training to be expected by the user and the environment in which the system is intended to be used.

Or. en

Amendment 1636

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

Proposal for a regulation

Article 9 – paragraph 4 – point a (new)

Text proposed by the Commission

Amendment

(a) techniquement et structurellement minimisés par le système d'I.A. à haut risque;

Or. fr

Amendment 1637

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

Proposal for a regulation

Article 9 – paragraph 4 – point b (new)

Text proposed by the Commission

Amendment

(b) jugés acceptables, à condition que le système d'I.A. à haut risque soit utilisé conformément à sa destination ou dans des conditions de mauvaise utilisation raisonnablement prévisibles.

Or. fr

Amendment 1638

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

Proposal for a regulation

Article 9 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 bis. L'utilisateur est informé de ces risques résiduels.

Amendment 1639

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ondej Kováč, Jan-Christoph Oetjen

Proposal for a regulation

Article 9 – paragraph 5

Text proposed by the Commission

5. High-risk AI systems shall be *tested* for the purposes of identifying the most appropriate risk management measures. **Testing** shall ensure that high-risk AI systems perform consistently for their intended purpose and they are in compliance with the requirements set out in this Chapter.

Amendment

5. High-risk AI systems shall be *evaluated* for the purposes of identifying the most appropriate *and targeted* risk management measures *and weighing any such measures against the potential benefits and intended goals of the system*. **Evaluations** shall ensure that high-risk AI systems perform consistently for their intended purpose and they are *in compliance* with the *relevant* requirements set out in this Chapter.

Amendment 1640

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 9 – paragraph 5

Text proposed by the Commission

5. High-risk AI systems shall be tested for the purposes of identifying ***the most*** appropriate risk management measures. Testing shall ensure that high-risk AI systems perform ***consistently for*** their intended purpose and they are in compliance with the requirements set out in this Chapter.

Amendment

5. High-risk AI systems shall be tested for the purposes of identifying appropriate risk management measures *for the specific scenario in which the system will be operating and to ensure that a system is performing appropriately for a given use case*. Testing shall ensure that high-risk AI systems perform ***in a manner that is consistent with*** their intended purpose and they are in compliance with the requirements set out in this Chapter.

Amendment 1641

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 5

Text proposed by the Commission

5. High-risk AI systems shall be **tested** for the purposes of identifying the most appropriate risk management measures. **Testing** shall ensure that high-risk AI systems perform consistently for their intended purpose and they are in compliance with the requirements set out in this Chapter.

Amendment

5. High-risk AI systems shall be **evaluated** for the purposes of identifying the most appropriate **and targeted** risk management measures **and weighing any such measures against the potential benefits and intended goals of the system**. **Evaluations** shall ensure that high-risk AI systems perform consistently for their intended purpose and they are in compliance with the **relevant** requirements set out in this Chapter.

Or. en

Amendment 1642

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

Proposal for a regulation

Article 9 – paragraph 5

Text proposed by the Commission

5. High-risk AI systems shall be tested for the purposes of identifying the most appropriate risk management measures. Testing shall ensure that high-risk AI systems perform consistently **for their intended purpose** and they are in compliance with the requirements set out in this Chapter.

Amendment

5. High-risk AI systems shall be tested for the purposes of identifying the most appropriate risk management measures. Testing shall ensure that high-risk AI systems perform consistently, **safely during reasonably foreseeable conditions of use or misuse**, and they are in compliance with the requirements set out in this Chapter.

Or. en

Amendment 1643

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

**Proposal for a regulation
Article 9 – paragraph 5**

Text proposed by the Commission

5. High-risk AI systems shall be *tested* for the purposes of identifying the most appropriate risk management measures. *Testing shall ensure that high-risk AI systems perform consistently for their intended purpose and they are in compliance with the requirements set out in this Chapter.*

Amendment

5. High-risk AI systems shall be *evaluated* for the purposes of identifying the most appropriate *and targeted* risk management measures *and weighing any such measures against the potential benefits and intended goals of the system.*

Or. en

Amendment 1644

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Article 9 – paragraph 5**

Text proposed by the Commission

5. High-risk AI systems shall be tested for the purposes of identifying the most appropriate risk management measures. Testing shall ensure that high-risk AI systems perform consistently for their intended purpose and they are in compliance with the requirements set out in this Chapter.

Amendment

5. High-risk AI systems shall be tested for the purposes of identifying the most appropriate risk management measures. Testing shall ensure that high-risk AI systems perform consistently for their intended purpose *or reasonably foreseeable use* and they are in compliance with the requirements set out in this Chapter.

Or. en

Amendment 1645

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

**Proposal for a regulation
Article 9 – paragraph 6**

Text proposed by the Commission

Amendment

6. Testing procedures shall be suitable to achieve the intended purpose of the AI system and do not need to go beyond what is necessary to achieve that purpose.

deleted

Or. en

Amendment 1646

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

Proposal for a regulation

Article 9 – paragraph 6

Text proposed by the Commission

Amendment

6. Les procédures de test sont appropriées pour remplir la destination du système *d'IA et ne doivent pas aller au-delà de ce qui est nécessaire pour atteindre cet objectif.*

6. Les procédures de test sont appropriées pour remplir la destination du système *d'IA.*

Or. fr

Amendment 1647

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 9 – paragraph 6

Text proposed by the Commission

Amendment

6. Testing procedures shall be suitable to achieve the intended purpose of the AI system and do not need to go beyond what is necessary to achieve that purpose.

6. Testing procedures shall be suitable to achieve the intended purpose *or reasonably foreseeable use* of the AI system and do not need to go beyond what is necessary to achieve that purpose.

Or. en

Amendment 1648

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 9 – paragraph 6**

Text proposed by the Commission

6. Testing procedures shall be suitable to achieve the intended purpose of the AI system ***and do not need to go beyond what is necessary to achieve that purpose.***

Amendment

6. ***Evaluation or*** testing procedures shall be suitable to achieve the intended purpose of the AI system.

Or. en

Amendment 1649

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

Proposal for a regulation

Article 9 – paragraph 6 – subparagraph 1 (new)

Text proposed by the Commission

Amendment

Elles éprouvent :

Or. fr

Amendment 1650

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

Proposal for a regulation

Article 9 – paragraph 6 – point a (new)

Text proposed by the Commission

Amendment

(a) *la capacité du système d'I.A. à haut risque à générer un résultat exact et robuste;*

Or. fr

Amendment 1651

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

Garraud

Proposal for a regulation

Article 9 – paragraph 6 – point b (new)

Text proposed by the Commission

Amendment

(b) la fiabilité du système d'I.A. à haut risque et sa capacité à générer effectivement un résultat tel que celui attendu conformément à sa destination;

Or. fr

Amendment 1652

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

Proposal for a regulation

Article 9 – paragraph 6 – point c (new)

Text proposed by the Commission

Amendment

(c) la capacité structurelle et technique du système d'I.A. à haut risque à ne pas être détourné de son utilisation conformément à sa destination.

Or. fr

Amendment 1653

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 9 – paragraph 7

Text proposed by the Commission

Amendment

7. The testing of the high-risk AI systems shall be performed, *as appropriate, at any point in time throughout the development process, and, in any event*, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined

7. The testing of the high-risk AI systems shall be performed prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI

metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.

system.

Or. en

Amendment 1654

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

Proposal for a regulation

Article 9 – paragraph 7

Text proposed by the Commission

7. Les tests des systèmes d'IA à haut risque sont effectués, selon les besoins, à tout moment pendant le processus de développement et, en tout état de cause, avant la mise sur le marché ou la mise en service. Les tests sont effectués sur la base de métriques et de seuils probabilistes préalablement définis, qui sont adaptés à la destination du système d'IA à haut risque.

Amendment

7. Les tests des systèmes d'IA à haut risque sont effectués, selon les besoins, à tout moment pendant le processus de développement et, en tout état de cause, avant la mise sur le marché ou la mise en service. Les tests sont effectués sur la base de métriques et de seuils probabilistes préalablement définis *par des normes ou des spécifications techniques communes*, qui sont adaptés à la destination du système d'IA à haut risque.

Or. fr

Amendment 1655

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 9 – paragraph 7

Text proposed by the Commission

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI

Amendment

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended purpose *or reasonably*

system.

foreseeable use of the high-risk AI system.

Or. en

Amendment 1656

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

Proposal for a regulation

Article 9 – paragraph 7

Text proposed by the Commission

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended ***purpose*** of the high-risk AI system.

Amendment

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended ***use or reasonably foreseeable misuse*** of the high-risk AI system.

Or. en

Amendment 1657

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 7

Text proposed by the Commission

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against ***preliminarily*** defined metrics ***and*** probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.

Amendment

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against ***prior*** defined metrics, ***such as*** probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.

Amendment 1658

Kosma Złotowski, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 9 – paragraph 7

Text proposed by the Commission

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and ***probabilistic thresholds*** that are appropriate to the intended purpose of the high-risk AI system.

Amendment

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and ***rubrics*** that are appropriate to the intended purpose of the high-risk AI system.

Amendment 1659

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Morten Løkkegaard, Alin Mituță, Michal Šimečka

Proposal for a regulation

Article 9 – paragraph 8

Text proposed by the Commission

8. When implementing the risk management system described in paragraphs 1 to 7, specific consideration shall be given to whether the high-risk AI system is likely to be accessed by or have an impact on children.

Amendment

8. When implementing the risk management system described in paragraphs 1 to 7, specific consideration shall be given to whether the high-risk AI system is likely to be accessed by or have an impact on children ***or natural persons suffering from disabilities that render them legally unable to give their consent.***

Amendment 1660

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

Proposal for a regulation**Article 9 – paragraph 8***Text proposed by the Commission*

8. When implementing the risk management system described in paragraphs 1 to 7, specific consideration shall be given to whether the high-risk AI system is likely to **be accessed by or have an impact on children.**

Amendment

8. When implementing the risk management system described in paragraphs 1 to 7, specific consideration shall be given to whether the high-risk AI system is likely to:

Or. en

Justification

moved into subpoints

Amendment 1661

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation**Article 9 – paragraph 8***Text proposed by the Commission*

8. When implementing the risk management system described in paragraphs 1 to 7, specific consideration **shall be given** to whether the high-risk AI system is likely to be accessed by or have an impact on children.

Amendment

8. When implementing the risk management system described in paragraphs 1 to 7, **shall give** specific consideration to whether the high-risk AI system is likely to be accessed by or have an impact on children.

Or. en

Amendment 1662

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

Proposal for a regulation**Article 9 – paragraph 8 – point a (new)**

Text proposed by the Commission

Amendment

(a) adversely affect specific groups of people, in particular on the basis of gender, sexual orientation, age, ethnicity, disability, religion, socio-economic standing, religion or origin, including asylum seekers including migrants, refugees and asylum seekers;

Or. en

Amendment 1663

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

Proposal for a regulation

Article 9 – paragraph 8 – point b (new)

Text proposed by the Commission

Amendment

(b) have an adverse impact on the environment, or;

Or. en

Amendment 1664

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

Proposal for a regulation

Article 9 – paragraph 8 – point c (new)

Text proposed by the Commission

Amendment

(c) be implemented on children;

Or. en

Amendment 1665

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

Proposal for a regulation

Article 9 – paragraph 8 – point d (new)

Text proposed by the Commission

Amendment

(d) have an adverse effect on mental health, individual's behaviour;

Or. en

Amendment 1666

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

Proposal for a regulation

Article 9 – paragraph 8 – point e (new)

Text proposed by the Commission

Amendment

(e) amplify the spread of disinformation and amplify polarisation;

Or. en

Amendment 1667

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

Proposal for a regulation

Article 9 – paragraph 8 – point f (new)

Text proposed by the Commission

Amendment

(f) amplify the spread of disinformation and amplify polarisation;

Or. en

Amendment 1668

Kosma Złotowski, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 9 – paragraph 9

Text proposed by the Commission

Amendment

9. For *credit institutions regulated by Directive 2013/36/EU*, the aspects described in paragraphs 1 to 8 shall be part of the risk management procedures established by those institutions pursuant to Article 74 of that Directive.

9. For *AI systems already covered by Union law that requires a specific risk assessment*, the aspects described in paragraphs 1 to 8 may be incorporated into that risk assessment, without the need to conduct a separate, additional risk assessment in order to comply with this Article.

Or. en

Amendment 1669

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

Proposal for a regulation Article 9 – paragraph 9

Text proposed by the Commission

9. For *credit institutions regulated by Directive 2013/36/EU*, the aspects described in paragraphs 1 to 8 shall be part of the risk management procedures established by those institutions pursuant to Article 74 of that Directive.

Amendment

9. For *providers and AI systems already covered by Union law that require them to establish a specific risk management*, the aspects described in paragraphs 1 to 8 shall be part of the risk management procedures established by that Union law or deemed to be covered as part of it.

Or. en

Amendment 1670

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation Article 9 – paragraph 9

Text proposed by the Commission

9. For *credit institutions regulated by Directive 2013/36/EU*, the aspects described in paragraphs 1 to 8 shall be part of the risk management procedures established by those institutions pursuant to Article 74 of that Directive.

Amendment

9. For *AI systems already covered by Union law that require them to carry out specific risk assessments*, the aspects described in paragraphs 1 to 8 shall be combined with the risk assessment procedures established by that Union law or deemed to be covered as part of it.

Amendment 1671

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä, Sylwia Spurek

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 a (new)

Text proposed by the Commission

Amendment

Article 9 a

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

1. Providers, and deployers at each proposed deployment, must designate the categories of individuals and groups likely to be impacted by the system, assess the system's impact on fundamental rights, its accessibility for persons with disabilities, and its impact on the environment and broader public interest. Deployers of high-risk AI systems as defined in Article 6(2) shall, prior to putting the system into use, publish a fundamental rights impact assessment of the systems' impact in the context of use throughout the entire lifecycle. This assessment shall include at least:

- a) the intended purpose for which the system will be used;*
- b) the intended geographic and temporal scope of the system;*
- c) the potential risks of the use to the rights and freedoms of natural persons, including any indirect impacts or consequences of the systems;*
- d) the categories of natural persons and groups likely or foreseen to be affected;*
- e) the proportionality and necessity of the system's use;*
- f) verification of the legality of the use of the system in accordance with Union and*

national law;

g) any specific risk of harm likely to impact marginalised, vulnerable persons or groups at risk of discrimination, and risk of increasing existing societal inequalities;

h) the foreseeable impact of the use of the system on the environment over its entire life cycle, including but not limited to energy consumption;

i) any other negative impact on the public interest and clear plans relating to how the harms identified will be mitigated, and how effective this mitigation is expected to be; and

j) the governance system the deployer will put in place, including human oversight, complaint-handling and redress.

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 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. Deployers shall consult with relevant stakeholders, in particular groups of natural persons exposed to heightened risks from the AI system, civil society and social partners when preparing the impact assessment. The impact assessment shall be repeated on a regular basis throughout the entire lifecycle.

5. Publication of the results of the impact assessment shall be part of the registration of use pursuant to Article 51(2).

6. Where the deployer 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. Deployers of high-risk AI systems shall use the information provided under Article 13 to comply with their obligation under paragraph 1.

Or. en

Amendment 1672

Pernando Barrena Arza, Cornelia Ernst

**Proposal for a regulation
Article 10 – paragraph 1**

Text proposed by the Commission

1. High-risk AI systems which make use of techniques involving the training of models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Amendment

1. High-risk AI systems which make use of techniques involving the training of models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Techniques such as unsupervised learning and reinforcement learning that do not use validation and testing data sets shall be developed on the basis of training data sets the quality criteria referred to in paragraphs 2 to 5.

Or. en

Amendment 1673

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ondej Kováčik, Jan-Christoph Oetjen

**Proposal for a regulation
Article 10 – paragraph 1**

Text proposed by the Commission

1. High-risk AI systems which make

Amendment

1. High-risk AI systems which make

use of techniques involving the training of models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

use of techniques involving the training of models with data shall be, *as far as this can be reasonably expected and is feasible from a technical and economical point of view*, developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Or. en

Amendment 1674

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems which make use of techniques involving the training of models with data shall be developed *on the basis of* training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Amendment

1. High-risk AI systems which make use of techniques involving the training of models with data shall be, *as far this can be reasonably expected and is feasible from a technical point of view*, developed *with the best efforts to ensure* training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Or. en

Amendment 1675

Karlo Ressler

Proposal for a regulation

Article 10 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems which make use of techniques involving the training of models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Amendment

1. High-risk AI systems which make use of techniques involving the training of models with data shall be, *with reasonable expectations and in accordance with the state-of-art*, developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in

paragraphs 2 to 5;

Or. en

Amendment 1676

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 10 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems which make use of techniques involving the training of models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Amendment

1. High-risk AI systems which make use of techniques involving the training of models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5, *when applicable*.

Or. en

Amendment 1677

Kosma Złotowski, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 10 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems which make use of techniques involving the training of models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Amendment

1. High-risk AI systems which make use of techniques involving the training of models with data shall be developed on the basis of training, validation and testing data sets that meet the quality *and fairness* criteria referred to in paragraphs 2 to 5.

Or. en

Amendment 1678

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 10 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. Validation datasets shall be separate datasets from both the testing and the training datasets, in order for the evaluation to be unbiased. If only one dataset is available, it shall be divided in three parts: a training set, a validation set, and a testing set. Each set shall comply with paragraph 3 of this Article.

Or. en

Amendment 1679

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

Proposal for a regulation

Article 10 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. Techniques such as unsupervised learning and reinforcement learning, that do not use validation and testing data sets, shall be developed on the basis of training data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Or. en

Amendment 1680

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 10 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

1 b. Techniques such as unsupervised learning and reinforcement learning, that do not use validation and testing datasets,

shall be developed on the basis of training datasets that meet the quality criteria referred to in paragraphs 2 to 4.

Or. en

Amendment 1681

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 10 – paragraph 2 – introductory part

Text proposed by the Commission

2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. Those practices shall concern in particular,

Amendment

2. Training, validation and testing data sets *as well as data that is collected, fed into, or used by the AI system, after deployment of the system and throughout its lifecycle* shall be subject to appropriate data governance and management practices. Those practices shall concern in particular,

Or. en

Amendment 1682

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 10 – paragraph 2 – introductory part

Text proposed by the Commission

2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. Those practices shall concern in particular,

Amendment

2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices *for the entire lifecycle of data processing. Where relevant to appropriate risk management measures*, those practices shall concern in particular,

Or. en

Amendment 1683

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ondej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 10 – paragraph 2 – introductory part

Text proposed by the Commission

2. Training, validation and testing data sets shall be subject to *appropriate* data governance and management practices. Those practices shall concern in particular,

Amendment

2. Training, validation and testing data sets shall be subject to data governance and management practices *appropriate for the context of the use as well as the intended purpose of the AI system*. Those practices shall concern in particular,

Or. en

Amendment 1684

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

Proposal for a regulation

Article 10 – paragraph 2 – introductory part

Text proposed by the Commission

2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. Those practices shall concern in particular,

Amendment

2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. *throughout the entire lifecycle of the AI system*. Those practices shall concern in particular,

Or. en

Amendment 1685

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – introductory part

Text proposed by the Commission

2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices.

Amendment

2. Training, *machine-learning* validation and testing data sets shall be subject to appropriate data governance and

Those practices shall concern *in particular*,

management practices *during the expected lifetime*. Those practices shall concern, *where relevant*:

Or. en

Amendment 1686

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Brando Benifei, Maria Grapini

Proposal for a regulation

Article 10 – paragraph 2 – introductory part

Text proposed by the Commission

2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. Those practices shall concern in particular,

Amendment

2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices *for the entire lifecycle of data processing*. Those practices shall concern in particular,

Or. en

Amendment 1687

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

Proposal for a regulation

Article 10 – paragraph 2 – point a

Text proposed by the Commission

(a) les choix de conception pertinents;

Amendment

(a) les choix de conception pertinents *intégrant l'auditabilité et la reproductibilité du fonctionnement des algorithmes*;

Or. fr

Amendment 1688

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point a

Text proposed by the Commission

Amendment

(a) the **relevant** design choices;

(a) the design choices **for training and machine learning validation**;

Or. en

Amendment 1689

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini, Brando Benifei

Proposal for a regulation

Article 10 – paragraph 2 – point a

Text proposed by the Commission

Amendment

(a) the **relevant** design choices;

(a) the design choices;

Or. en

Amendment 1690

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

Proposal for a regulation

Article 10 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) data collection;

(b) data collection **processes**;

Or. en

Amendment 1691

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) data collection;

(b) data collection **processes**;

Amendment 1692

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point c

Text proposed by the Commission

(c) **relevant** data preparation processing operations, such as annotation, labelling, cleaning, enrichment and aggregation;

Amendment

(c) data preparation processing operations, such as annotation, labelling, cleaning, enrichment and aggregation;

Amendment 1693

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

Proposal for a regulation

Article 10 – paragraph 2 – point c

Text proposed by the Commission

(c) **relevant** data preparation processing operations, such as annotation, labelling, cleaning, enrichment and aggregation;

Amendment

(c) data preparation processing operations, such as annotation, labelling, cleaning, enrichment and aggregation;

Amendment 1694

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini, Brando Benifei

Proposal for a regulation

Article 10 – paragraph 2 – point c

Text proposed by the Commission

(c) **relevant** data preparation processing operations, such as annotation, labelling, cleaning, enrichment and

Amendment

(c) data preparation processing operations, such as annotation, labelling,

aggregation;

cleaning, enrichment and aggregation;

Or. en

Amendment 1695

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 10 – paragraph 2 – point d

Text proposed by the Commission

(d) the formulation of relevant assumptions, notably with respect to the information that the data are supposed to measure and represent;

Amendment

(d) the formulation of relevant, ***justified and reasonable*** assumptions, notably with respect to the information that the data are supposed to measure and represent;

Or. en

Amendment 1696

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point e

Text proposed by the Commission

(e) ***a prior assessment of the availability, quantity and suitability of the data sets that are needed;***

Amendment

deleted

Or. en

Amendment 1697

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 10 – paragraph 2 – point e

Text proposed by the Commission

(e) ***a prior*** assessment of the availability, quantity and suitability of the

Amendment

(e) ***an*** assessment of the availability, quantity and suitability of the data sets that

data sets that are needed;

are needed;

Or. en

Amendment 1698

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

Proposal for a regulation

Article 10 – paragraph 2 – point f

Text proposed by the Commission

(f) examination in view of possible biases;

Amendment

(f) examination in view of possible biases *defined as a statistical error or a top-down introduction of assumptions harmful to an individual, that are likely to affect health and safety of persons or lead to discrimination prohibited by Union law;*

Or. en

Amendment 1699

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point f

Text proposed by the Commission

(f) examination in view of possible biases;

Amendment

(f) examination in view of possible *unfair* biases *that are likely to affect the health and safety of persons or lead to discrimination prohibited under Union law;*

Or. en

Amendment 1700

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Vincenzo Sofo, Adam Bielan

Proposal for a regulation

Article 10 – paragraph 2 – point f

Text proposed by the Commission

(f) examination in view of possible biases;

Amendment

(f) examination in view of possible biases, *that are likely to affect health and safety of persons or lead to discrimination prohibited by Union law*;

Or. en

Amendment 1701

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

Proposal for a regulation

Article 10 – paragraph 2 – point f

Text proposed by the Commission

(f) examination *in view* of possible biases;

Amendment

(f) examination of possible biases, *especially where data outputs are used as an input for future operations ('feedback loops')*;

Or. en

Amendment 1702

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 10 – paragraph 2 – point f

Text proposed by the Commission

(f) examination in view of possible biases;

Amendment

(f) examination in view of possible biases *that are likely to affect the output of the AI system*;

Or. en

Amendment 1703

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation
Article 10 – paragraph 2 – point f

Text proposed by the Commission

(f) examination in view of **possible** biases;

Amendment

(f) examination in view of biases;

Or. en

Amendment 1704

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Vincenzo Sofo, Adam Bielan

Proposal for a regulation
Article 10 – paragraph 2 – point g

Text proposed by the Commission

(g) the identification of any **possible** data gaps or shortcomings, and how those gaps and shortcomings can be addressed.

Amendment

(g) the identification of any **other** data gaps or shortcomings *that materially increase the risks of harm to the health, natural environment and safety or the fundamental rights of persons*, and how those gaps and shortcomings can be addressed.

Or. en

Amendment 1705

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 10 – paragraph 2 – point g

Text proposed by the Commission

(g) the identification of **any possible** data gaps or shortcomings, and how those gaps and shortcomings can be addressed.

Amendment

(g) the identification of **significant and consequential** data gaps or shortcomings, and how those gaps and shortcomings can be addressed;

Or. en

Amendment 1706

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation

Article 10 – paragraph 2 – point g

Text proposed by the Commission

(g) the identification of **any** possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed.

Amendment

(g) the identification of **relevant** possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed.

Or. en

Amendment 1707

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova īk, Jan-Christoph Oetjen

Proposal for a regulation

Article 10 – paragraph 2 – point g

Text proposed by the Commission

(g) the identification of **any possible** data gaps or shortcomings, and how those gaps and shortcomings can be addressed.

Amendment

(g) the identification of **significant** data gaps or shortcomings, and how those gaps and shortcomings can be addressed.

Or. en

Amendment 1708

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 10 – paragraph 2 – point g

Text proposed by the Commission

(g) the identification of **any** possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed.

Amendment

(g) the identification of possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed.

Or. en

Amendment 1709

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point g a (new)

Text proposed by the Commission

Amendment

(g a) the presumable context of the use as well as the intended purpose of the AI System.

Or. en

Amendment 1710

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

Proposal for a regulation

Article 10 – paragraph 2 – point g a (new)

Text proposed by the Commission

Amendment

(g a) verification of the legality of the sources of the data.

Or. en

Amendment 1711

René Repasi, Marc Angel, Andreas Schieder, Maria-Manuel Leitão-Marques

Proposal for a regulation

Article 10 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. the evaluation of the impacts of a high-risk AI system, designed to ensure it is functioning as intended, that there are no errors or risks left unaddressed and that the system continues to meet the state-of-the-art standards required by this Regulation (ex post requirement).

Or. en

Amendment 1712

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing data sets shall be relevant, representative, free of errors and complete. They shall have the appropriate *statistical* properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. **These** characteristics *of the data sets may* be met at the level of individual *data sets or a combination thereof*.

Amendment

3. Training *data sets*, validation and testing data sets, *including the labels, as well as data that is collected, fed into, or used by the AI system, after deployment of the system and throughout its lifecycle* shall be relevant, representative, free of errors and complete. They shall have the appropriate properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. **The required** characteristics **should** be met at the level of *each* individual *dataset, whether in combination or not*.

Training validation and testing data sets shall be relevant, representative, free of errors and complete. They shall have the appropriate properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used.

Or. en

Amendment 1713

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing data sets shall be relevant, representative, *free of errors* and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the

Amendment

3. Training, validation and testing data sets shall be relevant, representative and *as complete and close to zero error as possible, having regard to the intended purpose of the AI system*. They shall have the appropriate statistical properties,

high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof. *In case of observational data, a common approach on data requirements shall be defined together with regulators.*

Or. en

Amendment 1714
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 10 – paragraph 3

Text proposed by the Commission

3. Les jeux de données d'entraînement, de validation et de test sont pertinents, représentatifs, *exempts d'erreurs* et complets. *Ils possèdent les propriétés statistiques appropriées, y compris, le cas échéant, en ce qui concerne les personnes ou groupes de personnes à l'égard desquels le système d'IA à haut risque est destiné à être utilisé.* Ces caractéristiques des jeux de données peuvent être présentes au niveau des jeux de données pris individuellement ou d'une combinaison de ceux-ci.

Amendment

3. Les jeux de données d'entraînement, de validation et de test sont pertinents, représentatifs, *fiables, limités en termes de biais* et complets. Ces caractéristiques des jeux de données peuvent être présentes au niveau des jeux de données pris individuellement ou d'une combinaison de ceux-ci.

Or. fr

Amendment 1715
Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation
Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing data

Amendment

3. *High-risk AI systems shall be*

sets shall be relevant, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

designed and developed with the best efforts to ensure that training, validation and testing data sets shall be relevant, representative, and to the best extent possible, free of errors and complete in accordance with industry standards. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Or. en

Amendment 1716

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

Proposal for a regulation Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing **data** sets shall be relevant, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Amendment

3. Training, validation and testing **datasets** sets shall be relevant, representative, *up-to-date, and to the extent that it could be reasonably expected, taking into account the state of the art*, free of errors and *as complete as could be reasonably expected*. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Or. en

Amendment 1717

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

Proposal for a regulation
Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing data sets **shall be** relevant, representative, **free of errors and complete**. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the **data sets** may be met at the level of individual data sets or a combination thereof.

Amendment

3. **High risk AI systems should be designed and developed with the best efforts to ensure that, where appropriate,** training, validation and testing data sets **are sufficiently** relevant, representative **and appropriately vetted for** errors. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the **datasets** may be met at the level of individual data sets or a combination thereof.

Or. en

Amendment 1718

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Brando Benifei, Maria Grapini

Proposal for a regulation
Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing **data sets** shall be relevant, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the **data sets may** be met at the level of individual data **sets or a combination thereof**.

Amendment

3. Training **datasets, and where applicable**, validation and testing **datasets, including the labels**, shall be relevant, representative, **up-to-date, and to the best extent possible**, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the **datasets shall** be met at the level of **each** individual data **set**.

Or. en

Amendment 1719

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 10 – paragraph 3**

Text proposed by the Commission

3. Training, validation and testing **data sets** shall be relevant, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the **data sets may** be met at the level of individual **data sets or a combination thereof.**

Amendment

3. Training, validation and testing **datasets** shall be relevant, representative, **up-to-date, and to the best extent possible, taking into account the state of the art,** free of errors and **be as complete as possible.** They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the **datasets shall** be met at the level of **each** individual **dataset.**

Or. en

Amendment 1720

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

**Proposal for a regulation
Article 10 – paragraph 3**

Text proposed by the Commission

3. Training, validation and testing data sets shall be relevant, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Amendment

3. Training, validation and testing data sets shall be relevant, **sufficiently diverse to mitigate bias, and, to the best extent possible**, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Or. en

Amendment 1721
Geoffroy Didier

Proposal for a regulation
Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing data sets shall be relevant, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Amendment

3. Training, validation and testing data sets shall be relevant, representative, **and to the best extent possible** free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk **uses of** AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Or. en

Justification

Article 10(3) provides an obligation to use error-free datasets, which is disproportionate et impossible in practice. Indeed, even if it is necessary to strengthen data learning, it is impossible to guarantee a total absence of errors in the datasets used in the development processes of the systems (in machine-learning particularly).

The concept of zero error in data is contrary even to the notion of AI which conceptually integrates this ability to reproduce human analysis. With interventions of DG Connect, it seems that the authorities do not expect perfect datasets but as reliable as possible

Amendment 1722

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

Proposal for a regulation
Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing data sets shall be relevant, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons **on which** the high-risk AI system is intended to be used. These

Amendment

3. Training, validation and testing data sets shall be relevant, representative, free of errors and **statistically** complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons **in relation to whom** the high-risk AI system

characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Or. en

Amendment 1723

Marion Walsmann

Proposal for a regulation

Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing data sets shall be relevant, representative, *free of errors and complete*. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Amendment

3. Training, validation and testing data sets shall be relevant *and* representative. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Or. en

Amendment 1724

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing data sets shall be relevant, representative, *free of errors and complete*. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Amendment

3. Training, validation and testing data sets shall be relevant *and* representative. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Justification

It is impossible to create data sets that are completely free of errors, and no data set can ever be considered "complete" in the right sense of the word.

Amendment 1725

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing data sets **shall be relevant, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used.** These characteristics **of the data sets** may be met at the level of individual data sets or a combination thereof.

Amendment

3. **High Risk AI systems should be designed and developed with the best efforts to ensure that, where appropriate, training datasets, machine-learning validation and testing data sets are sufficiently accurate, relevant and representative in view of the intended purpose of the AI system.** These characteristics may be met at the level of individual data sets or a combination thereof.

Amendment 1726

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. In assessing the quality of a data set, account shall be taken to the extent to which the data set is constructed with a view to fulfilling in particular the following aspects:

a) provides a similar output for relevant demographic Groups impacted by the system;

- b) minimizes disparities in outcomes for relevant demographic groups impacted by the system, in case where the system allocates resources or opportunities to natural persons;*
- c) minimizes the potential for stereotyping, demeaning, or erasing relevant demographic groups impacted by the system where the system describes, depicts, or otherwise represents people, cultures, or society.*

Or. en

Amendment 1727

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 4

Text proposed by the Commission

4. Training, validation and testing data sets shall take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.

Amendment

deleted

Or. en

Amendment 1728

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 10 – paragraph 4

Text proposed by the Commission

4. Training, validation and testing data sets shall take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical,

Amendment

4. Training, validation and testing data sets **as well as data that is collected, fed into, or used by the AI system, after deployment of the system and throughout its lifecycle** shall take into account, to the

behavioural or functional setting within which the high-risk AI system is intended to be used.

extent required by the intended purpose *or reasonably foreseeable use*, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.

Or. en

Amendment 1729

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

Proposal for a regulation

Article 10 – paragraph 4

Text proposed by the Commission

4. ***Training, validation and testing*** data sets shall take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.

Amendment

4. Data sets shall take into account, to the extent required by the intended purpose, the *foreseeable uses and reasonably foreseeable misuses of AI systems with indeterminate uses*, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.

Or. en

Amendment 1730

Sophia in 't Veld, Michal Šimeka

Proposal for a regulation

Article 10 – paragraph 4

Text proposed by the Commission

4. Training, validation and testing data sets shall take into account, ***to the extent required by the intended purpose***, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within

Amendment

4. Training, validation and testing data sets shall take into account the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is used.

which the high-risk AI system is *intended to be* used.

Or. en

Amendment 1731

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 10 – paragraph 4

Text proposed by the Commission

4. Training, validation and testing data sets shall *take into account*, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.

Amendment

4. Training, validation and testing data sets shall *be sufficiently diverse to accurately capture*, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.

Or. en

Amendment 1732

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 10 – paragraph 4

Text proposed by the Commission

4. ***Training, validation and testing*** data sets shall take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.

Amendment

4. Data sets shall take into account, to the extent required by the intended purpose, the *reasonably foreseeable uses and misuses of AI systems, the* characteristics or elements that are particular to the specific geographical, *cultural*, behavioural or functional setting within which the high-risk AI system is intended to be used.

Or. en

Amendment 1733
Axel Voss, Deirdre Clune

Proposal for a regulation
Article 10 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. The processing of personal data to train, validate and test data sets of an AI system in order to meet the requirements of this Regulation shall be lawful for the purpose of the legitimate interest of the provider as referred to in Article 6(1f) GDPR or in accordance with Article 6(4) GDPR subject to appropriate safeguards in line with Article 89 GDPR for ensuring to the extent necessary and proportionate one or more of the following objectives:

- a) national and common security;*
- b) functioning of the internal market;*
- c) 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;*
- d) exercise of public authorities' official mission, such as tax and customs authorities, financial investigation units, independent administrative authorities, or financial market authorities responsible for the regulation and supervision of securities markets should not be regarded as recipients if they process personal data to train, validate and test an AI system which are necessary to carry out a particular inquiry in the general interest, in accordance with Union or Member State law;*
- e) network and information security to the extent necessary and proportionate for this purpose;*
- f) protection of an interest which is essential for the life of the data subject or that of another natural person, in*

particular where it is necessary for reasons of public interest in the areas of public health.

Or. en

Amendment 1734

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

Proposal for a regulation

Article 10 – paragraph 5

Text proposed by the Commission

Amendment

5. *Dans la mesure où cela est strictement nécessaire aux fins de la surveillance, de la détection et de la correction des biais en ce qui concerne les systèmes d'IA à haut risque, les fournisseurs de ces systèmes peuvent traiter des catégories particulières de données à caractère personnel visées à l'article 9, paragraphe 1, du règlement (UE) 2016/679, à l'article 10 de la directive (UE) 2016/680 et à l'article 10, paragraphe 1, du règlement (UE) 2018/1725, sous réserve de garanties appropriées pour les droits et libertés fondamentaux des personnes physiques, y compris des limitations techniques relatives à la réutilisation ainsi que l'utilisation des mesures les plus avancées en matière de sécurité et de protection de la vie privée, telles que la pseudonymisation, ou le cryptage lorsque l'anonymisation peut avoir une incidence significative sur l'objectif poursuivi.*

Or. fr

Amendment 1735

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

Proposal for a regulation

Article 10 – paragraph 5

Text proposed by the Commission

Amendment

5. *To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.*

Or. en

Amendment 1736

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

Proposal for a regulation

Article 10 – paragraph 5

Text proposed by the Commission

Amendment

5. *To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-*

of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.

Or. en

Amendment 1737

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 10 – paragraph 5

Text proposed by the Commission

Amendment

5. *To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.*

deleted

Or. en

Amendment 1738

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 10 – paragraph 5

Text proposed by the Commission

Amendment

5. To the extent that it is *strictly* necessary for the purposes of ensuring bias

5. To the extent that it is necessary for the purposes of ensuring bias monitoring,

monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems **may** process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including ***technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.***

detection and correction in relation to the high-risk AI systems, the providers of such systems ***will have a legal basis and necessary exception to*** process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including:

- (i) state-of-the-art security and privacy-preserving measures, such as ***data-minimization***, pseudonymisation, encryption, ***and*** where anonymisation may significantly affect the purpose pursued;
- (ii) ***measures ensuring availability and resilience of processing systems and services, and the ability to restore the availability and access to special category personal data in a timely manner in the event of a physical or technical incident;***
- (iii) ***processes for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures in order to ensure the security of the processing;***
- (iv) ***measures for user identification, authorisation, protection of data during transmission, protection of data during storage, ensuring physical security of locations at which personal data are processed, internal IT and IT security governance and management, certification/assurance of processes and products;***
- (v) ***measures for ensuring data minimisation, data quality, limited data retention, and data portability and ensuring erasure.***

Or. en

Amendment 1739**Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura****Proposal for a regulation****Article 10 – paragraph 5***Text proposed by the Commission*

5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.

Amendment

5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued. ***This should also guarantee explainability of AI driven recommendations or decisions.***

Or. en

Amendment 1740**Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan****Proposal for a regulation****Article 10 – paragraph 5***Text proposed by the Commission*

5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU)

Amendment

5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU)

2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.

2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption *or biometric template protection technologies* where anonymisation may significantly affect the purpose pursued.

Or. en

Amendment 1741

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

Proposal for a regulation

Article 10 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 bis. La dissémination de données par un système d'I.A. avec d'autres systèmes d'I.A., qu'ils soient ou non de même provenance et qu'ils soient ou non installés sur le même support, est contrôlée par le fournisseur et peut être, si nécessaire, rétractée.

Or. fr

Amendment 1742

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 10 – paragraph 6

Text proposed by the Commission

Amendment

6. *Appropriate data governance and management practices shall apply* for the development of high-risk AI systems *other*

6. For the development of high-risk AI systems *not using* techniques involving the training of models, *paragraphs 2 to 5*

*than those which make use of techniques involving the training of models **in order to ensure that those high-risk AI systems comply with paragraph 2.***

shall apply only to the testing data sets.

Or. en

Amendment 1743

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6 a. Providers and user may comply with the obligations set out in this Article through the use of third-parties that offer certified compliance services including verification of data governance, data set integrity, and data training, validation and testing practices.

Or. en

Amendment 1744

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

Proposal for a regulation

Article 10 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6 a. The training, testing and validation processes of data sets should have a duration based on the training periodicity of the systems, the timing of notification of incidents and the normal supervisory activity of the national competent authority

Or. en

Amendment 1745

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 6 b (new)

Text proposed by the Commission

Amendment

6 b. Where the provider cannot comply with the obligations laid down in this Article because it does not have access to the data and/or the data is held exclusively by the user, the user may, on the basis of a contract, be made responsible for any infringement of this Article.

Or. en

Amendment 1746

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

Proposal for a regulation

Article 10 a (new)

Text proposed by the Commission

Amendment

Article 10 a

Environmental Impact of high-risk AI systems

1. High-risk AI systems shall be designed and developed making use of state-of-the-art methods to reduce energy use, resource use and waste, as well as to increase energy efficiency, and the overall efficiency of the system. They shall be designed and developed and set up with capabilities enabling the measurement and logging of the consumption of energy and resources, and other environmental impact the deployment and use of the systems may have over their entire lifecycle.

2. Member States shall ensure that relevant national authorities issue guidelines and provide support to

providers and deployers in their efforts to reduce the environmental impact and resource use of high-risk AI systems.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 73 to detail the measurement and logging procedures, taking into account state-of-the-art methods, in particular to enable the comparability of the environmental impact of systems, and taking into account the economies of scale.

Or. en

Amendment 1747

Milan Brglez, Hilde Vautmans, Catharina Rinzema

**Proposal for a regulation
Article 10 a (new)**

Text proposed by the Commission

Amendment

Article 10 a

Risk management system for AI systems likely to interact with children

AI systems likely to interact with or impact on children shall implement a riskmanagement system addressing content, contact, conduct and contract risks to children;

Or. en

Amendment 1748

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 11 – paragraph 1 – introductory part**

Text proposed by the Commission

Amendment

1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market

1. The technical documentation of a high-risk AI system shall be drawn up, ***where possible, relevant, and without***

or put into service and shall be kept up-to date.

compromising intellectual property rights or trade secrets, before that system is placed on the market or put into service and shall be kept up-to date.

Or. en

Amendment 1749

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

Proposal for a regulation

Article 11 – paragraph 1 – introductory part

Text proposed by the Commission

1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date.

Amendment

1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date *throughout its entire lifecycle, and where appropriate, beyond*.

Or. en

Amendment 1750

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 11 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.

Amendment

The technical documentation shall be drawn up, *where possible, relevant, and without compromising intellectual property rights or trade secrets*, in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV *or in the case of SME's and start-ups*,

any equivalent documentation meeting the same objectives, subject to approval of the competent national authority.

Or. en

Amendment 1751

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

Proposal for a regulation

Article 11 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The technical documentation shall **be** drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.

Amendment

The technical documentation shall **vary according to each use of the AI system and** drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV **or in the case of SMEs and start-ups, any equivalent documentation meeting the same objectives, subject to approval of the competent national authority.**

Or. en

Amendment 1752

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 11 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and

Amendment

The technical documentation shall be **appropriate to the context of application or use of the AI system and** drawn up in such a way to demonstrate that the high-risk AI system complies with the

notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.

requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV *or any equivalent documentation meeting the same objectives, subject to approval of the competent authority.*

Or. en

Amendment 1753

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Ondřej Kováčík, Jan-Christoph Oetjen

Proposal for a regulation

Article 11 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.

Amendment

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV *or, in the case of SMEs and start-ups, any equivalent documentation meeting the same objectives, subject to approval of the competent authority.*

Or. en

Amendment 1754

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Mituță, Ramona Strugariu, Drago Pîslaru, Lucia Šuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 11 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.

Amendment

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV *or equivalent documentation meeting the same objectives, subject to the approval of the competent authority.*

Or. en

Amendment 1755

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

Proposal for a regulation

Article 11 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.

Amendment

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide *the national supervisory authority, the* national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.

Or. en

Amendment 1756

Marion Walsmann

Proposal for a regulation

Article 11 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with ***all*** the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.

Amendment

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.

Or. en

Amendment 1757

Nathalie Colin-Oesterlé

Proposal for a regulation

Article 11 – paragraph 1 – point 1 (new)

Text proposed by the Commission

Amendment

(1) La documentation technique n'est pas obligatoire mais recommandée lorsqu'il s'agit d'un essai du système IA à haut risque avant mise sur le marché ou mise à disposition.

Or. fr

Amendment 1758

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 11 – paragraph 2

Text proposed by the Commission

Amendment

2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service one single technical documentation shall be drawn up containing all the information set

2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service ***only*** one single ***and appropriate*** technical documentation shall be drawn up ***for each***

out in Annex IV as well as the information required under those legal acts.

product, containing all the information set out in Annex IV as well as the information required under those legal acts.

Or. en

Amendment 1759

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia urîș Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation

Article 11 – paragraph 2

Text proposed by the Commission

2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service one single technical documentation shall be drawn up containing all the information set out in *Annex IV* as well as the information required under those legal acts.

Amendment

2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service one single technical documentation shall be drawn up containing all the information set out in *paragraph 1* as well as the information required under those legal acts.

Or. en

Amendment 1760

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 11 – paragraph 2

Text proposed by the Commission

2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service **one single** technical documentation shall be drawn up containing all the information set out in Annex IV as well as the information required under those legal acts.

Amendment

2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service **appropriate** technical documentation shall be drawn up containing all the information set out in Annex IV as well as the information required under those legal acts.

Or. en

Amendment 1761

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 11 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. To ensure that a single technical documentation is possible, terms and definitions related to this required documentation and any required documentation in the appropriate Union sectoral legislation shall be aligned as much as possible;

Or. en

Amendment 1762

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 11 – paragraph 3

Text proposed by the Commission

Amendment

3. The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend Annex IV where necessary to ensure that, in the light of technical progress, the technical documentation provides all the necessary information to assess the compliance of the system with the requirements set out in this Chapter.

deleted

Or. en

Amendment 1763

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

Proposal for a regulation

Article 11 – paragraph 3

Text proposed by the Commission

3. La Commission est habilitée à adopter des actes délégués conformément à l'article 73 pour **modifier** l'annexe IV lorsque cela est nécessaire afin de garantir que, compte tenu du progrès technique, la documentation technique fournit toutes les informations requises pour évaluer la conformité du système avec les exigences énoncées dans le présent chapitre.

Amendment

3. La Commission est habilitée à adopter des actes délégués conformément à l'article 73 pour **compléter par des ajouts** l'annexe IV lorsque cela est nécessaire afin de garantir que, compte tenu du progrès technique, la documentation technique fournit toutes les informations requises pour évaluer la conformité du système avec les exigences énoncées dans le présent chapitre.

Or. fr

Amendment 1764

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 11 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

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

Or. en

Justification

moved up from Article 18.

Amendment 1765

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

Proposal for a regulation

Article 12 – paragraph 1

Text proposed by the Commission

1. La conception et le développement des systèmes d'IA à haut risque prévoient des fonctionnalités permettant l'enregistrement automatique des événements («journaux») pendant le fonctionnement de ces systèmes. Ces fonctionnalités d'enregistrement sont conformes à des normes ou à des spécifications communes reconnues.

Amendment

1. La conception et le développement des systèmes d'IA à haut risque prévoient des fonctionnalités permettant l'enregistrement automatique des événements («journaux») pendant le fonctionnement de ces systèmes. Ces fonctionnalités d'enregistrement sont conformes à des normes ou à des spécifications communes reconnues. *Dans la mesure du possible, ces fonctionnalités sont locales et les journaux sont conservés sur le support de l'utilisateur du système d'IA.*

Or. fr

Amendment 1766

Morten Løkkegaard

Proposal for a regulation Article 12 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the high-risk AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications.

Amendment

1. *Where reasonably practicable* high-risk AI systems, *which are capable of changing behaviour during operation*, shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the high-risk AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications.

Or. en

Justification

This article requires automatic recording of events (logs) while high-risk AI systems is operating. In the case where the AI is incapable of changing behaviour during the lifetime of the product, there is nothing supporting this requirement, so it is suggested that it only applies in case the AI in question is actually capable of changing behaviour. Furthermore, for machine manufacturers this requirement will be problematic and a big burden to implement, as approximately half of all the machines on the marked are not online, making it unclear

how to perform logging. One of the most basic recommendations regarding cyber security is not to connect your machines to the internet. This requirement will therefore risk making machines in Europe more exposed to cyber-attacks. Additionally, there might be examples where the logging of data is in conflict with legislation regarding data protection, such as GDPR or local Member State regulation, which makes the requirements for logging problematic.

Amendment 1767

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 12 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall ***be designed and developed with capabilities enabling the automatic recording of events ('logs') while the high-risk AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications.***

Amendment

1. High-risk AI systems shall ***technically allow the automatic recording of events ('logs') over the durations of the lifetime of the system.***

Or. en

Amendment 1768

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

Proposal for a regulation

Article 12 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the high-risk AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications.

Amendment

1. High-risk AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the high-risk AI systems is operating. Those logging capabilities shall conform to ***the state of the art and*** recognised standards or common specifications.

Or. en

Amendment 1769
Kosma Złotowski, Patryk Jaki

Proposal for a regulation
Article 12 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall be designed and developed with *capabilities enabling the automatic recording of events ('logs')* while the high-risk AI systems is operating. Those *logging capabilities shall conform to recognised standards or common specifications.*

Amendment

1. High-risk AI systems shall be designed and developed with *appropriate technical and organizational measures to enable effective monitoring and human oversight* by those *using the system as well as effective supervision by regulators.*

Or. en

Amendment 1770
Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 12 – paragraph 1

Text proposed by the Commission

1. **High-risk** AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the **high-risk** AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications.

Amendment

1. **All** AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications.

Or. en

Amendment 1771
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 12 – paragraph 2

Text proposed by the Commission

2. **The logging capabilities shall** ensure a level of traceability of the AI

Amendment

2. **In order to** ensure a level of traceability of the AI system's functioning

system's functioning *throughout its lifecycle* that is appropriate to the intended purpose of the system.

which is appropriate to the intended purpose of the system, *the logging capabilities shall enable the recording of events relevant for the identification of situations that may:*

- (i) result in the AI system presenting a risk within the meaning of Article 65 (1); or*
- (ii) lead to a substantial modification that facilitates the post market monitoring referred to in Article 61.*

Or. en

Amendment 1772

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation Article 12 – paragraph 2

Text proposed by the Commission

2. The logging capabilities shall ensure a level of traceability of the AI system's functioning *throughout its lifecycle* that is appropriate to the intended purpose of the system.

Amendment

2. The logging capabilities shall ensure a level of traceability of the AI system's functioning that is appropriate to the intended purpose of the system. *The storage period should be determined on the business needs and informational value, without exceeding a maximum of 10 fiscal years*

Or. en

Amendment 1773

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 12 – paragraph 2

Text proposed by the Commission

2. The logging capabilities shall ensure a level of traceability of the AI

Amendment

2. The logging capabilities shall ensure a level of traceability of the AI

system's functioning throughout its lifecycle that is appropriate to the intended purpose of the system.

system's functioning throughout its lifecycle that is appropriate to the intended purpose **or reasonably foreseeable use** of the system.

Or. en

Amendment 1774

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 12 – paragraph 2

Text proposed by the Commission

2. The logging capabilities shall ensure a level of traceability of the AI system's functioning throughout its lifecycle that is appropriate to the intended purpose of the system.

Amendment

2. The logging capabilities shall ensure a level of traceability of the AI system's functioning throughout its lifecycle that is appropriate to the intended purpose **or reasonably foreseeable use** of the system.

Or. en

Amendment 1775

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 12 – paragraph 2

Text proposed by the Commission

2. The logging capabilities shall ensure a level of traceability of the AI system's functioning **throughout** its lifecycle that is appropriate to the intended purpose of the system.

Amendment

2. The logging capabilities shall ensure a level of traceability of the AI system's functioning **while the AI system is used within** its lifecycle that is appropriate to the intended purpose of the system.

Or. en

Amendment 1776

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 12 – paragraph 3**

Text proposed by the Commission

Amendment

3. *In particular, logging capabilities shall enable the monitoring of the operation of the high-risk AI system with respect to the occurrence of situations that may result in the AI system presenting a risk within the meaning of Article 65(1) or lead to a substantial modification, and facilitate the post-market monitoring referred to in Article 61.*

deleted

Or. en

Amendment 1777

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

**Proposal for a regulation
Article 12 – paragraph 3 a (new)**

Text proposed by the Commission

Amendment

3 a. *For records constituting trade secrets as defined in Article 2 of Directive (EU) 2016/943, provider may elect to confidentially provide such trade secrets only to relevant public authorities to the extent necessary for such authorities to perform their obligations hereunder.*

Or. en

Amendment 1778

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ondej Kovařík, Jan-Christoph Oetjen

**Proposal for a regulation
Article 12 – paragraph 4**

Text proposed by the Commission

Amendment

4. *For high-risk AI systems referred*

deleted

to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a minimum:

- (a) recording of the period of each use of the system (start date and time and end date and time of each use);*
- (b) the reference database against which input data has been checked by the system;*
- (c) the input data for which the search has led to a match;*
- (d) the identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5).*

Or. en

Amendment 1779

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 12 – paragraph 4

Text proposed by the Commission

Amendment

4. For high-risk AI systems referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a minimum:

- (a) recording of the period of each use of the system (start date and time and end date and time of each use);*
- (b) the reference database against which input data has been checked by the system;*
- (c) the input data for which the search has led to a match;*
- (d) the identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5).*

Or. en

Amendment 1780

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

Proposal for a regulation

Article 12 – paragraph 4

Text proposed by the Commission

Amendment

4. *For high-risk AI systems referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a minimum:*

- (a) *recording of the period of each use of the system (start date and time and end date and time of each use);*
- (b) *the reference database against which input data has been checked by the system;*
- (c) *the input data for which the search has led to a match;*
- (d) *the identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5).*

deleted

Or. en

Amendment 1781

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 12 – paragraph 4 – introductory part

Text proposed by the Commission

Amendment

4. For high-risk AI systems referred to in *paragraph 1, point (a) of Annex III*, the logging capabilities shall provide, at a minimum:

4. For high-risk AI systems referred to in Annex III, the logging capabilities shall provide, at a minimum:

Or. en

Amendment 1782

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 12 – paragraph 4 – point a

Text proposed by the Commission

(a) recording of the period of each use of the system (*start date and time and end date and time of each use*);

Amendment

(a) recording of the period of each use of the system;

Or. en

Amendment 1783

Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Marc Angel

Proposal for a regulation

Article 12 – paragraph 4 – point c

Text proposed by the Commission

(c) *the input data for which the search has led to a match;* *deleted*

Amendment

Or. en

Justification

this and the previous amendment are consistent with the expansion of the prohibitions to remote biometric identification.

Amendment 1784

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 12 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. For high-risk self-learning AI systems the logging of self-learning shall be maintained. The logging shall provide, at a minimum:

- (a) *the input data used for self-learning;*
- (b) *the used algorithms of the input data interpretation;*
- (c) *the results of self-learning.*

Or. en

Amendment 1785

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 12 – paragraph 4 b (new)

Text proposed by the Commission

Amendment

- 4 b. Where a decision and/or proposal of decision is the outcome of an AI system, the logging shall cover information comprehensively sufficient for further human manual review of the decision/proposal with no need to refer to the AI system itself. The logging shall provide, at a minimum:*
- (a) *the input data;*
 - (b) *the reference database, if such present;*
 - (c) *the algorithms that could had been used;*
 - (d) *the algorithms that actually had been used;*
 - (e) *output data (decision and/or proposal);*
 - (f) *comprehensive mechanism of how the input data resulted into the output data.*

Or. en

Amendment 1786

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 12 – paragraph 4 c (new)

Text proposed by the Commission

Amendment

4 c. For all high-risk AI systems, including those mentioned in paragraphs 4–6 above, the logging shall provide, at a minimum:

- (a) log-in information (user, date, time, authentication type);*
- (b) the input data;*
- (c) the output data.*

Or. en

Amendment 1787

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 12 – paragraph 4 d (new)

Text proposed by the Commission

Amendment

4 d. The Commission is empowered to adopt delegated acts in accordance with Article 73 to define more minimum logging requirements for AI systems or their certain types.

Or. en

Amendment 1788

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

Proposal for a regulation

Article 13 – title

Text proposed by the Commission

Amendment

Transparency and provision of information
to *users*

Transparency and provision of information
to *deployers and AI subjects*

Or. en

Amendment 1789

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 13 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users to *interpret* the system's *output and use it appropriately*. An appropriate type and degree of transparency shall be ensured, with a view to achieving compliance with the relevant obligations of the user and of the provider set out in **Chapter 3** of this Title.

Amendment

1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users to *reasonably understand* the system's *functioning*. An appropriate type and degree of transparency shall be ensured, *depending on the intended purpose of the system*, with a view to achieving compliance with the relevant obligations of the user and of the provider set out in **Article 16 and Article 29** of this Title. *The explanation shall be provided at least in the language of the country where the AI system is deployed.*

Transparency shall thereby mean that, to the extent that can be reasonably expected and is feasible in technical terms at the time when the AI system is placed on the market, the AI system is interpretable to the provider, in that the provider can understand the rationale of decisions taken by the high risk AI system, while enabling the user to understand and use the AI system appropriately, by generally knowing how the AI system works and what data it processes.

Or. en

Amendment 1790

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Ondřej Kovářík, Jan-Christoph Oetjen

Proposal for a regulation
Article 13 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently

Amendment

1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently

transparent to enable users to interpret the system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured, with a view to achieving compliance with the relevant obligations of the user and of the provider set out in Chapter 3 of this Title.

transparent to enable users to interpret the system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured, with a view to achieving compliance with the relevant obligations of the user and of the provider set out in Chapter 3 of this Title.

Transparency shall thereby mean that, to the extent that can be reasonably expected and is feasible in technical terms, the AI systems output is interpretable by the user and the user is able to understand the general functionality of the AI system and its use of data.

Or. en

Amendment 1791

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

Proposal for a regulation Article 13 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable **users** to interpret the system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured, with a view to achieving compliance with the relevant obligations of the **user** and of the provider set out in Chapter 3 of this Title.

Amendment

1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable **deployers** to interpret the system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured, with a view to achieving compliance with the relevant obligations of the **deployer** and of the provider set out in Chapter 3 of this Title. ***Where individuals are passively subject to AI systems (AI subjects), information to ensure an appropriate type and degree of transparency shall be made publicly available, with full respect to the privacy, personality, and related rights of subjects.***

Or. en

Amendment 1792**Axel Voss, Deirdre Clune, Eva Maydell****Proposal for a regulation****Article 13 – paragraph 2***Text proposed by the Commission*

2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, *complete*, correct and clear information that *is* relevant, accessible and comprehensible to users.

Amendment

2. High-risk AI systems shall be accompanied by *comprehensible* instructions for use in an appropriate digital format or *made* otherwise *available* that include concise, correct and clear information that *helps supporting informed decision-making by users and is reasonably* relevant, accessible and comprehensible to users.

Or. en

Amendment 1793**Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova įk, Jan-Christoph Oetjen****Proposal for a regulation****Article 13 – paragraph 2***Text proposed by the Commission*

2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to users.

Amendment

2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that *helps supporting informed decision-making by users and is* relevant, accessible and comprehensible to users.

Or. en

Amendment 1794**Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä**
on behalf of the Verts/ALE Group**Proposal for a regulation****Article 13 – paragraph 2**

Text proposed by the Commission

2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to *users*.

Amendment

2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, *statistically* complete, correct and clear information that is relevant, accessible and comprehensible to *deployers*.

Or. en

Amendment 1795

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 13 – paragraph 3 – introductory part

Text proposed by the Commission

3. The information referred to in paragraph 2 shall specify:

Amendment

3. *To the extent necessary to achieve the outcomes referred to in paragraph 1,* the information referred to in paragraph 2 shall specify:

Or. en

Amendment 1796

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 13 – paragraph 3 – point a

Text proposed by the Commission

(a) the identity and the contact details of the provider *and*, where applicable, of *its* authorised representative;

Amendment

(a) the identity and the contact details of the provider, where applicable, of *their* authorised representative;

Or. en

Amendment 1797

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 13 – paragraph 3 – point b – introductory part

Text proposed by the Commission

(b) the **characteristics**, capabilities and limitations of performance of the high-risk AI system, including:

Amendment

(b) the capabilities and limitations of performance of the high-risk AI system ***that are relevant to the material risks associated with the intended purpose***, including ***where appropriate***:

Or. en

Amendment 1798

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 13 – paragraph 3 – point b – point ii

Text proposed by the Commission

(ii) the level of accuracy, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;

Amendment

(ii) the level of accuracy, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity, ***including an overview of the capabilities and performance metrics of the AI system, and of representative use cases based on the intended purpose***;

Or. en

Amendment 1799

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

Proposal for a regulation

Article 13 – paragraph 3 – point b – point ii

Text proposed by the Commission

Amendment

(ii) the level of accuracy, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of **accuracy**, robustness and cybersecurity;

(ii) **the performance metrics and its appropriateness, including** the level of accuracy, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of **performance**, robustness and cybersecurity;

Or. en

Justification

This amendment is necessary as Article 13 is referred to in Article 9 and in Article 29, i.e. it is relevant for risk management and for the obligations placed on users. "The most appropriate risk management measures" in Article 9 (4) cannot be identified if Article 13 is not amended. In addition, we are introducing amendments to the obligations of providers in Article 16 and these should be reflected in Article 13 as well, in order to ensure consistency of the provisions.

Amendment 1800

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

Proposal for a regulation

Article 13 – paragraph 3 – point b – point ii

Text proposed by the Commission

ii) le niveau d'exactitude, de robustesse et de cybersécurité visé à l'article 15 qui a servi de référence pour les tests et la validation du système d'IA à haut risque et qui peut être attendu, ainsi que toutes circonstances connues et prévisibles susceptibles d'avoir une incidence sur le niveau attendu d'exactitude, de robustesse et de cybersécurité;

Amendment

ii) le niveau d'exactitude, de robustesse et de cybersécurité visé à l'article 15 qui a servi de référence pour les tests et la validation du système d'IA à haut risque **avant sa mise sur le marché** et qui peut être attendu, ainsi que toutes circonstances connues et prévisibles susceptibles d'avoir une incidence sur le niveau attendu d'exactitude, de robustesse et de cybersécurité;

Or. fr

Amendment 1801

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner,

Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 13 – paragraph 3 – point b – point iii

Text proposed by the Commission

Amendment

(iii) *any known or foreseeable circumstance, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health and safety or fundamental rights;*

deleted

Or. en

Justification

This aspect is misplaced under this Article and should rather be part of the risk assessment.

Amendment 1802

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 13 – paragraph 3 – point b – point iii

Text proposed by the Commission

Amendment

(iii) *any known or foreseeable circumstance, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health and safety or fundamental rights;*

(iii) *the known or foreseeable circumstances, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health and safety or fundamental rights, including, where appropriate, illustrative examples of such limitations and of scenarios for which the system should not be used;*

Or. en

Amendment 1803

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

Proposal for a regulation
Article 13 – paragraph 3 – point b – point iii

Text proposed by the Commission

(iii) any known or foreseeable circumstance, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health **and** safety **or** fundamental rights;

Amendment

(iii) any known or foreseeable circumstance, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable **use or** misuse, which may lead to risks to the health, safety, fundamental rights, **the environment, or democracy**;

Or. en

Amendment 1804
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 13 – paragraph 3 – point b – point v

Text proposed by the Commission

(v) **when appropriate, specifications for the** input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the AI system.

Amendment

(v) **relevant information about user actions that may influence system performance, including type or quality of** input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the AI system.

Or. en

Amendment 1805
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Maria Grapini

Proposal for a regulation
Article 13 – paragraph 3 – point b – point v

Text proposed by the Commission

(v) when appropriate, specifications for the input data, or any other relevant

Amendment

(v) when appropriate, specifications for the input data, or any other relevant

information in terms of the ***training, validation and testing*** data sets used, taking into account the intended purpose of the AI system.

information in terms of the data sets used, ***including their limitation and assumptions***, taking into account the intended purpose, ***the foreseeable and reasonably foreseeable misuses*** of the AI system.

Or. en

Justification

This amendment is necessary as Article 13 is referred to in Article 9 and in Article 29, i.e. it is relevant for risk management and for the obligations placed on users. "The most appropriate risk management measures" in Article 9 (4) cannot be identified if Article 13 is not amended. In addition, we are introducing amendments to the obligations of providers in Article 16 and these should be reflected in Article 13 as well, in order to ensure consistency of the provisions.

Amendment 1806

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

Proposal for a regulation

Article 13 – paragraph 3 – point d

Text proposed by the Commission

(d) the human oversight measures referred to in Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the ***users***;

Amendment

(d) the human oversight measures referred to in Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the ***deployers***;

Or. en

Amendment 1807

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 13 – paragraph 3 – point e a (new)

Text proposed by the Commission

Amendment

(e a) a description of the mechanisms included within the AI system that allow users to properly collect, store and

interpret the logs in accordance with Art 12(1), where relevant.

Or. en

Amendment 1808

**Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto ,
Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen**

Proposal for a regulation

Article 13 – paragraph 3 – point e a (new)

Text proposed by the Commission

Amendment

(e a) a description of the mechanisms included within the AI system that allow users to properly collect, store and interpret the logs in accordance with Article 12(1).

Or. en

Amendment 1809

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

Proposal for a regulation

Article 13 – paragraph 3 – point e a (new)

Text proposed by the Commission

Amendment

(e a) the level of extraction and consumption of natural resources.

Or. en

Amendment 1810

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 13 a (new)

Text proposed by the Commission

Amendment

Article 13 a

Transparency for affectees of AI systems

- 1) High-risk AI systems shall be designed, developed and used in such a way that an affectee can obtain an explanation from the developer and user for any decision taken or supported by a high-risk AI system that significantly affects the affectee;*
- 2) Providers and users of high-risk AI systems shall provide access to the person of persons designated with the exercise of 'human oversight' as described in Art. 14 to discuss and to clarify the facts, circumstances and reasons having led to the decision by the AI system;*
- 3) Providers and users of high-risk AI systems shall provide the affectee with a written statement of the reasons for any decision taken or supported by a high-risk AI system;*
- 4) Where the affectee is not satisfied with the explanation or the written statement of reasons obtained or consider that the decision referred to in paragraph (1) jeopardizes their health, safety or fundamental rights, the provider or user, as the case may be, shall review that decision, upon reasonable request by the affectee. The provider or user, as the case maybe, shall respond to such request by providing the affectee with a substantiated reply without undue delay and in any event within one week of receipt of the request.*

Or. en

Amendment 1811

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation Article 14 – paragraph 1

Text proposed by the Commission

Amendment

1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they *can be effectively overseen* by natural persons during the *period in which* the AI system *is in use*.

1. *Where proportionate to the risks associated with the high-risk system and where technical safeguards are not sufficient*, high-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they *allow informed oversight* by natural persons during the *expected lifetime of the device*. *Oversight capabilities should be tailored to the AI system's intended purpose and the context of use and take into account cases where human oversight may compromise the correct and safe functioning of the AI system*.

Or. en

Amendment 1812

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ond ej Kova īk, Jan-Christoph Oetjen

Proposal for a regulation Article 14 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use.

Amendment

1. *Where proportionate to the risks associated with the high-risk system and where technical safeguards are not sufficient*, high-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use.

Or. en

Amendment 1813

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

Proposal for a regulation Article 14 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use.

Amendment

1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use, *where required by the risk analysis as foreseen in the product legislations listed in Annex II.*

Or. en

Amendment 1814

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

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use.

Amendment

1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use, *and to allow for thorough investigation after an incident.*

Or. en

Amendment 1815

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

Proposal for a regulation
Article 14 – paragraph 2

Text proposed by the Commission

2. Le contrôle humain vise à prévenir ou à réduire au minimum les risques pour la santé, la sécurité ou les droits

Amendment

2. Le contrôle humain vise à prévenir ou à réduire au minimum les risques pour la santé, la sécurité ou les droits

fondamentaux qui peuvent apparaître lorsqu'un système d'IA à haut risque est utilisé conformément à sa destination ou dans des conditions de mauvaise utilisation raisonnablement prévisible, *en particulier lorsque de tels* risques persistent nonobstant l'application d'autres exigences énoncées dans le présent chapitre.

fondamentaux qui peuvent apparaître lorsqu'un système d'IA à haut risque est utilisé conformément à sa destination ou dans des conditions de mauvaise utilisation raisonnablement prévisible, *dans la mesure où ces* risques, *s'ils* persistent nonobstant l'application d'autres exigences énoncées dans le présent chapitre, *ne rendent pas obligatoire le rappel ou le retrait du système d'IA à haut risque.*

Or. fr

Amendment 1816

Pernando Barrena Arza, Cornelia Ernst, Kate ina Kone ná

Proposal for a regulation Article 14 – paragraph 2

Text proposed by the Commission

2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when *a high-risk AI system is* used in accordance with *its intended purpose* or under conditions of reasonably foreseeable misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.

Amendment

2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when *AI systems that pose risks to health and safety or fundamental rights or AI systems subjected to the transparency obligations ex Article 52 are* used in accordance with *their foreseeable uses* or under conditions of reasonably foreseeable misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.

Or. en

Amendment 1817

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

Proposal for a regulation Article 14 – paragraph 2

Text proposed by the Commission

Amendment

2. Human oversight shall aim at preventing or minimising the risks to health, safety **or** fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.

2. Human oversight shall aim at preventing or minimising the risks to health, safety, fundamental rights, **democracy, or the environment** that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable **use or** misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.

Or. en

Amendment 1818

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation Article 14 – paragraph 2

Text proposed by the Commission

2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose **or under conditions of reasonably foreseeable misuse**, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.

Amendment

2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.

Or. en

Justification

Misuse should not be part of the compliance system. Preventing it should be/is part of robustness and security requirements.

Amendment 1819

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation Article 14 – paragraph 3 – introductory part

Text proposed by the Commission

3. Human oversight shall be ensured through either one or all of the following measures:

Amendment

3. ***The degree of*** human oversight ***shall be adapted to the specific risks, the level of automation, and context of the AI system and*** shall be ensured through either one or all of the following ***types of*** measures:

Or. en

Amendment 1820

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

Proposal for a regulation

Article 14 – paragraph 3 – introductory part

Text proposed by the Commission

3. Human oversight shall be ensured through either one or all of the following measures:

Amendment

3. ***The degree of*** human oversight ***shall be adapted to the specific risks, the level of automation, and context of the AI system and*** shall be ensured through either one or all of the following measures:

Or. en

Amendment 1821

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

Proposal for a regulation

Article 14 – paragraph 3 – introductory part

Text proposed by the Commission

3. Human oversight shall be ensured through either one or ***all*** of the following ***measures***:

Amendment

3. Human oversight shall be ensured through either one or ***both*** of the following:

Or. en

Amendment 1822

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

Proposal for a regulation**Article 14 – paragraph 3 – point a***Text proposed by the Commission*

- (a) identified **and built**, when technically feasible, into the high-risk AI system **by the provider** before it is placed on the market or put into service;

Amendment

- (a) **measures identified by the provider building human oversight**, when technically feasible, into the high-risk AI system before it is placed on the market or put into service;

Or. en

Amendment 1823

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation**Article 14 – paragraph 3 – point a***Text proposed by the Commission*

- (a) identified and built, when technically feasible, into the high-risk AI system by the provider before it is placed on the market or put into service;

Amendment

- (a) identified and built, when technically feasible **and appropriate**, into the high-risk AI system by the provider before it is placed on the market or put into service;

Or. en

Amendment 1824

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

Proposal for a regulation**Article 14 – paragraph 3 – point b***Text proposed by the Commission*

- (b) identified by the provider before placing the high-risk AI system on the market or putting it into service and that are appropriate to be implemented by the

Amendment

- (b) **other measures** identified by the provider before placing the high-risk AI system on the market or putting it into service and that are appropriate to be

user.

implemented by the *deployer, such as user guides.*

Or. en

Amendment 1825

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 3 – point b

Text proposed by the Commission

(b) identified by the provider before placing the high-risk AI system on the market or putting it into service and that are appropriate to be implemented by the user.

Amendment

(b) identified by the provider *operationalized* before placing the high-risk AI system on the market or putting it into service and that are appropriate to be implemented by the user;

Or. en

Amendment 1826

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 3 – point b a (new)

Text proposed by the Commission

Amendment

(b a) required of the user, if appropriate, for their implementation;

Or. en

Amendment 1827

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 3 – point b b (new)

Text proposed by the Commission

Amendment

(b b) included during the development, testing, or monitoring processes.

Amendment 1828

Barbara Thaler, Lukas Mandl, Axel Voss, Deirdre Clune

Proposal for a regulation

Article 14 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. The commission, in accordance with the relevant stakeholders, shall provide comprehensive guidelines, in order to clarify the required form of human supervision for high-risk AI systems.

Amendment 1829

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 4 – introductory part

Text proposed by the Commission

Amendment

4. The measures referred to in paragraph 3 shall enable the individuals to whom human oversight is assigned to do the following, as appropriate to the circumstances:

4. For the purpose of implementing paragraphs 1 to 3, the high-risk AI system shall be provided to the user in such a way that natural persons to whom human oversight is assigned can do the following, as appropriate and proportionate to the circumstances and instructions for use and in accordance with industry standards:

Amendment 1830

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 14 – paragraph 4 – introductory part

Text proposed by the Commission

4. ***The measures referred to in paragraph 3 shall enable*** the individuals to whom human oversight is assigned ***to do the following***, as appropriate to the circumstances:

Amendment

4. ***For the purpose of implementing paragraphs 1 to 3, the high-risk AI system shall be provided to the user in such a way that*** the individuals to whom human oversight is assigned ***are enabled*** as appropriate ***and proportionate***, to the circumstances ***and in accordance with industry standards***:

Or. en

Amendment 1831

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 4 – point a

Text proposed by the Commission

(a) ***fully understand the capacities and limitations of the high-risk AI system and be able to duly monitor its operation, so that signs of anomalies, dysfunctions and unexpected performance can be detected and addressed as soon as possible;***

Amendment

(a) ***to be aware and sufficiently understand the relevant capacities and limitations of the high-risk AI system and be able to duly monitor its operation, so that signs of anomalies, dysfunctions and unexpected performance can be detected and addressed as soon as possible;***

Or. en

Amendment 1832

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova įk, Jan-Christoph Oetjen

Proposal for a regulation

Article 14 – paragraph 4 – point a

Text proposed by the Commission

(a) ***fully understand the capacities and limitations of the high-risk AI system and be able to duly monitor its operation, so that signs of anomalies, dysfunctions and***

Amendment

(a) ***to be aware of and sufficiently understand the capacities and limitations of the high-risk AI system and be able to duly monitor its operation, so that signs of***

unexpected performance can be detected and addressed as soon as possible;

anomalies, dysfunctions and unexpected performance can be detected and addressed as soon as possible;

Or. en

Amendment 1833

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 14 – paragraph 4 – point b

Text proposed by the Commission

(b) remain aware of the possible tendency of automatically relying or over-relying on the output produced by a high-risk AI system ('automation bias'), ***in particular for high-risk AI systems used to provide information or recommendations for decisions to be taken by natural persons;***

Amendment

(b) remain aware of the possible tendency of automatically relying or over-relying on the output produced by a high-risk AI system ('automation bias');

Or. en

Amendment 1834

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 4 – point b

Text proposed by the Commission

(b) remain aware of the possible tendency of automatically relying or over-relying on the output produced by a high-risk AI system ('automation bias'), ***in particular for high-risk AI systems used to provide information or recommendations for decisions to be taken by natural persons;***

Amendment

(b) remain aware of the possible tendency of automatically relying or over-relying on the output produced by a high-risk AI system ('automation bias');

Or. en

Amendment 1835

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

Proposal for a regulation

Article 14 – paragraph 4 – point b

Text proposed by the Commission

(b) ***remain aware of the possible tendency*** of automatically relying or over-relying on the output produced by a high-risk AI system ('automation bias'), in particular for high-risk AI systems used to provide information or recommendations for decisions to be taken by natural persons;

Amendment

(b) ***mitigate the risk*** of automatically relying or over-relying on the output produced by a high-risk AI system ('automation bias'), in particular for high-risk AI systems used to provide information or recommendations for decisions to be taken by natural persons;

Or. en

Amendment 1836

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

Proposal for a regulation

Article 14 – paragraph 4 – point c

Text proposed by the Commission

(c) ***be able*** to correctly interpret the high-risk AI system's output, taking into account ***in particular the characteristics of the system and*** the interpretation tools and methods available;

Amendment

(c) to correctly interpret the high-risk AI system's output, taking into account ***for example*** the interpretation tools and methods available;

Or. en

Amendment 1837

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 4 – point c

Text proposed by the Commission

(c) be able to correctly interpret the

Amendment

(c) be able to correctly interpret the

high-risk AI system's output, taking into account *in particular the characteristics of the system and* the interpretation tools and methods available;

high-risk AI system's output, taking into account, *for example*, the interpretation tools and methods available;

Or. en

Amendment 1838

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

Proposal for a regulation

Article 14 – paragraph 4 – point d

Text proposed by the Commission

(d) be able to decide, in any particular situation, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system;

Amendment

(d) *to* be able to decide, in any particular situation, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system;

Or. en

Amendment 1839

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

Proposal for a regulation

Article 14 – paragraph 4 – point d

Text proposed by the Commission

(d) be *able* to decide, in any particular situation, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system;

Amendment

(d) be *free* to decide, in any particular situation, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system;

Or. en

Amendment 1840

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 14 – paragraph 4 – point e

Text proposed by the Commission

- (e) be able to intervene on the operation of the high-risk AI system or interrupt the system through a “stop” button or a similar procedure.

Amendment

- (e) be able to intervene on the operation of the high-risk AI system or interrupt, ***where reasonable and technically feasible***, the system through a “stop” button or a similar procedure, ***except if the human interference increases the risk or would negatively impact the performance in consideration of generally acknowledged state-of-the-art***.

Or. en

Amendment 1841

**Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto ,
Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen**

Proposal for a regulation
Article 14 – paragraph 4 – point e

Text proposed by the Commission

- (e) be able to intervene on the operation of the high-risk AI system or interrupt the system ***through a “stop” button or a similar procedure***.

Amendment

- (e) ***to*** be able to intervene on the operation of the high-risk AI system, ***halt*** or interrupt the system ***where reasonable and technically feasible and except if the human interference increases the risks or would negatively impact the performance in consideration of generally acknowledged state-of-the-art***.

Or. en

Amendment 1842

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

Proposal for a regulation
Article 14 – paragraph 4 – point e

Text proposed by the Commission

Amendment

(e) be able to intervene ***on*** the operation of the high-risk AI system or interrupt the system through a “stop” button or a similar procedure.

(e) be able to intervene ***in*** the operation of the high-risk AI system or interrupt the system through a “stop” button or a similar procedure ***that allows the system to come to a halt in a safe state.***

Or. en

Amendment 1843

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation Article 14 – paragraph 5

Text proposed by the Commission

5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the identification resulting from the system unless this has been verified and confirmed by at least two natural persons.

Amendment

5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the identification resulting from the system unless this has been ***separately*** verified and confirmed by at least two natural persons ***on-site or remotely, except for temporary actions or decisions which cannot be delayed due to safety or security reasons for the purpose of law enforcement.***

Or. en

Amendment 1844

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

Proposal for a regulation Article 14 – paragraph 5

Text proposed by the Commission

5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the identification resulting from the system

Amendment

5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the identification resulting from the system

unless this has been verified and confirmed by at least two natural persons.

unless this has been verified and confirmed by at least two natural persons *separately*.

Or. en

Amendment 1845

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

Proposal for a regulation Article 14 – paragraph 5

Text proposed by the Commission

5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the *user* on the basis of the *identification resulting* from the system unless this has been verified and confirmed by at least two natural persons.

Amendment

5. For high-risk AI systems referred to in point 1(a) *and 1(b)* of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the *deployer* on the basis of the *output* from the system unless this has been verified and confirmed by at least two natural persons.

Or. en

Amendment 1846

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation Article 14 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. For the purpose of implementing paragraph 2, in the case where the result of an identification is inconclusive, the human oversight requirements from paragraphs 3 to 5 shall be performed directly internally by the closest entity to the user in the supply chain of the high-risk AI system.

Or. en

Amendment 1847

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 5 b (new)

Text proposed by the Commission

Amendment

5 b. With the exception of high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall not be interpreted as requiring a human to review every action or decision taken by the AI system. Full automation of such systems shall be possible provided that technical measures are put in place to comply with provisions in paragraphs 1 to 4.

Or. en

Amendment 1848

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 1

Text proposed by the Commission

Amendment

1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their *lifecycle*.

1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose *and to the extent that can be reasonably expected and is in accordance with relevant industry standards*, an appropriate level of accuracy, *reliability*, robustness and cybersecurity, and *the basic pillars of information security and protection, such as confidentiality, integrity and availability as well as to* perform consistently in those respects throughout their *lifetime while taking their evolving nature into account*.

Or. en

Amendment 1849

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

Proposal for a regulation**Article 15 – paragraph 1***Text proposed by the Commission*

1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle.

Amendment

1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose, *the foreseeable uses and reasonably foreseeable misuses*, an appropriate level of *perfomance (such as* accuracy, *reliability and true positive rate*), robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle.

Or. en

Justification

Consequential amendment related to our amendments of Annex IV. It is needed to ensure consistency of the provisions throughout the text.

Amendment 1850

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation**Article 15 – paragraph 1***Text proposed by the Commission*

1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle.

Amendment

1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose *and to the extent that can be reasonably expected and is in accordance with relevant industry standards*, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle.

Or. en

Amendment 1851

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

Proposal for a regulation

Article 15 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, ***and perform consistently in those respects*** throughout their lifecycle.

Amendment

1. High-risk AI systems shall be designed and developed in such a way that they achieve ***security by design and by default***, in the light of their intended purpose, an appropriate level of accuracy, ***reliability***, robustness, ***resilience, safety*** and cybersecurity throughout their lifecycle.

Or. en

Amendment 1852

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. To address the technical aspects of how to measure the appropriate levels of accuracy and robustness in paragraph 1, the European Artificial Intelligence Board shall bring together national metrology and benchmarking authorities and provide non-binding guidance on the matter as per Article 56(2a) of this Regulation.

Or. en

Amendment 1853

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

**Proposal for a regulation
Article 15 – paragraph 2**

Text proposed by the Commission

2. The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use.

Amendment

2. The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be *assessed by an independent entity and* declared in the accompanying instructions of use. *The language used shall be clear, free of misunderstandings or misleading statements.*

Or. en

Amendment 1854

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

**Proposal for a regulation
Article 15 – paragraph 2**

Text proposed by the Commission

2. The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use.

Amendment

2. *The performance metrics and its appropriateness, including* the levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use.

Or. en

Justification

Consequential amendment related to our amendments of Annex IV. It is needed to ensure consistency of the provisions throughout the text.

Amendment 1855

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 15 – paragraph 2**

Text proposed by the Commission

2. The *levels of accuracy* and the

Amendment

2. The *range of expected*

relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use.

performance and the operational factors that affect that performance, shall be declared, **where possible**, in the accompanying instructions of use.

Or. en

Amendment 1856

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ondej Kováčik, Jan-Christoph Oetjen

Proposal for a regulation

Article 15 – paragraph 2

Text proposed by the Commission

2. The *levels of accuracy* and the *relevant accuracy metrics of high-risk AI systems* shall be declared in the accompanying instructions of use.

Amendment

2. The *range of expected performance* and the *operational factors that affect that performance* shall be declared in the accompanying instructions of use.

Or. en

Amendment 1857

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 3 – introductory part

Text proposed by the Commission

3. High-risk AI systems shall be *resilient* as regards errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems.

Amendment

3. High-risk AI systems shall be *designed and developed with safety and security by design mechanism by default so that they achieve, in the light of their intended purpose, an appropriate level of cyber resilience* as regards errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems.

Or. en

Amendment 1858

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ondej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 15 – paragraph 3 – introductory part

Text proposed by the Commission

3. High-risk AI systems shall be **resilient** as regards errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems.

Amendment

3. High-risk AI systems shall be **designed and developed with safety and security-by-design mechanism so that they achieve, in the light of their intended purpose, an appropriate level of cyber resilience** as regards **to** errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems.

Or. en

Amendment 1859

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

Proposal for a regulation

Article 15 – paragraph 3 – introductory part

Text proposed by the Commission

3. High-risk AI systems shall be **resilient** as regards errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems.

Amendment

3. High-risk AI systems shall be **robust** as regards errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems.

Or. en

Amendment 1860

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 15 – paragraph 3 – subparagraph 1

Text proposed by the Commission

The robustness of high-risk AI systems may be achieved through technical redundancy solutions, which may include backup or fail-safe plans.

Amendment

The robustness of high-risk AI systems may be achieved through *diverse* technical redundancy solutions, which may include *reasonably designed* backup or fail-safe plans *by the appropriate provider or user or as mutually agreed by the provider and the user.*

Or. en

Amendment 1861

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

Proposal for a regulation
Article 15 – paragraph 3 – subparagraph 2

Text proposed by the Commission

High-risk AI systems that continue to learn after being *placed on the market or* put into service shall *be developed in such a way to* ensure that *possibly biased outputs due to outputs used as an input for future operations ('feedback loops') are duly* addressed with appropriate mitigation measures.

Amendment

High-risk AI systems that continue to learn after being put into service shall ensure that '*feedback loops' caused by* biased outputs *are adequately* addressed with appropriate mitigation measures.

Or. en

Amendment 1862

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 15 – paragraph 3 – subparagraph 2

Text proposed by the Commission

High-risk AI systems that continue to learn after being placed on the market or put into

Amendment

High-risk AI systems that continue to learn after being placed on the market or put into

service shall be developed in such a way to ensure that possibly biased outputs ***due to outputs used as*** an input for future operations ('feedback loops') are duly addressed with appropriate mitigation measures.

service shall be developed in such a way to ensure that possibly biased outputs ***influencing*** an input for future operations ('feedback loops') are duly addressed with appropriate mitigation measures.

Or. en

Amendment 1863

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova īk, Jan-Christoph Oetjen

Proposal for a regulation

Article 15 – paragraph 3 – subparagraph 2

Text proposed by the Commission

High-risk AI systems that continue to learn after being placed on the market or put into service shall be developed in such a way to ensure that possibly biased outputs ***due to outputs used as an*** input for future operations ('feedback loops') are duly addressed with appropriate mitigation measures.

Amendment

High-risk AI systems that continue to learn after being placed on the market or put into service shall be developed in such a way to ensure that possibly biased outputs ***influencing*** input for future operations ('feedback loops') are duly addressed with appropriate mitigation measures.

Or. en

Amendment 1864

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

Proposal for a regulation

Article 15 – paragraph 3 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

Le fonctionnement des systèmes d'I.A. à haut risque est auditabile et reproductible par l'utilisateur, le fournisseur, la ou les autorités nationales compétentes et la Commission européenne, selon le cas.

Or. fr

Amendment 1865

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. In accordance with Article 42 (2), the compliance with Article 15 for high-risk AI systems that have already been certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 shall be assumed.

Or. en

Amendment 1866

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

Proposal for a regulation

Article 15 – paragraph 4 – introductory part

Text proposed by the Commission

Amendment

4. High-risk AI systems shall be *resilient as regards* attempts by unauthorised third parties to alter their use or performance *by exploiting the system vulnerabilities.*

4. High-risk AI systems shall be *adequately protected against* attempts by unauthorised third parties to alter their use or performance.

Or. en

Amendment 1867

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

Proposal for a regulation

Article 15 – paragraph 4 – subparagraph 1

Text proposed by the Commission

Amendment

The technical solutions aimed at ensuring the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks.

The technical solutions aimed at ensuring ***and organisational measures designed to uphold*** the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks.

Or. en

Amendment 1868

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 4 – subparagraph 1

Text proposed by the Commission

The technical solutions ***aimed at ensuring*** the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks.

Amendment

The technical solutions ***and organisational measures designed to uphold*** the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks.

Or. en

Amendment 1869

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

Proposal for a regulation

Article 15 – paragraph 4 – subparagraph 1

Text proposed by the Commission

The technical ***solutions*** aimed at ensuring the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks.

Amendment

The technical ***and organisational measures*** aimed at ensuring the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks.

Or. en

Amendment 1870

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 4 – subparagraph 2

Text proposed by the Commission

The technical solutions **to address AI specific vulnerabilities shall** include, where appropriate, measures to prevent and control for attacks trying to manipulate the training dataset ('data poisoning'), inputs designed to cause the model to make a mistake ('adversarial examples'), or model flaws.

Amendment

The technical solutions **may** include, where appropriate, measures to prevent and control for attacks trying to manipulate the training dataset ('data poisoning'), inputs designed to cause the model to make a mistake ('adversarial examples'), or model flaws, **or exploratory attacks that may aim to extract knowledge, algorithms, trade secrets or training information from the AI.**

Or. en

Amendment 1871

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

Proposal for a regulation

Article 15 – paragraph 4 – subparagraph 2

Text proposed by the Commission

The technical **solutions** to address AI specific vulnerabilities shall include, where appropriate, measures to prevent and control **for** attacks trying to manipulate the training dataset ('data poisoning'), inputs designed to cause the model to make a mistake ('adversarial examples'), or model flaws.

Amendment

The technical **and organisational measures** to address AI specific vulnerabilities shall include **at least**, where appropriate, measures to prevent and control attacks trying to manipulate the training dataset ('data poisoning'), inputs designed to cause the model to make a mistake ('adversarial examples'), or model flaws.

Or. en

Amendment 1872

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

Proposal for a regulation

Article 15 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. High risk AI shall be accompanied by security solutions and patches for the lifetime of the product it is embedded in, or in case of the absence of dependence on a specific product, for a time that needs to be stated by the manufacturer and cannot be less than 10 years.

Or. en

Amendment 1873

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 15 a (new)

Text proposed by the Commission

Amendment

Article 15 a

Sustainable AI systems reporting

1. Providers of high-risk AI systems shall make publicly available information on the energy consumption of the AI system, in particular its carbon footprint with regard to the development of hardware, computational resources, as well as algorithm design and training, testing and validating processes of the high-risk AI systems. The provider shall include this information in the technical documentation referred to in Article 11.

2. The Commission shall develop, by means of an implementing act, a standardised document to facilitate the disclosure of information on the energy used in the training and execution of AI systems and their carbon intensity.

Or. en

Amendment 1874

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

Proposal for a regulation
Title III – Chapter 3 – title

Text proposed by the Commission

3 OBLIGATIONS OF PROVIDERS
AND **USERS** OF HIGH-RISK AI
SYSTEMS and other parties

Amendment

3 OBLIGATIONS OF PROVIDERS
AND **DEPLOYERS** OF HIGH-RISK AI
SYSTEMS and other parties

Or. en

Amendment 1875

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

Proposal for a regulation
Article 16 – title

Text proposed by the Commission

Obligations of providers of high-risk AI systems

Amendment

Obligations of providers **and deployers** of high-risk AI systems

Or. en

Amendment 1876

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation
Article 16 – paragraph 1 – introductory part

Text proposed by the Commission

Providers of high-risk AI systems shall:

Amendment

As long as providers of high-risk AI systems **exercise full control over the systems, they** shall:

Or. en

Amendment 1877

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

Proposal for a regulation
Article 16 – paragraph 1 – introductory part

Text proposed by the Commission

Providers of high-risk AI systems shall:

Amendment

Providers *and, where applicable, deployers* of high-risk AI systems shall:

Or. en

Amendment 1878

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation
Article 16 – paragraph 1 – point a

Text proposed by the Commission

(a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title;

Amendment

(a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title *before placing them on the market or putting them into service, and shall be responsible for compliance of these systems after that point only to the extent that they exercise actual control over relevant aspects of the system;*

Or. en

Amendment 1879

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 16 – paragraph 1 – point a

Text proposed by the Commission

(a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title;

Amendment

(a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title *before placing them on the market or putting them into service;*

Or. en

Amendment 1880

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 16 – paragraph 1 – point a

Text proposed by the Commission

- (a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title;

Amendment

- (a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title *as long as the provider exercise control over the AI systems*;

Or. en

Amendment 1881

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 16 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

- (a a) indicate their name, registered trade name or registered trade mark, the address at which they can be contacted on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as applicable;*

Or. en

Amendment 1882

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 16 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) indicate their name, registered trade name or registered trade mark, and their address on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as appropriate;

Or. en

Amendment 1883

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

Proposal for a regulation

Article 16 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) ensure that the performance of their high-risk AI system is measured appropriately, including its level of accuracy, robustness and cybersecurity;

Or. en

Amendment 1884

Sophia in 't Veld, Michal Šimeka

Proposal for a regulation

Article 16 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) ensure that, in the case of a general purpose AI system, the reasonably foreseeable uses of this system are assessed.

Or. en

Amendment 1885

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

Proposal for a regulation
Article 16 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) include name and contact information;

Or. en

Amendment 1886

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

Proposal for a regulation
Article 16 – paragraph 1 – point a b (new)

Text proposed by the Commission

Amendment

(a b) provide specifications for the input data, or any other relevant information in terms of the data sets used, including their limitation and assumptions, taking into account of the intended purpose and the foreseeable and reasonably foreseeable misuses of the AI system;

Or. en

Amendment 1887

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

Proposal for a regulation
Article 16 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) draw-up the technical documentation of the high-risk AI system;

(c) draw-up the technical documentation of the high-risk AI system referred to in Article 18;

Or. en

Amendment 1888

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 16 – paragraph 1 – point c

Text proposed by the Commission

- (c) *draw-up the technical documentation of the high-risk AI system;*

Amendment

- (c) *keep the documentation referred to in Article 18;*

Or. en

Amendment 1889

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

Proposal for a regulation

Article 16 – paragraph 1 – point d

Text proposed by the Commission

- (d) when under their control, keep the logs automatically generated by their high-risk AI systems;

Amendment

- (d) when under their control, keep the logs automatically generated by their high-risk AI systems *for a period of at least two years, or as long as is appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under Union or national law;*

Or. en

Amendment 1890

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 16 – paragraph 1 – point d

Text proposed by the Commission

- (d) when under their control, keep the logs automatically generated by their high-risk AI systems;

Amendment

- (d) when under their control, keep the logs automatically generated by their high-risk AI systems, *in accordance with Article 20;*

Or. en

Amendment 1891

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

Proposal for a regulation

Article 16 – paragraph 1 – point d

Text proposed by the Commission

(d) ***when under their control***, keep the logs automatically generated by their high-risk AI systems;

Amendment

(d) keep the logs automatically generated by their high-risk AI systems ***as referred to in Article 20***;

Or. en

Amendment 1892

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

Proposal for a regulation

Article 16 – paragraph 1 – point e

Text proposed by the Commission

(e) veillent à ce que le système d'IA à haut risque soit soumis à la procédure d'évaluation de la conformité applicable, avant sa mise sur le marché ou sa mise en service;

Amendment

(e) veillent à ce que le système d'IA à haut risque soit soumis à la procédure d'évaluation de la conformité applicable, avant sa mise sur le marché ou sa mise en service, ***et à sa révision périodique***;

Or. fr

Amendment 1893

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

Proposal for a regulation

Article 16 – paragraph 1 – point e

Text proposed by the Commission

(e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure, prior to its placing

Amendment

(e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure ***as referred to in Article 43***, prior to its placing on the

on the market or putting into service;

market or putting into service;

Or. en

Amendment 1894

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 16 – paragraph 1 – point e

Text proposed by the Commission

- (e) ensure that the high-risk AI system undergoes the relevant *conformity* assessment procedure, prior to its placing on the market or putting into service;

Amendment

- (e) ensure that the high-risk AI system undergoes the relevant *independent third party* assessment procedure, prior to its placing on the market or putting into service;

Or. en

Amendment 1895

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

Proposal for a regulation

Article 16 – paragraph 1 – point e

Text proposed by the Commission

- (e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure, prior to its placing on the market or putting into service;

Amendment

- (e) ensure that the high-risk AI system undergoes the relevant *third party* conformity assessment procedure, prior to its placing on the market or putting into service;

Or. en

Amendment 1896

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 16 – paragraph 1 – point e

Text proposed by the Commission

(e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure, prior to its placing on the market or putting into service;

Amendment

(e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure, prior to its placing on the market or putting into service *or use*;

Or. en

Amendment 1897

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 16 – paragraph 1 – point e

Text proposed by the Commission

(e) *ensure that the high-risk AI system undergoes* the relevant conformity assessment procedure, prior to its placing on the market or putting into service;

Amendment

(e) *carry out* the relevant conformity assessment procedure, *as provided for in Article 19*, prior to its placing on the market or putting into service;

Or. en

Amendment 1898

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

Proposal for a regulation

Article 16 – paragraph 1 – point g

Text proposed by the Commission

(g) prennent les mesures correctives nécessaires si le système d'IA à haut risque n'est pas conforme aux exigences énoncées au chapitre 2 du présent titre;

Amendment

(g) prennent les mesures correctives nécessaires si le système d'IA à haut risque n'est pas conforme aux exigences énoncées au chapitre 2 du présent titre, *préalablement à la mise sur le marché, à la mise à disposition sur le marché ou à la mise en service dudit système d'I.A. à haut risque, ou de sa nouvelle mise sur le marché, mise à disposition sur le marché ou mise en service s'il s'agit d'un système d'I.A. à haut risque ayant été retiré ou rappelé*;

Amendment 1899

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

Proposal for a regulation

Article 16 – paragraph 1 – point g

Text proposed by the Commission

(g) take the necessary corrective actions, if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title;

Amendment

(g) take the necessary corrective actions *as referred to in Article 21*, if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title;

Or. en

Amendment 1900

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 16 – paragraph 1 – point g

Text proposed by the Commission

(g) take the necessary corrective actions, if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title;

Amendment

(g) take the necessary corrective actions *as referred to in Art 21*, if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title;

Or. en

Amendment 1901

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 16 – paragraph 1 – point i

Text proposed by the Commission

(i) *to* affix the CE marking to their high-risk AI systems to indicate the

Amendment

(i) affix the CE marking to their high-risk AI systems to indicate the conformity

conformity with this Regulation in accordance with Article 49;

with this Regulation in accordance with Article 49;

Or. en

Amendment 1902

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 16 – paragraph 1 – point j

Text proposed by the Commission

(j) upon request of a national competent authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title.

Amendment

(j) upon ***reasoned*** request of a national competent authority, ***provide the relevant information and documentation to*** demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title.

Or. en

Amendment 1903

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

Proposal for a regulation

Article 16 – paragraph 1 – point j

Text proposed by the Commission

(j) upon request of a national competent authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title.

Amendment

(j) upon request of ***a national supervisory authority or*** a national competent authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title.

Or. en

Amendment 1904

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 16 – paragraph 1 – point j

Text proposed by the Commission

- (j) upon request of a national competent authority, demonstrate the conformity of the high-risk AI system *with the requirements set out in Chapter 2 of this Title.*

Amendment

- (j) upon *reasoned* request of a national competent authority, *provide the relevant information and documentation to* demonstrate the conformity of the high-risk AI system.

Or. en

Amendment 1905

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 16 – paragraph 1 – point j a (new)

Text proposed by the Commission

Amendment

- (j a) 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 1906

Rob Rooken
on behalf of the ECR Group

Proposal for a regulation
Article 16 – paragraph 1 – point j a (new)

Text proposed by the Commission

Amendment

- (j a) conduct and publish a fundamental rights impact assessment.*

Or. en

Amendment 1907

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 16 – paragraph 1 – point j b (new)

Text proposed by the Commission

Amendment

(j b) ensure that the individual to whom human oversight is assigned shall either be fully independent from the provider or user or, be adequately protected against negative consequences for their position within the organisation, resulting from or related to their exercise of human oversight.

Or. en

Amendment 1908

Vincenzo Sofo, Kosma Złotowski

Proposal for a regulation

Article 16 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The obligations contained in paragraph 1 shall be without prejudice to obligations applicable to providers of high-risk AI systems arising from Regulation (EU) 2016/679 of the European Parliament and of the Council and Regulation (EU) 2018/1725 of the European Parliament and of the Council

Or. en

Amendment 1909

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Article 16 a (new)

Text proposed by the Commission

Amendment

Article 16 a

Obligations of users of high-risk AI systems

Users of high-risk AI systems shall conduct and publish a fundamental rights impact assessment, detailing specific information relating to the context of use of the high-risk AI system in question, including:

- (a) the affected persons,*
- (b) intended purpose,*
- (c) geographic and temporal scope,*
- (d) assessment of the legality and fundamental rights impacts of the system,*
- (e) compatibility with accessibility legislation,*
- (f) potential direct and indirect impact on fundamental rights,*
- (g) any specific risk of harm likely to impact marginalised persons or those at risk of discrimination,*
- (h) the foreseeable impact of the use of the system on the environment,*
- (i) any other negative impact on the public interest,*
- (j) clear steps as to how the harms identified will be mitigated and how effective this mitigation is likely to be.*

Or. en

Amendment 1910

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 17 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

1. *Unless existing risk management systems are already in place to warrant the quality of the high-risk AI systems*, providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

Or. en

Amendment 1911

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

Proposal for a regulation

Article 17 – paragraph 1 – introductory part

Text proposed by the Commission

1. Providers of high-risk AI systems shall **put** a quality management system **in place that ensures** compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

Amendment

1. *In case there are no risk management systems already in place*, providers **and users** of high-risk AI systems shall **implement** a quality management system **to ensure** compliance with this Regulation **and corresponding obligations**. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

Or. en

Amendment 1912

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

Proposal for a regulation

Article 17 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

1. Providers *and, where applicable, deployers* of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

Or. en

Amendment 1913

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 17 – paragraph 1 – introductory part

Text proposed by the Commission

1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

Amendment

1. Providers of high-risk AI systems shall put a quality management system in place, *certified by an independent third party* that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

Or. en

Amendment 1914

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 17 – paragraph 1 – introductory part

Text proposed by the Commission

1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly

Amendment

1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly

manner in the form of written policies, procedures **and** instructions, and shall include at least the following aspects:

manner in the form of written policies, procedures **or** instructions, and shall include at least the following aspects:

Or. en

Amendment 1915

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – introductory part

Text proposed by the Commission

1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. ***That system*** shall be ***documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:***

Amendment

1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation ***and that*** shall be ***incorporated as part of an existing quality management system under sectoral legislation or as provided by the International Organisation for Standardization.***

Or. en

Amendment 1916

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ond ej Kova īk, Jan-Christoph Oetjen

Proposal for a regulation

Article 17 – paragraph 1 – point a

Text proposed by the Commission

(a) ***a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the high-risk AI system;***

Amendment

deleted

Or. en

Amendment 1917

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 17 – paragraph 1 – point a**

Text proposed by the Commission

Amendment

(a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the high-risk AI system;

deleted

Or. en

**Amendment 1918
Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation
Article 17 – paragraph 1 – point b**

Text proposed by the Commission

Amendment

(b) techniques, procedures and systematic actions to be used for the design, design control and design verification of the high-risk AI system;

deleted

Or. en

**Amendment 1919
Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation
Article 17 – paragraph 1 – point c**

Text proposed by the Commission

Amendment

(c) techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the high-risk AI system;

deleted

Or. en

Amendment 1920
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 17 – paragraph 1 – point d

Text proposed by the Commission

Amendment

(d) examination, test and validation procedures to be carried out before, during and after the development of the high-risk AI system, and the frequency with which they have to be carried out; *deleted*

Or. en

Amendment 1921
Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation
Article 17 – paragraph 1 – point e

Text proposed by the Commission

Amendment

(e) technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, the means to be used to ensure that the high-risk AI system complies with the requirements set out in Chapter 2 of this Title; *deleted*

Or. en

Amendment 1922
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 17 – paragraph 1 – point e

Text proposed by the Commission

Amendment

(e) technical specifications, including standards, to be applied and, where the relevant harmonised standards are not *deleted*

applied in full, the means to be used to ensure that the high-risk AI system complies with the requirements set out in Chapter 2 of this Title;

Or. en

Amendment 1923

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

Proposal for a regulation

Article 17 – paragraph 1 – point e

Text proposed by the Commission

(e) technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, the means to be used to ensure that the high-risk AI system complies with the requirements set out in Chapter 2 of this Title;

Amendment

(e) technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, *or do not cover all of the relevant requirements*, the means to be used to ensure that the high-risk AI system complies with the requirements set out in Chapter 2 of this Title;

Or. en

Amendment 1924

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point f

Text proposed by the Commission

(f) systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market or putting into service of high-risk AI systems;

Amendment

deleted

Or. en

Amendment 1925

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

Proposal for a regulation

Article 17 – paragraph 1 – point f

Text proposed by the Commission

(f) systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market *or* putting into service of high-risk AI systems;

Amendment

(f) systems and procedures for data management, including *data acquisition*, data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market, putting into service, *and deployment* of high-risk AI systems;

Or. en

Amendment 1926

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

Proposal for a regulation

Article 17 – paragraph 1 – point f

Text proposed by the Commission

(f) systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before *and* for the purposes of the placing on the market or putting into service of high-risk AI systems;

Amendment

(f) systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before for the purposes of the placing on the market or putting into service of high-risk AI systems, *and after deployment of the high-risk AI*;

Or. en

Amendment 1927

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 17 – paragraph 1 – point f

Text proposed by the Commission

(f) systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market or putting into service of high-risk AI systems;

Amendment

(f) systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market or putting into service **or use** of high-risk AI systems;

Or. en

Amendment 1928

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point g

Text proposed by the Commission

(g) the risk management system referred to in Article 9;

Amendment

deleted

Or. en

Amendment 1929

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point h

Text proposed by the Commission

(h) the setting-up, implementation and maintenance of a post-market monitoring system, in accordance with Article 61;

Amendment

deleted

Or. en

Amendment 1930

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point i

Text proposed by the Commission

Amendment

(i) *procedures related to the reporting
of serious incidents and of
malfunctioning in accordance with
Article 62;* *deleted*

Or. en

Amendment 1931

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

Proposal for a regulation

Article 17 – paragraph 1 – point i

Text proposed by the Commission

Amendment

(i) procedures related to the reporting
of serious incidents and of malfunctioning
in accordance with Article 62;

(i) procedures related to the reporting
of serious incidents and of malfunctioning,
including near misses, in accordance with
Article 62;

Or. en

Justification

One example of near miss for AI systems is the case of a self-driving car running a red light, but not hitting anyone on that occasion. This could have been a serious incident if the car had hit a pedestrian, for example. Fixing this issue before another such incident occurs is important. Hence, the importance of near miss reporting.

There are several references to 'near misses' in different legislations such as Directive (EU) 2016/798 on railway safety and ECM Regulation 445/2011.

Amendment 1932

Fernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 17 – paragraph 1 – point i

Text proposed by the Commission

(i) procedures related to the reporting of serious incidents and of malfunctioning in accordance with Article 62;

Amendment

(i) procedures related to the reporting of serious incidents and of malfunctioning, ***including near misses***, in accordance with Article 62;

Or. en

Amendment 1933

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point j

Text proposed by the Commission

(j) the handling of communication with national competent authorities, competent authorities, including sectoral ones, providing or supporting the access to data, notified bodies, other operators, customers or other interested parties;

Amendment

deleted

Or. en

Amendment 1934

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 17 – paragraph 1 – point j

Text proposed by the Commission

(j) the handling of communication with national competent authorities, competent authorities, including sectoral ones, *providing or supporting the access to data, notified bodies, other operators, customers or other interested parties;*

Amendment

(j) the handling of communication with national competent authorities, competent authorities, including sectoral ones;

Or. en

Amendment 1935

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ondej Kovač, Jan-Christoph Oetjen

Proposal for a regulation

Article 17 – paragraph 1 – point k

Text proposed by the Commission

Amendment

(k) *systems and procedures for record keeping of all relevant documentation and information;* *deleted*

Or. en

Amendment 1936

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point k

Text proposed by the Commission

Amendment

(k) *systems and procedures for record keeping of all relevant documentation and information;* *deleted*

Or. en

Amendment 1937

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point l

Text proposed by the Commission

Amendment

(l) *resource management, including security of supply related measures;* *deleted*

Or. en

Amendment 1938
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 17 – paragraph 1 – point m

Text proposed by the Commission

Amendment

(m) an accountability framework setting out the responsibilities of the management and other staff with regard to all aspects listed in this paragraph.

deleted

Or. en

Amendment 1939

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

Proposal for a regulation
Article 17 – paragraph 2

Text proposed by the Commission

Amendment

2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation.

deleted

Or. en

Amendment 1940

Marion Walsmann

Proposal for a regulation
Article 17 – paragraph 2

Text proposed by the Commission

Amendment

2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation.

*2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation **and can be fulfilled by further elaborating existing quality management systems.***

Amendment 1941

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

Proposal for a regulation

Article 17 – paragraph 2

Text proposed by the Commission

2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation.

Amendment

2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's **and user's** organisation.

Amendment 1942

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

Proposal for a regulation

Article 17 – paragraph 3

Text proposed by the Commission

3. For providers that are credit institutions regulated by Directive 2013/36/EU, **the obligation to put a quality management system in place shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to Article 74 of that Directive. In that context, any harmonised standards referred to in Article 40 of this Regulation shall be taken into account.**

Amendment

3. **This Article applies without prejudice to the obligations** for providers that are credit institutions regulated by Directive 2013/36/EU.

Amendment 1943

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Article 17 – paragraph 3 a (new)**

Text proposed by the Commission

Amendment

3 a. High-risk AI systems shall make use of high quality models, that use relevant, justified and reasonable parameters and features and optimise for justified goals;

Or. en

Amendment 1944

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Article 17 – paragraph 3 b (new)**

Text proposed by the Commission

Amendment

3 b. High-risk AI systems shall only be used in a different domain or environment where they are generalisable to such domain or environment

Or. en

Amendment 1945

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 18**

Text proposed by the Commission

Amendment

Article 18

deleted

Obligation to draw up technical documentation

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

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

Or. en

Justification

Given the addition of new paragraph 4 in Article 11, Article 18 is not needed anymore.

Amendment 1946

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 18 – paragraph 1**

Text proposed by the Commission

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

Amendment

1. **The provider shall, for a period of 3 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 **and** Annex IV;
- (b) **the documentation concerning the quality management system referred to in Article 17;**
- (c) **the documentation concerning the changes approved by notified bodies where applicable;**
- (d) **the decisions and other documents issued by the notified bodies where applicable;**
- (e) **the EU declaration of conformity referred to in Article 48.**

Or. en

Amendment 1947

Jörgen Warborn, Arba Kokalari, Tomas Tobé

**Proposal for a regulation
Article 18 – paragraph 1**

Text proposed by the Commission

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

Amendment

1. Providers of high-risk AI systems shall draw up the technical **documentation** referred to in Article 11 in accordance with Annex IV. **When applicable, the technical documentation shall be treated as containing trade secrets as regulated by Directive (EU) 2016/943.**

Or. en

Amendment 1948

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

**Proposal for a regulation
Article 18 – paragraph 1**

Text proposed by the Commission

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

Amendment

1. Providers of high-risk AI systems shall draw up the technical documentation referred to in Article 11 in accordance with Annex IV **and make it available at the request of a national competent authority.**

Or. en

Amendment 1949

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Article 19 – title**

Text proposed by the Commission

Conformity assessment

Amendment

Independent Third party Conformity assessment

Or. en

Amendment 1950

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 19 – paragraph 1

Text proposed by the Commission

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

Amendment

1. Providers of high-risk AI systems shall ensure that their systems undergo *an independent third party* conformity assessment procedure in accordance with Article 43 *and Annex VII*, prior to their placing on the market or putting into service. Where the compliance of the AI systems with the requirements set out in Chapter 2 of this Title has been demonstrated following that conformity assessment, the providers shall draw up an EU declaration of conformity in accordance with Article 48 and affix the CE marking of conformity in accordance with Article 49. *The conformity assessment shall be publicly available.*

Or. en

Amendment 1951

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

Proposal for a regulation

Article 19 – paragraph 1

Text proposed by the Commission

1. Les fournisseurs de systèmes d'IA à haut risque veillent à ce que leurs systèmes soient soumis à la procédure d'évaluation de la conformité applicable conformément à l'article 43, avant leur mise sur le marché ou leur mise en service. Lorsqu'il a été démontré, à la suite de cette évaluation de la conformité, que les systèmes d'IA satisfont aux exigences énoncées au chapitre 2 du présent titre, les fournisseurs

Amendment

1. Les fournisseurs de systèmes d'IA à haut risque veillent à ce que leurs systèmes soient soumis à la procédure d'évaluation de la conformité applicable conformément à l'article 43, avant leur *mise sur le marché, leur mise à disposition* sur le marché ou leur mise en service. Lorsqu'il a été démontré, à la suite de cette évaluation de la conformité, que les systèmes d'IA satisfont aux exigences énoncées au

établissent une déclaration UE de conformité conformément à l'article 48 et apposent le marquage «CE» de conformité conformément à l'article 49.

chapitre 2 du présent titre, les fournisseurs établissent une déclaration UE de conformité conformément à l'article 48 et apposent le marquage «CE» de conformité conformément à l'article 49.

Or. fr

Justification

Correspond à l'ensemble des définitions données à l'article 3.

Amendment 1952

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 19 – paragraph 1

Text proposed by the Commission

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

Amendment

1. Providers of high-risk AI systems shall ensure that their systems undergo the relevant conformity assessment procedure in accordance with Article 43, prior to their placing on the market or putting into service **or use**. Where the compliance of the AI systems with the requirements set out in Chapter 2 of this Title has been demonstrated following that conformity assessment, the providers shall draw up an EU declaration of conformity in accordance with Article 48 and affix the CE marking of conformity in accordance with Article 49.

Or. en

Amendment 1953

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 20 – paragraph 1

Text proposed by the Commission

1. Providers of high-risk AI systems

Amendment

1. Providers of high-risk AI systems

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

shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. The logs shall be kept for a period that is appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under Union or national law. *When applicable, the automatically generated logs shall be treated as containing trade secrets as regulated by Directive (EU) 2016/943.*

Or. en

Amendment 1954

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

Proposal for a regulation

Article 20 – paragraph 1

Text proposed by the Commission

1. Les fournisseurs de systèmes d'IA à haut risque **assurent la tenue** des journaux générés automatiquement par leurs systèmes d'IA à haut risque, dans la mesure où ces journaux se trouvent sous leur contrôle en vertu d'un arrangement contractuel avec l'utilisateur ou d'autres modalités prévues par la loi. Les journaux sont conservés pendant une période appropriée au regard de la destination du système d'IA à haut risque et des obligations légales applicables en vertu du droit de l'Union ou du droit national.

Amendment

1. Les fournisseurs de systèmes d'IA à haut risque **garantissent la conservation, dans la mesure du possible sur les supports des utilisateurs**, des journaux générés automatiquement par leurs systèmes d'IA à haut risque, dans la mesure où ces journaux se trouvent sous leur contrôle en vertu d'un arrangement contractuel avec l'utilisateur ou d'autres modalités prévues par la loi. Les journaux sont conservés pendant une période appropriée au regard de la destination du système d'IA à haut risque et des obligations légales applicables en vertu du droit de l'Union ou du droit national.

Or. fr

Amendment 1955

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 20 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 1956

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

Proposal for a regulation
Article 20 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 1957

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

**Proposal for a regulation
Article 20 – paragraph 1**

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 1958

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 20 – paragraph 1**

Text proposed by the Commission

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

Amendment

1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by *law as well as under their factual control and to the extent that it is technically feasible. They shall keep them for a period of at least six months, unless provided otherwise in* applicable Union or national law.

Or. en

Amendment 1959

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 21 – paragraph 1**

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 1960

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

**Proposal for a regulation
Article 21 – paragraph 1**

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 1961

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

Proposal for a regulation

Article 21 – paragraph 1

Text proposed by the Commission

Les fournisseurs de systèmes d'IA à haut risque qui considèrent ou ont des raisons de considérer qu'un système d'IA à haut risque qu'ils ont mis sur le marché ou mis en service n'est pas conforme au présent règlement prennent immédiatement les mesures correctives nécessaires pour le ***mettre en conformité***, ***le*** retirer ou le rappeler, selon le cas. Ils informent les distributeurs du système d'IA à haut risque en question et, le cas échéant, le mandataire et les importateurs en conséquence.

Amendment

Les fournisseurs de systèmes d'IA à haut risque qui considèrent ou ont des raisons de considérer qu'un système d'IA à haut risque qu'ils ont mis sur le marché ou mis en service n'est pas conforme au présent règlement prennent immédiatement les mesures correctives nécessaires pour le retirer ou le rappeler, selon le cas, ***afin de le mettre en conformité***. Ils informent les distributeurs du système d'IA à haut risque en question et, le cas échéant, le mandataire et les importateurs en conséquence.

Or. fr

Amendment 1962

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

Proposal for a regulation

Article 21 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

In the cases referred to in paragraph 1, providers shall immediately inform the distributors of the high-risk AI system and, where applicable, the legal representative, importers and users accordingly. They shall also immediately inform the national supervisory authority and the national competent authorities of the Member States where they made the AI system available or put it into service, and where applicable, the notified body of the non-compliance and of any corrective actions taken.

Amendment 1963

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

Proposal for a regulation

Article 22 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Amendment 1964

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 22 – paragraph 1

Text proposed by the Commission

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

Amendment

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

actions taken.

relevant corrective actions taken *by the provider*.

Or. en

Amendment 1965

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

Proposal for a regulation

Article 22 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 1966

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

Proposal for a regulation

Article 22 – paragraph 1

Text proposed by the Commission

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

Amendment

Where the high-risk AI system presents a risk within the meaning of Article 65(1) and the provider of the system ***becomes aware of that risk***, that provider shall immediately inform the competent authorities of the Member States in which it made the system available and, where applicable, the notified body that issued a certificate for the high-risk AI system, in

non-compliance and of any corrective actions taken.

particular of the non-compliance and of any corrective actions taken.

Or. en

Amendment 1967

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tef Nută, Ramona Strugariu, Drago Pîslaru, Lucia Ūriš Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation

Article 23 – title

Text proposed by the Commission

Cooperation with competent authorities

Amendment

Cooperation with competent authorities,
the AI Office and the Commission

Or. en

Amendment 1968

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 23 – paragraph 1

Text proposed by the Commission

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

Amendment

Providers of high-risk AI systems shall, upon *a reasoned* request by a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in *a language that can be easily understood by that national competent authority*. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. *Any information submitted in accordance with the provision of this article shall be*

considered by the national competent authority a trade secret of the company that is submitting such information and kept strictly confidential.

Or. en

Amendment 1969

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ondej Kováč, Jan-Christoph Oetjen

Proposal for a regulation

Article 23 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 1970

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Mituță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission

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

Amendment

Providers of high-risk AI systems **and where applicable, users** shall, upon request by a national competent authority **or where applicable, by the AI Office or the Commission**, provide **them** with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member State concerned.

Or. en

Amendment 1971

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

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission

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

Amendment

Providers **and, where applicable, users** of high-risk AI systems shall, upon request by a national **supervisory authority or a national** competent authority **or, where applicable, by the Board or the Commission**, provide **them** with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member State concerned.

risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.

Or. en

Amendment 1972

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

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 1973

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission

Providers of high-risk AI systems shall, upon request by a national competent

Amendment

Providers of high-risk AI systems shall, upon ***reasoned*** request by a national

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

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

Or. en

Amendment 1974

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Nută, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Malik Azmani, Alin Mituța, Michal Šimek, Irena Joveva

Proposal for a regulation

Article 23 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Upon a reasoned request by a national competent authority or, where applicable, by the Commission, providers and, where applicable, users shall also give the requesting national competent authority or the Commission, as applicable, access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. The national competent authorities or, where applicable, the Commission, shall keep confidential all trade secrets contained in the information received, in accordance with Article 70(2).

Or. en

Amendment 1975

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

Proposal for a regulation

Article 23 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Upon a reasoned request by a national supervisory authority or a national competent authority or, where applicable, by the Board or the Commission, providers and, where applicable, users shall also give them access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.

Or. en

Amendment 1976

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 23 a (new)

Text proposed by the Commission

Amendment

Article 23 a

Clarification of responsibilities along the AI value chain

1. Concerning high risk AI systems, any natural or legal person shall be considered a new 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 put their name or trademark on a high-risk AI system already placed on the market or put into service, without prejudice to contractual arrangements stipulating that the obligations are

allocated otherwise;

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

(c) they modify the intended purpose of a non high-risk AI system already placed on the market or put into service, in a way which makes the modified system a high-risk AI System;

(d) they adapt a general purpose AI system system, already placed on the market or put into service, to a specific intended purpose.

2 . Where the circumstances referred to in paragraphs 1(a), (b) and (c) occur, the former provider shall no longer be considered a provider for the purposes of this Regulation. The former provider shall upon request and without compromising its own intellectual property rights or trade secrets, provide the new provider with all essential, relevant and reasonably expected information that is necessary to comply with the obligations set out in this Regulation.

3. The original provider of a general purpose AI system shall, without compromising its own intellectual property rights or trade secrets and to the extent appropriate and feasible:

(a) ensure that the general purpose AI system which may be used as high-risk AI system complies with the requirements established in Article 9, 10, 11, 13(2)/(3) and 15 of this Regulation;

(b) comply with the obligations set out in Art 16aa, 16e, 16f, 16g, 16i, 16j, 48 and 61 of this Regulation;

(c) assess the reasonable foreseeable misuses of the general purpose AI system that may arise during the expected lifetime and install mitigation measures against those cases based on the generally acknowledged state of the art;

(d) provide the new provider referred to in paragraph 1(d) with all essential, relevant and reasonably expected information that is necessary to comply with the obligations set out in this Regulation.

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

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

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

5. Third parties involved in the sale and the supply of software including general purpose application programming interfaces (API), software tools and components, providers who develop and train AI systems on behalf of a deploying company in accordance with their instruction, or providers of network services shall not be considered providers for the purposes of this Regulation.

Or. en

Amendment 1977

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

Proposal for a regulation

Article 23 a (new)

Text proposed by the Commission

Amendment

Article 23 a

Conditions for other persons to be subject to the obligations of a provider

1. Concerning high risk AI systems any natural or legal person 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 put their name or trademark on a high-risk AI system already placed on the market or put into service, without prejudice to contractual arrangements stipulating that the obligations are allocated otherwise;*
- (b) they make a substantial modification to or modify the intended purpose of a high-risk AI system already placed on the market or put into service;*
- (c) they modify the intended purpose of a non-high-risk AI system already placed on the market or put it to service, in a way which makes the modified system a high-risk AI system;*
- (d) they fulfil the conditions referred in Article 3a(2).*

2. Where the circumstances referred to in paragraph 1 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. The initial provider subject to the previous sentence, shall upon request and without compromising its own intellectual property rights or trade secrets, provide the new provider referred to in paragraph (1a), (1b) or (1c) with all essential, relevant and reasonably expected information that is necessary to comply with the obligations set out in this Regulation.

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

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

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

4. Third parties involved in the sale and the supply of software including general purpose application programming interfaces (API), software tools and components, providers who develop and train AI systems on behalf of a deploying company in accordance with their instruction, or providers of network services shall not be considered providers for the purposes of this Regulation.

Or. en

Justification

Following a proposal by the Council, this article in combination with new Art. 3a on General Purpose AI, Art 16, 25, 26, 27, 29 aims at adequately addressing the roles of the various actors involved in developing and deploying AI systems. The new article clarifies which actor is responsible in which situation.

Amendment 1978

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 24

Text proposed by the Commission

Amendment

Article 24

deleted

Obligations of product manufacturers

Where a high-risk AI system related to products to which the legal acts listed in Annex II, section A, apply, is placed on the market or put into service together with the product manufactured in accordance with those legal acts and under the name of the product

manufacturer, the manufacturer of the product shall take the responsibility of the compliance of the AI system with this Regulation and, as far as the AI system is concerned, have the same obligations imposed by the present Regulation on the provider.

Or. en

Amendment 1979

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 24

Text proposed by the Commission

Amendment

Article 24

deleted

Obligations of product manufacturers

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

Or. en

Amendment 1980

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

Proposal for a regulation

Article 25

Article 25

deleted

Authorised representatives

1. Prior to making their systems available on the Union market, where an importer cannot be identified, providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.

2. The authorised representative shall perform the tasks specified in the mandate received from the provider. The mandate shall empower the authorised representative to carry out the following tasks:

(a) keep a copy of the EU declaration of conformity and the technical documentation at the disposal of the national competent authorities and national authorities referred to in Article 63(7);

(b) provide a national competent authority, upon a reasoned request, with all the information and documentation necessary to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law;

(c) cooperate with competent national authorities, upon a reasoned request, on any action the latter takes in relation to the high-risk AI system.

Or. en

Justification

Article moved so that it does not cover only high-risk AI systems.

Amendment 1981

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

Proposal for a regulation**Article 25 – paragraph 1***Text proposed by the Commission*

1. Prior to making their systems available on the Union market, ***where an importer cannot be identified***, providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.

Amendment

1. Prior to making their systems available on the Union market providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.

Or. en

Amendment 1982

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation**Article 25 – paragraph 1***Text proposed by the Commission*

1. Prior to making their systems available on the Union market, ***where an importer cannot be identified***, providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.

Amendment

1. Prior to making their systems available on the Union market, providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.

Or. en

Amendment 1983

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

Proposal for a regulation**Article 25 – paragraph 1 a (new)***Text proposed by the Commission**Amendment*

I bis. Le mandataire doit, à partir du moment de sa désignation, être en mesure de correspondre, d'échanger des informations techniques et de réaliser les tâches qui lui incombent conformément au présent règlement avec les autorités nationales et dans les langues officielles de tous les États membres.

Or. fr

Amendment 1984

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 25 – paragraph 2 – introductory part

Text proposed by the Commission

2. The authorised representative shall perform the tasks specified in the mandate received from the provider. The mandate shall empower the authorised representative to carry out the following tasks:

Amendment

2. The authorised representative shall perform the tasks specified in the mandate received from the provider. *For the purpose of this Regulation*, the mandate shall empower the authorised representative to carry out *only* the following tasks:

Or. en

Amendment 1985

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

Proposal for a regulation

Article 25 – paragraph 2 – point a

Text proposed by the Commission

(a) *tenir à la disposition des autorités nationales compétentes et des autorités nationales visées à l'article 63, paragraphe 7, une copie de la déclaration de conformité UE et de la documentation technique;*

Amendment

(a) *réaliser ou faire réaliser l'évaluation de la conformité prévue à l'article 43;*

Or. fr

Amendment 1986

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 25 – paragraph 2 – point a

Text proposed by the Commission

- (a) *keep a copy of* the EU declaration of conformity and the technical documentation *at the disposal of the national competent authorities and national authorities referred to in Article 63(7);*

Amendment

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

Or. en

Amendment 1987

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

Proposal for a regulation

Article 25 – paragraph 2 – point b

Text proposed by the Commission

- (b) *à la demande motivée d'une autorité nationale compétente, communiquer à cette dernière toutes les informations et tous les documents nécessaires à la démonstration de la conformité d'un système d'IA à haut risque avec les exigences énoncées au chapitre 2 du présent titre, et notamment lui donner accès aux journaux automatiquement générés par le système d'IA à haut risque, dans la mesure où ces journaux se trouvent sous le contrôle du fournisseur en vertu d'un arrangement contractuel avec l'utilisateur ou d'autres modalités prévues par la loi;*

Amendment

- (b) *tenir à la disposition des autorités nationales compétentes et des autorités nationales visées à l'article 63, paragraphe 7, une copie de la déclaration de conformité UE et de la documentation technique;*

Or. fr

Amendment 1988

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

Proposal for a regulation

Article 25 – paragraph 2 – point b

Text proposed by the Commission

(b) provide 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***;

Amendment

(b) provide a national competent authority 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;

Or. en

Amendment 1989

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 25 – paragraph 2 – point b a (new)

Text proposed by the Commission

Amendment

(b a) keep at the disposal of the national competent authorities and national authorities referred to in Article 63(7), for a period ending 3 years after the high-risk AI system has been placed on the market or put into service, a copy of the EU declaration of conformity, the technical documentation and, if applicable, the certificate issued by the notified body;

Or. en

Amendment 1990

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

Garraud

Proposal for a regulation

Article 25 – paragraph 2 – point c

Text proposed by the Commission

(c) à la demande motivée *des autorités nationales compétentes, coopérer avec elles à toute mesure prise par ces dernières à l'égard du* système d'IA à haut risque.

Amendment

(c) à la demande motivée *d'une autorité nationale compétente, communiquer à cette dernière toutes les informations et tous les documents nécessaires à la démonstration de la conformité d'un* système d'IA à haut risque *avec les exigences énoncées au chapitre 2 du présent titre, et notamment lui donner accès aux journaux automatiquement générés par le système d'IA à haut risque, dans la mesure où ces journaux se trouvent sous le contrôle du fournisseur en vertu d'un arrangement contractuel avec l'utilisateur ou d'autres modalités prévues par la loi;*

Or. fr

Amendment 1991

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

Proposal for a regulation

Article 25 – paragraph 2 – point c

Text proposed by the Commission

(c) cooperate with competent national authorities, upon a reasoned request, on any action the latter takes *in relation to the* high-risk AI system.

Amendment

(c) cooperate with competent national authorities, upon a reasoned request, on any action the latter takes to *reduce and mitigate the risks posed by a* high-risk AI system *covered by the authorised representative's mandate.*

Or. en

Amendment 1992

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 25 – paragraph 2 – point c**

Text proposed by the Commission

- (c) cooperate with **competent** national authorities, upon a reasoned request, on any action the latter takes in relation to the high-risk AI system.

Amendment

- (c) cooperate with national **supervisory** authorities, upon a reasoned request, on any action the latter takes in relation to the high-risk AI system;

Or. en

Amendment 1993

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 25 – paragraph 2 – point c a (new)**

Text proposed by the Commission

Amendment

- (c a) comply with the registration obligations referred to in Article 51 or, if the registration is carried out by the provider itself, ensure that the information referred to in point 3 of Annex VIII is correct.**

Or. en

Amendment 1994

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

**Proposal for a regulation
Article 25 – paragraph 2 – point c a (new)**

Text proposed by the Commission

Amendment

- (c bis) à la demande motivée des autorités nationales compétentes, coopérer avec elles à toute mesure prise par ces dernières à l'égard du système d'IA à haut risque.**

Or. fr

Amendment 1995

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 25 – paragraph 2 – subparagraph 1 (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 1996

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 26 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

1. Before placing a high-risk AI system on the market, importers of such system shall ensure that:

1. Before placing a high-risk AI system on the market, importers of such system shall ensure that *such a system is in conformity with this Regulation by ensuring that:*

Or. en

Amendment 1997

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

Proposal for a regulation

Article 26 – paragraph 1 – point a

Text proposed by the Commission

(a) le fournisseur de ce système d'IA a suivi la procédure appropriée d'évaluation de la conformité;

Amendment

(a) le fournisseur de ce système d'IA a suivi la procédure appropriée d'évaluation de la conformité *postérieurement à son importation et antérieurement à son déploiement*;

Or. fr

Amendment 1998

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 26 – paragraph 1 – point a

Text proposed by the Commission

(a) the *appropriate* conformity assessment procedure has been carried out by the provider of that AI system

Amendment

(a) the *relevant* conformity assessment procedure *referred to in Article 43* has been carried out by the provider of that AI system;

Or. en

Amendment 1999

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 26 – paragraph 1 – point c

Text proposed by the Commission

(c) the system bears the required conformity marking and is accompanied by the required documentation and instructions of use.

Amendment

(c) the system bears the required conformity marking and is accompanied by the required documentation and instructions of use;

Or. en

Amendment 2000

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 26 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) the authorised representative referred to in Article 25 has been established by the Provider.

Or. en

Amendment 2001
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 26 – paragraph 2

Text proposed by the Commission

Amendment

2. Where an importer considers or has reason to consider that a high-risk AI system is not in conformity with this Regulation, it shall not place that system on the market until that AI system has been brought into conformity. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the importer shall inform the provider of the AI system and the market surveillance authorities to that effect.

2. Where an importer considers or has reason to consider that a high-risk AI system is not in conformity with this Regulation, *or is falsified, or accompanied by falsified documentation* it shall not place that system on the market until that AI system has been brought into conformity. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the importer shall inform the provider of the AI system and the market surveillance authorities to that effect.

Or. en

Amendment 2002
Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 26 – paragraph 3

Text proposed by the Commission

Amendment

3. Importers shall indicate their name, registered trade name or registered trade mark, and the address at which they can be

3. Importers shall indicate their name, registered trade name or registered trade mark, and the address at which they can be

contacted on the high-risk AI system *or, where that is not possible*, on its packaging or its accompanying documentation, *as applicable*.

contacted on the high-risk AI system *and*, on its packaging or its accompanying documentation, *where applicable*.

Or. en

Amendment 2003

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 26 – paragraph 4

Text proposed by the Commission

4. Importers shall *ensure that, while a high-risk AI system is under their responsibility*, where applicable, *storage or transport conditions do not jeopardise its compliance with the requirements set out in Chapter 2 of this Title*.

Amendment

4. Importers shall *keep, for a period ending 3 years after the AI system has been placed on the market or put into service, a copy of the certificate issued by the notified body*, where applicable, *of the instructions for use and of the EU declaration of conformity*.

Or. en

Amendment 2004

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

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

Amendment

5. Importers shall provide *the national supervisory authority and the* national competent authorities, upon a reasoned request, with all *the* 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 *them*, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of

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.

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 *the national supervisory authority and the* national competent authority *take* in relation to that system.

Or. en

Amendment 2005

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

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. Importers shall provide national competent authorities, upon 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. They shall also cooperate with those authorities on any action national competent authority takes in relation to that system.

Or. en

2019-2024



*Committee on the Internal Market and Consumer Protection
Committee on Civil Liberties, Justice and Home Affairs*

2021/0106(COD)

13.6.2022

AMENDMENTS

2006 - 2355

Draft report
Brando Benifei, Drago 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))

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United in diversity

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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, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 26 – paragraph 5

Text proposed by the Commission

5. À la demande motivée des autorités nationales compétentes, les importateurs communiquent à ces dernières toutes les informations et tous les documents nécessaires pour démontrer la conformité d'un système d'IA à haut risque avec les exigences énoncées au chapitre 2 du présent titre, dans une langue *aisément compréhensible par* cette autorité nationale compétente, et leur accordent

Amendment

5. À la demande motivée des autorités nationales compétentes, les importateurs communiquent à ces dernières toutes les informations et tous les documents nécessaires pour démontrer la conformité d'un système d'IA à haut risque avec les exigences énoncées au chapitre 2 du présent titre, dans une langue *officielle de* cette autorité nationale compétente, et leur accordent notamment l'accès aux journaux

notamment l'accès aux journaux automatiquement générés par le système d'IA à haut risque, dans la mesure où ces journaux se trouvent sous le contrôle du fournisseur en vertu d'un arrangement contractuel avec l'utilisateur ou d'autres modalités prévues par la loi. Ils coopèrent également avec ces autorités à toute mesure prise par l'autorité nationale compétente à l'égard de ce système.

automatiquement générés par le système d'IA à haut risque, dans la mesure où ces journaux se trouvent sous le contrôle du fournisseur en vertu d'un arrangement contractuel avec l'utilisateur ou d'autres modalités prévues par la loi. Ils coopèrent également avec ces autorités à toute mesure prise par l'autorité nationale compétente à l'égard de ce système.

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, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , 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,

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 applicable, to that effect.

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

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituța, 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

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 applicable, to that effect.

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 **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, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , 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

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 **provider or the importer of the system as well as 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 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. Lorsqu'un distributeur considère ou a des raisons de considérer qu'un système d'IA à haut risque qu'il a mis à disposition sur le marché n'est pas conforme aux exigences énoncées au chapitre 2 du présent titre, il prend les mesures

Amendment

4. Lorsqu'un distributeur considère ou a des raisons de considérer qu'un système d'IA à haut risque qu'il a mis à disposition sur le marché n'est pas conforme aux exigences énoncées au chapitre 2 du présent titre, il prend les mesures

correctives nécessaires pour ***mettre*** ce système en conformité avec lesdites exigences, ***le retirer ou le rappeler*** ou veille à ce que le fournisseur, l'importateur ou tout opérateur concerné, selon le cas, prenne ces mesures correctives. Lorsque le système d'IA à haut risque présente un risque au sens de l'article 65, paragraphe 1, le distributeur en informe immédiatement les autorités nationales compétentes des États membres dans lesquels il a mis le produit à disposition et précise, notamment, le cas de non-conformité et les éventuelles mesures correctives prises.

correctives nécessaires pour ***retirer ou rappeler*** ce système ***afin de la mettre*** en conformité avec lesdites exigences, ou veille à ce que le fournisseur, l'importateur ou tout opérateur concerné, selon le cas, prenne ces mesures correctives. Lorsque le système d'IA à haut risque présente un risque au sens de l'article 65, paragraphe 1, le distributeur en informe immédiatement les autorités nationales compétentes des États membres dans lesquels il a mis le produit à disposition et précise, notamment, le cas de non-conformité et les éventuelles mesures correctives prises.

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 Boto , Moritz Körner, Ondej Kováčik, 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

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tefnută, Ramona Strugariu, Drago Pîslaru, Lucia Šuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

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.

Or. en

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.*

Or. en

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.

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 Boto , 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 Złotowski, 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

Amendment

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:

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:

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, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(b bis) il a mis sur le marché ou mis en service un système d'I.A. à haut risque s'étant substantiellement modifié par ses propres moyens;

Or. fr

Amendment 2030

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 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 Złotowski, 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

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Mituță, Ramona Strugariu, Drago Pîslaru, Lucia Ūriș Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

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, Kateina 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, Drago Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , 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

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia uríš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Morten Løkkegaard, Alin Mituță, 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 **use such systems** in accordance with the instructions of use accompanying the systems, **pursuant to paragraphs 2 and 5.**

Amendment

1. 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 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, Drago Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 29 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

I 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

I 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

Kate ina Kone ná, 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

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.

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

provider.

Or. en

Amendment 2049

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , 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

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituță

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 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 **and, when relevant, 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 Boto , 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

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**

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.

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 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

Fernando Barrena Arza, Kate ina Kone ná, 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 Boto , Moritz Körner, Ond ej Kova ík, 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

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Mituță, Ramona Strugariu, Drago Pîslaru, Lucia Šuriš Nicholsonová, Irena Joveva, Malik Azmani, Róza Thun und Hohenstein, Alin Mituță

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 Boto ,
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 Šime ka

**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 Šime ka

**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 foreseeable 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.

Amendment 2068

Svenja Hahn, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , 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.

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.

Amendment 2070

Kosma Złotowski, 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.

Amendment 2071

Pernando Barrena Arza, Kate ina Kone ná, 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.

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

Kate ina Kone ná, 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 Rooken

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 Boto , Moritz Körner, Ond ěj Kova īk, 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 Złotowski, Patryk Jaki, Vincenzo Sofo

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

Kate ina Kone ná, 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, Kate ina Kone ná, 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

Kate ina Kone ná, 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 allrelevant 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

Jörgen Warborn, Arba Kokalari, Tomas Tobé

**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 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. *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

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 ***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

Jörgen 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

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.

size of an undertaking, the sector in which it operates, its structure and the degree of 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, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 30 – paragraph 8

Text proposed by the Commission

8. Les autorités notifiantes veillent à ce que les évaluations de la conformité soient effectuées de manière proportionnée, en évitant les charges inutiles pour les fournisseurs, et à ce que les organismes notifiés accomplissent leurs activités en tenant dûment compte de la taille des entreprises, du secteur dans lequel elles exercent leurs activités, de leur structure *et* du degré de complexité *du* système d'IA en question.

Amendment

8. Les autorités notifiantes veillent à ce que les évaluations de la conformité soient effectuées de manière proportionnée, en évitant les charges inutiles pour les fournisseurs, et à ce que les organismes notifiés accomplissent leurs activités en tenant dûment compte de la taille des entreprises, du secteur dans lequel elles exercent leurs activités, de leur structure, du degré de complexité *et du risque posé par le* système d'IA en question.

Or. fr

Amendment 2092

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 30 – paragraph 8

Text proposed by the Commission

8. Notifying authorities shall make

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.

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.

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 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.

Amendment

3. Where the conformity assessment body concerned cannot provide an 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

Amendment

3. The notification *referred to in paragraph 2* shall include full details of the

activities, the conformity assessment module or modules and the artificial intelligence technologies concerned.

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).*

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. L'organisme d'évaluation de la conformité concerné ne peut effectuer les activités propres à un organisme notifié que si aucune objection n'est émise par la Commission ou les autres États membres dans le mois qui suit la notification.

Amendment

4. L'organisme d'évaluation de la conformité concerné ne peut *commencer à* effectuer les activités propres à un organisme notifié que si aucune objection n'est émise par la Commission ou les autres États membres dans le mois qui suit la 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

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. *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.*

Amendment 2105

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Vincenzo Sofo, Adam Bielan

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.*

Amendment 2106

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

Proposal for a regulation

Article 33 – paragraph 7

Text proposed by the Commission

7. Les organismes notifiés disposent de procédures pour accomplir leurs

Amendment

7. Les organismes notifiés disposent de procédures pour accomplir leurs

activités qui tiennent dûment compte de la taille des entreprises, du secteur dans lequel elles exercent leurs activités, de leur structure *et* du degré de complexité *du* système d'IA en question.

activités qui tiennent dûment compte de la taille des entreprises, du secteur dans lequel elles exercent leurs activités, de leur structure, du degré de complexité *et du risque posé par le* système d'IA en question.

Or. fr

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, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 34 – paragraph 3

Text proposed by the Commission

3. Des activités ne peuvent être sous-

Amendment

3. Des activités ne peuvent être sous-

traitées ou réalisées par une filiale qu'avec l'accord du fournisseur.

traitées ou réalisées par une filiale qu'avec l'accord du fournisseur *et de l'autorité notifiante*.

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

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

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.

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.

Or. en

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

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 **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, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 37 – paragraph 4

Text proposed by the Commission

4. Lorsque la Commission établit qu'un organisme notifié ne répond pas ou ne répond plus aux exigences fixées à l'article 33, elle adopte une décision motivée demandant à l'État membre notifiant de prendre les mesures correctives qui s'imposent, y compris le retrait de la notification si nécessaire. **Cet acte d'exécution est adopté** en conformité avec la procédure d'examen visée à l'article 74, paragraphe 2.

Amendment

4. Lorsque la Commission établit qu'un organisme notifié ne répond pas ou ne répond plus aux exigences fixées à l'article 33, elle adopte une décision motivée demandant à l'État membre notifiant de prendre les mesures correctives qui s'imposent, y compris le retrait de la notification si nécessaire. **Cette demande est adoptée** en conformité avec la procédure d'examen visée à l'article 74, paragraphe 2.

Or. fr

Justification

La terminologie employée créait une ambiguïté concernant le caractère contraignant de la décision de la Commission, ambiguïté que nous résolvons au bénéfice des États membres.

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

Article 39

*Organismes d'évaluation de la conformité
de pays tiers*

*Les organismes d'évaluation de la
conformité établis conformément à la
législation d'un pays tiers avec lequel
l'Union a conclu un accord peuvent être
autorisés à exercer les activités
d'organismes notifiés au titre du présent
règlement.*

Amendment

supprimé

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

Amendment

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

Amendment

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.

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

Les systèmes d'IA à haut risque conformes à des normes harmonisées ou à des parties de normes harmonisées dont les références ont été publiées au Journal officiel de l'Union européenne **sont présumés conformes aux exigences visées au chapitre 2 du présent titre**, dans la mesure où celles-ci sont couvertes par ces normes.

Amendment

Les systèmes d'IA à haut risque **sont** conformes à des normes harmonisées ou à des parties de normes harmonisées dont les références ont été publiées au Journal officiel de l'Union européenne, dans la mesure où celles-ci sont couvertes par ces normes.

Or. fr

Justification

Il est dangereux de créer un régime de présomption juridique permettant de déroger à toutes les obligations et garanties du Titre III, surtout s'agissant des systèmes d'IA à haut risque vu le risque spécifique qu'ils posent. Une vérification approfondie et exhaustive de ces systèmes devrait être effectuée systématiquement.

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 allrelevant 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

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Alin Mituța

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.

Or. en

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.

Or. en

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.

Or. en

Amendment 2129

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 41

Text proposed by the Commission

Amendment

Article 41

deleted

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

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. The Commission may, by means of 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 Commissions 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

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Alin Mituța

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

Kate ina Kone ná, 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

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).

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).

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, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ondej Kováčik, 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 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 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

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

Article 74(2).

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

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).

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 2138

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ěej Ková ěk, 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

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuťă, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Malik Azmani, Svenja Hahn, Andrus Ansip, Dita Charanzová, Morten Løkkegaard, Alin Mituťa

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

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.

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, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Ondej Kovačík, 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

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.

relevant bodies, **stakeholders** or expert groups established under relevant sectorial Union law.

Or. en

Amendment 2145

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

Proposal for a regulation

Article 41 – paragraph 3

Text proposed by the Commission

Amendment

3. Les systèmes d'IA à haut risque conformes aux spécifications communes visées au paragraphe 1 sont présumés conformes aux exigences énoncées au chapitre 2 du présent titre, dans la mesure où celles-ci sont couvertes par ces spécifications communes.

supprimé

Or. fr

Justification

Il est dangereux de créer un régime de présomption juridique permettant de déroger aux obligations et garanties du Titre III, surtout s'agissant des systèmes d'IA à haut risque vu le risque spécifique qu'ils posent. Une vérification approfondie et exhaustive de ces systèmes devrait être effectuée systématiquement.

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

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.

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.

Or. en

Amendment 2147

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

Proposal for a regulation

Article 41 – paragraph 4

Text proposed by the Commission

Amendment

4. *Lorsque les fournisseurs ne respectent pas les spécifications communes visées au paragraphe 1, ils justifient dûment avoir adopté des solutions techniques au moins équivalentes auxdites spécifications.* *supprimé*

Or. fr

Justification

Le but du présent règlement est de permettre une mise sur le marché sécurisée des systèmes d'I.A., y compris à haut risque, à l'aide d'obligations et de garanties adaptées. Il est incohérent d'édicter ces obligations et d'ensuite autoriser les fournisseurs à ne pas les respecter. Cela ne fera que générer de la complexité pratique chez les fournisseurs et rendre illisibles les obligations du présent règlement.

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

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.

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 Boto , Moritz Körner, Ond ej Kova ík, 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, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, 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, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 42

Text proposed by the Commission

Amendment

Article 42

deleted

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 Council⁶³ 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.*

⁶³ 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

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

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 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 Council⁶³ 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.

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 Council⁶³ **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.

⁶³ 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

⁶³ 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).

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

Kate ina Kone ná, 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, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 43 – paragraph 1 – introductory part

Text proposed by the Commission

1. Pour les systèmes d'IA à haut risque énumérés à l'annexe III, point 1, lorsque, pour démontrer la conformité d'un système d'IA à haut risque avec les exigences énoncées au chapitre 2 du présent titre, le fournisseur a appliqué les normes harmonisées visées à l'article 40 ou, le cas échéant, les spécifications communes visées à l'article 41, il suit *l'une des procédures suivantes:*

Amendment

1. Pour les systèmes d'IA à haut risque énumérés à l'annexe III, point 1, lorsque, pour démontrer la conformité d'un système d'IA à haut risque avec les exigences énoncées au chapitre 2 du présent titre, le fournisseur a appliqué les normes harmonisées visées à l'article 40 ou, le cas échéant, les spécifications communes visées à l'article 41, il suit *la procédure d'évaluation de la conformité fondée sur l'évaluation du système de gestion de la qualité et l'évaluation de la documentation technique, avec l'intervention d'un organisme notifié, visée à l'annexe 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

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*

the following procedures:

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, 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 *opt for* one of the following procedures:

Or. en

Amendment 2162

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

Proposal for a regulation

Article 43 – paragraph 1 – point a

Text proposed by the Commission

(a) *la procédure d'évaluation de la conformité fondée sur le contrôle interne visée à l'annexe VI;*

Amendment

supprimé

Or. fr

Justification

Nous proposons de supprimer la procédure d'évaluation fondée sur le contrôle interne.

Amendment 2163

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 43 – paragraph 1 – point a

Text proposed by the Commission

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

Amendment

deleted

Or. en

Amendment 2164

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 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) la procédure d'évaluation de la conformité fondée sur l'évaluation du système de gestion de la qualité et l'évaluation de la documentation technique, avec l'intervention d'un organisme notifié, visée à l'annexe VII.

supprimé

Or. fr

Justification

Le sous-paragraphe a) étant supprimé, l'existence d'un sous-paragraphe b) ne se justifie plus, son texte étant directement intégré dans le corps du paragraphe 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

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

integrated into para 1

Justification

Amendment 2170

Kate ina Kone ná, 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

(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.

Amendment

(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

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.

Amendment

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 Šimeka

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

deleted

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 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

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

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 to101 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 to101 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

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

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 to101 of that Directive.

referred to in Articles 97 to101 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 to101 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 to101 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

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.

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, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation Article 43 – paragraph 2

Text proposed by the Commission

2. Pour les systèmes d'IA à haut risque visés à l'annexe III, points 2 à 8, les fournisseurs suivent la procédure d'évaluation de la conformité fondée sur ***le contrôle interne visée à l'annexe VI, qui ne prévoit pas d'intervention*** d'un organisme notifié. Pour les systèmes d'IA à haut risque visés à l'annexe III, point 5 b), mis sur le marché ou mis en service par des établissements de crédit régis par la directive 2013/36/UE, l'évaluation de la conformité est effectuée dans le cadre de la procédure visée aux articles 97 à 101 de ladite directive.

Amendment

2. Pour les systèmes d'IA à haut risque visés à l'annexe III, points 2 à 8, les fournisseurs suivent la procédure d'évaluation de la conformité fondée sur ***l'évaluation du système de gestion de la qualité et l'évaluation de la documentation technique, avec l'intervention*** d'un organisme notifié, ***visée à l'annexe VII.*** Pour les systèmes d'IA à haut risque visés à l'annexe III, point 5 b), mis sur le marché ou mis en service par des établissements de crédit régis par la directive 2013/36/UE, l'évaluation de la conformité est effectuée dans le cadre de la procédure visée aux articles 97 à 101 de ladite 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 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.

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 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

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.

Amendment

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

3 bis. Les systèmes d'IA à haut risque sont soumis périodiquement à une procédure de révision de l'évaluation de la conformité.

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

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.

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 Šimek

Proposal for a regulation

Article 43 – paragraph 4 – introductory part

Text proposed by the Commission

Amendment

4. High-risk AI systems shall undergo a new conformity assessment procedure whenever they are substantially modified,

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.

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

Jörgen 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, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova įk, 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,

Amendment

4. High-risk AI systems *that have already been subject to a conformity assessment procedure* shall undergo a new

regardless of whether the modified system is intended to be further distributed or continues to be used by the current user.

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, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova įk, 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

Kate ina Kone ná, Pernando 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, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 43 – paragraph 4 – subparagraph 1

Text proposed by the Commission

Pour les systèmes d'IA à haut risque qui continuent leur apprentissage après avoir

Amendment

Pour les systèmes d'IA à haut risque qui continuent leur apprentissage après avoir

été mis sur le marché ou mis en service, les modifications apportées au système d'IA à haut risque et à ses performances *qui* ont été déterminées au préalable par le fournisseur au moment de l'évaluation initiale de la conformité et font partie des informations contenues dans la documentation technique visée à l'annexe IV, point 2 f), ***ne constituent pas une modification substantielle.***

été mis sur le marché ou mis en service, les modifications apportées au système d'IA à haut risque et à ses performances ***constituent une modification substantielle, y compris si elles*** ont été déterminées au préalable par le fournisseur au moment de l'évaluation initiale de la conformité et font partie des informations contenues dans la documentation technique visée à l'annexe IV, point 2 f).

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

Amendment 2200

Axel Voss, Deirdre Clune, Eva Maydell

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 **amend** elements of the conformity assessment procedures that become necessary **or unnecessary** in light of technical progress.

Amendment 2201

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ondej 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.

Amendment 2202

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

Proposal for a regulation

Article 43 – paragraph 5

Text proposed by the Commission

5. La Commission est habilitée à adopter des actes délégués conformément à l'article 73 aux fins de la mise à jour *des annexes VI et VII* en vue d'introduire des éléments des procédures d'évaluation de la conformité qui s'avèrent nécessaires compte tenu du progrès technique.

Amendment

5. La Commission est habilitée à adopter des actes délégués conformément à l'article 73 aux fins de la mise à jour *de l'annexe VII* en vue d'introduire des éléments des procédures d'évaluation de la conformité qui s'avèrent nécessaires compte tenu du progrès technique.

Or. fr

Amendment 2203

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

Proposal for a regulation

Article 43 – paragraph 6

Text proposed by the Commission

6. *La Commission est habilitée à adopter des actes délégués visant à modifier les paragraphes 1 et 2 afin de soumettre les systèmes d'IA à haut risque visés à l'annexe III, points 2 à 8, à tout ou partie de la procédure d'évaluation de la conformité visée à l'annexe VII. La Commission adopte ces actes délégués en tenant compte de l'efficacité de la procédure d'évaluation de la conformité fondée sur le contrôle interne visée à l'annexe VI pour prévenir ou réduire au minimum les risques que ces systèmes font peser sur la santé et la sécurité et sur la protection des droits fondamentaux, ainsi que de la disponibilité de capacités et*

Amendment

supprimé

de ressources suffisantes au sein des organismes notifiés.

Or. fr

Justification

La procédure d'évaluation de la conformité fondée sur le contrôle interne visée à l'article VI étant supprimée, ainsi que ladite annexe VI, il n'est plus nécessaire que la Commission soumette exceptionnellement par acte délégué certains systèmes d'I.A. à haut risque à la procédure d'évaluation de la conformité visée à l'annexe 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.

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 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
Jörgen 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.

Or. en

Amendment 2207

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 43 – paragraph 6

Text proposed by the Commission

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.

Amendment

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, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ondej Kovařík, Jan-Christoph Oetjen

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.

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 2209

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

Proposal for a regulation Article 44 – paragraph 1

Text proposed by the Commission

1. Les certificats délivrés par les organismes notifiés conformément à l'annexe VII sont établis dans *une* langue officielle de l'Union *déterminée par* l'État membre d'établissement de l'organisme notifié *ou, à défaut, dans une langue officielle de l'Union acceptée par l'organisme notifié.*

Amendment

1. Les certificats délivrés par les organismes notifiés conformément à l'annexe VII sont établis dans *la* langue officielle de l'Union *de* l'État membre d'établissement de l'organisme notifié.

Or. fr

Amendment 2210

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

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 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.

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 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, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 46 – paragraph 2 – introductory part

Text proposed by the Commission

2. Chaque organisme notifié porte à la connaissance des autres organismes notifiés:

Amendment

2. Chaque organisme notifié porte à la connaissance des autres organismes notifiés *et de l'autorité notifiante*:

Or. fr

Amendment 2212

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 46 – paragraph 3

Text proposed by the Commission

Amendment

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.

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 Alametsä
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, Kate ina Kone ná, 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

<i>Text proposed by the Commission</i>	<i>Amendment</i>
[...]	<i>deleted</i>

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

<i>Text proposed by the Commission</i>	<i>Amendment</i>
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.	1. By way of derogation from Article 43, any market surveillance authority may <i>request a judicial authority to</i> 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

I 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.

Or. en

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 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 *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.

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

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 **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.

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

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

conformity shall be given to the relevant national competent authorities upon request.

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

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

into an official Union language or languages required by the Member State(s) in which the high-risk AI system is made available.

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.

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 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 *in digital format* for high-risk AI systems.

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.*

Amendment 2231

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

Proposal for a regulation**Article 49 – paragraph 1***Text proposed by the Commission*

1. Le marquage CE est apposé de façon visible, lisible et indélébile sur les systèmes d'AI à haut risque. Si cela est impossible ou injustifié étant donné la nature du système d'IA à haut risque, il est apposé sur l'emballage ou sur les documents d'accompagnement, selon le cas.

Amendment

1. Le marquage CE est apposé de façon visible, lisible et indélébile sur les systèmes d'AI à haut risque *avant que ceux-ci soient mis sur le marché, mis à disposition sur le marché ou mis en service*. Si cela est impossible ou injustifié étant donné la nature du système d'IA à haut risque, il est apposé sur l'emballage ou sur les documents d'accompagnement, selon le cas.

Or. fr

Amendment 2232

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, 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.

Or. en

Amendment 2234

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ondej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 49 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

I 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

I 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** 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 **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:

Or. en

Amendment 2241

**Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto ,
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**

Amendment

The provider shall, for **the entire lifecycle** of the AI system, keep at the disposal of

on the market or put into service, keep at the disposal of the national competent authorities:

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 Boto , 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

I. 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

Kate ina Kone ná, 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.

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, validate, 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;

Amendment 2251

Kate ina Kone ná, Pernando 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.

Amendment 2252

**Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto ,
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

Kate ina Kone ná, 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

Amendment

Transparency obligations *for certain AI systems*

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

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. 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.

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

Drago 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 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, unless this is obvious from the circumstances and the context of use.

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

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.

deleted

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

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.

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.

Amendment 2267
Drago Tudorache

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.

Amendment 2268
Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Vlad-Marius Boto , 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.

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 *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 audio or *visual* 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, Drago Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ondej Kováčik, 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

deleted

*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

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

Drago 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.

Or. en

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, Drago Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , 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 appropriate safeguards for the rights and freedoms of third parties.

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 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

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

Amendment

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 Title III of this Regulation.

Or. en

Amendment 2283

Kate ina Kone ná, 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 Złotowski, 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)

Text proposed by the Commission

Amendment

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

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*

compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.

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

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*

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.

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

Kate ina Kone ná, 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.**

Amendment 2293

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Morten Løkkegaard, Alin Mituța

**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. **Member States shall establish** AI regulatory sandboxes, which shall be 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.

Amendment 2294

Svenja Hahn, Drago Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ěj Kova ík, 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

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 ***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.

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.

Or. en

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 process.***

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 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. ***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 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 Złotowski, 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

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.

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

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Morten Løkkegaard, Alin Mituța

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

I 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

I 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

I 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.

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 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 ***and involved in the control of those aspects of the sandbox it supervises to the full extent of its respective powers.***

Amendment 2309

Svenja Hahn, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , 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 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 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 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

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

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

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.

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

Kate ina Kone ná, 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.

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 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 participation in* the AI regulatory sandboxes shall not affect the supervisory and corrective powers of the 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.*

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

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

mitigation takes place.

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.***

Amendment 2321

Morten Løkkegaard

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 inflicted on third parties as a result *of* the experimentation taking place in the sandbox.

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.

Amendment 2323

Axel Voss, Deirdre Clune, Eva Maydell

**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 ***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 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

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.

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 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

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 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

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.

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 Boto , Moritz Körner, Ond ěj Kova īk, 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 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 European Commission**, Member States' competent authorities **and other entities** that have established AI regulatory sandboxes shall coordinate their activities and cooperate within the 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

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae ȇtef nu  , Ramona Strugariu, Drago P  slaru, Lucia  uri   Nicholsonov  , Irena Joveva, Morten L  kkegaard, Alin Mitu  

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

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

recommendations on their setup and, where relevant, on the application of this Regulation **and other** Union legislation supervised within the sandbox.

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 Złotowski, 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

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

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.

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

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš 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

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituța

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. 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.*

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

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 ***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.***

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

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***

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

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

Kate ina Kone ná, 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 Boto , Moritz Körner, Ond ěej Kova īk, 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

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuťă, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituťa, 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 Šimeka

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

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Mituță, Ramona Strugariu, Drago Pîslaru, Lucia Šuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

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 shall be processed for the purposes of developing and testing certain 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

Amendment

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

(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

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

Amendment

(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

(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;

Amendment

deleted

Or. en

Amendment 2352

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Alin Mituță

Proposal for a regulation

Article 54 – paragraph 1 – point a – point i

Text proposed by the Commission

(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;

Amendment

(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 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, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 54 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a bis) les personnes physiques dont les données personnelles sont utilisées aux fins du développement et du test de certains systèmes d'I.A. innovants dans le bac à sable sont informés de la collecte et de l'usage de leurs données et y ont consenti;

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



*Committee on the Internal Market and Consumer Protection
Committee on Civil Liberties, Justice and Home Affairs*

2021/0106(COD)

13.6.2022

AMENDMENTS

2356 - 2726

Draft report
Brando Benifei, Drago 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))

AM_Com_LegReport

Amendment 2356

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 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 risks to the fundamental rights of the data subjects **and holders of intellectual property rights or trade secrets** may arise during the sandbox experimentation as well as response mechanism to promptly mitigate those risks and, where necessary, stop the processing;

Or. en

Amendment 2357

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 d***Text proposed by the Commission*

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

Amendment

(d) any personal data **or data protected by intellectual property rights or trade secrets** to be processed in the context of the sandbox are in a functionally separate, isolated and protected data processing environment under the control of the participants and only authorised persons have access to **those** data;

Or. en

Amendment 2358

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 54 – paragraph 1 – point e

Text proposed by the Commission

- (e) any personal data processed are not be transmitted, transferred or otherwise accessed by other parties;

Amendment

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

Or. en

Amendment 2359

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 e

Text proposed by the Commission

- (e) any personal data processed are not be transmitted, transferred or otherwise accessed by other parties;

Amendment

- (e) any personal data *or data protected by intellectual property rights or trade secrets* processed are not be transmitted, transferred or otherwise accessed by other parties;

Or. en

Amendment 2360

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 54 – paragraph 1 – point f

Text proposed by the Commission

- (f) any processing of personal data in the context of the sandbox *do not lead to measures or decisions affecting* the data subjects;

Amendment

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

Amendment 2361
Axel Voss, Deirdre Clune

Proposal for a regulation
Article 54 – paragraph 1 – point g

Text proposed by the Commission

(g) any personal data processed in the context of the sandbox are deleted once the participation in the sandbox has terminated or the personal data has reached the end of its retention period;

Amendment

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

Amendment 2362
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 g

Text proposed by the Commission

(g) any personal data processed in the context of the sandbox are deleted once the participation in the sandbox has terminated or the personal data has reached the end of its retention period;

Amendment

(g) any personal data ***or data protected by intellectual property rights or trade secrets*** processed in the context of the sandbox are deleted once the participation in the sandbox has terminated or the personal data has reached the end of its retention period;

Amendment 2363
Axel Voss, Deirdre Clune

Proposal for a regulation
Article 54 – paragraph 1 – point h

Text proposed by the Commission

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

Amendment

(h) the logs of the processing of personal data in the context of the sandbox are kept for the duration of the participation in the sandbox;

Or. en

Amendment 2364

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 h

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 2365

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Alin Mituță

Proposal for a regulation

Article 54 – paragraph 1 – point j

Text proposed by the Commission

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

Amendment

(j) a short summary of the AI project developed in the sandbox, its objectives, ***hypotheses*** and expected results, ***and non-confidential testing results***, *is* published on the website of the competent authorities.

Or. en

Amendment 2366

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 j

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 2367

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 54 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

I a. Provided that the conditions of paragraph 1 are met, personal data processed for developing and testing innovative AI systems in the sandbox shall be considered compatible for the purposes of Article 6(4) GDPR.

Or. en

Amendment 2368

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

**Proposal for a regulation
Article 54 – paragraph 2**

Text proposed by the Commission

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

Amendment

2. Paragraph 1 *further specifies Article 89 of Regulation (EU) 2016/679 and* is without prejudice to Union or Member States legislation excluding processing for other purposes than those explicitly mentioned in that legislation *or to Union or Member States legislation excluding the use of data protected by intellectual property or trade secrets under the conditions covered by Paragraph 1.*

Or. en

Amendment 2369

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 a (new)**

Text proposed by the Commission

Amendment

Article 54 a

Promotion of AI research and development in support of socially and environmentally beneficial outcomes

1. Member States shall promote research and development of AI solutions which support socially and environmentally beneficial outcomes, including but not limited to development of AI-based solutions to increase accessibility for persons with disabilities, tackle socio-economic inequalities, and meet sustainability and environmental targets, by:

- (a) providing relevant projects with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions;
- (b) earmarking public funding, including from relevant EU funds, for AI research and development in support of socially and environmentally beneficial outcomes;
- (c) organising specific awareness raising activities about the application of this Regulation, the availability of and application procedures for dedicated funding, tailored to the needs of those projects;
- (d) where appropriate, establishing accessible dedicated channels, including within the sandboxes, for communication with projects to provide guidance and respond to queries about the implementation of this Regulation.

2. Without prejudice to Article 55 a (new)1(a), Member States shall ensure that relevant projects are led by civil society and social stakeholders that set the project priorities, goals, and outcomes.

Or. en

Amendment 2370

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 55 – title

Text proposed by the Commission

Measures for *small-scale* providers and users

Amendment

Measures for providers and users *that are SME's or start-ups*

Or. en

Amendment 2371

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

Proposal for a regulation
Article 55 – title

Text proposed by the Commission

Measures for small-scale providers and
users

Amendment

Measures for small-scale providers and
deployers

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

Or. en

Amendment 2372

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ondej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation
Article 55 – title

Text proposed by the Commission

Measures for *small-scale providers* and
users

Amendment

Measures for *SMEs, start-ups* and users

Or. en

Amendment 2373

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

Proposal for a regulation
Article 55 – paragraph 1 – introductory part

Text proposed by the Commission

1. *Member States* shall undertake the following actions:

Amendment

1. *The national supervisory authority* shall undertake the following actions:

Or. en

Justification

Amendment necessary to ensure consistency with new articles on national supervisory authorities.

Amendment 2374

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 55 – paragraph 1 – point a

Text proposed by the Commission

- (a) provide ***small-scale providers*** and start-ups with priority access to ***the*** AI regulatory sandboxes to the extent that ***they*** fulfil the eligibility conditions;

Amendment

- (a) provide ***SMEs*** and start-ups with priority access to ***and make*** AI regulatory sandboxes ***reusable as well as affordable*** to the extent that ***SMEs and start-ups*** fulfil the eligibility conditions;

Or. en

Amendment 2375

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Ondej Kováčik, Jan-Christoph Oetjen

Proposal for a regulation

Article 55 – paragraph 1 – point a

Text proposed by the Commission

- (a) provide ***small-scale providers*** and start-ups with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions;

Amendment

- (a) provide ***SMEs*** and start-ups with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions;

Or. en

Amendment 2376

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 55 – paragraph 1 – point b

Text proposed by the Commission

- (b) organise specific awareness raising activities about the application of this Regulation tailored to the needs of ***the***

Amendment

- (b) organise specific awareness raising ***and training*** activities about the application of this Regulation tailored to

small-scale providers and users;

the needs of *SME's and start-ups*;

Or. en

Amendment 2377

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Ondej Kováčik, Jan-Christoph Oetjen

Proposal for a regulation

Article 55 – paragraph 1 – point b

Text proposed by the Commission

(b) organise specific awareness raising activities about the application of this Regulation tailored to the needs of *the small-scale providers* and users;

Amendment

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

Or. en

Amendment 2378

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 55 – paragraph 1 – point c

Text proposed by the Commission

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

Amendment

(c) where appropriate, establish a dedicated channel for communication with *SME's and start-ups* and user and other innovators to provide guidance and respond to queries about the implementation of this Regulation;

Or. en

Amendment 2379

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Ondej Kováčik, Jan-Christoph Oetjen

Proposal for a regulation

Article 55 – paragraph 1 – point c

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 2380

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 55 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) consult representative organisations of SMEs and start ups and involve them in the development of relevant standards;

Or. en

Amendment 2381

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 55 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) support SME's increased participation in the standardisation development process;

Or. en

Amendment 2382

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 55 – paragraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(c b) create development paths and services for SMEs and start ups, ensuring that government support is provided at all stages of their development, in particular by promoting digital tools and developing AI transition plans;

Or. en

Amendment 2383

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 55 – paragraph 1 – point c c (new)

Text proposed by the Commission

Amendment

(c c) promote industry best practices and responsible approaches to AI development and use self-regulatory commitments as a criterion for public procurement projects or as a factor that allows more opportunities to use and share data responsibly;

Or. en

Amendment 2384

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 55 – paragraph 1 – point c d (new)

Text proposed by the Commission

Amendment

(c d) offer tax breaks for doing research, better access to computer capacities and datasets, an EU-Visa

schema for tech-talents, temporary support in technology scouting or in paying salaries of AI specialists, and state aid exemptions in the area of AI education, training and reskilling of employees;

Or. en

Amendment 2385

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 55 – paragraph 1 – point c e (new)

Text proposed by the Commission

Amendment

(c e) reduce extensive reporting, information or documentation obligations, establish a single EU online portal in different languages concerning all necessary procedures and formalities to operate in another EU country, a single point of contact in the home country that can certify the company's eligibility to provide services in another EU country as well as a standardized EU-wide VAT declaration in the respective native language.

Or. en

Amendment 2386

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 55 – paragraph 2

Text proposed by the Commission

Amendment

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

2. The specific interests and needs of the **SME's and start-ups** shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size and market size, **by granting subsidies**

or even exempting SMEs and start ups from paying.

Or. en

Amendment 2387

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Ondřej Kováčík, Jan-Christoph Oetjen

Proposal for a regulation

Article 55 – paragraph 2

Text proposed by the Commission

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

Amendment

2. The specific interests and needs of the **SMEs and start-ups** shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size and market size.

Or. en

Amendment 2388

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 55 a (new)

Text proposed by the Commission

Amendment

Article 55 a

Promoting research and development of AI in support of socially and environmentally beneficial outcomes led by civil society

1. Member States shall promote research and development of AI solutions which support socially and environmentally beneficial outcomes, including but not limited to development of AI-based solutions to increase accessibility for persons with disabilities, tackle socio-economic inequalities, and meet

sustainability and environmental targets, by:

- (a) providing relevant projects with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions;*
- (b) earmarking public funding, including from relevant EU funds, for AI research and development in support of socially and environmentally beneficial outcomes;*
- (c) organising specific awareness raising activities about the application of this Regulation, the availability of and application procedures for dedicated funding, tailored to the needs of those projects;*
- (d) where appropriate, establishing accessible dedicated channels for communication with projects to provide guidance and respond to queries about the implementation of this Regulation.*

2. Member States shall ensure that when conformity assessment is required under Article 43, cost of such assessment is covered by public, including EU, funds available for AI research and development.

3. Without prejudice to Article 55 a (new)1(a), Member States shall ensure that relevant projects are led by civil society and social stakeholders that set the project priorities, goals, and outcomes.

Or. en

Amendment 2389

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Jan-Christoph Oetjen

**Proposal for a regulation
Article 55 a (new)**

Text proposed by the Commission

Amendment

Article 55 a

Promoting research and development of AI in support of socially and environmentally beneficial outcomes

Member States shall promote research and development of AI solutions which support socially and environmentally beneficial outcomes, including but not limited to development of AI-based solutions to increase accessibility for persons with disabilities, tackle socio-economic inequalities, and meet sustainability and environmental targets, by:

- (a) providing relevant projects with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions;*
- (b) earmarking public funding, including from relevant EU funds, for AI research and development in support of socially and environmentally beneficial outcomes;*
- (c) organising specific awareness raising activities about the application of this Regulation, the availability of and application procedures for dedicated funding, tailored to the needs of those projects;*
- (d) where appropriate, establishing accessible dedicated channels for communication with projects to provide guidance and respond to queries about the implementation of this Regulation.*

Or. en

Amendment 2390

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 55 b (new)

Text proposed by the Commission

Amendment

Article 55 b

Right not to be subject to non-compliant

AI systems

Natural persons shall have the right not to be subject to AI systems that:

- (a) pose an unacceptable risk pursuant to Article 5, or*
- (b) otherwise do not comply with the requirements of this Regulation.*

Or. en

Amendment 2391

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 55 c (new)

Text proposed by the Commission

Amendment

Article 55 c

Right to information about the use and functioning of AI systems

- 1. Natural persons shall have the right to be informed that they have been exposed to high-risk AI systems as defined in Article 6, and other AI systems as defined in Article 52.*
- 2. Natural persons shall have the right to be provided upon request, with an explanation for decisions producing legal effects or otherwise affecting them or outcomes related to them taken by or with the assistance of systems within the scope of this Regulation, pursuant to Article 52 paragraph (3b).*
- 3. The information outlined in paragraphs 1 and 2 shall be provided in a clear, easily understandable and intelligible way, in a manner that is accessible for persons with disabilities.*

Or. en

Amendment 2392

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Alin Mituță

**Proposal for a regulation
Title VI – Chapter 1 – title**

Text proposed by the Commission

1 European Artificial Intelligence
Board

Amendment

1 European Artificial Intelligence
Office

Or. en

Justification

This change shall be consistently reflected throughout the entire Regulation

Amendment 2393

Jorge Buxadé Villalba

**Proposal for a regulation
Article 56**

Text proposed by the Commission

Article 56

Amendment

suprimido

*Constitución del Comité Europeo de
Inteligencia Artificial*

*1. Se establece un «Comité Europeo de
Inteligencia Artificial» (el «Comité»).*

*2. El Comité ofrecerá asesoramiento y
asistencia a la Comisión a fin de:*

*a) contribuir a la cooperación efectiva de
las autoridades nacionales de supervisión
y la Comisión con respecto a las materias
reguladas por el presente Reglamento;*

*b) coordinar y contribuir a las
orientaciones y los análisis de la
Comisión y las autoridades nacionales de
supervisión y otras autoridades
competentes sobre problemas emergentes
en el mercado interior con respecto a las
materias reguladas por el presente
Reglamento;*

*c) asistir a las autoridades nacionales de
supervisión y a la Comisión para*

garantizar la aplicación coherente del presente Reglamento.

Or. es

Amendment 2394

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Nută, Ramona Strugariu, Drago Pîslaru, Lucia Ūriș Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation

Article 56 – title

Text proposed by the Commission

Establishment of the European Artificial Intelligence **Board**

Amendment

Establishment of the European Artificial Intelligence **Office**

Or. en

Amendment 2395

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

Proposal for a regulation

Article 56 – title

Text proposed by the Commission

Establishment of the European Artificial Intelligence Board

Amendment

European Artificial Intelligence Board

Or. en

Amendment 2396

Fernando Barrena Arza, Kateina Konevá, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 56 – title

Text proposed by the Commission

Establishment of the European Artificial Intelligence Board

Amendment

European Artificial Intelligence Board

Or. en

Amendment 2397

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation

Article 56 – paragraph 1

Text proposed by the Commission

Amendment

1. A ‘European Artificial Intelligence Board’ (the ‘Board’) is established. *deleted*

Or. en

Amendment 2398

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 56 – paragraph 1

Text proposed by the Commission

Amendment

1. A ‘European Artificial Intelligence Board’ (the ‘Board’) is established.

1. A ‘European Artificial Intelligence Board’ (the ‘Board’) is established *as an independent body with its own legal personality. The Board shall have a Secretariat, a strong mandate as well as sufficient resources and skilled personnel at its disposal for the assistance in the performance of its tasks laid down in Article 58.*

Or. en

Amendment 2399

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

Proposal for a regulation

Article 56 – paragraph 1

Text proposed by the Commission

Amendment

1. A ‘European Artificial Intelligence Board’ (the ‘Board’) is established.

1. *An independent* ‘European Artificial Intelligence Board’ (the ‘Board’) is *hereby* established *as a body of the Union and shall have legal personality*.

Or. en

Amendment 2400

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

Proposal for a regulation

Article 56 – paragraph 1

Text proposed by the Commission

1. A ‘European Artificial Intelligence Board’ (the ‘Board’) is established.

Amendment

1. A ‘European Artificial Intelligence Board’ (the ‘Board’) is established *as a body of the Union and shall have legal personality*.

Or. en

Amendment 2401

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

Proposal for a regulation

Article 56 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

I a. The Board shall monitor and ensure the effective and consistent application, and contribute to the effective and consistent enforcement, of this Regulation throughout the Union, including with regard to cases involving two or more Member States as set out in Article 59b.

Or. en

Amendment 2402

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 56 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

I a. The Board shall be independent in the fulfilment of its task. It shall have legal personality.

Or. en

Amendment 2403

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 56 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

I b. The Board shall ensure the consistent application of this Regulation.

Or. en

Amendment 2404

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia uriaș Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation

Article 56 – paragraph 2

Text proposed by the Commission

Amendment

2. The Board shall provide advice and assistance to the Commission in order to:

(a) contribute to the effective cooperation of the national supervisory authorities and the Commission with regard to matters covered by this Regulation;

(b) coordinate and contribute to guidance and analysis by the Commission and the national supervisory authorities and other competent authorities on emerging issues

deleted

across the internal market with regard to matters covered by this Regulation;

(c) assist the national supervisory authorities and the Commission in ensuring the consistent application of this Regulation.

Or. en

Amendment 2405

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Ondej Kovač, Jan-Christoph Oetjen

Proposal for a regulation

Article 56 – paragraph 2 – introductory part

Text proposed by the Commission

2. The Board shall provide advice and assistance to the Commission in order to:

Amendment

2. The Board shall provide advice and assistance to the Commission **and to the national supervisory authorities** in order to:

Or. en

Amendment 2406

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 56 – paragraph 2 – introductory part

Text proposed by the Commission

2. The Board shall provide advice and assistance to the Commission in order to:

Amendment

2. The Board shall provide advice and assistance to the Commission **and the national authorities** in order to:

Or. en

Amendment 2407

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 56 – paragraph 2 – point a

Text proposed by the Commission

- (a) contribute to the effective cooperation of the national supervisory authorities and the Commission with regard to matters covered by this Regulation;

Amendment

- (a) contribute to the effective cooperation of the national supervisory authorities and the Commission with regard to matters covered by this Regulation;

Or. en

Amendment 2408

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

Proposal for a regulation

Article 56 – paragraph 2 – point b

Text proposed by the Commission

- (b) coordinate and **contribute to** guidance and analysis by the Commission and the national supervisory authorities and other competent authorities on emerging issues across the internal market with regard to matters covered by this Regulation;

Amendment

- (b) coordinate and **provide** guidance and analysis by the Commission and the national supervisory authorities and other competent authorities on emerging issues across the internal market with regard to matters covered by this Regulation;

Or. en

Amendment 2409

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 56 – paragraph 2 – point c

Text proposed by the Commission

- (c) assist the national supervisory authorities and **the Commission** in ensuring the consistent application of this Regulation.

Amendment

- (c) assist the **Commission**, national supervisory authorities and **other competent authorities** in ensuring the consistent application of this Regulation, **in particular in line with the consistency mechanism referred to in Article 59a(3)**;

Amendment 2410

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

Proposal for a regulation

Article 56 – paragraph 2 – point c

Text proposed by the Commission

(c) assist the national supervisory authorities and the Commission in *ensuring the consistent application of this Regulation.*

Amendment

(c) *contribute to the effective and consistent application of this Regulation and* assist the national supervisory authorities and the Commission in *that regard.*

Amendment 2411

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 56 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(c a) *carry out annual reviews and analyses of the complaints sent to and findings by national competent authorities, of the serious incidents and malfunctioning reports referred to in Article 62, and of the new registration in the EU Database referred to in Article 60 to identify trends and potential emerging issues threatening the future health and safety and fundamental rights of citizens and not adequately addressed by this Regulation; to carry out biannual horizon scanning and foresight exercises to extrapolate the impact these trends and emerging issues can have on the Union; and to annually publish recommendations to the Commission, including but not limited to recommendations on the categorization of prohibited practices,*

high-risk systems, and codes of conduct for AI systems that are not classified as high-risk.

Or. en

Amendment 2412

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 56 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(c a) provide particular oversight, monitoring and regular dialogue with the providers of general purpose AI systems about their compliance with the Regulation. Any such meeting shall be open to national supervisory authorities, notified bodies and market surveillance authorities to attend and contribute

Or. en

Amendment 2413

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

Proposal for a regulation

Article 56 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(c a) contribute to the effective cooperation with the competent authorities of third countries and with international organisations.

Or. en

Amendment 2414

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ondřej Kovářík, Jan-Christoph Oetjen

Proposal for a regulation
Article 56 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(c a) contribute to the effective cooperation with the competent authorities of third countries and with international organisations.

Or. en

Amendment 2415

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

Proposal for a regulation

Article 56 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(c a) propose amendments to Annexes I and III to the Commission.

Or. en

Amendment 2416

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 56 – paragraph 2 – point c b (new)

Text proposed by the Commission

Amendment

(c b) bring together national metrology and benchmarking authorities to provide guidance to address the technical aspects of how to measure appropriate levels of accuracy and robustness.

Or. en

Amendment 2417

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 56 – paragraph 2 – point c b (new)

Text proposed by the Commission

Amendment

*(c b) represent and defend the interest
of the broad civil society, including Social
Partners.*

Or. en

Amendment 2418

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 56 – paragraph 2 – point c c (new)

Text proposed by the Commission

Amendment

*(c c) launch an evaluation procedure
for an AI system*

Or. en

Amendment 2419

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 56 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

*2 a. The Board shall have a sufficient
number of competent personnel at their
disposal for assistance in the proper
performance of their tasks.*

Or. en

Amendment 2420

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Article 56 – paragraph 2 b (new)**

Text proposed by the Commission

Amendment

2 b. The Board shall be organised and operated so as to safeguard the independence, objectivity and impartiality of their activities. The Board shall document and implement a structure and procedures to safeguard impartiality and to promote and apply the principles of impartiality throughout its activities.

Or. en

Amendment 2421

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Alin Mituță

**Proposal for a regulation
Article 56 a (new)**

Text proposed by the Commission

Amendment

Article 56 a

SECTION 1: General provisions

An independent ‘European Artificial Intelligence Office’ (the ‘AI Office’) is hereby established. The European Union Artificial Intelligence Office shall be an Office of the Union, shall have legal personality, and shall be adequately funded and staffed. The Office shall enjoy in all the Member States the most extensive legal capacity accorded to legal persons under their laws.

Or. en

Amendment 2422

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation

Article 56 b (new)

Text proposed by the Commission

Amendment

Article 56 b

Mandate

1. The AI Office shall carry out the tasks assigned to it under this Regulation for the purpose of achieving a high level of trustworthiness and of protection of health, safety, fundamental rights and the Union values enshrined in Article 2 TEU across the Union with regards to artificial intelligence systems, including by actively supporting Member States, Union institutions, bodies, offices and agencies in matters pertaining to this Regulation. The AI Office shall act as a reference point for advice and expertise on artificial intelligence for Union institutions, bodies, offices and agencies, for Member States and their national supervisory authorities, as well as for other relevant Union stakeholders.

2. The AI Office shall contribute to reducing the fragmentation of the internal market and to increasing the uptake of artificial intelligence throughout the Union by carrying out the tasks assigned to it under this Regulation.

3. When carrying out its tasks, the AI Office shall act independently while avoiding the duplication of Member State activities and taking into consideration Member State competences.

4. The AI Office shall organise consultations with stakeholders twice a year to assess the evolution of trends in technology, issues related to the implementation and the effectiveness of this Regulation, regulatory gaps or loopholes observed in practice. Such stakeholders shall include representatives from industry, start-ups and SMEs, civil society organisations, such as NGOs, consumer associations, the social partners and academia.

5. The AI Office may consult national authorities, such as national equality bodies, where the issues discussed are of relevance for them. The AI Office may also consult, where appropriate, external experts and observers and interested third parties, including stakeholders such as those referred to in paragraph 5, and may hold exchanges with them.

6. The AI Office shall cooperate with Union institutions, bodies, offices, agencies and advisory groups and shall make the results of that cooperation publicly available.

Or. en

Amendment 2423

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Karen Melchior, Alin Mituță

Proposal for a regulation

Article 56 c (new)

Text proposed by the Commission

Amendment

Article 56 c

Accountability, transparency, and independence

1. The AI Office shall be accountable to the European Parliament and to the Council in accordance with this Regulation.

2. The AI Office shall develop good administrative practices in order to ensure the highest possible level of transparency concerning its activities. Regulation (EC) No 1049/2001 shall apply to documents held by the AI Office.

3. The AI Office shall fulfil its tasks in complete independence.

Or. en

Amendment 2424

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tef Nută, Ramona Strugariu, Drago Pîslaru, Lucia Uriš Nicholsonová, Irena Joveva, Alin Mituța

Proposal for a regulation

Article 56 d (new)

Text proposed by the Commission

Amendment

Article 56 d

Administrative and management structure

- 1. The administrative and management structure of the AI Office shall comprise:***
- (a) a management board***
 - (b) an executive director***
 - (c) an advisory forum***
 - (d) where appropriate, other advisory bodies established by the management board to support the AI Office in technical or scientific matters related to this Regulation.***

Or. en

Amendment 2425

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tef Nută, Ramona Strugariu, Drago Pîslaru, Lucia Uriš Nicholsonová, Irena Joveva, Alin Mituța

Proposal for a regulation

Article 56 e (new)

Text proposed by the Commission

Amendment

Article 56 e

Objectives

1. The AI Office shall:

- (a) contribute to the uptake of artificial intelligence in the Union, including through supporting innovation and the development of regulatory sandboxes provided for in this Regulation;***
- (b) contribute to a high level of trustworthiness and of protection of health, safety, fundamental rights and the***

Union values enshrined in Article 2 TEU with regard to artificial intelligence systems in the Union;

(c) contribute to the effective cooperation of the national supervisory authorities and the Commission with regard to matters covered by this Regulation;

(d) provide forecasts, guidance, and analysis to the Commission, Member States, and to the national supervisory authorities and other competent authorities on emerging issues across the internal market with regard to matters covered by this Regulation and related issues;

(e) contribute to the effective and consistent application of this Regulation and assist Member States, the national supervisory authorities, and the Commission in this regard;

(f) contribute to the effective cooperation with the competent authorities of third countries and with international organisations;

(g) contribute to the development, promotion, and adoption of harmonized standards, common specifications, common benchmarking standards, and voluntary codes of conduct;

(h) contribute to the effective and consistent enforcement of this Regulation throughout the Union, including by issuing binding decisions with regard to cases involving two or more Member States asset out in Article 59b.

Or. en

Amendment 2426
Jorge Buxadé Villalba

Proposal for a regulation
Article 57

Article 57

suprimido

Estructura del Comité

1. El Comité estará compuesto por las autoridades nacionales de supervisión, que estarán representadas por el jefe de dicha autoridad o un funcionario de alto nivel equivalente, y el Supervisor Europeo de Protección de Datos. Se podrá invitar a otras autoridades nacionales a las reuniones, cuando los temas tratados sean de relevancia para ellas.

2. El Comité adoptará su propio reglamento interno por mayoría simple de los miembros que lo componen, tras el dictamen conforme de la Comisión. En el reglamento interno se recogerán asimismo los aspectos operativos relacionados con la ejecución de las funciones del Comité previstas en el artículo 58. El Comité podrá establecer subgrupos, según proceda, para examinar cuestiones específicas.

3. El Comité estará presidido por la Comisión. La Comisión convocará las reuniones y elaborará el orden del día de conformidad con las funciones del Comité en virtud del presente Reglamento y con su reglamento interno. La Comisión prestará apoyo administrativo y analítico a las actividades del Comité en virtud del presente Reglamento.

4. El Comité podrá invitar a expertos y observadores externos a que asistan a sus reuniones y podrá realizar intercambios con terceros interesados para orientar sus actividades, en la medida en que se considere apropiado. Para ello, la Comisión podrá facilitar intercambios entre el Comité y otros organismos, oficinas, agencias y grupos consultivos de la Unión.

Or. es

Amendment 2427

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tefnută, Ramona Strugariu, Drago Pîslaru, Lucia Ūriš Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation

Article 57

Text proposed by the Commission

Amendment

Article 57

deleted

Structure of the Board

- 1. The Board shall be composed of the national supervisory authorities, who shall be represented by the head or equivalent high-level official of that authority, and the European Data Protection Supervisor. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.***
- 2. The Board shall adopt its rules of procedure by a simple majority of its members, following the consent of the Commission. The rules of procedure shall also contain the operational aspects related to the execution of the Board's tasks as listed in Article 58. The Board may establish sub-groups as appropriate for the purpose of examining specific questions.***
- 3. The Board shall be chaired by the Commission. The Commission shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. The Commission shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.***
- 4. The Board may invite external experts and observers to attend its meetings and may hold exchanges with interested third parties to inform its activities to an appropriate extent. To that end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory***

groups.

Or. en

Amendment 2428

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

Proposal for a regulation

Article 57 – title

Text proposed by the Commission

Amendment

Structure of the Board

Structure *and independence* of the Board

Or. en

Amendment 2429

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 57 – paragraph 1

Text proposed by the Commission

Amendment

1. The Board shall be composed of the national supervisory authorities, who shall be represented by the head or equivalent high-level official of that authority, ***and the European Data Protection Supervisor***. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.

1. The Board shall be composed of the national supervisory authorities, who shall be represented by the head or equivalent high-level official of that authority. Other national authorities may ***also*** be invited to the meetings, where the issues discussed are of relevance for them.

The European Data Protection Supervisor, the Chairperson of the EU Agency for Fundamental Rights, the Executive director of the EU Agency for Cybersecurity, the Chair of the High Level Expert Group on AI, the Director-General of the Joint Research Centre, and the presidents of the European Committee for Standardization, the European Committee for Electrotechnical Standardization, and the European Telecommunications Standards Institute shall be invited as permanent observers

with the right to speak but without voting rights.

Or. en

Amendment 2430

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

Proposal for a regulation

Article 57 – paragraph 1

Text proposed by the Commission

1. The Board shall be composed of the national supervisory authorities, who shall be represented by the head ***or equivalent high-level official*** of that authority, and the European Data Protection Supervisor. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.

Amendment

1. The Board shall be composed of the national supervisory authorities, who shall be represented by the head of that authority, and the European Data Protection Supervisor, ***the Chair of the European Data Protection Board, the Director of the Fundamental Rights Agency, the Executive Director of the European Union Agency for Cybersecurity or their respective representatives***. Other national authorities ***or Union agencies and bodies*** may be invited to the meetings, where the issues discussed are of relevance for them.

Or. en

Amendment 2431

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

Proposal for a regulation

Article 57 – paragraph 1

Text proposed by the Commission

1. The Board shall be composed of the national supervisory authorities, ***who shall be represented by the head or equivalent high-level official of that authority, and*** the European Data Protection Supervisor. Other national authorities may be invited to

Amendment

1. The Board shall be composed of the national supervisory authorities, the European Data Protection Supervisor ***as the EU Agency for Fundamental Rights, the EU Agency for Cybersecurity, the Joint Research Centre, the European***

the meetings, where the issues discussed are of relevance for them.

Committee for Standardization, the European Committee for Electrotechnical Standardization, and the European Telecommunications Standards Institute, each with one representative. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.

Or. en

Amendment 2432

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 57 – paragraph 1

Text proposed by the Commission

1. The Board shall be composed of the national supervisory authorities, who shall be represented by the head or equivalent high-level official of that authority, and the European Data Protection Supervisor. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.

Amendment

1. The Board shall be composed of the national supervisory authorities, who shall be represented by the head or equivalent high-level official of that authority, and the European Data Protection Supervisor, *the EU Agency for Fundamental Rights, ENISA, EIGE and social partners as well representatives of civil society*. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.

Or. en

Amendment 2433

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

Proposal for a regulation

Article 57 – paragraph 1

Text proposed by the Commission

1. Le Comité est composé des autorités de contrôle nationales, qui sont représentées par leur directeur ou un de leurs hauts fonctionnaires de niveau

Amendment

1. Le Comité est composé des autorités de contrôle nationales, qui sont représentées par leur directeur ou un de leurs hauts fonctionnaires de niveau

équivalent, *et* du Contrôleur européen de la protection des données. D'autres autorités nationales peuvent être invitées aux réunions, lorsque les questions examinées relèvent de leurs compétences.

équivalent, du Contrôleur européen *de la protection des données et des organismes nationaux* de la protection des données. D'autres autorités nationales peuvent être invitées aux réunions, lorsque les questions examinées relèvent de leurs compétences.

Or. fr

Amendment 2434

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 57 – paragraph 1

Text proposed by the Commission

1. The Board shall be composed of the national supervisory authorities, who shall be represented by the head or equivalent high-level official of that authority, and the European Data Protection Supervisor. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.

Amendment

1. The Board shall be composed of the national supervisory authorities, who shall be represented by the head or equivalent high-level official of that authority, and the European Data Protection Supervisor, *AI ethics experts and industry representatives*. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.

Or. en

Amendment 2435

Fernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 57 – paragraph 1

Text proposed by the Commission

1. The Board shall be composed of the national supervisory authorities, who shall be represented by the head or equivalent high-level official of that authority, *and* the European Data Protection Supervisor. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.

Amendment

1. The Board shall be composed of the national supervisory authorities, who shall be represented by the head or equivalent high-level official of that authority, the European Data Protection Supervisor *and the Fundamental Rights Agency*. Other national authorities *or EU agencies* may be invited to the meetings, where the issues discussed are of relevance for them.

Amendment 2436
Marion Walsmann

Proposal for a regulation
Article 57 – paragraph 1

Text proposed by the Commission

1. The Board shall be composed of the national supervisory authorities, who shall be represented by the head or equivalent high-level official of that authority, and the European Data Protection Supervisor. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.

Amendment

1. The Board shall be composed of the national supervisory authorities, who shall be represented by the head or equivalent high-level official of that authority, and the European Data Protection Supervisor **and relevant stakeholders including SMEs**. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.

Amendment 2437
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation
Article 57 – paragraph 1

Text proposed by the Commission

1. The Board shall be composed of the national supervisory authorities, who shall be represented by the head or equivalent high-level official of that authority, **and** the European Data Protection Supervisor. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.

Amendment

1. The Board shall be composed of the national supervisory authorities, who shall be represented by the head or equivalent high-level official of that authority, the European Data Protection Supervisor **and the FRA**. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.

Amendment 2438
Fernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 57 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. The Commission shall have the right to participate in the activities and meetings of the Board without voting right. The Commission shall designate a representative. The Chair of the Board shall communicate to the Commission the activities of the Board.

Or. en

Amendment 2439

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

Proposal for a regulation
Article 57 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. The Board shall act independently when performing its tasks or exercising its powers.

Or. en

Amendment 2440

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

Proposal for a regulation
Article 57 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. The Board shall be represented by its Chair.

Or. en

Amendment 2441

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

Proposal for a regulation

Article 57 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

I b. The Board shall act independently when performing its tasks or exercising its powers pursuant to Articles 58.

Or. en

Amendment 2442

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

Proposal for a regulation

Article 57 – paragraph 1 c (new)

Text proposed by the Commission

Amendment

I c. The Board shall take decisions by a simple majority of its voting members, unless otherwise provided for in this Regulation. Each national supervisory authority and the EDPS shall have one vote.

Or. en

Amendment 2443

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

Proposal for a regulation

Article 57 – paragraph 2

Text proposed by the Commission

Amendment

2. The Board shall adopt its rules of procedure by a simple majority of its members, *following the consent of the Commission. The rules of procedure shall*

2. The Board shall adopt its rules of procedure by a simple *two-thirds* majority of its *voting* members *and organise its own operational arrangements.*

also contain the operational aspects related to the execution of the Board's tasks as listed in Article 58. The Board may establish sub-groups as appropriate for the purpose of examining specific questions.

Or. en

Amendment 2444

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 57 – paragraph 2

Text proposed by the Commission

2. The Board shall adopt its rules of procedure by a simple majority of its members, *following the consent of the Commission*. The rules of procedure shall also contain the operational aspects related to the execution of the Board's tasks as listed in Article 58. The Board may establish sub-groups as appropriate for the purpose of examining specific questions.

Amendment

2. The Board shall adopt its rules of procedure by a simple majority of its members. The rules of procedure shall also contain the operational aspects related to the execution of the Board's tasks as listed in Article 58. The Board may establish sub-groups as appropriate for the purpose of examining specific questions.

Or. en

Amendment 2445

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

Proposal for a regulation

Article 57 – paragraph 2

Text proposed by the Commission

2. The Board shall adopt its rules of procedure by a simple majority of its members, *following the consent of the Commission*. The rules of procedure shall also contain the operational aspects related to the execution of the Board's tasks as listed in Article 58. The Board may establish sub-groups as appropriate for the

Amendment

2. The Board shall adopt its rules of procedure by *two-thirds majority and shall take decisions by* a simple majority of its members. The rules of procedure shall also contain the operational aspects related to the execution of the Board's tasks as listed in Article 58. The Board may establish sub-groups as appropriate for the purpose

purpose of examining specific questions.

of examining specific questions.

Or. en

Amendment 2446

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

**Proposal for a regulation
Article 57 – paragraph 2**

Text proposed by the Commission

2. Le Comité adopte son règlement intérieur à la majorité *simple* de ses membres *une fois celui-ci approuvé par la Commission*. Le règlement intérieur contient également les aspects opérationnels en rapport avec l'exécution des tâches du Comité telles qu'énumérées à l'article 58. Le Comité peut créer des sous-groupes, s'il y a lieu, afin d'examiner des questions spécifiques.

Amendment

2. Le Comité adopte son règlement intérieur à la majorité *des deux tiers* de ses membres. Le règlement intérieur contient également les aspects opérationnels en rapport avec l'exécution des tâches du Comité telles qu'énumérées à l'article 58. Le Comité peut créer des sous-groupes, s'il y a lieu, afin d'examiner des questions spécifiques.

Or. fr

Amendment 2447

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 57 – paragraph 2**

Text proposed by the Commission

2. The Board shall adopt its rules of procedure by a simple majority of its members, *following the consent of the Commission*. The rules of procedure shall also contain the operational aspects related to the execution of the Board's tasks as listed in Article 58. The Board may establish sub-groups as appropriate for the purpose of examining specific questions.

Amendment

2. The Board shall adopt its rules of procedure by a simple majority of its members. The rules of procedure shall also contain the operational aspects related to the execution of the Board's tasks as listed in Article 58. The Board may establish *standing or temporary* sub-groups as appropriate for the purpose of examining specific questions.

Or. en

Amendment 2448

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 57 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The Board may establish sub-groups as appropriate for the purpose of examining specific questions. The Board shall establish a permanent sub-group for the purpose of examining the question of the proper governance of general purpose AI systems. The Board shall also establish a permanent sub-group for the purpose of examining the question of the proper governance of research and development activities on the topic of AI and to inform the development of the governance framework.

Or. en

Amendment 2449

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

Proposal for a regulation

Article 57 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The Board may establish sub-groups as appropriate for the purpose of examining specific questions. In any case, the Board shall establish the following permanent sub-groups:

- a) for the purpose of examining the question of the proper governance of AI systems with indeterminate use;*
- b) for the purpose of examining the question of the proper governance of research and development activities on the topic of AI.*

Or. en

Amendment 2450

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

Proposal for a regulation

Article 57 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2 b. The Board shall elect a Chair and two deputy Chairs from among its voting members by simple majority. The term of office of the Chair and of the deputy Chairs shall be three years, renewable once.

Or. en

Amendment 2451

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 57 – paragraph 3

Text proposed by the Commission

Amendment

3. The Board shall be chaired by the Commission. The Commission shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. The Commission shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.

3. The Commission shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.

Or. en

Amendment 2452

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

Proposal for a regulation
Article 57 – paragraph 3

Text proposed by the Commission

3. Le Comité est présidé par *la Commission*. *La Commission* convoque les réunions et prépare l'ordre du jour conformément aux tâches du Comité au titre du présent règlement et à son règlement intérieur. La Commission apporte un appui administratif et analytique aux activités du Comité au titre du présent règlement.

Amendment

3. Le Comité est présidé par *l'autorité de contrôle nationale de l'État membre qui exerce la présidence du Conseil de l'Union européenne*. *Celui-ci* convoque les réunions et prépare l'ordre du jour conformément aux tâches du Comité au titre du présent règlement et à son règlement intérieur. La Commission apporte un appui administratif et analytique aux activités du Comité au titre du présent règlement.

Or. fr

Amendment 2453

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation
Article 57 – paragraph 3

Text proposed by the Commission

3. The Board shall be *chaired* by the Commission. The Commission shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. The Commission shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.

Amendment

3. The Board shall be *co-chaired* by the Commission *and a representative chosen from among the delegates of the Member States*. The Commission shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. The Commission shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.

Or. en

Amendment 2454

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

Proposal for a regulation

Article 57 – paragraph 3

Text proposed by the Commission

3. The **Board** shall **be chaired by the Commission**. The **Commission** shall convene the meetings and prepare **the agenda in accordance with** the tasks of the Board **pursuant to this Regulation and with its rules of procedure**. The **Commission** shall provide administrative and analytical support for the activities of the Board **pursuant to this Regulation**.

Amendment

3. The **Chair** shall **have the following tasks**:

- convene the meetings **of the Board** and prepare **its** agenda;
- **ensure the timely performance of** the tasks of the Board;
- **notify Member States and** the Commission of **any recommendations adopted by** the Board.

Or. en

Amendment 2455

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 57 – paragraph 3

Text proposed by the Commission

3. The Board shall be chaired by the Commission. The **Commission** shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. The **Commission** shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.

Amendment

3. The Board shall be chaired by the Commission. The **Board's Secretariat** shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. The **Board's Secretariat** shall **also** provide administrative and analytical support for the activities of the Board pursuant to this Regulation.

Or. en

Amendment 2456

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

**Proposal for a regulation
Article 57 – paragraph 3**

Text proposed by the Commission

3. The Board shall ***be chaired by the Commission. The Commission*** shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. ***The Commission shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.***

Amendment

3. The Board shall ***elect a chair and two deputy chairs from among its members. Their term of office shall be five years and be renewable once. . The Chair*** shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure.

Or. en

Amendment 2457

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

**Proposal for a regulation
Article 57 – paragraph 3 a (new)**

Text proposed by the Commission

Amendment

3 a. ***The Board shall establish a AI Advisory Council (Advisory Council). The Advisory Council shall be composed of relevant representatives from industry, research, academia, civil society, standardisation organisations, relevant common European data spaces and other relevant stakeholders or third parties appointed by the Board, representing all Member States to maintain geographical balance. The Advisory Council shall support the work of the Board by providing advice relating to the tasks of the Board. The Advisory Council shall nominate a relevant representative, depending on the configuration in which the Board meets, to attend meetings of the Board and to participate in its work. The composition of the Advisory Council and***

its recommendations to the Board shall be made public.

Or. en

Amendment 2458

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

Proposal for a regulation

Article 57 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. The secretariat of the Board shall have the necessary human and financial resources to be able to perform its tasks pursuant to this Regulation.

Or. en

Amendment 2459

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 57 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. The Board shall elect a chair and two deputy chairs from amongst its members by simple majority.

Or. en

Amendment 2460

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

Proposal for a regulation

Article 57 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3 b. The Commission shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.

Or. en

Amendment 2461

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 57 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3 b. The term of office of the Chair and of the deputy chairs shall be five years and be renewable once.

Or. en

Amendment 2462

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 57 – paragraph 4

Text proposed by the Commission

Amendment

4. The Board **may** invite external experts **and observers** to attend its meetings **and may hold exchanges with interested third parties to inform its activities to an appropriate extent. To that end** the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups.

4. The Board **shall regularly** invite external experts, **in particular from organisations representing the interests of the providers and users of AI systems, SMEs and start-ups, civil society organisations, representatives of affected persons, researchers, standardisation organisations, testing and experimentation facilities**, to attend its meetings **in order to ensure accountability and appropriate participation of external actors.** The Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups.

Or. en

Amendment 2463

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

Proposal for a regulation

Article 57 – paragraph 4

Text proposed by the Commission

4. The Board may invite external experts and observers to attend its meetings and may hold exchanges with interested third parties to inform its activities to an appropriate extent. To that end the **Commission may** facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups.

Amendment

4. The Board may invite external experts and observers to attend its meetings and may hold exchanges with interested third parties to inform its activities to an appropriate extent. To that end the **Chair shall** facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups. **The Board shall ensure a balanced representation of stakeholders from academia, research, industry and civil society when it invites external experts and observers, and actively stimulate participation from underrepresented categories.**

Or. en

Amendment 2464

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ondej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 57 – paragraph 4

Text proposed by the Commission

4. The Board may invite external experts and observers to attend its meetings and may hold exchanges with interested third parties to inform its activities to an appropriate extent. **To that end** the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups.

Amendment

4. The Board may invite external experts and observers to attend its meetings and may hold exchanges with interested third parties to inform its activities to an appropriate extent, **and hold consultations with relevant stakeholders and ensure appropriate participation. The Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory.** The Commission may facilitate exchanges

between the Board and other Union bodies, offices, agencies and advisory groups.

Or. en

Amendment 2465

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Article 57 – paragraph 4**

Text proposed by the Commission

4. The Board may invite external experts and observers *to attend its meetings and may hold exchanges with interested third parties to inform its activities to an appropriate extent*. To that end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and *advisory groups*.

Amendment

4. The Board may invite external experts and observers. To that end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and *specialised bodies*.
The composition of the specialised body shall ensure fair representation of consumer organisations, civil society organisations and academics specialised on AI. Its meetings and their minutes shall be published online.

Or. en

Amendment 2466

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

**Proposal for a regulation
Article 57 – paragraph 4**

Text proposed by the Commission

4. The Board may invite external experts and observers to attend its meetings and may hold exchanges with *interested third parties to inform its activities to an appropriate extent. To that end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups*.

Amendment

4. The Board may invite *national authorities, such as national equality bodies, to its meetings, where the issues discussed are of relevance for them. The Board may also invite, where appropriate, external experts, and observers and interested third parties, including stakeholders, such as those referred to in Article 58, paragraph 1c*, to attend its meetings and may hold exchanges with

them.

Or. en

Amendment 2467

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 57 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. Without prejudice to paragraph 4, the Board's Secretariat shall organise four additional meetings between the Board and the High Level Expert Group on AI to allow them to share their practical and technical expertise every quarter of the year.

Or. en

Amendment 2468

Sophia in 't Veld, Michal Šimek

Proposal for a regulation

Article 57 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. The Board shall take into consideration advice provided by the EDPB, particularly on new or evolving risks of high-risk AI systems processing personal data.

Or. en

Amendment 2469

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

Proposal for a regulation

Article 57 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. The Board shall cooperate with Union institutions, bodies, offices, agencies and advisory groups and shall make the results of that cooperation publicly available.

Or. en

Amendment 2470

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

Proposal for a regulation

Article 57 a (new)

Text proposed by the Commission

Amendment

Article 57 a

Secretariat

1. The Board shall have a secretariat, which shall be provided by the European Data Protection Supervisor.

2. The secretariat shall perform its tasks exclusively under the instructions of the Chair of the Board.

3. The staff of the European Data Protection Supervisor involved in carrying out the tasks conferred on the Board by this Regulation shall be subject to separate reporting lines from the staff involved in carrying out tasks conferred on the European Data Protection Supervisor.

4. Where appropriate, the Board and the European Data Protection Supervisor shall establish and publish a Memorandum of Understanding implementing this Article, determining the terms of their cooperation, and applicable to the staff of the European Data Protection Supervisor involved in carrying out the tasks conferred on the Board by this Regulation.

5. The secretariat shall provide analytical, administrative and logistical support to the Board.

6. The secretariat shall be responsible in particular for:

- (a) the day-to-day business of the Board;*
- (b) communication between the members of the Board, its Chair and the Commission;*
- (c) communication with other institutions and the public;*
- (d) the use of electronic means for the internal and external communication;*
- (e) the translation of relevant information;*
- (f) the preparation and follow-up of the meetings of the Board;*
- (g) the preparation, drafting and publication of opinions, guidelines, and other texts to be adopted by the Board.*

7. For the exercise of point (g) of paragraph 6, the secretariat shall, under the guidance of the Chair and the deputy Chairs, establish a European Centre of Excellence for Artificial Intelligence (ECE-AI, “the Centre”). The Centre shall be provided with sufficient resources and facilities to attract the highest level of expertise on artificial intelligence from technical and humanities sciences. In particular it shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, fundamental rights, health and safety risks and environmental risks, and knowledge of existing standards and legal requirements, including competition law.

Or. en

Justification

European Center of Excellence from the testimony and advice of Frances Haugen.

Amendment 2471

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tefnuță, Ramona Strugariu, Drago Pîslaru, Lucia Uriș Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation

Article 57 a (new)

Text proposed by the Commission

Amendment

Article 57 a

Composition of the management board

- 1. The management board shall be composed of one representative of each Member State, the Commission, and the European Data Protection Supervisor, and the Fundamental Rights Agency. Each Member State and the Commission shall have one vote. The EDPS and the FRA shall not have voting rights.*
- 2. Each member of the management board shall have an alternate. That alternate shall represent the member in the member's absence.*
- 3. The Commission and the Member States shall aim to achieve gender balance on the management board.*
- 4. The list of the members and alternate members of the management board shall be made public and shall be updated by the AI Office on its web site.*
- 5. The term of office of the members of the management board and their alternates shall be four years. That term shall be renewable once.*

Or. en

Amendment 2472

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tefnuță, Ramona Strugariu, Drago Pîslaru, Lucia Uriș Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation

Article 57 b (new)

Article 57 b

Functions of the management board

1. The management board shall be responsible for taking the strategic decisions of the AI Office in accordance with this Regulation. In particular, the management board shall:

- (a) Establish the general direction of the operation of the AI Office and ensure that the AI Office operates in accordance with the rules and principles laid down in this Regulation;*
- (b) Adopt, on the basis of the draft submitted by the Office's executive director and after the Commission has delivered an opinion, the single programming document of the AI Office containing, *inter alia*, the AI Office's multiannual programming and its work programme for the following year. The single programming document shall be transmitted to the European Parliament, the Council and the Commission;*
- (c) Appoint the executive director and, where relevant, extend his or her term of office or remove him or her from office;*
- (d) Produce, on the basis of a draft drawn up by the executive director, the estimate budget of the AI Office for the following financial year. This estimate, which shall initially include a draft establishment plan by the date of entry into force of this Regulation, shall be transmitted by the management board to the Commission within the first quarter of each year;*
- (e) Adopt the AI Office's annual draft and final budgets;*
- (f) Assess and adopt the consolidated annual report on the AI Office activities, including an evaluation based on performance indicators; submit both the annual report and the assessment thereof to the European Parliament, to the Council, to the Commission and to the*

Court of Auditors, and make the annual report public;

(g) Adopt the AI Office's rules of procedure on the basis of the draft submitted by the executive director after the Commission has delivered an opinion;

(h) Take decisions, based on the executive director's recommendation, concerning the establishment of the AI Office's internal structures and, where necessary, the modification of those internal structures, taking into consideration technological developments that may create additional operational needs and having regard to sound budgetary management;

Or. en

Amendment 2473

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation

Article 57 c (new)

Text proposed by the Commission

Amendment

Article 57 c

Meetings of the management board

1. The meetings of the management board shall be convened by the Chair. The Chair shall prepare the agenda of the meetings in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure.

2. The meetings of the management board shall be considered to be quorate where at least two-thirds of its members are present.

3. The management board shall hold at least two ordinary meetings a year. It shall also hold extraordinary meetings at the request of the Chair, at the request of the Commission, or at the request of at

least one third of its members.

4. The executive director shall take part in the meetings of the management board but shall not have the right to vote.

5. Members of the advisory forum may take part in the meetings of the management board at the invitation of the Chair, but shall not have the right to vote.

6. The members of the management board and their alternates may be assisted at the meetings of the management board by advisers or experts, subject to the rules of procedure of the management board.

7. The AI Office shall provide the secretariat of the management board and support the management Board in its operations.

Or. en

Amendment 2474

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation

Article 57 c (new)

Text proposed by the Commission

Amendment

Article 57 c

Chair of the management board

1. The management board shall elect a Chair and a deputy Chair from among its voting members by simple majority. The term of office of the Chair and of the deputy Chair shall be three years. The terms of the Chair and of the deputy Chair may be renewed once. The Deputy Chair shall replace the Chair ex officio if the Chair is unable to attend to his or her duties.

Or. en

Amendment 2475

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tefnută, Ramona Strugariu, Drago Pîslaru, Lucia Ūriš Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation

Article 57 d (new)

Text proposed by the Commission

Amendment

Article 57 d

Voting rules of the management board

- 1. The management board shall take its decisions by a majority of its members, unless otherwise provided for in this Regulation.*
- 2. A majority of two-thirds of the members of the management board shall be required for the adoption of the single programming document and of the annual budget and for the appointment, extension of the term of office or removal of the executive director.*
- 3. Each member shall have one vote. In the absence of a member, their alternate shall be entitled to exercise the member's right to vote.*
- 4. The Chair of the management board shall take part in the voting.*
- 5. The executive director shall not take part in the voting.*
- 6. The management board's rules of procedure shall establish more detailed voting arrangements, in particular the circumstances in which a member may act on behalf of another member.*

Or. en

Amendment 2476

Jorge Buxadé Villalba

Proposal for a regulation

Article 58

Text proposed by the Commission

Amendment

Article 58

suprimido

Funciones del Comité

Cuando preste asesoramiento y asistencia a la Comisión en el contexto del artículo 56, apartado 2, el Comité, en particular:

- a) recopilará y compartirá conocimientos técnicos y buenas prácticas entre los Estados miembros;*
- b) contribuirá a uniformizar las prácticas administrativas en los Estados miembros, incluidas las relativas al funcionamiento de los espacios controlados de pruebas a que se refiere el artículo 53;*
- c) emitirá dictámenes, recomendaciones o contribuciones por escrito sobre cuestiones relacionadas con la aplicación del presente Reglamento, en particular:*
 - i) sobre especificaciones técnicas o normas existentes relativas a los requisitos establecidos en el título III, capítulo 2;*
 - ii) sobre el uso de normas armonizadas o especificaciones comunes a que se refieren los artículos 40 y 41;*
 - iii) sobre la preparación de documentos de orientación, incluidas las directrices relativas a la fijación de multas administrativas a que se refiere el artículo 71.*

Or. es

Amendment 2477

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Alin Mitu

Proposal for a regulation

Article 58 – title

Text proposed by the Commission

Amendment

Tasks of the Board

Tasks

Amendment 2478

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

Proposal for a regulation

Article 58 – paragraph -1 (new)

Text proposed by the Commission

Amendment

-1 The Board shall ensure the consistent application of this Regulation and shall have the competent supervisory authority to enforce this Regulation where one of the following criteria is met:

- (a) The aggregate worldwide turnover of an undertaking or the undertaking to which another undertaking belongs is more than EUR 2 500 million;**
- (b) in each of at least three Member States, the aggregate turnover of an undertaking or the undertaking to which another undertaking belongs is more than EUR 100 million;**
- (c) in each of at least three Member States included for the purpose of point (b), the aggregate turnover of an undertaking or the undertaking to which another undertaking belongs is more than EUR 25 million; and**
- (d) the aggregate Union-wide turnover of an undertaking or the undertaking to which another undertaking belongs is more than EUR 100 million, unless each of the undertakings concerned achieves more than two-thirds of its aggregate Community-wide turnover within one and the same Member State.**

Justification

For effective enforcement, large undertakings with an impact in multiple Member States, with clear Union dimension should be subject to one supervisory authority with all issues related

to application of this regulation. Definition based on 'community dimension' defined in Article 1(3) of Regulation 139/200 (Merger Regulation).

Amendment 2479

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

Proposal for a regulation

Article 58 – paragraph -1 a (new)

Text proposed by the Commission

Amendment

-1 a In order to ensure consistent application of this Regulation, the Board shall, on its own initiative or, where relevant, at the request of the Commission, in particular:

- (a) monitor and ensure the correct application of Title III of this Regulation without prejudice to the tasks of national supervisory authorities;*
- (b) advise the Commission on any issue related to the development and use of artificial intelligence in the Union, including on any proposed amendment of this Regulation;*
- (c) issue guidelines, recommendations, and best practices on procedures, information and documentation as referred to in Titles III and VIII;*
- (d) examine, on its own initiative, on request of one of its members or on request of the Commission, any question covering the application of this Regulation and issue guidelines, recommendations and best practices in order to encourage consistent application of this Regulation;*
- (e) draw up guidelines for supervisory authorities concerning the application of this Regulation;*
- (f) draw up guidelines for supervisory authorities concerning the setting of administrative fines pursuant to Article 72;*

- (g) *review the practical application of the guidelines, recommendations and best practices referred to in points (e) and (f);*
- (h) *encourage the drawing-up of codes of conduct pursuant to Article 69;*
- (i) *issue opinions on codes of conduct drawn up at Union level pursuant to Article 69(3a);*
- (j) *issue decisions pursuant to Articles 66 and 67;*
- (k) *promote the cooperation and the effective bilateral and multilateral exchange of information and best practices between the supervisory authorities;*
- (l) *promote common training programmes and facilitate personnel exchanges between the supervisory authorities and, where appropriate, with the supervisory authorities of third countries or with international organisations;*
- (m) *promote the exchange of knowledge and documentation on relevant legislation and practice with supervisory authorities whose scope includes artificial intelligence worldwide;*
- (n) *maintain a publicly accessible electronic register of decisions taken by supervisory authorities and courts on issues handled pursuant to Chapter 3 of Title VIII.*

Or. en

Amendment 2480

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

Proposal for a regulation

Article 58 – paragraph -1 b (new)

Text proposed by the Commission

Amendment

-1 b Where the Commission requests advice from the Board, it may indicate a time limit, taking into account the urgency of the matter.

Or. en

Amendment 2481

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

Proposal for a regulation

Article 58 – paragraph -1 c (new)

Text proposed by the Commission

Amendment

-1 c The Board shall forward its opinions, guidelines, recommendations, and best practices to the Commission and to the committee referred to in Article 73 and make them public.

Or. en

Amendment 2482

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

Proposal for a regulation

Article 58 – paragraph -1 d (new)

Text proposed by the Commission

Amendment

-1 d The Board shall, where appropriate, consult interested parties and give them the opportunity to comment within a reasonable period. The Board shall make the results of the consultation procedure publicly available.

Or. en

Amendment 2483

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

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 58 – paragraph -1 e (new)

Text proposed by the Commission

Amendment

-1 e When providing advice and assistance to the Commission in the context of Article 56(2), the Board shall in particular:

- (a) collect and share expertise and best practices among Member States;***
- (b) contribute to uniform administrative practices in the Member States, including for the functioning of regulatory sandboxes referred to in Article 53;***
- (c) issue opinions, recommendations or written contributions on matters related to the implementation of this Regulation, in particular on***
 - (i) technical specifications or existing standards regarding the requirements set out in Title III, Chapter 2,***
 - (ii) the use of harmonised standards or common specifications referred to in Articles 40 and 41,***
 - (iii) the preparation of guidance documents, including the guidelines concerning the setting of administrative fines referred to in Article 71,***
 - (iii a) amendments to the Annexes I and III.***

Or. en

Amendment 2484

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Ondej Kováčik, Jan-Christoph Oetjen

Proposal for a regulation

Article 58 – paragraph 1 – introductory part

Text proposed by the Commission

When providing advice and assistance to the Commission in the context of Article 56(2), the Board shall in particular:

Amendment

When providing advice and assistance to the Commission ***and to the national supervisory authorities*** in the context of Article 56(2), the Board shall in particular:

Or. en

Amendment 2485

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

Proposal for a regulation

Article 58 – paragraph 1 – introductory part

Text proposed by the Commission

When providing advice and assistance to the Commission in the context of Article 56(2), the Board shall in particular:

Amendment

When providing advice and assistance to the Commission ***and the national supervisory authorities*** in the context of Article 56(2), the Board shall in particular:

Or. en

Amendment 2486

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia uriš Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation

Article 58 – paragraph 1 – introductory part

Text proposed by the Commission

When providing advice and assistance to the Commission in the context of Article 56(2), the Board shall in particular:

Amendment

In fulfilling its objectives, the AI Office shall in particular:

Or. en

Amendment 2487

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

Proposal for a regulation
Article 58 – paragraph 1 – introductory part

Text proposed by the Commission

When providing advice and assistance to the Commission in the context of Article 56(2), the Board shall in particular:

Amendment

I. When providing advice and assistance to the Commission in the context of Article 56(2), the Board shall in particular:

Or. en

Amendment 2488

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 58 – paragraph 1 – introductory part

Text proposed by the Commission

When *providing advice and assistance to the Commission in the context of Article 56(2)*, the Board shall in particular:

Amendment

When *ensuring the consistent application of this Regulation*, the Board shall in particular:

Or. en

Amendment 2489

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

Proposal for a regulation
Article 58 – paragraph 1 – point -a (new)

Text proposed by the Commission

Amendment

(-a) issue opinions, recommendations or written contributions with a view to ensuring the consistent implementation of this Regulation;

Or. en

Amendment 2490

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

Proposal for a regulation
Article 58 – paragraph 1 – point -a a (new)

Text proposed by the Commission

Amendment

(-a a) examine, on its own initiative or on request of one of its members, any question covering the application of this Regulation and issue guidelines, recommendations and best practices with a view to ensuring the consistent implementation of this Regulation;

Or. en

Amendment 2491
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 58 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) collect and share expertise and best practices among Member States;

(a) collect and share expertise and best practices among Member States, *including on the promotion of awareness raising initiatives on Artificial Intelligence and the Regulation;*

Or. en

Amendment 2492
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation
Article 58 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) collect and share expertise and best practices *among Member States*;

(a) collect and share expertise and best practices *in implementation of this Regulation*;

Or. en

Amendment 2493

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Mituță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță, Michal Šimečka

Proposal for a regulation**Article 58 – paragraph 1 – point a a (new)**

Text proposed by the Commission

Amendment

(a a) issue opinions, recommendations or written contributions on matters related to the implementation of this Regulation;

Or. en

Amendment 2494

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Mituță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță, Michal Šimečka

Proposal for a regulation**Article 58 – paragraph 1 – point a b (new)**

Text proposed by the Commission

Amendment

(a b) examine, on its own initiative or on request of its management board, any question covering the application of this Regulation and issue guidelines, recommendations and best practices with a view to ensuring the consistent implementation of this Regulation;

Or. en

Amendment 2495

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Mituță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation**Article 58 – paragraph 1 – point a c (new)**

Text proposed by the Commission

Amendment

(a c) provide the Commission, in the cases referred to in Article 68a (1)(a) and(1)(b), with all the available information at its disposal, including market studies, impact assessments, and analyses referred to in paragraph (f) of this article, to prepare the decision for triggering the Commission's intervention and opening of proceedings pursuant to Article 68a;

Or. en

Amendment 2496

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța, Michal Šimečka

Proposal for a regulation

Article 58 – paragraph 1 – point a d (new)

Text proposed by the Commission

Amendment

(a d) assist Member States in developing the organizational and technical expertise required for the implementation of this Regulation;

Or. en

Amendment 2497

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation

Article 58 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) contribute to uniform *administrative* practices in the Member States, including *for the* functioning of regulatory sandboxes referred to in Article

(b) contribute to uniform practices in the Member States, including *by assisting Member States, the Commission, and, where applicable, other authorities in the*

53;

establishment, development, and functioning of regulatory sandboxes referred to in Article 53, including by providing input and support in drafting the delegated acts referred to in Article 53(6);

Or. en

Amendment 2498

Svenja Hahn, Drago Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 58 – paragraph 1 – point b

Text proposed by the Commission

(b) contribute to uniform administrative practices in the Member States, including for the functioning of regulatory sandboxes referred to in Article 53;

Amendment

(b) contribute to uniform administrative practices in the Member States, including for the *assessment, establishing, managing with the meaning of fostering cooperation and guaranteeing consistency among regulatory sandboxes, and* functioning of regulatory sandboxes referred to in Article 53, *Article 54 and Annex IXa*;

Or. en

Amendment 2499

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point b

Text proposed by the Commission

(b) contribute to uniform administrative practices in the Member States, including for the functioning of regulatory sandboxes referred to in Article 53;

Amendment

(b) contribute to uniform administrative practices in the Member States, including for the *assessment, establishing, managing with the meaning of fostering cooperation and guaranteeing consistency among regulatory sandboxes, and* functioning of regulatory sandboxes referred to in Article 53;

Or. en

Amendment 2500

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

Proposal for a regulation

Article 58 – paragraph 1 – point b

Text proposed by the Commission

(b) contribute to uniform administrative practices ***in the Member States***, including for the functioning of regulatory sandboxes referred to in Article 53;

Amendment

(b) contribute to uniform administrative practices, including for the functioning of ***the*** regulatory sandboxes, ***as*** referred to in Article 53;

Or. en

Amendment 2501

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia urîș Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation

Article 58 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(b a) Support innovation by coordinating the exchange of information and good practices and by facilitating the cooperation among regulatory sandboxes established according to Article 53 and by making available on its website the information referred to in Article 53 (5).

Or. en

Amendment 2502

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia urîș Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation
Article 58 – paragraph 1 – point c – introductory part

Text proposed by the Commission

(c) issue opinions, recommendations or written contributions on matters related to the *implementation of this Regulation, in particular*

Amendment

(c) issue opinions, recommendations, written contributions, *or studies* on matters related to the *technical specifications or existing standards regarding the requirements set out in Title III, Chapter 2 and on the use of harmonised standards or common specifications referred to in Articles 40 and 41;*

Or. en

Amendment 2503

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

Proposal for a regulation

Article 58 – paragraph 1 – point c – introductory part

Text proposed by the Commission

(c) issue opinions, recommendations or written contributions on matters related to the implementation of this Regulation, in particular

Amendment

(c) issue opinions, recommendations or written contributions on matters related to the implementation of this Regulation, in *consultation with relevant stakeholders, in* particular

Or. en

Amendment 2504

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 58 – paragraph 1 – point c – introductory part

Text proposed by the Commission

(c) issue opinions, recommendations or written contributions on matters related to the implementation of this Regulation, in

Amendment

(c) issue opinions, recommendations or written contributions on matters related to the implementation of this Regulation,

particular

after consulting relevant stakeholders, in particular

Or. en

Amendment 2505

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia uríš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 58 – paragraph 1 – point c – point i

Text proposed by the Commission

Amendment

(i) on technical specifications or existing standards regarding the requirements set out in Title III, Chapter 2,

deleted

Or. en

Amendment 2506

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia uríš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 58 – paragraph 1 – point c – point ii

Text proposed by the Commission

Amendment

(ii) on the use of harmonised standards or common specifications referred to in Articles 40 and 41,

deleted

Or. en

Amendment 2507

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia uríš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 58 – paragraph 1 – point c – point iii

Text proposed by the Commission

Amendment

(iii) on the preparation of guidance documents, including the guidelines concerning the setting of administrative fines referred to in Article 71.

deleted

Or. en

Amendment 2508

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c – point iii a (new)

Text proposed by the Commission

Amendment

(iii a) on the need for the amendment of each of the Annexes as referred to in Article 73 as well as all other provisions in this Regulation that the Commission can amend, in light of the available evidence.

Or. en

Amendment 2509

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c – point iii b (new)

Text proposed by the Commission

Amendment

(iii b) on activities and decisions of Member States regarding post-market monitoring, information sharing, market surveillance referred to in Title VIII;

Or. en

Amendment 2510

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c – point iii c (new)

Text proposed by the Commission

Amendment

(iii c) on developing common criteria for market operators and competent authorities having the same understanding of concepts such as the 'generally acknowledged state of the art' referred to in Article 9 (3), 'foreseeable risks' referred to in Articles 9 (2) (a), 'foreseeable misuse' referred to in Article 3 (13), Article 9 (2) (b), Article 9 (4), Article 13 (3)(b)(iii) and Article 14 (2), and the 'type and degree of transparency' referred in Article 13 (1);

Or. en

Amendment 2511

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c – point iii d (new)

Text proposed by the Commission

Amendment

(iii d) verify alignment with the legal acts listed in Annex II, including with the implementation matters related to those acts.

Or. en

Amendment 2512

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) carry out annual reviews and

analyses of the complaints sent to and findings made by national supervisory authorities, of the serious incidents reports referred to in Article 62, and of the new registration in the EU Database referred to in Article 60 to identify trends and potential emerging issues threatening the future health and safety and fundamental rights of citizens that are not adequately addressed by this Regulation;

Or. en

Amendment 2513

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 58 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) carry out annual reviews and analyses of the complaints sent to and findings made by national competent authorities, of the serious incidents reports referred to in Article 62, and of the new registration in the EU Database referred to in Article 60 to identify trends and potential emerging issues threatening the future health and safety and fundamental rights of citizens that are not adequately addressed by this Regulation;

Or. en

Amendment 2514

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

Proposal for a regulation

Article 58 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) encourage, facilitate and support

the drawing up of codes of conduct intended to foster the voluntary application to AI systems of those codes of conduct in close cooperation with relevant stakeholders in accordance with Article 69;

Or. en

Amendment 2515

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 58 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) advise the Commission on the possible amendment of Article 5, to expand the prohibitions, based on national and cross-border cases that led to withdrawing or recalling AI systems from the market.

Or. en

Amendment 2516

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Mituță, Ramona Strugariu, Drago Pîslaru, Lucia Šuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță, Michal Šimečka

Proposal for a regulation

Article 58 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) support the Commission and the Member States in the preparation of guidance documents, including the guidelines concerning the setting of administrative fines referred to in Article 71;

Or. en

Amendment 2517

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 58 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) provide guidance in relation to governing general-purpose AI systems and their compliance with applicable requirements to meet the objectives of this Regulation.

Or. en

Amendment 2518

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

Proposal for a regulation

Article 58 – paragraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(c b) cooperate with the European Data Protection Board and with the FRA to receive guidance in relation to the respect of fundamental rights, in particular the right to non-discrimination and to equal treatment, the right to privacy, confidentiality of communications and the protection of personal data;

Or. en

Amendment 2519

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 58 – paragraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(c b) encourage, facilitate and support the drawing up of risk-commensurate codes of conduct intended to foster the voluntary application to AI systems of those codes of conduct in close cooperation with industry and other relevant stakeholders in accordance with Article 69;

Or. en

Amendment 2520

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 58 – paragraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(c b) provide guidance in relation to governing research and development activities for creating new or improving existing AI systems, and the alignment of these activities with the objectives of this Regulation.

Or. en

Amendment 2521

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 58 – paragraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(c b) coordinate among national competent authorities; issue guidelines, recommendations and best practices with a view to ensuring the consistent implementation of this Regulation;

Or. en

Amendment 2522

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(c b) carry out biannual horizon scanning and foresight exercises to extrapolate the impact the trends and emerging issues can have on the Union;

Or. en

Amendment 2523

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tefnută, Ramona Strugariu, Drago Pîslaru, Lucia Ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 58 – paragraph 1 – point c c (new)

Text proposed by the Commission

Amendment

(c c) carry out periodic in-depth horizon-scanning, foresight, and market monitoring exercises to analyse trends and emerging issues in respect of this Regulation, with a particular focus on emerging technologies and their interaction with artificial intelligence, European global competitiveness in artificial intelligence, the uptake of artificial intelligence technologies, the development of digital skills, and emerging systemic threats related to artificial intelligence, including those referred to in Article 68a (1)(a) and (1)(b);

Or. en

Amendment 2524

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 58 – paragraph 1 – point c c (new)

Text proposed by the Commission

Amendment

(c c) The Board shall provide statutory guidance in relation to children’s rights, applicable law and minimum standards for the evaluation of automated decision-making systems to meet the objectives of this Regulation pertaining to children and to investigate the design goals, data inputs, model selection, implementation and outcomes of such systems.

Or. en

Amendment 2525

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c c (new)

Text proposed by the Commission

Amendment

(c c) annually publish recommendations to the Commission, in particular on the categorization of prohibited practices, high-risk systems, and codes of conduct for AI systems that are not classified as high-risk;

Or. en

Amendment 2526

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 58 – paragraph 1 – point c c (new)

Text proposed by the Commission

Amendment

(c c) promote the cooperation and

effective bilateral and multilateral exchange of information and best practices between the national supervisory authorities;

Or. en

Amendment 2527

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

Proposal for a regulation

Article 58 – paragraph 1 – point c c (new)

Text proposed by the Commission

Amendment

(c c) promote public awareness and understanding of the benefits, risks, rules and safeguards and rights in relation to the use of AI systems;

Or. en

Amendment 2528

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Mituță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 58 – paragraph 1 – point c d (new)

Text proposed by the Commission

Amendment

(c d) cooperate with the European Data Protection Board and with the FRA to provide guidance in relation to the respect of fundamental rights, in particular the right to non-discrimination and to equal treatment, the right to privacy and the protection of personal data;

Or. en

Amendment 2529

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

Proposal for a regulation

Article 58 – paragraph 1 – point c d (new)

Text proposed by the Commission

Amendment

(c d) annually publish recommendations to the Commission, in particular on the categorization of prohibited practices, high-risk systems, and codes of conduct for AI systems that are not classified as high-risk;

Or. en

Amendment 2530

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

Proposal for a regulation

Article 58 – paragraph 1 – point c d (new)

Text proposed by the Commission

Amendment

(c d) promote the cooperation and effective bilateral and multilateral exchange of information and best practices between the national supervisory authorities;

Or. en

Amendment 2531

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c d (new)

Text proposed by the Commission

Amendment

(c d) encourage and facilitate the drawing up of codes of conduct as referred to in Article 69;

Amendment 2532

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

Proposal for a regulation

Article 58 – paragraph 1 – point c e (new)

Text proposed by the Commission

Amendment

(c e) promote common training programmes and facilitate personnel exchanges between the national supervisory authorities and, where appropriate, with the national supervisory authorities of third countries or with international organisations;

Amendment 2533

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

Proposal for a regulation

Article 58 – paragraph 1 – point c e (new)

Text proposed by the Commission

Amendment

(c e) carry out biannual horizon scanning and foresight exercises to extrapolate the impact the trends and emerging issues can have on the Union;

Amendment 2534

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Mituță, Ramona Strugariu, Drago Pîslaru, Lucia Ūriș Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță, Michal Šimečka

Proposal for a regulation

Article 58 – paragraph 1 – point c e (new)

Text proposed by the Commission

Amendment

(c e) promote public awareness and understanding of the benefits, risks, rules and safeguards and rights in relation to the use of AI systems;

Or. en

Amendment 2535

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c e (new)

Text proposed by the Commission

Amendment

(c e) coordinate among national supervisory authorities and make sure that the consistency mechanism in Article 59a(3) is observed;

Or. en

Amendment 2536

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c f (new)

Text proposed by the Commission

Amendment

(c f) adopt binding decisions for national supervisory authorities in case the consistency mechanism is not able to solve the conflict among national supervisory authorities as it is clarified in Article 59a(6);

Or. en

Amendment 2537

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

Proposal for a regulation
Article 58 – paragraph 1 – point c f (new)

Text proposed by the Commission

Amendment

(c f) advise the Commission on the possible amendment of the Annexes by means of delegated act in accordance with Article 73, in particular the annex listing high-risk AI systems;

Or. en

Amendment 2538

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Mituță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță, Michal Šimeka

Proposal for a regulation
Article 58 – paragraph 1 – point c f (new)

Text proposed by the Commission

Amendment

(c f) promote the cooperation and effective bilateral and multilateral exchange of information and best practices between the national supervisory authorities;

Or. en

Amendment 2539

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto, Catharina Rinzema, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation
Article 58 – paragraph 1 – point c f (new)

Text proposed by the Commission

Amendment

(c f) promote public awareness and understanding of the benefits, rules and safeguards and rights in relation to the use of AI systems.

Or. en

Amendment 2540

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Mituță, Ramona Strugariu, Drago Pîslaru, Lucia Šuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 58 – paragraph 1 – point c g (new)

Text proposed by the Commission

Amendment

(c g) facilitate cooperation between the supervisory authorities of Member States and other supervisory authorities that might be responsible for the enforcement of this Regulation;

Or. en

Amendment 2541

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c g (new)

Text proposed by the Commission

Amendment

(c g) issue yearly reports on the implementation of the Regulation, including an assessment of the impact of the Regulation on economic operators.

Or. en

Amendment 2542

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

Proposal for a regulation

Article 58 – paragraph 1 – point c g (new)

Text proposed by the Commission

Amendment

(c g) ensure that the national supervisory authorities actively cooperate in the implementation of this Regulation;

Or. en

Amendment 2543

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța, Michal Šimečka

Proposal for a regulation

Article 58 – paragraph 1 – point c h (new)

Text proposed by the Commission

Amendment

(c h) support capacity and expertise building in supervisory authorities that are responsible for the enforcement of this Regulation;

Or. en

Amendment 2544

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța, Michal Šimečka

Proposal for a regulation

Article 58 – paragraph 1 – point c i (new)

Text proposed by the Commission

Amendment

(c i) advise the Commission on the possible amendment of the Annexes by means of delegated acts in accordance with Article 73, in particular the annex listing high-risk AI systems;

Or. en

Amendment 2545

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin

Mituța, Michal Šimečka

Proposal for a regulation

Article 58 – paragraph 1 – point c j (new)

Text proposed by the Commission

Amendment

(c j) ensure that the national supervisory authorities actively cooperate in the implementation of this Regulation;

Or. en

Amendment 2546

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia uríš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation

Article 58 – paragraph 1 – point c k (new)

Text proposed by the Commission

Amendment

(c k) adopt binding decisions for national competent authorities in cases of serious disagreements pursuant to article 59a (5);

Or. en

Amendment 2547

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia uríš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation

Article 58 – paragraph 1 – point c l (new)

Text proposed by the Commission

Amendment

(c l) promote the development of a common European approach to benchmarking by cooperating with national metrology and benchmarking authorities and by issuing opinions, recommendations, written contributions,

or studies with a view to ensure consistent and harmonised European benchmarking standards;

Or. en

Amendment 2548

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Mituță, Ramona Strugariu, Drago Pîslaru, Lucia uriuš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță, Michal Šimečka

Proposal for a regulation

Article 58 – paragraph 1 – point c m (new)

Text proposed by the Commission

Amendment

(c m) provide guidance in relation to children's rights, applicable law and minimum standards to meet the objectives of this Regulation that pertain to children;

Or. en

Amendment 2549

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Mituță, Ramona Strugariu, Drago Pîslaru, Lucia uriuš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 58 – paragraph 1 – point c n (new)

Text proposed by the Commission

Amendment

(c n) promote and support the accessible development and use of artificial intelligence systems, in accordance with the provisions of Directive (EU) 2019/882;

Or. en

Amendment 2550

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

Proposal for a regulation
Article 58 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

When acting in the context of Article 59c on cases involving two or more Member States, the Board shall adopt binding decisions for national supervisory authorities.

Or. en

Amendment 2551

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

Proposal for a regulation
Article 58 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

The Board shall organise consultations with stakeholders twice a year. Such stakeholders shall include representatives from industry, start-ups and SMEs, organisations from the civil society organisations such as NGOs, consumer associations, the social partners and academia, to assess the evolution of trends in technology, issues related to the implementation and the effectiveness of this Regulation, regulatory gaps or loopholes observed in practice.

Or. en

Amendment 2552

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation
Article 58 a (new)

Article 58 a

SECTION 3: the Executive Director

Functions and powers of the executive director

1. The AI Office shall be managed by its executive director, who shall be completely independent in the performance of his or her duties. Without prejudice to the respective competencies of the Union institutions and the management board, the executive director shall neither seek nor take instructions from any government or from any other body.

2. The executive director may be called upon at any time by the European Parliament or by the Council to attend a hearing on any matter linked to the AI Office's activities or to report on the carrying out of his or her tasks. This includes reporting on the activities of the AI Office, the implementation of its annual programming, the annual activity report for the previous year, and any other matter related to the activities of the AO Office. The executive director shall also make a statement before the European Parliament, if requested, and shall answer in writing any question put forward by a Member of the European Parliament within 15 calendar days from receipt of such question. The executive director shall report regularly to the appropriate bodies and committees of the European Parliament.

3. Except where specific deadlines are provided for in this Regulation, the executive director shall ensure that reports are transmitted to the European Parliament, to the Council and to the Commission as soon as possible, and in any event within six months of the end of the reporting period, unless the executive director duly justifies a delay in writing.

4. The executive director shall be

responsible for the preparation and implementation of the strategic decisions taken by the management board and for the taking of decisions related to the operational activities of the AI Office in accordance with this Regulation. The executive director shall have the following functions and powers:

- (a) to propose, prepare and implement the strategic decisions and programmes and activities adopted by the management board within the limits set out in this Regulation, its implementing rules and any applicable law;*
- (b) to take all necessary steps, including the adoption of internal administrative instructions and the publication of notices, to ensure the day-to-day administration and functioning of the AI Office in accordance with this Regulation;*
- (c) to prepare each year the draft single programming document pursuant to Article 57a (b) and to submit it to the management board for endorsement before that draft is sent to the European Parliament, to the Council and to the Commission;*
- (d) to draw up a draft statement of estimates of the revenues and expenditure of the AI Office as part of the single programming document pursuant to Article 57a (d) and to implement the budget of the AI Office;*
- (e) to prepare each year the annual activity report on the Agency's activities and submit it to the management board;*
- (f) to coordinate all staff matters and all matters of day-to-day administration of the AI Office;*
- (g) to prepare appropriate draft implementing rules to give effect to the Staff Regulations and the Conditions of Employment of Other Servants in accordance with Article 110 of the Staff Regulations;*

- (h) to protect the values and interests of the Union by drawing up, submitting to the management board for approval, and implementing effective internal anti-fraud, anti-corruption, data protection and equal opportunity strategies, procedures, and safeguards;*
 - (i) to establish and implement effective monitoring and evaluation procedures relating to the performance of the AI Office against its objectives and to report annually to the management board on the results of the monitoring;*
 - (j) to consult the advisory forum and to facilitate its operations;*
 - (k) to develop and maintain contact with industry, standardization bodies, academia, and civil society, including organizations protecting fundamental and digital rights, consumers, workers, children, persons with disabilities, and other vulnerable categories, to ensure regular dialogue with relevant stakeholders;*
 - (l) to cooperate and to exchange views and information regularly with Union institutions, bodies, offices and agencies regarding artificial intelligence and related domains such as data, digital infrastructure, platform and internet governance, and cybersecurity, to ensure coherence in the development and the implementation of Union policy;*
 - (m) to represent the AI Office in international fora for cooperation on Artificial Intelligence;*
 - (n) To support the Chair of the management board in preparing and planning the management board meetings;*
 - (o) to perform other tasks pursuant to this Regulation.*
- 5. The executive director shall be accountable for his or her activities to the management board. 6. The executive director shall be the legal representative**

of the AI Office.

Or. en

Amendment 2553

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 a (new)

Text proposed by the Commission

Amendment

Article 58 a

Guidelines from the Commission on the implementation of this Regulation

Upon the request of the Member States or the Board, or on its own initiative, the Commission shall issue guidelines on the practical implementation of this Regulation and in particular on:

- (i) the application of the requirements referred to in Articles 8 - 15;*
- (ii) the prohibited practices referred to in Article 5;*
- (iii) the practical implementation of the provisions related to substantial modification;*
- (iv) the identification and application of criteria and use cases related to high risk AI systems referred to in Annex III;*
- (v) the practical implementation of transparency obligations laid down in Article 52;*
- (vi) the relationship of this Regulation with other relevant Union legislation.*

When issuing such guidelines, the Commission shall pay particular attention to the needs of SMEs and start-ups as well as sectors most likely to be affected by this Regulation.

Or. en

Amendment 2554

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

Proposal for a regulation

Article 58 a (new)

Text proposed by the Commission

Amendment

Article 58 a

Independence of the Board

- 1. The Board shall act with complete independence in performing its tasks and exercising its powers in accordance with this Regulation.***
- 2. The members of the Board shall, in the performance of their tasks and exercise of their powers in accordance with this Regulation, remain free from external influence, whether direct or indirect, and shall neither seek nor take instructions from anybody.***
- 3. The members of the Board shall refrain from any action incompatible with their duties and shall not, during their term of office, engage in any incompatible occupation, whether gainful or not.***

Or. en

Amendment 2555

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia uriaș Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation

Article 58 b (new)

Text proposed by the Commission

Amendment

Article 58 b

SECTION 4: the Advisory Forum

The advisory forum

- 1. An advisory forum shall be established by the AI Office to advise it in the fulfilment of its tasks by providing***

stakeholder input in matters pertaining to this Regulation, in particular on:

- (a) technological developments and trends related to artificial intelligence;*
- (b) potential updates of this Regulation, including prohibited practices, high-risk AI systems, AI systems requiring additional transparency obligations, and novel techniques used for the development of artificial intelligence;*
- (c) best practices to optimise compliance and to reduce compliance costs and regulatory burden;*
- (d) measures in support of innovation, start-ups, and SMEs, including improving participation in regulatory sandboxes;*
- (e) the development, promotion, and uptake of harmonised standards, harmonised benchmarking standards, and common specifications;*
- (f) emerging threats to health, safety, fundamental rights, or the values of the Union as enshrined in Article 2 TEU related to artificial intelligence;*

2. The advisory forum shall have a balanced composition and represent the views of different stakeholders, with a third of its members representing industry, a third of its members representing start-ups, SMEs, and the innovation environment, and a third of its members representing civil society and academia.

3. Stakeholders established outside the Union shall only participate in the advisory forum if they are established in third countries that are subject to a decision of the Commission adopted in accordance with Article 36 of Directive (EU) 2016/680 or Article 45 of Regulation 2016/679 ('adequacy decision') or that are part of an international agreement concluded between the Union and that third country or international organisation pursuant to Article 218 TFEU adducing adequate safeguards

with respect to the protection of privacy and fundamental rights and freedoms of individuals.

4. Members of the advisory forum shall be appointed by the management board, based on a recommendation from the executive director, following a transparent call for applications and selection procedure.

5. When drawing up the call for applications and the selection procedure, the executive director shall ensure that:

(a) the composition criteria set out in paragraph 2 are met;

(b) the representation of industry, start-up, SMEs and the innovation environment is varied and includes stakeholders of different sizes and representing different industries;

(c) the representation of civil society is varied and includes, at a minimum, organizations for the protection of democracy, fundamental rights, consumer rights, the rights of persons with disabilities, and children's rights;

(d) the advisory forum is balanced in terms of geographical distribution and gender.

6. The term of office of the members of the advisory forum shall be two years. To ensure diversity and balanced representation, the term of office for members of the advisory forum shall not be renewable consecutively.

7. The advisory forum shall draw up its rules of procedure and elect three co-Chairs from among its members according to the presentation criteria set out in paragraph 2. Their term of office shall be two years, non-renewable.

8. The advisory forum shall hold regular meetings at least four times a year. The advisory forum can invite experts and other stakeholders to its meetings. The executive director can attend, ex officio,

the meetings of the advisory forum.

9. In fulfilling its role as set out in paragraph 1, the advisory forum can prepare opinions, recommendations or written contributions and forward these to the attention of the executive director.

10. The advisory forum shall prepare an annual report of its activities. That report shall be made publicly available, including on the AI Office website.

11. The AI Office shall provide secretarial assistance to the advisory forum to ensure its proper functioning.

Or. en

Amendment 2556

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

Proposal for a regulation

Title VI – Chapter 2 – title

Text proposed by the Commission

2 national competent authorities

Amendment

2 National competent authorities *and national supervisory authorities*

Or. en

Amendment 2557

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Title VI – Chapter 2 – title

Text proposed by the Commission

2 national *competent* authorities

Amendment

2 national *supervisory* authorities

Or. en

Amendment 2558

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 59 – title

Text proposed by the Commission

Designation of national **competent** authorities

Amendment

Designation of national **supervisory** authorities

Or. en

Amendment 2559

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 59 – paragraph 1

Text proposed by the Commission

1. **National competent authorities shall be established or designated by each Member State for the purpose of ensuring the application and implementation of this Regulation.** National **competent authorities** shall be organised so as to safeguard the objectivity and impartiality of **their** activities and tasks.

Amendment

1. Each Member State **shall establish or designate one** national **supervisory authority, which** shall be organised so as to safeguard the objectivity and impartiality of **its** activities and tasks.

Or. en

Amendment 2560

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

Proposal for a regulation

Article 59 – paragraph 1

Text proposed by the Commission

1. National competent authorities shall be established or designated by each Member State for the purpose of ensuring the application **and** implementation of this Regulation. National competent authorities shall be organised so as to safeguard the

Amendment

1. National competent authorities shall be established or designated by each Member State for the purpose of ensuring the application, implementation **and enforcement** of this Regulation. National competent authorities shall be organised so

objectivity and impartiality of their activities and tasks.

as to safeguard the objectivity and impartiality of their activities and tasks.

Or. en

Amendment 2561

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

Proposal for a regulation

Article 59 – paragraph 2

Text proposed by the Commission

Amendment

2. Each Member State shall designate a national supervisory authority among the national competent authorities. The national supervisory authority shall act as notifying authority and market surveillance authority unless a Member State has organisational and administrative reasons to designate more than one authority.

deleted

Or. en

Justification

Moved to a separate article on national supervisory authorities

Amendment 2562

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 59 – paragraph 2

Text proposed by the Commission

Amendment

2. Each Member State shall designate a national supervisory authority among the national competent authorities. The national supervisory authority shall act as notifying authority and market surveillance authority unless a Member State has organisational and administrative reasons to designate more

2. The national supervisory authority shall be in charge to ensure the application and implementation of this Regulation. With regard to high-risk AI systems, related to products to which legal acts listed in Annex II apply, the competent authorities designated under those legal acts shall continue to lead the

than one authority.

administrative procedures. However, to the extent a case involves aspects covered by this Regulation, the competent authorities shall be bound by measures issued by the national supervisory authority designated under this Regulation. The national supervisory authority shall *also* act as notifying authority and market surveillance authority.

Or. en

Amendment 2563

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 59 – paragraph 2

Text proposed by the Commission

2. Each Member State shall designate a national supervisory authority among the national competent authorities. The national supervisory authority shall act as notifying authority and market surveillance authority *unless a Member State has organisational and administrative reasons to designate more than one authority.*

Amendment

2. Each Member State shall designate a national supervisory authority among the national competent authorities. The national supervisory authority shall act as notifying authority and market surveillance authority.

Or. en

Amendment 2564

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

Proposal for a regulation

Article 59 – paragraph 2

Text proposed by the Commission

2. Each Member State shall designate *a* national supervisory authority among the national competent authorities. The national supervisory authority shall act as notifying authority and market surveillance

Amendment

2. Each Member State shall designate *the national data protection authority as the* national supervisory authority among the national competent authorities. The national supervisory

authority unless a Member State has organisational and administrative reasons to designate more than one authority.

authority shall act as notifying authority and market surveillance authority unless a Member State has organisational and administrative reasons to designate more than one authority.

Or. en

Amendment 2565

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte

Proposal for a regulation

Article 59 – paragraph 2

Text proposed by the Commission

2. Chaque État membre désigne une **autorité** de contrôle **nationale** parmi les autorités nationales compétentes. **L'autorité** de contrôle **nationale agit** en tant **qu'autorité notifiante et autorité** de surveillance du marché, **sauf si un État membre a des raisons organisationnelles et administratives de désigner plus d'une autorité.**

Amendment

2. Chaque État membre désigne une **ou plusieurs autorités** de contrôle **nationales** parmi les autorités nationales compétentes. **La ou les autorités** de contrôle **nationales agissent** en tant **qu'autorités notifiantes et autorités** de surveillance du marché.

Or. fr

Amendment 2566

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 59 – paragraph 3

Text proposed by the Commission

3. Member States shall inform the Commission of their **designation or** designations **and, where applicable, the reasons for designating more than one authority.**

Amendment

3. **The national supervisory authority in each Member State shall be the lead authority, ensure adequate coordination and act as single point of contact for this Regulation.** Member States shall inform the Commission of their designations.

Or. en

Amendment 2567

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

Proposal for a regulation**Article 59 – paragraph 3***Text proposed by the Commission*

3. Les États membres font connaître à la Commission le ou les noms de la ou des autorités désignées *et, le cas échéant, les raisons pour lesquelles ils ont désigné plusieurs autorités.*

Amendment

3. Les États membres font connaître à la Commission le ou les noms de la ou des autorités désignées.

Or. fr

Amendment 2568

Fernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation**Article 59 – paragraph 3***Text proposed by the Commission*

3. Member States shall inform the Commission of their designation or designations and, where applicable, the reasons for designating more than one authority.

Amendment

3. Member States shall inform ***the Board and*** the Commission of their designation or designations and, where applicable, the reasons for designating more than one authority.

Or. en

Amendment 2569

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

Proposal for a regulation**Article 59 – paragraph 4***Text proposed by the Commission*

4. Member States shall ensure that national competent authorities are provided with adequate financial and human resources to fulfil their tasks under this

Amendment

4. Member States shall ensure that ***the*** national competent authorities are provided with adequate ***technical,*** financial and human resources, ***premises and***

Regulation. In particular, national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements.

infrastructure necessary to fulfil their tasks under this Regulation. In particular, national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, **personal data protection**, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. **Member States shall assess and update competence and resource requirements referred to in this paragraph on an annual basis.**

Or. en

Amendment 2570

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 59 – paragraph 4

Text proposed by the Commission

4. Member States shall ensure that national **competent authorities are** provided with adequate financial and human resources to fulfil **their** tasks under this Regulation. In particular, national **competent** authorities shall have a sufficient number of **personnel** permanently available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, fundamental rights, health and safety risks **and** knowledge of existing standards and legal requirements.

Amendment

4. Member States shall ensure that national **supervisory authority is** provided with adequate financial and human resources to fulfil **its** tasks under this Regulation. In particular, national **supervisory** authorities shall have a sufficient number of permanently available **personnel**, whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data, **data protection** and data computing, **cybersecurity, competition law**, fundamental rights, health and safety risks **as well as** knowledge of existing standards and legal requirements.

Or. en

Amendment 2571

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

on behalf of the Verts/ALE Group

**Proposal for a regulation
Article 59 – paragraph 4**

Text proposed by the Commission

4. Member States shall ensure that national competent authorities are provided with adequate financial and human resources to fulfil their tasks under this Regulation. In particular, national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements.

Amendment

4. Member States shall ensure that national competent authorities are provided with adequate financial and human **and technical** resources to fulfil their tasks **effectively** under this Regulation. In particular, national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, fundamental rights, **competition law**, health and safety risks and knowledge of existing standards and **other** legal requirements.

Or. en

Amendment 2572

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

**Proposal for a regulation
Article 59 – paragraph 4**

Text proposed by the Commission

4. Member States shall ensure that national competent authorities are provided with adequate financial and human resources to fulfil their tasks under this Regulation. In particular, national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements.

Amendment

4. Member States shall ensure that national competent authorities are provided with adequate financial, **technical** and human resources to fulfil their tasks under this Regulation. In particular, national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements.

Or. en

Amendment 2573

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 59 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. National supervisory authorities 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 2574

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Vincenzo Sofo, Adam Bielan

Proposal for a regulation

Article 59 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. National competent authorities 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 2575

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Vincenzo Sofo, Adam Bielan

**Proposal for a regulation
Article 59 – paragraph 4 b (new)**

Text proposed by the Commission

Amendment

4 b. Any information and documentation obtained by the national competent authorities pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.

Or. en

**Amendment 2576
Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation
Article 59 – paragraph 4 b (new)**

Text proposed by the Commission

Amendment

4 b. Any information and documentation obtained by the national supervisory authorities pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.

Or. en

**Amendment 2577
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group**

**Proposal for a regulation
Article 59 – paragraph 5**

Text proposed by the Commission

Amendment

5. Member States shall report to the Commission on an annual basis on the status of the financial and human resources of the national competent authorities with *an* assessment of their adequacy. The

5. Member States shall report to the Commission on an annual basis on the status of the financial and human resources of the national competent authorities with *a qualified* assessment of their adequacy.

Commission shall transmit that information to the Board for discussion and possible recommendations.

The Commission shall transmit that information to the Board for discussion and possible recommendations *and formally accept or reject the assessments. Where an assessment is rejected, a new assessment shall be requested.*

Or. en

Amendment 2578
Jorge Buxadé Villalba

Proposal for a regulation
Article 59 – paragraph 5

Text proposed by the Commission

5. Los Estados miembros presentarán a la Comisión un informe anual acerca del estado de los recursos financieros y humanos de las autoridades nacionales competentes, que incluirá una evaluación de su idoneidad. *La Comisión transmitirá dicha información al Comité para su debate y la formulación de posibles recomendaciones.*

Amendment

5. Los Estados miembros presentarán a la Comisión un informe anual acerca del estado de los recursos financieros y humanos de las autoridades nacionales competentes, que incluirá una evaluación de su idoneidad.

Or. es

Amendment 2579
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Article 59 – paragraph 5

Text proposed by the Commission

5. Les États membres font annuellement rapport à la Commission sur l'état des ressources financières et humaines des autorités nationales compétentes, *et lui présentent une évaluation de l'adéquation de ces ressources.* La Commission transmet ces informations au Comité pour discussion et

Amendment

5. Les États membres font annuellement rapport à la Commission sur l'état des ressources financières et humaines des autorités nationales compétentes. La Commission transmet ces informations au Comité pour discussion et recommandations éventuelles.

recommandations éventuelles.

Or. fr

Amendment 2580

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 59 – paragraph 5

Text proposed by the Commission

5. Member States shall report to the Commission on an annual basis on the status of the financial and human resources of the national competent authorities with an assessment of their adequacy. The Commission shall transmit that information to the Board for discussion and possible recommendations.

Amendment

5. Member States shall report to **the Board and** the Commission on an annual basis on the status of the financial and human resources of the national competent authorities with an assessment of their adequacy. The Commission shall transmit that information to the Board for discussion and possible recommendations.

Or. en

Amendment 2581

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Alin Mituța

Proposal for a regulation

Article 59 – paragraph 5

Text proposed by the Commission

5. Member States shall report to the Commission on an annual basis on the status of the financial and human resources of the national competent authorities with an assessment of their adequacy. The Commission shall transmit that information to the **Board** for discussion and possible recommendations.

Amendment

5. Member States shall report to the Commission on an annual basis on the status of the financial and human resources of the national competent authorities with an assessment of their adequacy. The Commission shall transmit that information to the **AI Office** for discussion and possible recommendations.

Or. en

Amendment 2582

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 59 – paragraph 5**

Text proposed by the Commission

5. Member States shall report to the Commission on an annual basis on the status of the financial and human resources of the national ***competent authorities*** with an assessment of their adequacy. The Commission shall transmit that information to the Board for discussion and possible recommendations.

Amendment

5. Member States shall report to the Commission on an annual basis on the status of the financial and human resources of the national ***supervisory authority*** with an assessment of their adequacy. The Commission shall transmit that information to the Board for discussion and possible recommendations.

Or. en

Amendment 2583

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

**Proposal for a regulation
Article 59 – paragraph 6**

Text proposed by the Commission

6. The Commission shall facilitate the exchange of experience between national competent authorities.

Amendment

6. The Commission ***and the Board*** shall facilitate the exchange of experience between national competent authorities.

Or. en

Amendment 2584

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

**Proposal for a regulation
Article 59 – paragraph 6**

Text proposed by the Commission

6. The Commission shall facilitate the exchange of experience between national competent authorities.

Amendment

6. The Commission ***and the board*** shall facilitate the exchange of experience between national competent authorities.

Or. en

Amendment 2585

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 59 – paragraph 6

Text proposed by the Commission

6. The Commission shall facilitate the exchange of experience between national **competent** authorities.

Amendment

6. The Commission **and board** shall facilitate the exchange of experience between national **supervisory** authorities.

Or. en

Amendment 2586

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

Proposal for a regulation

Article 59 – paragraph 6

Text proposed by the Commission

6. The **Commission** shall facilitate the exchange of experience between national competent authorities.

Amendment

6. The **Board** shall facilitate the exchange of experience between national competent authorities.

Or. en

Amendment 2587

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 59 – paragraph 7

Text proposed by the Commission

7. National competent authorities may provide guidance and advice on the implementation of this Regulation, including to small-scale providers. Whenever national competent authorities intend to provide guidance and advice with

Amendment

7. National competent authorities may provide guidance and advice on the implementation of this Regulation, including to small-scale providers. Whenever national competent authorities intend to provide guidance and advice with

regard to an AI system in areas covered by other Union legislation, the competent national authorities under that Union legislation shall be consulted, as appropriate. Member States ***may*** also establish one central contact point for communication with operators.

regard to an AI system in areas covered by other Union legislation, the competent national authorities under that Union legislation shall be consulted, as appropriate. Member States ***shall*** also establish one central contact point for communication with operators. ***In addition, the central contact point of each Member State should be contactable through electronic communications means.***

Or. en

Amendment 2588

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

Proposal for a regulation Article 59 – paragraph 7

Text proposed by the Commission

7. National competent authorities may provide guidance and advice on the implementation of this Regulation, including to small-scale providers. Whenever national competent authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the competent national authorities under that Union legislation ***shall be consulted***, as appropriate. ***Member States may also establish one central contact point for communication with operators.***

Amendment

7. National competent authorities may provide guidance and advice on the implementation of this Regulation, including to small-scale providers. Whenever national competent authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the ***guidance shall be drafted in consultation with the*** competent national authorities under that Union legislation, as appropriate.

Or. en

Amendment 2589

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation Article 59 – paragraph 7

Text proposed by the Commission

7. National competent authorities may provide guidance and advice on the implementation of this Regulation, including to **small-scale providers**. Whenever national competent authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the competent national authorities under that Union legislation shall be consulted, as appropriate. Member States **may** also establish one central contact point for communication with operators.

Amendment

7. National competent authorities may provide guidance and advice on the implementation of this Regulation, including to **SMEs and start-ups**. Whenever national competent authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the competent national authorities under that Union legislation shall be consulted, as appropriate. Member States **shall** also establish one central contact point for communication with operators **and other stakeholders**.

Or. en

Amendment 2590

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

Proposal for a regulation

Article 59 – paragraph 7

Text proposed by the Commission

7. **National competent authorities** may provide guidance and advice on the implementation of this Regulation, including to small-scale providers. Whenever **national competent authorities intend** to provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the competent national authorities under that Union legislation shall be consulted, as appropriate. Member States may also establish one central contact point for communication with operators.

Amendment

7. **The Board** may provide guidance and advice on the implementation of this Regulation, including to small-scale providers. Whenever **the Board intends** to provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the competent national authorities under that Union legislation shall be consulted, as appropriate. Member States may also establish one central contact point for communication with operators.

Or. en

Amendment 2591

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation
Article 59 – paragraph 7

Text proposed by the Commission

7. National competent authorities may provide guidance and advice on the implementation of this Regulation, including to small-scale providers. Whenever national competent authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the competent national authorities under that Union legislation shall be consulted, as appropriate. Member States **may** also establish one central contact point for communication with operators.

Amendment

7. National competent authorities may provide guidance and advice on the implementation of this Regulation, including to small-scale providers. Whenever national competent authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the competent national authorities under that Union legislation shall be consulted, as appropriate. Member States **shall** also establish one central contact point for communication with operators.

Or. en

Amendment 2592
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 59 – paragraph 7

Text proposed by the Commission

7. National **competent** authorities may provide guidance and advice on the implementation of this Regulation, including to **small-scale providers**. Whenever national **competent** authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the competent **national** authorities under that Union legislation shall be consulted, as appropriate. **Member States may also establish one central contact point for communication with operators.**

Amendment

7. National **supervisory** authorities may provide guidance and advice on the implementation of this Regulation, including to **SMEs and start-ups, as long as it is not in contradiction with the Board's or the Commission's guidance and advice**. Whenever national **supervisory** authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the competent authorities under that Union legislation shall be consulted, as appropriate.

Or. en

Amendment 2593

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 59 – paragraph 8

Text proposed by the Commission

8. When Union institutions, agencies and bodies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as the competent authority for their supervision.

Amendment

8. When Union institutions, agencies and bodies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as the competent authority for their supervision ***and coordination***.

Or. en

Amendment 2594

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 59 – paragraph 8

Text proposed by the Commission

8. ***When Union institutions, agencies and bodies fall within the scope of this Regulation***, the European Data Protection Supervisor shall act as the competent authority for ***their*** supervision.

Amendment

8. The European Data Protection Supervisor shall act as the competent authority for ***the supervision of Union institutions, agencies and bodies***.

Or. en

Amendment 2595

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

Proposal for a regulation

Article 59 a (new)

Text proposed by the Commission

Amendment

Article 59 a
Independent national supervisory authority

- 1. Each Member State shall establish or designate a single national supervisory authority within 3 months after the entering into force of this Regulation.*
- 2. The national supervisory authority shall act as the lead authority and be responsible for ensuring the effective coordination between the national competent authorities regarding the implementation of this Regulation. It shall represent its Member State on the Board, in accordance with Article 57.*
- 3. Each national supervisory authority shall act with complete independence in performing its tasks and exercising its powers in accordance with this Regulation.*
- 4. The members of each national supervisory authority shall, in the performance of their tasks and exercise of their powers in accordance with this Regulation, remain free from external influence, whether direct or indirect, and shall neither seek nor take instructions from any other body.*
- 5. Members of each national supervisory authority shall refrain from any action incompatible with their duties and shall not, during their term of office, engage in any incompatible occupation, whether gainful or not.*
- 6. Each Member State shall ensure that each national supervisory authority is provided with the human, technical and financial resources, premises and infrastructure necessary for the effective performance of its tasks and exercise of its powers, including those to be carried out in the context of mutual assistance, cooperation and participation in the Board.*
- 7. Each Member State shall ensure that each national supervisory authority chooses and has its own staff which shall be subject to the exclusive direction of the member or members of the supervisory authority concerned.*

8. Each Member State shall ensure that each national supervisory authority is subject to financial control which does not affect its independence and that it has separate, public annual budgets, which may be part of the overall state or national budget.

9. Each member of the national supervisory authority shall have the qualifications, experience and skills, in particular an in-depth understanding of artificial intelligence technologies, data and data computing, personal data protection, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements, to perform their duties and exercise their powers.

10. The duties of a member of the national supervisory authority shall end in the event of the expiry of the term of office, resignation or compulsory retirement, in accordance with the law of the Member State concerned.

11. A member of the national supervisory authority shall be dismissed only in cases of serious misconduct or if the member no longer fulfils the conditions required for the performance of the duties.

12. Member States shall make publicly available and communicate to the Commission and the Board, the national supervisory designation, and information on how it can be contacted, by [three months after the entry into force of this Regulation].

13. For the purposes of the consistent application of the Regulation and for reasons of necessary cooperation with the market surveillance authorities, each national supervisory authority shall have at least one staff member from the market surveillance authority posted as a liaison officer to the national supervisory authority.

Or. en

Amendment 2596

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 59 a (new)

Text proposed by the Commission

Amendment

Article 59 a

Consistency mechanism for cross-border cases

- 1. Each national supervisory authority shall perform the tasks assigned to and the exercise of the powers conferred on it in accordance with this Regulation on the territory of its own Member State.*
- 2. The national supervisory authority of the Member State where the provider's place of central administration in the Union is present or established shall be competent to act as lead national supervisory authority for a cross-border case that involves an AI-system that falls under this Regulation and that is being placed on the market or put into service in two or more Member States.*
- 3. In order to contribute to the consistent application of this Regulation throughout the Union, national supervisory authorities shall cooperate with each other and, where relevant, with the Commission and the Board, through the consistency mechanism as set out in the following paragraphs.*
- 4. The lead national supervisory authority shall cooperate with the other supervisory authorities in an endeavour to reach consensus. The lead national supervisory authority and the other national supervisory authorities concerned shall exchange all relevant information with each other, provide mutual assistance and execute joint operations.*
- 5. The lead national supervisory authority shall, without delay, communicate the*

relevant information on the matter to the other national supervisory authorities concerned. It shall without delay submit a draft decision to the other national supervisory authorities concerned for their opinion and take due account of their views.

6. In case the Board, after being notified by another national supervisory authority, finds that the lead national supervisory authority did not use its investigative, corrective or authorisation power despite being notified by another national supervisory authority or came to a decision that is clearly incompatible with provisions of this Regulation, other national supervisory authorities may address the case on their own, taking into account the procedure described in paragraph 3 or request that the Board issue a binding decision.

Or. en

Amendment 2597

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation

Article 59 a (new)

Text proposed by the Commission

Amendment

Article 59 a

Cooperation mechanism between national supervisory authorities in cases involving two or more Member States

1. Each national supervisory authority shall perform its tasks and powers conferred on in accordance with this Regulation on the territory of its own Member State.

2. In the event of a case involving two or more national supervisory authorities, the national supervisory authority of the Member State where the provider or the

user of the concerned AI system is established or where the authorised representative is appointed shall be considered to be the lead national supervisory authority.

3. In the cases referred to in paragraph 2, the relevant national supervisory authorities shall cooperate and exchange all relevant information in due time.

National supervisory authorities shall cooperate in order to reach a consensus.

4. In the case of a serious disagreement between two or more national supervisory authorities, the national supervisory authorities shall notify the AI Office and communicate without delay all relevant information related to the case to the AI Office.

5. The AI Office shall, within three months of receipt of the notification referred to in paragraph 4, issue a binding decision to the national supervisory authorities.

Or. en

Amendment 2598

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

Proposal for a regulation Article 59 a (new)

Text proposed by the Commission

Amendment

Article 59 a

Independence

1. Each supervisory authority shall act with complete independence in performing its tasks and exercising its powers in accordance with this Regulation.

2. The member or members of each supervisory authority shall, in the performance of their tasks and exercise of

their powers in accordance with this Regulation, remain free from external influence, whether direct or indirect, and shall neither seek nor take instructions from anybody.

3. The member or members of each supervisory authority shall refrain from any action incompatible with their duties and shall not, during their term of office, engage in any incompatible occupation, whether gainful or not.

4. Each Member State shall ensure that each supervisory authority chooses and has its own staff which shall be subject to the exclusive direction of the member or members of the supervisory authority concerned.

5. Each Member State shall ensure that each supervisory authority is subject to financial control which does not affect its independence and that it has separate, public annual budgets, which may be part of the overall state or national budget.

Or. en

Amendment 2599

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

**Proposal for a regulation
Article 59 b (new)**

Text proposed by the Commission

Amendment

Article 59 b

Powers

1. Each supervisory authority shall have all of the following investigative powers:

(a) to order the provider or deployer of an AI system, and, where applicable, their representative, to provide any information it requires for the performance of its tasks;

- (b) to carry out investigations of providers or deployers of AI systems in the form of
 - (i) audits;
 - (ii) reviews of fundamental rights impact assessments;
 - (iii) reviews of certifications of conformity;
 - (iv) any other investigation to assess compliance with this Regulation;
- (c) to carry out a review on certifications issued pursuant to Article 44;
- (d) to notify the provider or deployer of an AI system of an alleged infringement of this Regulation;
- (e) to obtain, from the provider or deployer of an AI system, access to all data and to all information necessary for the performance of its tasks;
- (f) to obtain access to any premises of the provider or deployer of an AI system, including to any data processing equipment and means, in accordance with Union or Member State procedural law.

2. Each supervisory authority shall have all of the following corrective powers:

- (a) to issue warnings to a provider or deployer of an AI system that the use or reasonably foreseeable misuse of that system is likely to infringe provisions of this Regulation;
- (b) to issue reprimands to a provider or deployer of an AI system where they have infringed provisions of this Regulation;
- (c) to order the provider or deployer of an AI system to comply with a subject's request to exercise his or her rights pursuant to this Regulation;
- (d) to order the provider or deployer of an AI system to bring operations into compliance with the provisions of this Regulation, where appropriate, in a specified manner and within a specified period;

(e) to order the controller to communicate an infringement of this Regulation to the affected subject;

(f) to impose a temporary or definitive limitation including a ban of the operation of an AI system;

(g) to order the erasure of all data and of the related logic underlying automated processing, which had been generated as part of the development, training, or operation of an AI system that was subsequently found in breach of this Regulation;

(h) to withdraw a certification or to order the certification body to withdraw a certification issued pursuant to Articles 44, or to order the certification body not to issue certification if the requirements for the certification are not or are no longer met;

(i) to impose an administrative fine pursuant to Article 71, in addition to, or instead of measures referred to in this paragraph, depending on the circumstances of each individual case;

(j) to order the suspension of the placing on the market of an AI system or of its export to a third country or to an international organisation.

3. The exercise of the powers conferred on the supervisory authority pursuant to this Article shall be subject to appropriate safeguards, including effective judicial remedy and due process, set out in Union and Member State law in accordance with the Charter.

4. Each Member State shall provide by law that its supervisory authority shall have the power to bring infringements of this Regulation to the attention of the judicial authorities and where appropriate, to commence or engage otherwise in legal proceedings, in order to enforce the provisions of this Regulation.

5. Each Member State may provide by law that its supervisory authority shall have

additional powers to those referred to in paragraphs 1, 2 and 3. The exercise of those powers shall not impair the effective operation of this Regulation.

Or. en

Amendment 2600

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

Proposal for a regulation

Article 59 b (new)

Text proposed by the Commission

Amendment

Article 59 b

Tasks of the national supervisory authority

1. Without prejudice to other tasks set out under this Regulation, each national supervisory authority shall on the territory of its Member State:

- (a) monitor and enforce the application of this Regulation, in particular as to the upholding of the principles of article 4a, fundamental rights of individuals and the Union values, as enshrined in Article 2 TEU;*
- (b) promote public awareness and understanding of the risks, rules, safeguards and rights in relation to use of AI systems;*
- (c) promote the awareness of operators of their obligations under this Regulation;*
- (d) monitor operators' data governance and management practices, in particular in relation to training, validation and testing datasets;*
- (e) upon request, provide information to affected persons concerning the exercise of their rights under this Regulation and, if appropriate, cooperate with the supervisory authorities in other Member*

States to that end;

(f) handle complaints lodged by an affected person, organisation or association in accordance with Articles 68a and 68b, and investigate, to the extent appropriate, the subject matter of the complaint and inform the complainant of the progress and the outcome of the investigation within a reasonable period, in particular if further investigation or coordination with another national supervisory authority or national competent authority is necessary;

(g) assist small-scale providers and users in accordance with Article 55;

(h) cooperate with, including by sharing information and providing mutual assistance to, other national supervisory authorities and national competent authorities with a view to ensuring the consistency of application and enforcement of this Regulation;

(i) conduct investigations on the application of this Regulation, including on the basis of information received from another national supervisory authority, national competent authority or other public authority;

(j) cooperate with other competent authorities in their fields of competence, as necessary;

(k) monitor relevant developments, insofar as they have an impact on the protection of fundamental rights and the values enshrined in Article 2 TEU, in particular the development of technologies and commercial practices;

(l) contribute to the activities of the Board;

2. National supervisory authorities may establish regulatory sandboxes in accordance with Article 53.

3. Each national supervisory authority shall facilitate the submission of complaints referred to in point (f) of paragraph 1 by measures such as a

complaint submission form which can also be completed electronically, without excluding other means of communication.

4. The performance of the tasks of each national supervisory authority shall be free of charge for the affected person.

Or. en

Amendment 2601

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

Proposal for a regulation

Article 59 c (new)

Text proposed by the Commission

Amendment

Article 59 c

Cooperation and consistency

In order to contribute to the consistent application of this Regulation throughout the Union, the national supervisory authorities shall cooperate with each other and, where relevant, with the market surveillance authorities and the Commission, in order to reach consensus.

Or. en

Justification

To be part of a new Chapter 3 'Cooperation, consistency and dispute resolutions between national supervisory authorities'

Amendment 2602

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

Proposal for a regulation

Article 59 d (new)

Text proposed by the Commission

Amendment

Article 59 d

Cooperation mechanism in cases involving two or more Member States

- 1. Each national supervisory authority shall perform its tasks and powers conferred to it in accordance with this Regulation, on the territory of its own Member State.*
- 2. In the event of a case involving two or more national supervisory authorities, the national supervisory authority of the Member State where the provider or the user of the concerned AI system is established, or where the legal representative resides, shall be considered to be the lead national supervisory authority.*
- 3. In case it is not clear which national supervisory authority should act as the lead authority pursuant to paragraph 2, the Board shall issue a binding decision according to Article 59e.*
- 4. In cases referred to in paragraph 2, the relevant national supervisory authorities shall cooperate and exchange all relevant information in due time.*
- 5. The national supervisory authorities shall, where appropriate, conduct joint operations, including joint investigations, in which members or staff of the national supervisory authorities of other Member States are involved.*
- 6. In case of a serious disagreement between two or more national supervisory authorities, the national supervisory authorities shall notify the Board and communicate without delay all relevant information related to the case to the Board for a binding decision.*

Or. en

Amendment 2603

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

**Proposal for a regulation
Article 59 e (new)**

Text proposed by the Commission

Amendment

Article 59 e

Binding decisions by the Board

1. In order to ensure the correct and consistent application of this Regulation in individual cases, the Board shall adopt a binding decision in the following cases:

- (a) where there are conflicting views on which of the national supervisory authorities concerned would be the lead authority pursuant to Article 59c;***
- (b) where, in a case referred to in Article 59c(4), there is a serious disagreement between national supervisory authorities concerned regarding a matter involving two or more Member States;***
- (c) where, in a case referred to in Article 67a, a national supervisory authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a risk to the compliance with obligations under Union or national law intended to protect fundamental rights, the principles of Article 4a, the values as enshrined in Article 2 TEU, the environment, or to other aspects of public interest protection;***

2. The decisions referred to in paragraph 1, point (a) shall be adopted within one week from the referral of the subject-matter, by a two-thirds majority of the members of the Board.

3. The decisions referred to in paragraph 1, points (b) and (c) shall be adopted within one month from the referral of the subject-matter, by a two-thirds majority of the members of the Board. That period may be extended by a further month on account of the complexity of the subject-matter. The decision referred to in paragraph 1, points (b) and (c) shall be reasoned and addressed to the lead national supervisory authority and all the

national supervisory authorities concerned and be binding on them.

4. Where the Board has been unable to adopt a decision within the periods referred to in paragraph 3, it shall adopt its decision within two weeks following the expiration of the second month referred to in paragraph 2 by a simple majority of the members of the Board. Where the members of the Board are split, the decision shall be adopted by the vote of its Chair.

5. The national supervisory authorities concerned shall not adopt a decision on the subject matter submitted to the Board under paragraph 1, points (b) and (c) during the periods referred to in paragraphs 3 and 4.

6. The Chair of the Board shall notify, without undue delay, the decision referred to in paragraph 1 to the national supervisory authorities concerned. It shall also inform the Commission thereof. The decision shall be published on the website of the Board without delay after the national supervisory authorities have been notified.

Or. en

Amendment 2604

Rob Rooken

on behalf of the ECR Group

Proposal for a regulation

Title VI – Chapter 2 a (new)

Text proposed by the Commission

Amendment

2 a Effective remedies

Create a comprehensive remedies framework for affected persons, including a right for individuals to bring complaints, a right to bring collective action; and a right to information.

Amendment 2605

Rob Rooken

on behalf of the ECR Group

Proposal for a regulation

Title VI – Chapter 2 b (new)

Text proposed by the Commission

Amendment

2 b *The right to object to the use of automated decision-making in high-risk areas*

Individuals shall have the right not to be subject to a decision based solely on automated processing by high-risk AI systems in Annex III which significantly affects them.

Amendment 2606

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Title VII

Text proposed by the Commission

Amendment

VII EU DATABASE FOR STAND-ALONE HIGH-RISK AI SYSTEMS

deleted

60 EU database for stand-alone high-risk AI systems

1. The Commission shall, in collaboration with the Member States, set up and maintain a EU database containing information referred to in paragraph 2 concerning high-risk AI systems referred to in Article 6(2) which are registered in accordance with Article 51.

2. The data listed in Annex VIII shall be entered into the EU database by the providers. The Commission shall provide them with technical and administrative

support.

3. Information contained in the EU database shall be accessible to the public.

4. The EU database shall contain personal data only insofar as necessary for collecting and processing information in accordance with this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider.

5. The Commission shall be the controller of the EU database. It shall also ensure to providers adequate technical and administrative support.

Or. en

Justification

This is unnecessarily bureaucratic and creates no added value in terms of safety and trustworthiness of AI systems.

Amendment 2607

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

Proposal for a regulation

Title VII

Text proposed by the Commission

Amendment

**EU DATABASE FOR STAND-ALONE
HIGH-RISK AI SYSTEMS**

**EU DATABASE FOR STAND-ALONE
AI SYSTEMS**

Or. en

Amendment 2608

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Title VII

Text proposed by the Commission

EU DATABASE FOR **STAND-ALONE**
HIGH-RISK AI SYSTEMS

Amendment

EU DATABASE FOR HIGH-RISK AI
SYSTEMS

Or. en

Amendment 2609

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

Proposal for a regulation

Title VII

Text proposed by the Commission

EU DATABASE FOR **STAND-ALONE**
HIGH-RISK AI SYSTEMS

Amendment

EU DATABASE FOR AI SYSTEMS

Or. en

Amendment 2610

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 60 – title

Text proposed by the Commission

60 EU database for stand-alone high-risk AI systems

Amendment

60 EU database for stand-alone high-risk, **general purpose and certain** AI systems, **uses thereof, and uses of AI systems by public authorities** AI systems

Or. en

Amendment 2611

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

Proposal for a regulation

Article 60 – title

Text proposed by the Commission

EU database for stand-alone **high-risk** AI systems

Amendment

EU database for stand-alone AI systems

Or. en

Amendment 2612

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 60 – title

Text proposed by the Commission

EU database for **stand-alone** high-risk AI systems

Amendment

EU database for high-risk AI systems

Or. en

Amendment 2613

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

Proposal for a regulation

Article 60 – title

Text proposed by the Commission

EU database for **stand-alone high-risk** AI systems

Amendment

EU database for AI systems

Or. en

Amendment 2614

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 60 – paragraph 1

Text proposed by the Commission

1. The Commission shall, in collaboration with the Member States, set

Amendment

1. The Commission shall, in collaboration with the Member States, set

up and maintain a EU database containing information referred to in paragraph 2 concerning high-risk AI systems referred to in Article 6(2) which are registered in accordance with Article 51.

up and maintain a EU database containing information referred to in paragraph 2 concerning *AI systems which are registered in accordance with Article 51 and general purpose AI systems, in accordance with Article xx:*

- a. high-risk AI systems referred to in Article 6(2) which are registered in accordance with Article 51(1);*
- b. any AI systems referred to in Article 52 paragraphs 1b and 2 which are registered in accordance with Article 51(1);*
- c. any uses of high-risk AI systems referred to in Article 6(2) which are registered in accordance with Article 51(2);*
- d. any uses of AI systems referred to in Article 52 paragraph 1b and 2 which are registered in accordance with Article 51(2);*
- e. any uses of AI systems by or on behalf of public authorities registered in accordance with Article 51(3).*

Or. en

Amendment 2615

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

Proposal for a regulation Article 60 – paragraph 1

Text proposed by the Commission

1. The Commission shall, in collaboration with the Member States, set up and maintain a EU database containing information referred to in paragraph 2 concerning high-risk AI systems *referred to in Article 6(2)* which are registered in accordance with Article 51.

Amendment

1. The Commission shall, in collaboration with the Member States, set up and maintain a EU database containing information referred to in paragraph 2 concerning high-risk AI systems *in one of the areas listed in Annex III* which are registered in accordance with Article 51 *and their uses by public authorities and Union institutions, bodies, offices or agencies or on their behalf.*

Or. en

Amendment 2616

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 60 – paragraph 1

Text proposed by the Commission

1. The Commission shall, in collaboration with the Member States, set up and maintain a EU database containing information referred to in paragraph 2 concerning high-risk AI systems *referred to in Article 6(2)* which are registered in accordance with Article 51.

Amendment

1. The Commission shall, in collaboration with the Member States *and by building on the existing Business Registries in line with Directive 2012/17/EU*, set up and maintain a EU database containing information referred to in paragraph 2 concerning high-risk AI systems *listed in Annex III* which are registered in accordance with Article 51.

Or. en

Amendment 2617

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

Proposal for a regulation

Article 60 – paragraph 1

Text proposed by the Commission

1. The Commission shall, in collaboration with the Member States, set up and maintain a EU database containing information referred to in paragraph 2 concerning *high-risk* AI systems *referred to in Article 6(2)* which are registered in accordance with Article 51.

Amendment

1. The Commission shall, in collaboration with the Member States, set up and maintain a EU database containing information referred to in paragraph 2 *and 2a* concerning AI systems which are registered in accordance with Article 51, *as well as users of any AI systems by public authorities and Union institutions, bodies, offices or agencies*.

Or. en

Amendment 2618

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

**Proposal for a regulation
Article 60 – paragraph 1**

Text proposed by the Commission

1. The Commission shall, in collaboration with the Member States, set up and maintain a EU database containing information referred to in paragraph 2 concerning high-risk AI systems **referred to in Article 6(2)** which are registered in accordance with Article 51.

Amendment

1. The Commission shall, in collaboration with the Member States, set up and maintain a **public** EU database containing information referred to in paragraph 2 concerning high-risk AI systems which are registered in accordance with Article 51.

Or. en

Amendment 2619

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 60 – paragraph 2**

Text proposed by the Commission

2. The **data listed in Annex VIII** shall **be entered into the EU database by the providers. The Commission shall provide them with technical and administrative support.**

Amendment

2. The **post-market monitoring system** shall **actively and systematically collect, document and analyse relevant data provided by users or collected through other sources, to the extent such data are readily accessible to the provider and taking into account the limits resulting from data protection, copyright and competition law, on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.**

Or. en

Amendment 2620

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Article 60 – paragraph 2**

Text proposed by the Commission

2. The data listed in Annex VIII shall be entered into the EU database by the providers. **The Commission shall provide them with technical and administrative support.**

Amendment

2. ***The Commission shall provide providers and users entering data into the EU database with technical and administrative support. The following information should be included in the EU database:***

(a) For registrations according to paragraph 1(a) and 1(b), the data listed in Annex VIII point 1 shall be entered into the EU database by the providers.

(b) For registrations according to paragraph 1(c), 1(d) and 1(e), the data listed in Annex VIII point 2 shall be entered into the EU database by the users.

Or. en

Amendment 2621

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

**Proposal for a regulation
Article 60 – paragraph 2**

Text proposed by the Commission

2. The data listed in Annex VIII shall be entered into the EU database by the providers. The Commission shall provide them with technical and administrative support.

Amendment

2. The data listed in Annex VIII shall be entered into the EU database by the providers, ***and, where relevant, deployers.*** The Commission shall provide them with technical and administrative support.

Or. en

Amendment 2622

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

**Proposal for a regulation
Article 60 – paragraph 2 a (new)**

Text proposed by the Commission

Amendment

2 a. The data listed in Annex VIII, point (2), shall be entered into the EU database by the users, including those who are or who act on behalf of public authorities or Union institutions, bodies, offices or agencies. The Commission shall provide them with technical and administrative support.

Or. en

Amendment 2623

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

**Proposal for a regulation
Article 60 – paragraph 3**

Text proposed by the Commission

Amendment

3. Information contained in the EU database shall be accessible to the public.

3. Information contained in the EU database shall be *freely available and* accessible to the public, *comply with the accessibility requirements of Annex I to Directive 2019/882, and be user-friendly, navigable, and machine-readable, containing structured digital data based on a standardised protocol.*

Or. en

Amendment 2624

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Article 60 – paragraph 3**

Text proposed by the Commission

Amendment

3. Information contained in *the EU database* shall be *accessible* to the public.

3. *The EU database and the* information contained in *it* shall be *freely available* to the public, *comply with the accessibility requirements of Annex I to*

Directive 2019/882, and be user-friendly, navigable, and machine-readable, containing structured digital data based on a standardised protocol.

Or. en

Amendment 2625

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

Proposal for a regulation

Article 60 – paragraph 3

Text proposed by the Commission

3. Information contained in the EU database shall be accessible to the public.

Amendment

3. Information contained in the EU database shall be accessible to the public, ***user-friendly and machine-readable.***

Or. en

Amendment 2626

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 60 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. Users should register deployments of high-risk AI systems into the EU database before putting them into use. The users should include information in the database, not limited to, the identity of the provider and the user, the context of the purpose and of deployment, the designation of impacted persons, and the results of the impact assessment.

Or. en

Amendment 2627

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-

Marius Boto , Moritz Körner, Jan-Christoph Oetjen

**Proposal for a regulation
Article 60 – paragraph 4**

Text proposed by the Commission

4. The EU database shall contain personal data only insofar as necessary for collecting and processing information in accordance with this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider.

Amendment

4. The EU database shall contain personal data only insofar as necessary for collecting and processing information in accordance with this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider *or the user, if the user is a public authority or a Union institution, body, office or agency or a user acting on their behalf.*

Or. en

Amendment 2628

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Article 60 – paragraph 4**

Text proposed by the Commission

4. The EU database shall contain personal data only insofar as necessary for collecting and processing information in accordance with this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider.

Amendment

4. The EU database shall contain personal data only insofar as necessary for collecting and processing information in accordance with this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider, *or the user.*

Or. en

Amendment 2629

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

**Proposal for a regulation
Article 60 – paragraph 4**

Text proposed by the Commission

4. The EU database shall contain personal data only insofar as necessary for collecting and processing information in accordance with this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider.

Amendment

4. The EU database shall contain personal data only insofar as necessary for collecting and processing information in accordance with this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider ***or the user.***

Or. en

Amendment 2630

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

**Proposal for a regulation
Article 60 – paragraph 4 a (new)**

Text proposed by the Commission

Amendment

4 a. *The EU database shall not contain any confidential business information or trade secrets of a natural or legal person, including source code.*

Or. en

Amendment 2631

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 60 – paragraph 4 a (new)**

Text proposed by the Commission

Amendment

4 a. *The EU database shall not contain any confidential business information or trade secrets of a natural or legal person, including source code.*

Or. en

Amendment 2632

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 60 – paragraph 5

Text proposed by the Commission

5. The Commission shall be the controller of the EU database. It shall also ensure to providers adequate technical and administrative support.

Amendment

5. The Commission shall be the controller of the EU database. It shall also ensure to providers **and users** adequate technical and administrative support, **in particular in relation to registrations according to paragraph 1(e)**.

Or. en

Amendment 2633

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

Proposal for a regulation

Article 60 – paragraph 5

Text proposed by the Commission

5. The Commission shall be the controller of the EU database. ***It shall also ensure to providers adequate technical and administrative support.***

Amendment

5. The Commission shall be the controller of the EU database.

Or. en

Amendment 2634

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

Proposal for a regulation

Article 60 – paragraph 5

Text proposed by the Commission

5. The Commission shall be the controller of the EU database. It shall also ensure to providers adequate technical and

Amendment

5. The Commission shall be the controller of the EU database. It shall also ensure to providers **and, where relevant,**

administrative support.

deployers, adequate technical and administrative support.

Or. en

Amendment 2635

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Vincenzo Sofo, Adam Bielan

Proposal for a regulation

Article 60 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. Any information and documentation obtained by the Commission and Member States pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.

Or. en

Amendment 2636

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 60 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. Any information and documentation obtained by the Commission and Member States pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.

Or. en

Amendment 2637

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Article 60 – paragraph 5 a (new)**

Text proposed by the Commission

Amendment

5 a. The database shall comply with the accessibility requirements of Annex I to Directive 2019/882.

Or. en

Amendment 2638

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Article 60 a (new)**

Text proposed by the Commission

Amendment

Article 60 a

Systemic transparency and monitoring of societal implications

1. The Commission shall, in collaboration with the Member States, set up and maintain a relational database of digital and AI systems that interact with high-risk or general purpose AI systems or with AI systems with transparency obligations. Among others, the relational database shall include digital and AI systems whose input directly or indirectly come from a high-risk or general purpose AI system or whose output directly or indirectly is taken as input by a high-risk or general purpose AI system.

2. For each entry in the EU database referred to in Article 60, the provider shall enter the upstream and downstream digital and AI systems into the relational database, as well as, to the extent it is possible, the digital and AI systems upstream of the upstream AI systems and the digital and AI systems downstream of the downstream AI systems.

3. The European AI Board and the Commission shall regularly assess the

relational map to facilitate incident response and to identify AI systems ('Societally Significant AI systems') whose output is used as input into many downstream digital and AI systems. 4. The European AI Board and the Commission shall develop a Code of Conduct for Societally Significant AI Systems.

Or. en

Amendment 2639

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 61 – paragraph 1

Text proposed by the Commission

1. Providers shall establish and document a post-market monitoring system in a manner that is proportionate to the *nature of the artificial intelligence technologies and* the risks of the high-risk AI system.

Amendment

1. Providers shall establish and document a post-market monitoring system in a manner that is proportionate to the the risks of the high-risk AI system.

Or. en

Amendment 2640

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 61 – paragraph 2

Text proposed by the Commission

2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.

Amendment

2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.

Post-market monitoring must include continuous analysis of the AI environment, including other devices, software, and other AI systems that will interact with the AI system.

Or. en

Amendment 2641

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini, Brando Benifei

Proposal for a regulation

Article 61 – paragraph 2

Text proposed by the Commission

2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.

Amendment

2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2. *Post-market monitoring must include continuous analysis of the AI environment, including other devices, software, and other AI systems that will interact with the AI system.*

Or. en

Amendment 2642

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

Proposal for a regulation

Article 61 – paragraph 2

Text proposed by the Commission

2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data

Amendment

2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data

provided by *users* or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.

provided by *deployers* or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2. *Post-market monitoring shall include continuous analysis of the AI environment, including other devices, software, and other AI systems that interact with the AI system.*

Or. en

Amendment 2643

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ondej Kováčik, Jan-Christoph Oetjen

Proposal for a regulation

Article 61 – paragraph 2

Text proposed by the Commission

2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.

Amendment

2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources, *to the extent such data are readily accessible to the provider and taking into account the limits resulting from data protection, copyright and competition law*, on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.

Or. en

Amendment 2644

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 61 – paragraph 2

Text proposed by the Commission

2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources on the performance of high-risk AI systems ***throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.***

Amendment

2. ***In order to allow the provider to evaluate the compliance of AI systems with the requirements set out in Title III, Chapter 2 throughout their lifetime, the post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources, to the extent such data are readily accessible to the provider and taking into account the limits resulting from data protection, copyright and competition law,*** on the performance of high-risk AI systems.

Or. en

Amendment 2645

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

**Proposal for a regulation
Article 61 – paragraph 2**

Text proposed by the Commission

2. Le système de surveillance après commercialisation collecte, documente et analyse, de manière active et systématique, les données pertinentes fournies par les utilisateurs ou collectées via d'autres sources sur les performances des systèmes d'IA à haut risque tout au long de leur cycle de vie, et permet au fournisseur d'évaluer si les systèmes d'IA respectent en permanence les exigences énoncées au titre III, chapitre 2.

Amendment

2. Le système de surveillance après commercialisation collecte, documente et analyse, de manière active et systématique, les données pertinentes fournies par les utilisateurs ou collectées via d'autres sources, ***à l'exception du transfert automatisé de données,*** sur les performances des systèmes d'IA à haut risque tout au long de leur cycle de vie, et permet au fournisseur d'évaluer si les systèmes d'IA respectent en permanence les exigences énoncées au titre III, chapitre 2.

Or. fr

Amendment 2646

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation
Article 61 – paragraph 2

Text proposed by the Commission

2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.

Amendment

2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users *and end-users* or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.

Or. en

Amendment 2647

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

Proposal for a regulation
Article 61 – paragraph 3

Text proposed by the Commission

3. Le système de surveillance après commercialisation repose sur un plan de surveillance après commercialisation. Le plan de surveillance après commercialisation fait partie de la documentation technique visée à l'annexe IV. La Commission adopte un acte d'exécution fixant des dispositions détaillées établissant un modèle pour le plan de surveillance après commercialisation et la liste des éléments à inclure dans le plan.

Amendment

3. Le système de surveillance après commercialisation repose sur un plan de surveillance après commercialisation. Le plan de surveillance après commercialisation fait partie de la documentation technique visée à l'annexe IV. La Commission adopte un acte d'exécution fixant des dispositions détaillées établissant un modèle pour le plan de surveillance après commercialisation et la liste des éléments à inclure dans le plan. *Ces dispositions ne peuvent prévoir la transmission automatisée et systématique de données.*

Or. fr

Amendment 2648

**Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto ,
Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen**

**Proposal for a regulation
Article 61 – paragraph 3**

Text proposed by the Commission

3. The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt an implementing act laying down detailed provisions establishing a template for the post-market monitoring plan and the list of elements to be included in the plan.

Amendment

3. The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt an implementing act laying down detailed provisions establishing a template for the post-market monitoring plan and the list of elements to be included in the plan *by ... [12 months following the entry into force of this Regulation]*.

Or. en

Amendment 2649

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Title VIII – Chapter 2 – title**

Text proposed by the Commission

2 Sharing of information on incidents *and malfunctioning*

Amendment

2 Sharing of information on incidents

Or. en

Amendment 2650

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 62 – title**

Text proposed by the Commission

Reporting of serious incidents *and of malfunctioning*

Amendment

Reporting of serious incidents

Amendment 2651

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 62 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

1. Providers ***and, where users have identified a serious incident or malfunctioning, users*** of high-risk AI systems placed on the Union market shall report any serious incident or any malfunctioning of those systems which constitutes a breach of obligations under Union law to the market surveillance authorities of the Member States where that incident or breach occurred ***and to the affected persons and, where the incident or breach occurs or is likely to occur in at least two Member States, to the Commission.***

Amendment 2652

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

Proposal for a regulation

Article 62 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

1. Providers ***and, where users have identified a serious incident or malfunctioning, users*** of AI systems placed on the Union market shall report any serious incident or any malfunctioning, ***including near misses,*** of those systems which constitutes a breach of obligations under Union law ***to the national***

occurred.

supervisory authorities and the market surveillance authorities of the Member States where that incident or breach occurred *and, where relevant, to the Commission and to the affected persons.*

Or. en

Amendment 2653

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 62 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

1. Providers of high-risk AI systems placed on the Union market shall report any serious incident to the market surveillance authorities of the Member States where that incident occurred.

Or. en

Amendment 2654

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 62 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

1. Providers *and, where users have identified a* serious incident or malfunctioning, *including near misses, users of high-risk or general purpose* systems which constitutes a breach of obligations under Union law intended to protect fundamental rights, *health and safety* to the market surveillance authorities of the Member States where that incident

or breach occurred, *and to the Commission..*

Or. en

Justification

Article 62 (1) in the Commission's text says that providers must report serious problems to MSAs only after they have established "a causal link" between their AI systems and the incidents, or a reasonable likelihood of one. This allows providers to evade their responsibility by finding explanations that do not include their own AI systems, especially when these are part of a larger system.

Article 62 should require that operators report an incident or malfunction whenever an AI system is a part of the system concerned, and not only for serious incidents. This should include near-misses so that other operators can learn from these incidents. This will also have broad societal benefit of helping operators identify and fix problems before a serious incident occurs.

Amendment 2655

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

Proposal for a regulation

Article 62 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

1. Providers *and, where applicable, users* of high-risk AI systems placed on the Union market shall report any serious incident or any malfunctioning of those systems which constitutes a breach of obligations under Union law intended to

surveillance authorities of the Member States where that incident or breach occurred.

protect fundamental rights to the market surveillance authorities of the Member States where that incident or breach occurred.

Or. en

Amendment 2656

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

Proposal for a regulation

Article 62 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 2657

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

Proposal for a regulation

Article 62 – paragraph 1 – subparagraph 1

Text proposed by the Commission

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

Amendment

Such notification shall be made **without undue delay** after the provider has established a causal link between the AI system and the incident or malfunctioning or the reasonable likelihood of such a link, and, in any event, not later than **72 hours** after the providers becomes aware of the serious incident or of the malfunctioning.

Or. en

Amendment 2658

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

Proposal for a regulation

Article 62 – paragraph 1 – subparagraph 1

Text proposed by the Commission

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

Amendment

Such notification shall be made immediately after the provider has established a causal link between the AI system and the incident or malfunctioning or the reasonable likelihood of such a link, and, in any event, not later than **72 hours** after the providers becomes aware of the serious incident or of the malfunctioning.

Or. en

Amendment 2659

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

Proposal for a regulation

Article 62 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Cette notification est effectuée immédiatement après que le fournisseur a établi un lien de causalité, ou la probabilité raisonnable qu'un tel lien existe, entre le système d'IA et l'incident ou le dysfonctionnement et, en tout état de cause, au plus tard **15 jours** après que le fournisseur a eu connaissance de l'incident grave ou du dysfonctionnement.

Amendment

Cette notification est effectuée immédiatement après que le fournisseur a établi un lien de causalité, ou la probabilité raisonnable qu'un tel lien existe, entre le système d'IA et l'incident ou le dysfonctionnement et, en tout état de cause, au plus tard **72 heures** après que le fournisseur a eu connaissance de l'incident grave ou du dysfonctionnement.

Or. fr

Justification

Délai aligné sur celui de l'article 33 du Règlement (UE) 2016/679 du Parlement européen et

du Conseil du 27 avril 2016 relatif à la protection des personnes physiques à l'égard du traitement des données à caractère personnel et à la libre circulation de ces données, et abrogeant la directive 95/46/CE (règlement général sur la protection des données).

Amendment 2660

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

Proposal for a regulation

Article 62 – paragraph 1 – subparagraph 1

Text proposed by the Commission

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

Amendment

Such notification shall be made immediately **when an AI system is involved in an** incident or malfunctioning, **including near misses**, and, in any event, not later than **72 hours** after the providers **or, where applicable, the user** becomes aware of the serious incident or of the malfunctioning.

Or. en

Amendment 2661

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 62 – paragraph 1 – subparagraph 1

Text proposed by the Commission

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

Amendment

Such notification shall be made immediately **when an AI system is involved in** the incident or malfunctioning, **including near misses**, and, in any event, not later than **72 hours** after the providers **or, where applicable, the user** becomes aware of the serious incident or of the malfunctioning.

Or. en

Amendment 2662

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 62 – paragraph 1 – subparagraph 1

Text proposed by the Commission

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

Amendment

Such notification shall be made **without undue delay** after the provider has established a causal link between the AI system and the **serious** incident or the reasonable likelihood of such a link, and, in any event, not later than **72 hours** after the providers becomes aware of the serious incident.

Or. en

Amendment 2663

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 62 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

No report under this Article is required if the serious incident also leads to reporting requirements under other laws. In that case, the authorities competent under those laws shall forward the received report to the national competent authority.

Or. en

Amendment 2664

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 62 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

No report under this Article is required if the serious incident also leads to reporting requirements under other laws. In that case, the authorities competent under those laws shall forward the received report to the national competent authority.

Or. en

Amendment 2665

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 62 – paragraph 2**

Text proposed by the Commission

2. Upon receiving a notification related to a **breach of obligations under Union law intended to protect fundamental rights**, the market surveillance authority shall inform the national public authorities or bodies referred to in Article 64(3). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1. That guidance shall be issued 12 months after the entry into force of this Regulation, at the latest.

Amendment

2. Upon receiving a notification related to a **serious incident referred to in Article 3(44), the relevant** market surveillance authority shall inform the national public authorities or bodies referred to in Article 64(3). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1. That guidance shall be issued 12 months after the entry into force of this Regulation, at the latest.

Or. en

Amendment 2666

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

**Proposal for a regulation
Article 62 – paragraph 2**

Text proposed by the Commission

2. Upon receiving a notification related to a breach of obligations under Union law **intended to protect** fundamental

Amendment

2. Upon receiving a notification related to a breach of obligations under Union law **or of** fundamental rights, the

rights, the market surveillance authority shall inform the national public authorities or bodies referred to in Article 64(3). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1. That guidance shall be issued **12** months after the entry into force of this Regulation, at the latest.

market surveillance authority shall inform the national public authorities or bodies referred to in Article 64(3). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1. That guidance shall be issued **3** months after the entry into force of this Regulation, at the latest.

Or. en

Amendment 2667

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 62 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The market surveillance authorities shall take appropriate measures within 7 days from the date it received the notification referred to in paragraph 1. Where the infringement takes place or is likely to take place in other Member States, the market surveillance authority shall notify the Commission, the Board and the relevant national competent authorities of these Member States.

Or. en

Justification

the 7 days deadline is introduced in order to provide a timeframe after which it is reasonable to consider inaction by that Member State and therefore the enforcement procedure at EU level is triggered.

Amendment 2668

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

Proposal for a regulation
Article 62 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. Upon establishing a causal link between the AI system and the serious incident or malfunctioning or the reasonable likelihood of such a link, providers shall take appropriate corrective actions pursuant to Article 21.

Or. en

Amendment 2669
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 62 – paragraph 3

Text proposed by the Commission

Amendment

3. For high-risk AI systems referred to in point 5(b) of Annex III which are placed on the market or put into service by providers that are *credit institutions regulated by Directive 2013/36/EU and for high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746*, the notification of serious incidents *or malfunctioning* shall be limited to those *that constitute a breach of obligations under Union law intended to protect fundamental rights*.

3. For high-risk AI systems referred to in point 5(b) of Annex III which are placed on the market or put into service by providers that are *subject to regulations that require solutions equivalent to those set out in this Regulation*, the notification of serious incidents shall be limited to those *referred to in Article 3(44)*.

Or. en

Amendment 2670
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 62 – paragraph 3

Text proposed by the Commission

3. For high-risk AI systems referred to in point 5(b) of Annex III which are placed on the market or put into service by providers that are credit institutions regulated by Directive 2013/36/EU and for high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746, the notification of serious incidents or malfunctioning shall be limited to those that constitute a breach of obligations under Union law intended to protect fundamental rights.

Amendment

3. For high-risk AI systems referred to in point 5(b) of Annex III which are placed on the market or put into service by providers that are credit institutions regulated by Directive 2013/36/EU and for high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulation (EU) 2017/745 and Regulation(EU) 2017/746, the notification of serious incidents or malfunctioning **for the purposes of this Regulation** shall be limited to those that constitute a breach of obligations under Union law intended to protect fundamental rights **and the environment**.

Or. en

Amendment 2671

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

**Proposal for a regulation
Article 62 – paragraph 3**

Text proposed by the Commission

3. For high-risk AI systems referred to in point 5(b) of Annex III which are placed on the market or put into service by providers that are credit institutions regulated by Directive 2013/36/EU and for high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746, the notification of serious incidents or malfunctioning shall be limited to those that constitute a breach of obligations under Union law **intended to protect** fundamental rights.

Amendment

3. For high-risk AI systems referred to in point 5(b) of Annex III which are placed on the market or put into service by providers that are credit institutions regulated by Directive 2013/36/EU and for high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746, the notification of serious incidents or malfunctioning shall be limited to those that constitute a breach of obligations under Union law **or** fundamental rights.

Or. en

Amendment 2672

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 62 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. Requirements in place in existing EU legislation shall be taken into account with regard to reporting of information of incidents, in view of avoiding duplications and harmonizing the provisions on incident and event reporting.

Or. en

Amendment 2673

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

Proposal for a regulation

Article 62 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. National supervisory authorities shall on an annual basis notify the Board of the serious incidents and malfunctioning reported to them in accordance with this Article.

Or. en

Amendment 2674

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

Proposal for a regulation

Article 63 – paragraph 2

Text proposed by the Commission

Amendment

2. The national supervisory authority shall report to the Commission **on a regular basis** the outcomes of relevant

2. The national supervisory authority shall report **annually** to the Commission the outcomes of relevant market

market surveillance activities. The national supervisory authority shall report, without delay, to the Commission and relevant national competition authorities any information identified in the course of market surveillance activities that may be of potential interest for the application of Union law on competition rules.

surveillance activities. The national supervisory authority shall report, without delay, to the Commission and relevant national competition authorities any information identified in the course of market surveillance activities that may be of potential interest for the application of Union law on competition rules.

Or. en

Amendment 2675

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 63 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. For the purpose of regulating high-risk AI systems, Market surveillance authorities may have the power to:

(a) carry out unannounced on-site and remote inspections of high-risk AI systems;

(b) acquire samples related to high-risk AI systems, including through remote inspections, to reverse-engineer the AI systems and to acquire evidence to identify non-compliance.

Or. en

Amendment 2676

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

Proposal for a regulation

Article 63 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. The procedures referred to in Articles 65, 66, 67 and 68 of this Regulation shall not apply to AI systems

related to products, to which legal acts listed in Annex II, section A apply, when such legal acts already provide for procedures having the same objective. In such a case, these sectoral procedures shall apply instead.

Or. en

Amendment 2677

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 63 – paragraph 5

Text proposed by the Commission

5. For AI systems *listed in point 1(a) in so far as the systems* are used for law enforcement purposes, *points 6 and 7 of Annex III*, Member States shall designate as market surveillance authorities for the purposes of this Regulation *either* the competent data protection supervisory authorities under Directive (EU) 2016/680, or Regulation 2016/679 *or the national competent authorities supervising the activities of the law enforcement, immigration or asylum authorities putting into service or using those systems.*

Amendment

5. For AI systems *that* are used for law enforcement purposes, Member States shall designate as market surveillance authorities for the purposes of this Regulation the competent data protection supervisory authorities under Directive (EU) 2016/680, or Regulation 2016/679.

Or. en

Amendment 2678

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

Proposal for a regulation Article 63 – paragraph 5

Text proposed by the Commission

5. For AI systems listed in point 1(a) in so far as the systems are used for law

Amendment

5. For AI systems listed in point 1(a) in so far as the systems are used for law

enforcement purposes, ***points 6 and 7 of Annex III***, Member States shall designate as market surveillance authorities for the purposes of this Regulation ***either*** the competent data protection supervisory authorities under Directive (EU) 2016/680, or Regulation 2016/679 ***or the national competent authorities supervising the activities of the law enforcement, immigration or asylum authorities putting into service or using those systems.***

enforcement purposes Member States shall designate as market surveillance authorities for the purposes of this Regulation the competent data protection supervisory authorities under Directive (EU) 2016/680 or Regulation 2016/679.

Or. en

Amendment 2679

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation Article 64 – paragraph 1

Text proposed by the Commission

1. Access to data and documentation in the context of their activities, the market surveillance authorities shall be granted full access to the training, validation and testing datasets used by the provider, including through application programming interfaces ('API') or other appropriate technical means and tools enabling remote access.

Amendment

1. ***Without prejudice to powers provided under Regulation (EU) 2019/1020, and where relevant and limited to what is necessary to fulfil their tasks, market surveillance authorities may request*** access to data and documentation in the context of their activities, the market surveillance authorities shall be granted full access to the training, validation and testing datasets used by the provider ***that are strictly necessary for the purpose of its request., including, where appropriate and subject to security safeguards,*** through application programming interfaces ('API') or other appropriate technical means and tools enabling remote access.

Or. en

Amendment 2680

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 64 – paragraph 1

Text proposed by the Commission

1. Access to data and documentation in the context of their activities, the market surveillance authorities shall be granted **full** access to **the** training, validation and testing datasets used by the provider, **including through application programming interfaces ('API') or other appropriate technical means and tools enabling remote access.**

Amendment

1. **When appropriate and proportionate, market surveillance authorities may request** access to data and documentation in the context of their activities. The market surveillance authorities shall **only** be granted, access to **those** training, **machine-learning** validation and testing datasets used by the provider **that are relevant and strictly necessary for the purpose of its request, after it has been clearly demonstrated that the data and documentation provided under paragraph 1 was not sufficient to assess conformity.**

Or. en

Amendment 2681

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 64 – paragraph 1

Text proposed by the Commission

1. Access to data and documentation in the context of their activities, the market surveillance authorities shall be granted **full** access to the training, validation and testing datasets used by the provider, including through application programming interfaces ('API') or other appropriate technical means and tools enabling remote access.

Amendment

1. Access to data and documentation in the context of their activities, the market surveillance authorities shall be granted **sufficient** access to the training, validation and testing datasets used by the provider, including through application programming interfaces ('API') or other appropriate technical means and tools enabling remote access, **taking into account the scope of access agreed with the relevant data subjects or data holders.**

Or. en

Amendment 2682

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

Proposal for a regulation
Article 64 – paragraph 1

Text proposed by the Commission

1. ***Access to data and documentation*** in the context of their activities, the market surveillance authorities shall be granted full access to the training, validation and testing datasets used by the provider, including through application programming interfaces ('API') or other appropriate technical means and tools enabling remote access.

Amendment

1. In the context of their activities, the ***national supervisory authorities, the market surveillance authorities, or the Commission,*** shall be granted full access to the training ***data sets, and where applicable,*** validation and testing datasets used by the provider ***or, where relevant, the user,*** including through application programming interfaces ('API') or other appropriate technical means and tools enabling remote access.

Or. en

Amendment 2683
Marion Walsmann

Proposal for a regulation
Article 64 – paragraph 1

Text proposed by the Commission

1. ***Access to data and documentation in the context of their activities,*** the market surveillance authorities shall be granted ***full*** access to the training, validation and testing datasets used by the provider, including through application programming interfaces ('API') or other appropriate technical means and tools enabling remote access.

Amendment

1. ***Upon a reasoned request*** the market surveillance authorities shall be granted access to the training, validation and testing datasets used by the provider, including through application programming interfaces ('API') or other appropriate technical means and tools enabling remote access.

Or. en

Amendment 2684
Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation
Article 64 – paragraph 1

Text proposed by the Commission

1. Access to data and documentation in the context of their activities, the market surveillance authorities shall be granted **full** access to the training, validation and testing datasets used by the provider, including through application programming interfaces ('API') or other appropriate technical means and tools enabling remote access.

Amendment

1. Access to data and documentation in the context of their activities, the market surveillance authorities shall be granted access to the **relevant** training, validation and testing datasets used by the provider, including through application programming interfaces ('API') or other appropriate technical means and tools enabling remote access.

Or. en

Amendment 2685

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

Proposal for a regulation

Article 64 – paragraph 1

Text proposed by the Commission

1. **Access to data and documentation** in the context of their activities, the market surveillance authorities shall be granted full access to the training, validation and testing datasets used by the provider, including through application programming interfaces ('API') or other appropriate technical means and tools enabling remote access.

Amendment

1. In the context of their activities, the market surveillance authorities shall be granted full access to the **comprehensive** training, validation and testing datasets used by the provider, including through application programming interfaces ('API') or other appropriate technical means and tools enabling remote access.

Or. en

Amendment 2686

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 64 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

I a. Providers may challenge requests through an appeal procedure made available by Member States.

Amendment 2687

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 64 – paragraph 2

Text proposed by the Commission

Amendment

2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the market surveillance authorities shall be granted access to the source code of the AI system.

deleted

Amendment 2688

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Mituță, Ramona Strugariu, Drago Pîslaru, Lucia Šuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 64 – paragraph 2

Text proposed by the Commission

Amendment

2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the market surveillance authorities shall be granted access to the source code of the AI system.

*2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2, **after all other reasonable ways to verify conformity have been exhausted and have proven to be insufficient**, and upon a reasoned request, the market surveillance authorities **or, where applicable, the Commission**, shall be granted access to the source code of the AI system. **Such access shall be subject to existing Union law on the protection of intellectual property and trade secrets.***

Amendment 2689

**Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto ,
Moritz Körner, Ondej Kováčik, Jan-Christoph Oetjen**

Proposal for a regulation

Article 64 – paragraph 2

Text proposed by the Commission

2. *Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the market surveillance authorities shall be granted access to the source code of the AI system.*

Amendment

2. Market surveillance authorities shall be granted access to the source code of the **high-risk AI system upon a reasoned request and only when the following cumulative conditions are fulfilled:**

a) Access to source code is necessary to assess the conformity of a high-risk AI system with the requirements set out in Title III, Chapter 2, and

b) testing/auditing procedures and verifications based on the data and documentation provided by the provider have been exhausted or proved insufficient.

Or. en

Amendment 2690

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

Proposal for a regulation

Article 64 – paragraph 2

Text proposed by the Commission

2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the market surveillance authorities shall be granted access to the source code of the AI system.

Amendment

2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the **national supervisory authority, the market surveillance authorities or, where applicable, the Commission** shall be granted access to the source code of the AI

system.

Or. en

Amendment 2691

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 64 – paragraph 2

Text proposed by the Commission

2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, *the market surveillance authorities shall be granted access to the source code of the AI system.*

Amendment

2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request. *AI providers or deployers shall support market surveillance authorities with the necessary facilities to carry out testing to confirm compliance.*

Or. en

Amendment 2692

Karlo Ressler

Proposal for a regulation

Article 64 – paragraph 2

Text proposed by the Commission

2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the market surveillance authorities shall *be granted access to the source code* of the AI system.

Amendment

2. Where necessary to assess the conformity of the high-risk *uses of* AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the market surveillance authorities shall *ask for the explainability of the functioning of algorithms and criteria used by an* AI system.

Or. en

Amendment 2693

Geoffroy Didier

Proposal for a regulation
Article 64 – paragraph 2

Text proposed by the Commission

2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the market surveillance authorities shall **be granted access to the source code** of the AI system.

Amendment

2. Where necessary to assess the conformity of the high-risk **uses of** AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the market surveillance authorities shall **ask for the explainability of the functioning of algorithms and criteria used by an** AI system.

Or. en

Justification

Article 64 provides the possibility for the market surveillance authority to be granted access to the source code of the AI system to assess the conformity of high-risk AI systems. This obligation is disproportionate, particularly for preventive audits, for cybersecurity reasons, especially regarding the usefulness of this process. A traceability or an explainability of the system functioning would be a better and more useful solution than an access to source code.

If it is impossible to explain all digital parameters used in the training, it is possible to audit the training algorithm, the detailed and replicable training process, the performance measure realised during the training, the performance surveillance process after implementation, variables that influenced a prediction in a precise case.

Amendment 2694

Marion Walsmann

Proposal for a regulation
Article 64 – paragraph 2

Text proposed by the Commission

2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the market surveillance authorities shall be granted access to **the source code of the AI system**.

Amendment

2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the market surveillance authorities shall be granted access to **other data if no confidential business information are at risk**.

Or. en

Amendment 2695

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

Proposal for a regulation

Article 64 – paragraph 2

Text proposed by the Commission

2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon *a reasoned* request, the market surveillance authorities shall be granted access to the source code of the AI system.

Amendment

2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon request, the market surveillance authorities shall be granted access to the source code of the AI system.

Or. en

Amendment 2696

Sophia in 't Veld, Michal Šimek

Proposal for a regulation

Article 64 – paragraph 3

Text proposed by the Commission

3. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights in relation to the use of high-risk AI systems referred to in Annex III shall have the power to request and access any documentation created or maintained under this Regulation when access to that documentation is necessary for the fulfilment of the competences under their mandate within the limits of their jurisdiction. The relevant public authority or body shall inform the market surveillance authority of the Member State concerned of any such request.

Amendment

3. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights in relation to the use of high-risk AI systems referred to in Annex III shall have the power to request and access any documentation created or maintained under this Regulation, *including data protection impact assessments and human rights impact assessments carried out by the users of such systems*, when access to that documentation is necessary for the fulfilment of the competences under their mandate within the limits of their jurisdiction. The relevant public authority or body shall inform the market surveillance authority of the Member State concerned of any such request.

Amendment 2697

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

Proposal for a regulation

Article 64 – paragraph 3

Text proposed by the Commission

3. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights in relation to the use of high-risk AI systems referred to in Annex III shall have the power to request and access any documentation created or maintained under this Regulation when access to that documentation is necessary for the fulfilment of the competences under their mandate within the limits of their jurisdiction. ***The relevant public authority or body shall inform the market surveillance authority of the Member State concerned of any such request.***

Amendment

3. National public authorities or bodies, which supervise or enforce the respect of obligations under Union law protecting fundamental rights in relation to the use of high-risk AI systems referred to in Annex III shall have the power to request and access any documentation created or maintained under this Regulation when access to that documentation is necessary for the fulfilment of the competences under their mandate within the limits of their jurisdiction.

Amendment 2698

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

Proposal for a regulation

Article 64 – paragraph 4

Text proposed by the Commission

4. By 3 months after the entering into force of this Regulation, each Member State shall identify the public authorities or bodies referred to in paragraph 3 and make a list publicly available on the website of the national supervisory authority. Member States shall notify the

Amendment

deleted

list to the Commission and all other Member States and keep the list up to date.

Or. en

Amendment 2699

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 64 – paragraph 4

Text proposed by the Commission

4. By 3 months after the entering into force of this Regulation, each Member State shall identify the public authorities or bodies referred to in paragraph 3 and make a list publicly available on the website of the national supervisory authority. Member States shall notify the list to the Commission and all other Member States and keep the list up to date.

Amendment

4. By 3 months after the entering into force of this Regulation, each Member State shall identify the public authorities or bodies referred to in paragraph 3 and make a list publicly available on the website of the national supervisory authority. Member States shall notify the list to the Commission and all other Member States and keep the list up to date. ***The European Commission shall publish in a dedicated website the list of all the Competent authorities designated by the Member States in accordance with this article.***

Or. en

Amendment 2700

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

Proposal for a regulation

Article 64 – paragraph 5

Text proposed by the Commission

5. Where the documentation referred to in paragraph 3 is insufficient to ascertain whether a breach of obligations under Union law intended to protect fundamental rights has occurred, the public authority or body referred to paragraph 3 may make a reasoned request to the market surveillance

Amendment

5. Where the documentation referred to in paragraph 3 is insufficient to ascertain whether a breach of obligations under Union law intended to protect fundamental rights has occurred, the public authority or body referred to paragraph 3 may make a reasoned request to the ***national***

authority to organise testing of the high-risk AI system through technical means. The market surveillance authority shall organise the testing with the close involvement of the requesting public authority or body within reasonable time following the request.

supervisory authority, the market surveillance authority, ***or where applicable the Commission,*** to organise testing of the high-risk AI system through technical means. The ***national supervisory authority, the*** market surveillance authority ***or where applicable the Commission*** shall organise the testing with the close involvement of the requesting public authority or body within reasonable time following the request.

Or. en

Amendment 2701

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

Proposal for a regulation Article 64 – paragraph 5

Text proposed by the Commission

5. Where the documentation referred to in paragraph 3 is insufficient to ascertain whether a breach of obligations under Union law ***intended to protect*** fundamental rights has occurred, the public authority or body referred to paragraph 3 may make a reasoned request to the market surveillance authority to organise testing of the high-risk AI system through technical means. The market surveillance authority shall organise the testing with the close involvement of the requesting public authority or body within reasonable time following the request.

Amendment

5. Where the documentation referred to in paragraph 3 is insufficient to ascertain whether a breach of obligations under Union law ***or*** fundamental rights has occurred, the public authority or body referred to paragraph 3 may make a reasoned request to the market surveillance authority to organise testing of the high-risk AI system through technical means. The market surveillance authority shall organise the testing with the close involvement of the requesting public authority or body within reasonable time following the request.

Or. en

Amendment 2702

Marion Walsmann

Proposal for a regulation Article 64 – paragraph 6

Text proposed by the Commission

6. Any information and documentation obtained by the national public authorities or bodies referred to in paragraph 3 pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.

Amendment

6. Any information and documentation obtained by **the market surveillance authorities or** the national public authorities or bodies referred to in paragraph **1, 2 and** 3 pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.

Or. en

Amendment 2703

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 64 a (new)

Text proposed by the Commission

Amendment

Article 64 a

Market surveillance authorities

1. Market surveillance authorities shall, at a minimum, have the power to

(a) carry out unannounced on-site and remote inspections of AI systems.

(b) acquire samples related to AI systems, including through remote inspections, to reverse-engineer the AI systems and to acquire evidence to identify non-compliance.

2. Member States may authorise their market surveillance authorities to reclaim from the relevant operator the totality of the costs of their activities with respect to instances of non-compliance.

3. The costs referred to in paragraph 2 of this Article may include the costs of carrying out testing, computation, hardware, storage, and the costs of activities relating to AI systems that are found to be non-compliant and are subject to corrective action prior to their placing on the market.

Amendment 2704

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

Proposal for a regulation

Article 65 – title

Text proposed by the Commission

Procedure for dealing with AI systems presenting a risk *at national level*

Amendment

Procedure for dealing with AI systems presenting a risk

Amendment 2705

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 65 – paragraph 1

Text proposed by the Commission

1. AI systems presenting a risk *shall be understood as a product presenting a risk defined in Article 3, point 19 of Regulation (EU) 2019/1020 insofar as risks to the health or safety or to the protection of fundamental rights of persons are concerned.*

Amendment

1. AI systems presenting a risk *means an AI system having the potential to affect adversely fundamental rights, health and safety of persons in general, including in the workplace, protection of consumers, the environment, public security, the values enshrined in Article 2 TEU and other public interests, that are protected by the applicable Union harmonisation legislation, to a degree which goes beyond that considered reasonable and acceptable in relation to its intended purpose or under the normal or reasonably foreseeable conditions of use of the system concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements.*

Amendment 2706

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 65 – paragraph 1

Text proposed by the Commission

1. AI systems presenting a risk shall be understood as a product presenting a risk defined in Article 3, point 19 of Regulation (EU) 2019/1020 insofar as risks to the health or safety or to the protection of fundamental rights of persons are concerned.

Amendment

1. AI systems presenting a risk shall be understood as a product presenting a risk defined in Article 3, point 19 of Regulation (EU) 2019/1020 insofar as risks to the health or safety *in general, including safety in the workplace, protection of consumers, the environment,* or to the protection of fundamental rights of persons are concerned, *including autonomy of choice, access to goods and services, unfair discrimination and economic harm, privacy and data protection, as well as societal risks.*

Or. en

Amendment 2707

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte

Proposal for a regulation

Article 65 – paragraph 1

Text proposed by the Commission

1. On entend par systèmes d'IA présentant un risque, un produit présentant un risque au sens de l'article 3, point 19, du règlement (UE) 2019/1020, dans la mesure où les risques concernent la santé ou la sécurité ou la protection des droits fondamentaux des personnes.

Amendment

1. On entend par systèmes d'IA présentant un risque, un produit présentant un risque au sens de l'article 3, point 19, du règlement (UE) 2019/1020, dans la mesure où les risques concernent la santé ou la sécurité ou la protection des droits fondamentaux des personnes, *ou l'ordre public ou la sécurité nationale des États membres.*

Or. fr

Amendment 2708

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

Proposal for a regulation**Article 65 – paragraph 1***Text proposed by the Commission*

1. AI systems presenting a risk shall be understood as *a product presenting a risk defined in Article 3, point 19 of Regulation (EU) 2019/1020 insofar as risks to the health or safety or to the protection of fundamental rights of persons are concerned.*

Amendment

1. AI systems presenting a risk shall be understood as *AI systems having the potential to affect adversely the fundamental rights of persons, their health or safety, as well as AI systems having the potential to breach the principles defined in Art. 4a or the Union values as enshrined in Article 2 TEU.*

Or. en

Amendment 2709

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

Proposal for a regulation**Article 65 – paragraph 1***Text proposed by the Commission*

1. AI systems presenting a risk shall be understood as a product presenting a risk defined in Article 3, point 19 of Regulation (EU) 2019/1020 insofar as risks to the health or safety or to *the protection of* fundamental rights of persons are concerned.

Amendment

1. AI systems presenting a risk shall be understood as a product presenting a risk defined in Article 3, point 19 of Regulation (EU) 2019/1020 insofar as risks to the health or safety or to fundamental rights of persons are concerned.

Or. en

Amendment 2710

Milan Brglez, Hilde Vautmans, Catharina Rinzema

Proposal for a regulation**Article 65 – paragraph 1 a (new)**

Text proposed by the Commission

Amendment

I a. When AI systems are likely to interact with or impact on children, the precautionary principle shall apply.

Or. en

Amendment 2711

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 65 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

I a. When AI systems are likely to interact with or impact on children, the precautionary principle shall apply.

Or. en

Amendment 2712

Milan Brglez, Hilde Vautmans, Catharina Rinzema

Proposal for a regulation

Article 65 – paragraph 2 – introductory part

Text proposed by the Commission

Amendment

2. Where the market surveillance authority of a Member State has sufficient reasons to consider that an AI system presents a risk as referred to in paragraph 1, they shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. When risks to the protection of fundamental rights are present, the market surveillance authority shall also inform the relevant national public authorities or bodies referred to in Article 64(3). The relevant operators shall cooperate as necessary with the market surveillance authorities and the other national public

2. Where the market surveillance authority of a Member State has sufficient reasons to consider that an AI system presents a risk as referred to in paragraph 1, they shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. When risks to the protection of fundamental rights are present, the market surveillance authority shall also inform the relevant national public authorities or bodies referred to in Article 64(3). **Where there is sufficient reason to consider that that an AI system exploits the vulnerabilities of children or violates their**

authorities or bodies referred to in Article 64(3).

rights intentionally or unintentionally, the market surveillance authority shall have the duty to investigate the design goals, data inputs, model selection, implementation and outcomes of the AI system and the burden of proof shall be on the operator or operators of that system to demonstrate compliance with the provisions of this Regulation. The relevant operators shall cooperate as necessary with the market surveillance authorities and the other national public authorities or bodies referred to in Article 64(3), *including by providing access to personnel, documents, internal communications, code, data samples and on platform testing as necessary. Where, in the course of its evaluation, the market surveillance authority finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe. The corrective action can also be applied to AI systems in other products or services judged to be similar in their objectives, design or impact.*

Or. en

Amendment 2713

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 65 – paragraph 2 – introductory part

Text proposed by the Commission

2. Where the market surveillance authority of a Member State has sufficient reasons to consider that an AI system presents a risk as referred to in paragraph 1, they shall carry out an evaluation of the

Amendment

2. Where the market surveillance authority of a Member State has sufficient reasons to consider that an AI system presents a risk as referred to in paragraph 1, they shall carry out an evaluation of the

AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. When risks to the protection of fundamental rights are present, the market surveillance authority shall also inform the relevant national public authorities or bodies referred to in Article 64(3). The relevant operators shall cooperate as necessary with the market surveillance authorities and the other national public authorities or bodies referred to in Article 64(3).

AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. When risks to the protection of fundamental rights are present, the market surveillance authority shall also inform the relevant national public authorities, **Board** or bodies referred to in Article 64(3). *Where there is sufficient reason to consider that that an AI system exploits the vulnerabilities of children or violates their rights intentionally or unintentionally, the market surveillance authority shall have the duty to investigate the design goals, data inputs, model selection, implementation and outcomes of the AI system and the burden of proof shall be on the operator or operators of that system to demonstrate compliance with the provisions of this Regulation.* The relevant operators shall cooperate as necessary with the market surveillance authorities and the other national public authorities or bodies referred to in Article 64(3), *including by providing access to personnel, documents, internal communications, code, data samples and on platform testing as necessary.*

Or. en

Amendment 2714

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

Proposal for a regulation

Article 65 – paragraph 2 – introductory part

Text proposed by the Commission

2. Where the market surveillance authority of a Member State has sufficient reasons to consider that an AI system presents a risk *as referred to in paragraph 1*, they shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation.

Amendment

2. Where the market surveillance authority of a Member State has sufficient reasons to consider that an AI system presents a risk *to the health and safety of persons*, they shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and

When risks to the protection of fundamental rights are present, the market surveillance authority shall also inform the relevant national public authorities or bodies referred to in Article 64(3). The relevant operators shall cooperate as necessary with the market surveillance authorities and the other national public authorities or bodies referred to in Article 64(3).

obligations laid down in this Regulation.

Or. en

Amendment 2715

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

Proposal for a regulation

Article 65 – paragraph 2 – introductory part

Text proposed by the Commission

2. Where the market surveillance authority of a Member State has sufficient reasons to consider that an AI system presents a risk as referred to in paragraph 1, they shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. When risks to *the protection of* fundamental rights are present, the market surveillance authority shall also inform the relevant national public authorities or bodies referred to in Article 64(3). The relevant operators shall cooperate as necessary with the market surveillance authorities and the other national public authorities or bodies referred to in Article 64(3).

Amendment

2. Where the market surveillance authority of a Member State has sufficient reasons to consider that an AI system presents a risk as referred to in paragraph 1, they shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. When risks to fundamental rights are present, the market surveillance authority shall also inform the relevant national public authorities or bodies referred to in Article 64(3). The relevant operators shall cooperate as necessary with the market surveillance authorities and the other national public authorities or bodies referred to in Article 64(3).

Or. en

Amendment 2716

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 65 – paragraph 2 – subparagraph 1

Text proposed by the Commission

Where, in the course of **that** evaluation, the market surveillance authority finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

Amendment

Where, in the course of **its** evaluation, the market surveillance authority finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe. ***The corrective action can also be applied to AI systems in other products or services judged to be similar in their objectives, design or impact.***

Or. en

Amendment 2717

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 65 – paragraph 2 – subparagraph 1

Text proposed by the Commission

Where, in the course of that evaluation, the market surveillance authority finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

Amendment

Where, in the course of that evaluation, the market surveillance authority ***or, where relevant, the national public authority referred to in Article 64(3)*** finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe, ***and in any case no later than 15 working days.***

Amendment 2718

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

Proposal for a regulation

Article 65 – paragraph 2 – subparagraph 1

Text proposed by the Commission

Si, au cours de cette évaluation, l'autorité de surveillance du marché constate que le système d'IA ne respecte pas les exigences et obligations énoncées dans le présent règlement, elle invite sans tarder l'opérateur concerné à prendre toutes les mesures correctives appropriées *pour mettre le système d'IA en conformité, le retirer du marché ou le rappeler* dans un délai raisonnable et proportionné à la nature du risque, qu'elle prescrit.

Amendment

Si, au cours de cette évaluation, l'autorité de surveillance du marché constate que le système d'IA ne respecte pas les exigences et obligations énoncées dans le présent règlement, elle invite sans tarder l'opérateur concerné à prendre toutes les mesures correctives appropriées, dans un délai raisonnable et proportionné à la nature du risque, *et qu'elle prescrit, pour retirer du marché ou rappeler le système d'IA afin de le mettre en conformité.*

Or. fr

Amendment 2719

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

Proposal for a regulation

Article 65 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. Where the national supervisory authority has sufficient reasons to consider that an AI system presents a risk to the protection of fundamental rights, the principles as defined in Art 4a or the Union values, as enshrined in Article 2 TEU, they shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation.

Or. en

Amendment 2720

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

Proposal for a regulation

Article 65 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2 b. Where, in the course of that evaluation, the market surveillance authority or, where relevant, the national supervisory authority finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe, and in any case no later than 15 working days.

The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the first subparagraph.

Or. en

Amendment 2721

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

Proposal for a regulation

Article 65 – paragraph 3

Text proposed by the Commission

Amendment

3. Where the market surveillance authority considers that non-compliance is not restricted to its national territory, it shall inform the Commission and the *other*

3. Where the market surveillance authority *or, where relevant, the national supervisory authority*, considers that non-compliance is not restricted to its national

Member States of the results of the evaluation and of the actions which it has required the operator to take.

territory, it shall inform the **Board, the Commission** and the Member States' **competent authorities** of the results of the evaluation and of the actions which it has required the operator to take.

Or. en

Amendment 2722

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

Proposal for a regulation

Article 65 – paragraph 3

Text proposed by the Commission

3. Where the market surveillance authority considers that non-compliance is not restricted to its national territory, it shall inform the Commission and the other Member States of the results of the evaluation and of the actions which it has required the operator to take.

Amendment

3. Where the market surveillance authority considers that non-compliance is not restricted to its national territory, it shall inform the Commission and the other Member States **without undue delay** of the results of the evaluation and of the actions which it has required the operator to take.

Or. en

Amendment 2723

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia uriaș Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation

Article 65 – paragraph 3

Text proposed by the Commission

3. Where the market surveillance authority considers that non-compliance is not restricted to its national territory, it shall inform the Commission and the other Member States of the results of the evaluation and of the actions which it has required the operator to take.

Amendment

3. Where the market surveillance authority considers that non-compliance is not restricted to its national territory, it shall inform the Commission, **the AI Office** and the other Member States of the results of the evaluation and of the actions which it has required the operator to take.

Or. en

Amendment 2724

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

Proposal for a regulation

Article 65 – paragraph 5

Text proposed by the Commission

5. Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market, to withdraw the *product* from that market or to recall it. That authority shall inform the Commission and the *other* Member States, *without delay*, of those measures.

Amendment

5. Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2*b*, the market surveillance authority *or, where relevant, the national supervisory authority*, shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market *or put into service*, to withdraw the *AI system* from that market or to recall it. That authority shall *immediately* inform the Commission, *the Board* and the Member States' *market surveillance authorities*, of those measures.

Or. en

Amendment 2725

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 65 – paragraph 5

Text proposed by the Commission

5. Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market, to withdraw the *product* from that market or to recall it. That authority shall inform the

Amendment

5. Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market *or put into service*, to withdraw the *AI system* from that market or to recall it. That

Commission and the other Member States, ***without delay***, of those measures.

authority shall ***immediately*** inform the Commission, ***the Board*** and the other Member States, of those measures.

Or. en

Amendment 2726

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

Proposal for a regulation

Article 65 – paragraph 5

Text proposed by the Commission

5. Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market, to withdraw the product from that market or to recall it. That authority shall ***inform*** the Commission and the other Member States, without delay, of those measures.

Amendment

5. Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market, to withdraw the product from that market or to recall it. That authority shall ***notify*** the Commission and the other Member States, without delay, of those measures.

Or. en



*Committee on the Internal Market and Consumer Protection
Committee on Civil Liberties, Justice and Home Affairs*

2021/0106(COD)

13.6.2022

AMENDMENTS

2727 - 3019

Draft report
Brando Benifei, Drago 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))

AM_Com_LegReport

Amendment 2727

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

Proposal for a regulation**Article 65 – paragraph 6 – introductory part**

Text proposed by the Commission

6. The **information** referred to in paragraph 5 shall include all available details, in particular the **data** necessary for the identification of the non-compliant AI system, the origin of the AI system, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to one or more of the following:

Amendment

6. The **notification** referred to in paragraph 5 shall include all available details, in particular the **information** necessary for the identification of the non-compliant AI system, the origin of the AI system, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to one or more of the following:

Or. en

Amendment 2728

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 65 – paragraph 6 – point a**

Text proposed by the Commission

(a) a failure of the AI system to meet requirements set out in **Title III, Chapter 2**;

Amendment

(a) a failure of the AI system to meet requirements **and obligations** set out in **this Regulation**;

Or. en

Amendment 2729

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation
Article 65 – paragraph 6 – point a

Text proposed by the Commission

(a) a failure of the AI system to meet requirements set out in Title III, Chapter 2;

Amendment

(a) a failure of the **high-risk** AI system to meet requirements set out in Title III, Chapter 2;

Or. en

Amendment 2730

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

Proposal for a regulation
Article 65 – paragraph 6 – point b a (new)

Text proposed by the Commission

Amendment

(b a) non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;

Or. en

Amendment 2731

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

Proposal for a regulation
Article 65 – paragraph 6 – point b b (new)

Text proposed by the Commission

Amendment

(b b) non-compliance with provisions set out in Article 52;

Or. en

Amendment 2732

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

**Proposal for a regulation
Article 65 – paragraph 7**

Text proposed by the Commission

7. Les autorités de surveillance du marché des États membres autres que l'autorité de surveillance du marché de l'État membre qui a entamé la procédure informent sans retard la Commission et les autres États membres de toute mesure adoptée et de toute information supplémentaire dont elles disposent à propos de la non-conformité du système d'IA concerné *et, en cas de désaccord avec la mesure nationale notifiée, de leurs objections.*

Amendment

7. Les autorités de surveillance du marché des États membres autres que l'autorité de surveillance du marché de l'État membre qui a entamé la procédure informent sans retard la Commission et les autres États membres de toute mesure adoptée et de toute information supplémentaire dont elles disposent à propos de la non-conformité du système d'IA concerné.

Or. fr

Justification

La mesure concernée étant justifiée par l'existence d'un risque au niveau national, risque vérifié par l'évaluation et la demande de mesures correctives initiales prévues au paragraphe 2, et étant, de toute façon, limitée dans le temps, il n'est pas nécessaire de prévoir un mécanisme d'opposition.

Amendment 2733

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

**Proposal for a regulation
Article 65 – paragraph 7**

Text proposed by the Commission

7. The market surveillance authorities of the Member States *other than the market surveillance authority of the Member State initiating the procedure* shall without delay inform the Commission and the *other Member States* of any measures adopted and of any additional information at their disposal relating to the non-compliance of the AI system concerned, and, in the event of disagreement with the notified national measure, of their objections.

Amendment

7. The market surveillance authorities *or, where applicable, the national supervisory authorities* of the *other* Member States shall without delay inform the Commission, *the Board* and the *authority initiating the procedure* of any measures adopted and of any additional information at their disposal relating to the non-compliance of the AI system concerned, and, in the event of disagreement with the notified national measure, of their objections.

Amendment 2734

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

Proposal for a regulation

Article 65 – paragraph 8

Text proposed by the Commission

Amendment

8. *Lorsque, dans les trois mois suivant la réception des informations visées au paragraphe 5, aucune objection n'a été émise par un État membre ou par la Commission à l'encontre d'une mesure provisoire prise par un État membre, cette mesure est réputée justifiée. Cette disposition est sans préjudice des droits procéduraux de l'opérateur concerné conformément à l'article 18 du règlement (UE) 2019/1020.*

supprimé

Or. fr

Justification

Même raison.

Amendment 2735

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

Proposal for a regulation

Article 65 – paragraph 8

Text proposed by the Commission

Amendment

8. Where, within three months of receipt of the *information* referred to in paragraph 5, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified. This is without prejudice to the procedural rights of the concerned operator in accordance

8. Where, within three months of receipt of the *notification* referred to in paragraph 5, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified. This is without prejudice to the procedural rights of the concerned operator in accordance

with Article 18 of Regulation (EU) 2019/1020.

with Article 18 of Regulation (EU) 2019/1020. *The period referred to in the first sentence of this paragraph shall be reduced to 30 days in the case of non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5.*

Or. en

Amendment 2736

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

Proposal for a regulation Article 65 – paragraph 8

Text proposed by the Commission

8. Where, within three months of receipt of the information referred to in paragraph 5, no objection has been raised by either a **Member State** or the Commission in respect of a provisional measure taken by a **Member State**, that measure shall be deemed justified. This is without prejudice to the procedural rights of the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020.

Amendment

8. Where, within three months of receipt of the information referred to in paragraph 5, no objection has been raised by either a **market surveillance authority**, **a national supervisory authority**, or the Commission in respect of a provisional measure taken by a **market surveillance authority or a national supervisory authority**, that measure shall be deemed justified. This is without prejudice to the procedural rights of the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020.

Or. en

Amendment 2737

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

Proposal for a regulation Article 65 – paragraph 9

Text proposed by the Commission

9. The market surveillance authorities of all Member States shall ensure that

Amendment

9. The market surveillance authorities of all Member States shall ensure that

appropriate restrictive measures are taken in respect of the **product** concerned, such as withdrawal of the product from their market, without delay.

appropriate restrictive measures are taken in respect of the **AI system** concerned, such as withdrawal of the product from their market, without delay.

Or. en

Amendment 2738

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

Proposal for a regulation

Article 66

Text proposed by the Commission

Amendment

Article 66

supprimé

Procédure de sauvegarde de l'Union

1. Lorsque, dans un délai de trois mois suivant la réception de la notification visée à l'article 65, paragraphe 5, un État membre soulève des objections à l'encontre d'une mesure prise par un autre État membre ou que la Commission estime que cette mesure est contraire au droit de l'Union, la Commission entame sans tarder des consultations avec l'État membre et le ou les opérateurs concernés et procède à l'évaluation de la mesure nationale. En fonction des résultats de cette évaluation, la Commission décide si la mesure nationale est justifiée ou non dans un délai de 9 mois suivant la notification visée à l'article 65, paragraphe 5, et communique sa décision à l'État membre concerné.

2. Si la mesure nationale est jugée justifiée, tous les États membres prennent les mesures nécessaires pour s'assurer du retrait du système d'IA non conforme de leur marché et ils en informent la Commission. Si la mesure nationale est jugée non justifiée, l'État membre concerné la retire.

3. Lorsque la mesure nationale est jugée justifiée et que la non-conformité du

système d'IA est attribuée à des lacunes dans les normes harmonisées ou dans les spécifications communes visées aux articles 40 et 41 du présent règlement, la Commission applique la procédure prévue à l'article 11 du règlement (UE) n° 1025/2012.

Or. fr

Justification

Même raison.

Amendment 2739

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

**Proposal for a regulation
Article 66 – paragraph 1**

Text proposed by the Commission

1. Where, within three months of receipt of the notification referred to in Article 65(5), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall without delay enter into consultation with the relevant Member *State* and operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not within 9 months from the notification referred to in Article 65(5) and notify such decision to the Member State concerned.

Amendment

1. Where, within three months of receipt of the notification referred to in Article 65(5), *or 30 days in the case of non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5*, objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall without delay enter into consultation with the relevant Member *State's market surveillance authority* and operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not within 9 months, *or 60 days in the case of non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5, starting* from the notification referred to in Article 65(5) and notify such decision to the Member State concerned. *The Commission shall also inform all other*

Member States of such decision.

Or. en

Amendment 2740

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 66 – paragraph 1

Text proposed by the Commission

1. Where, within three months of receipt of the notification referred to in Article 65(5), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall without delay enter into consultation with the relevant Member State and operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not within 9 months from the notification referred to in Article 65(5) and notify such decision to the Member State concerned.

Amendment

1. Where, within three months of receipt of the notification referred to in Article 65(5), objections are raised by ***the European Parliament or*** a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, ***or has sufficient reasons to believe that an AI system presents a risk or affects consumers in more than one Member State*** the Commission shall without delay enter into consultation with the relevant Member State and operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not within 9 months from the notification referred to in Article 65(5) and notify such decision to the Member State concerned.

Or. en

Amendment 2741

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

Proposal for a regulation

Article 66 – paragraph 1

Text proposed by the Commission

1. Where, within three months of receipt of the notification referred to in

Amendment

1. Where, within three months of receipt of the notification referred to in

Article 65(5), objections are raised by a Member State against a measure taken by another Member State, or where the **Commission** considers the measure to be contrary to Union law, the **Commission** shall without delay enter into consultation with the relevant Member State and operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the **Commission** shall decide whether the national measure is justified or not within 9 months from the notification referred to in Article 65(5) and notify such decision to the Member State concerned.

Article 65(5), objections are raised by a Member State against a measure taken by another Member State, or where the **Board** considers the measure to be contrary to Union law, the **Board** shall without delay enter into consultation with the relevant Member State and operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the **Board** shall decide whether the national measure is justified or not within 9 months from the notification referred to in Article 65(5) and notify such decision to the Member State concerned.

Or. en

Amendment 2742

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

Proposal for a regulation Article 66 – paragraph 2

Text proposed by the Commission

2. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant AI system is withdrawn from their market, and shall inform the **Commission** accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.

Amendment

2. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant AI system is withdrawn from their market, and shall inform the **Board** accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.

Or. en

Amendment 2743

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation Article 66 – paragraph 3

Text proposed by the Commission

3. Where the national measure is considered justified and the non-compliance of the AI system is attributed to shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

Amendment

3. Where the national measure is considered justified and the non-compliance of the AI system is attributed to shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.*The Commission shall also have the possibility to suggest alternative measures to the Member State concerned.*

Or. en

Amendment 2744

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 66 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. If the national measure is found to be unjustified, the Member State concerned shall reimburse the operator for the costs and loss of revenue directly attributable to the measure found to be unjustified.

Or. en

Amendment 2745

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 66 a (new)

Text proposed by the Commission

Amendment

Article 66 a

Requests for Commission intervention

- 1. Where market surveillance authorities have reasons to suspect that the infringement of a provider or of a user of a high-risk AI system to this Regulation is liable to compromise the health or safety or fundamental of affected persons, the environment and the Union values enshrined in Article 2 TEU amount to a widespread infringement or a widespread infringement with a Union dimension or affects or is likely affect at least 45 million citizens in the Union. The market surveillance authority may request the Commission to take the necessary investigatory and enforcement measures to ensure compliance with this Regulation. Such request shall set out the reasons for the Commission to intervene.*
- 2. Prior to requesting the Commission to intervene, the market surveillance authority shall notify the Board which shall issue within 7 days a non-binding opinion on the request for the Commission to intervene. The market surveillance authority shall take into account the non-binding opinion of the Board before sending its request to the Commission.*

Or. en

Amendment 2746

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 67**

Text proposed by the Commission

Article 67

Amendment

deleted

Compliant AI systems which present a risk

1. Where, having performed an evaluation under Article 65, the market surveillance authority of a Member State finds that

although an AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons, to the compliance with obligations under Union or national law intended to protect fundamental rights or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The provider or other relevant operators shall ensure that corrective action is taken in respect of all the AI systems concerned that they have made available on the market throughout the Union within the timeline prescribed by the market surveillance authority of the Member State referred to in paragraph 1.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.

5. The Commission shall address its decision to the Member States.

Or. en

Amendment 2747

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

Proposal for a regulation

Article 67 – title

Text proposed by the Commission

Compliant AI systems which present a risk

Amendment

Compliant AI systems which present a risk
to the health and safety

Or. en

Amendment 2748

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 67 – paragraph 1

Text proposed by the Commission

1. Where, having performed an evaluation under Article 65, the market surveillance authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons, to the compliance with obligations under Union or national law intended to protect fundamental rights *or to other aspects of public interest protection*, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, *to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.*

Amendment

1. Where, having performed an evaluation under Article 65, the market surveillance authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons *or* to the compliance with obligations under Union or national law intended to protect fundamental rights, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk

Or. en

Amendment 2749

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 67 – paragraph 1

Text proposed by the Commission

1. Where, having performed an evaluation under Article 65, the market surveillance authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons, to the compliance with obligations under Union or national law intended to protect fundamental rights or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

Amendment

1. Where, having performed an evaluation under Article 65 ***in full cooperation with the relevant national public authority referred to in Article 64(3)***, the market surveillance authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons, to the compliance with obligations under Union or national law intended to protect fundamental rights, ***environment, European values as enshrined in Article 2 TEU*** or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

Or. en

Amendment 2750

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

Proposal for a regulation

Article 67 – paragraph 1

Text proposed by the Commission

1. Where, having performed an evaluation under Article 65, the market surveillance authority of a Member State

Amendment

1. Where, having performed an evaluation under Article 65, the market surveillance authority of a Member State

finds that although an AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons, ***to the compliance with obligations under Union or national law intended to protect fundamental rights or to other aspects of public interest protection***, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

finds that although an AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

Or. en

Amendment 2751

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation Article 67 – paragraph 1

Text proposed by the Commission

1. Where, having performed an evaluation under Article 65, the market surveillance authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons, ***to the compliance with obligations under Union or national law intended to protect fundamental rights or to other aspects of public interest protection***, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

Amendment

1. Where, having performed an evaluation under Article 65, the market surveillance authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons ***or to*** fundamental rights, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

Amendment 2752

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 67 – paragraph 1

Text proposed by the Commission

1. Where, having performed an evaluation under Article 65, the market surveillance authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons, to the compliance with obligations under Union or national law intended to protect fundamental rights or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

Amendment

1. Where, having performed an evaluation under Article 65, the market surveillance authority of a Member State finds **and demonstrates** that although an AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons, to the compliance with obligations under Union or national law intended to protect fundamental rights or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

Amendment 2753

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Mituță, Ramona Strugariu, Drago Pîslaru, Lucia Šuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 67 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. Should the provider or other relevant operators fail to take corrective action as referred to in paragraph 2 and should the AI system continue to present a

risk as referred to in paragraph 1, the market surveillance authority may require the relevant operator, as a measure of last resort, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk.

Or. en

Amendment 2754

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

**Proposal for a regulation
Article 67 – paragraph 3**

Text proposed by the Commission

3. The **Member State** shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.

Amendment

3. The **market surveillance authority** shall immediately inform the Commission, **the Board** and the other Member States' **market surveillance authorities**. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.

Or. en

Amendment 2755

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Mită, Ramona Strugariu, Drago Pîslaru, Lucia Šuriš Nicholsonová, Irena Joveva, Alin Mituță

**Proposal for a regulation
Article 67 – paragraph 3**

Text proposed by the Commission

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in

Amendment

3. The Member State shall immediately inform the Commission, **the AI Office**, and the other Member States. That information shall include all available

particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.

details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.

Or. en

Amendment 2756

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

Proposal for a regulation Article 67 – paragraph 3

Text proposed by the Commission

3. The Member State shall immediately inform the **Commission** and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.

Amendment

3. The Member State shall immediately inform the **Board** and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.

Or. en

Amendment 2757

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

Proposal for a regulation Article 67 – paragraph 4

Text proposed by the Commission

4. La Commission entame sans retard des consultations avec les États membres et l'opérateur concerné et évalue les mesures nationales prises. En fonction des résultats de cette évaluation, la Commission **décide si la mesure est justifiée ou non et, si**

Amendment

4. La Commission entame sans retard des consultations avec les États membres et l'opérateur concerné et évalue les mesures nationales prises. En fonction des résultats de cette évaluation, la Commission propose des mesures appropriées.

nécessaire, propose des mesures appropriées.

Or. fr

Amendment 2758

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

Proposal for a regulation

Article 67 – paragraph 4

Text proposed by the Commission

4. The Commission shall without delay enter into consultation with the Member States and the relevant operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.

Amendment

4. The Commission shall without delay enter into consultation with the Member States **concerned** and the relevant operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.

Or. en

Amendment 2759

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

Proposal for a regulation

Article 67 – paragraph 4

Text proposed by the Commission

4. The Commission shall without delay enter into consultation with the **Member States** and the relevant operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.

Amendment

4. The Commission shall without delay enter into consultation with the **market surveillance authorities** and the relevant operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.

Or. en

Amendment 2760

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

Proposal for a regulation

Article 67 – paragraph 4

Text proposed by the Commission

4. The **Commission** shall without delay enter into consultation with the Member States and the relevant operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the **Commission** shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.

Amendment

4. The **Board** shall without delay enter into consultation with the Member States and the relevant operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the **Board** shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.

Or. en

Amendment 2761

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

Proposal for a regulation

Article 67 – paragraph 5

Text proposed by the Commission

5. The Commission shall address its decision to the **Member States**.

Amendment

5. The Commission shall address its decision to the **market surveillance authorities and communicate it to them and to the relevant operators**.

Or. en

Amendment 2762

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

Proposal for a regulation

Article 67 – paragraph 5

Text proposed by the Commission

5. The Commission shall address its decision to the Member States.

Amendment

5. The Commission shall address its decision to the Member States ***concerned, and inform all other Member States.***

Or. en

Amendment 2763

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

Proposal for a regulation

Article 67 – paragraph 5

Text proposed by the Commission

5. The **Commission** shall address its decision to the Member States.

Amendment

5. The **Board** shall address its decision to the Member States.

Or. en

Amendment 2764

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

Proposal for a regulation

Article 67 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. The Board shall adopt guidelines to help national competent authorities to identify and rectify, where necessary, similar problems arising in other AI systems.

Or. en

Amendment 2765

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

Proposal for a regulation

Article 67 a (new)

Text proposed by the Commission

Amendment

Article 67 a

Compliant AI systems which present a risk to the fundamental rights

- 1. Where, having performed an evaluation under Article 65, the national supervisory authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a risk to the compliance with obligations under Union or national law intended to protect fundamental rights, the principles of Article 4a, the values as enshrined in Article 2 TEU, the environment, or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.***
- 2. The provider or other relevant operators shall ensure that corrective action is taken in respect of all the AI systems concerned that they have made available on the market throughout the Union within the timeline prescribed by the national supervisory authority of the Member State referred to in paragraph 1.***
- 3. The national supervisory authority shall immediately inform the Board, the Commission and the market surveillance authority. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.***
- 4. The Board shall without delay enter into consultation with the relevant operator and shall evaluate the national***

measures taken. On the basis of the results of that evaluation, the Board shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.

5. The Board shall address its decision to the national supervisory authority and to the relevant operators.

Or. en

Amendment 2766

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 68 – paragraph 1 – point b

Text proposed by the Commission

(b) the *conformity* marking has not been affixed;

Amendment

(b) the *CE* marking has not been affixed;

Or. en

Amendment 2767

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

Proposal for a regulation

Article 68 – paragraph 2

Text proposed by the Commission

2. Si le cas de non-conformité visé au paragraphe 1 persiste, l’État membre concerné prend toutes les mesures appropriées pour restreindre ou interdire la mise à disposition du système d’IA à haut risque sur le marché ou pour assurer son rappel ou son retrait du marché.

Amendment

2. Si le cas de non-conformité visé au paragraphe 1 persiste *au-delà d'une semaine après la réception de l'invitation*, l’État membre concerné prend toutes les mesures appropriées pour restreindre ou interdire la mise à disposition du système d’IA à haut risque sur le marché ou pour assurer son rappel ou son retrait du marché, *et lui inflige, le cas échéant, les sanctions prévues par le droit national*.

Or. fr

Amendment 2768**Axel Voss, Deirdre Clune, Eva Maydell****Proposal for a regulation****Article 68 – paragraph 2***Text proposed by the Commission*

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take *all appropriate* measures to restrict or prohibit the high-risk AI system being made available on the market *or ensure that it is recalled or withdrawn from the market.*

Amendment

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take *proportionate* measures to restrict or prohibit the high-risk AI system being made available on the market.

Or. en

Amendment 2769**Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ondej Kovařík, Jan-Christoph Oetjen****Proposal for a regulation****Article 68 – paragraph 2***Text proposed by the Commission*

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the high-risk AI system being made available on the market or ensure that it is recalled or withdrawn from the market.

Amendment

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate *and proportionate* measures to restrict or prohibit the high-risk AI system being made available on the market or ensure that it is recalled or withdrawn from the market.

Or. en

Amendment 2770**René Repasi, Marc Angel, Andreas Schieder****Proposal for a regulation****Article 68 a (new)***Text proposed by the Commission**Amendment*

Article 68 a

Insufficient application or non-application of Union law by the competent authority

1. Where a competent authority has failed to ensure that an AI system is in compliance with the requirements laid down in this Regulation, or where a competent authority fails to require sufficient corrective action from an operator of an AI system that is in compliance with this Regulation but presents a risk to the health or safety of persons, to the compliance with obligations under Union or national law intended to protect fundamental rights or to other aspects of public interest protection, the Commission shall act in accordance with the powers set out in the following paragraphs of this Article.

2. Upon request from one or more competent authorities, the European Parliament, the Council, the European Artificial Intelligence Board, or on its own initiative, including when this is based on well substantiated information from natural or legal persons, and after having informed the competent authority concerned, the Commission shall outline how it intends to proceed with the case and, where appropriate, investigate the alleged insufficient application or non-application of Union law.

The competent authority shall, without delay, provide the Commission with all information which the Commission considers necessary for its investigation.

The Commission may, after having informed the competent authority concerned, address a duly justified and reasoned request for information directly to other competent authorities whenever requesting information from the competent authority concerned has proven, or is deemed to be, insufficient to obtain the information that is deemed necessary for the purpose of investigating an alleged insufficient application or non-

application of Union law. The addressee of such a request shall provide the Commission with clear, accurate and complete information without undue delay.

Before issuing a recommendation as set out in paragraph 4, the Commission shall engage with the competent authority concerned where it considers such engagement appropriate in order to resolve the insufficient application or non-application of Union law, in an attempt to reach agreement on actions necessary for the competent authority to comply with Union law.

3. Where necessary to issue a recommendation as set out in paragraph 4, the Commission shall have the rights granted to the market surveillance authorities under Article 64.

4. The Commission may, not later than 2 months from initiating its investigation, address a recommendation to the competent authority concerned setting out the action necessary to comply with Union law. The competent authority shall, within ten working days of receipt of the recommendation, inform the Commission of the steps it has taken or intends to take to ensure compliance with Union law.

5. Where the competent authority has not complied with Union law within 1 month from receipt of the Commission's recommendation, the Commission may issue a formal opinion requiring the competent authority to take the action necessary to comply with Union law. The Commission shall issue such a formal opinion no later than 3 months after the adoption of the recommendation set out in paragraph 4. The Commission may extend this period by 1 month.

6. The competent authority shall, within ten working days of receipt of the formal opinion referred to in paragraph 5, inform the Commission of the steps it has taken or intends to take to comply with that

formal opinion.

7. Without prejudice to the powers of the Commission pursuant to Article 258 TFEU, where a competent authority does not comply with the formal opinion referred to in paragraph 5 of this Article within the period specified therein, the Commission may adopt an individual decision addressed to the operator of an AI system requiring it to take all necessary action to comply with its obligations under Union law.

The decision of the Commission shall be in conformity with the formal opinion issued pursuant to paragraph 5.

8. Decisions adopted in accordance with paragraph 7 shall prevail over any previous decision adopted by the competent authorities on the same matter. When taking action in relation to issues which are subject to a formal opinion pursuant to paragraph 5 or to a decision pursuant to paragraph 7, competent authorities shall comply with the formal opinion or the decision, as the case may be.

Or. en

Justification

The amendment, that drives inspiration from the ESMA Regulation, intends to solve the situation where a competent authority does not take action to impede an operator of an AI system from failing to comply to this Regulation by granting the Commission the right to intervene in order to order the operator to comply with its obligations under this Regulation.

Amendment 2771

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

Proposal for a regulation Article 68 a (new)

Text proposed by the Commission

Amendment

Article 68 a

Right to lodge a complaint with a supervisory authority

- 1. Without prejudice to any other administrative or judicial remedy, AI subjects and any natural or legal person affected by an AI system shall have the right to lodge a complaint with a supervisory authority, in particular in the Member State of his or her habitual residence, place of work or place of the alleged infringement if the subject considers that the use of a particular AI system, he or she is affected by, infringes this Regulation. Such a complaint may be lodged through a representative action for the protection of the collective interests of consumers as provided under Directive (EU) 2020/1828.***
- 2. Complainants shall have a right to be heard in the complaint handling procedure and in the context of any investigations or deliberations conducted by the competent authority as a result of their complaint.***
- 3. Supervisory authorities shall inform complainants or their representatives about the progress and outcome of their complaints. In particular, supervisory authorities shall take all the necessary actions to follow up on the complaints they receive and, within three months of the reception of a complaint, give the complainants a preliminary response indicating the measures they intend to take and the next steps in the procedure, if any.***
- 4. The supervisory authority shall take a decision on the complaint, including the possibility of a judicial remedy pursuant to Article 68b, without delay and no later than six months after the date on which the complaint was lodged.***

Or. en

Amendment 2772

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 68 a (new)

Text proposed by the Commission

Amendment

Article 68 a

Right to lodge a complaint with a supervisory authority

1. Without prejudice to any other administrative or judicial remedy, every natural or legal person shall have the right to lodge a complaint with a supervisory authority, in particular in the Member State of his or her habitual residence, place of work or place of the alleged infringement if the natural or legal person considers that their health, safety, or fundamental rights have been breached by an AI system falling within the scope of this Regulation.

2. Natural or legal persons shall have a right to be heard in the complaint handling procedure and in the context of any investigations conducted by the national supervisory authority as a result of their complaint.

3. The national supervisory authority with which the complaint has been lodged shall inform the complainants about the progress and outcome of their complaint. In particular, the national supervisory authority shall take all the necessary actions to follow up on the complaints it receives and, within three months of the reception of a complaint, give the complainant a preliminary response indicating the measures it intends to take and the next steps in the procedure, if any.

4. The national supervisory authority shall take a decision on the complaint and inform the complainant on the progress and the outcome of the complaint, including the possibility of a judicial

remedy pursuant to Article 68b, without delay and no later than six months after the date on which the complaint was lodged.

Or. en

Amendment 2773

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

Proposal for a regulation

Article 68 a (new)

Text proposed by the Commission

Amendment

Article 68 a

Right to lodge a complaint

1. Affected persons, affected by an AI system falling within the scope of this Regulation, shall have the right to lodge a complaint against the providers or users of such AI system, with the national supervisory authority of the Member State where they have their habitual place of residence or place of work or where the alleged infringement took place, if they consider that their fundamental rights, health or safety have been breached.

2. Affected persons shall have a right to be heard in the complaint handling procedure and in the context of any investigations conducted by the national supervisory authority as a result of their complaint.

3. The national supervisory authority with which the complaint has been lodged shall inform the complainants about the progress and outcome of their complaint. In particular, the national supervisory authority shall take all the necessary actions to follow up on the complaints it receives and, within three months of the reception of a complaint, give the complainant a preliminary response indicating the measures it intends to take

and the next steps in the procedure, if any.

4. The national supervisory authority shall take a decision on the complaint, without delay and no later than six months after the date on which the complaint was lodged.

Or. en

Amendment 2774

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

Proposal for a regulation

Article 68 a (new)

Text proposed by the Commission

Amendment

Article 68 a

Representation of affected persons and the right of public interest organisation to lodge complaints

1. Without prejudice to Directive 2020/1828/EC, natural persons or groups of natural persons affected by an AI system shall have the right to mandate a body, organisation or association to lodge a complaint referred to in Article 68 on their behalf, to exercise the right to remedy referred to in Article 68 on their behalf, and to exercise on their behalf other rights under this Regulation, in particular the right to receive an explanation referred to in Article 4a

2. Without prejudice to Directive 2020/1828/EC, the bodies, organisations or associations referred to in paragraph 1 shall have the right to lodge a complaint with national supervisory authorities, independently of the mandate of the natural person, if they consider that an AI system has been placed on the market, put into service, or used in a way that infringes this Regulation, or is otherwise in violation of fundamental rights or

other aspects of public interest protection, pursuant to article 67.

3. National supervisory authorities have the duty to investigate, in conjunction with relevant market surveillance authority if applicable, and respond within a reasonable period to all complaints referred to in paragraph 2.

Or. en

Amendment 2775

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 68 a (new)

Text proposed by the Commission

Amendment

Article 68 a

Commission fees

1. The Commission shall charge fees to market surveillance authorities when the Commission initiates proceedings in accordance with Article 68a(1)(c).

2. The overall amount of the fee shall cover the estimated costs the Commission incurs in relation to proceedings carried out under this Regulation, in particular costs related to the investigation and enforcement measures pursuant to Chapter 4 of Title VIII.

3. The Commission shall lay down in a delegated act, adopted pursuant to Article 73, the detailed methodology and procedures for:(a) the determination of the estimated costs referred to in paragraph 2 and the necessary payment modalities.

4. The fees charged pursuant to paragraph 1 shall constitute external assigned revenue in accordance with Article 21(5) of Regulation (EU,

Euratom) No 2018/1046 of the European Parliament and of the Council.

5. The Commission shall report annually to the European Parliament and to the Council on the overall amount of the costs incurred for the fulfilment of the tasks under this Regulation and the total amount of the fees charged in the preceding year.

Or. en

Justification

To complement the new enforcement mechanism at EU level proposed in the draft report, a new source of financing is needed in order to insure the proper implementation of such mechanism.

Amendment 2776

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 68 a (new)

Text proposed by the Commission

Amendment

Article 68 a

Right to lodge a complaint with a supervisory authority

- 1. Citizens have a right not to be subjected to prohibited AI systems.*
- 2. Citizens have a right not to be subjected to high-risk AI systems that fail to meet the requirements for high-risk systems.*
- 3. Without prejudice to any other administrative or judicial remedy, every citizen shall have the right to lodge a complaint with a supervisory authority, in particular in the Member State of his or her habitual residence, place of work or place of the alleged infringement if the citizen considers that he or she has been subjected to an AI system that infringes this Regulation.*
- 4. The supervisory authority with which the complaint has been lodged shall*

*inform the complainant on the progress
and the outcome of the complaint.*

*5. Without prejudice to any other
administrative or non-judicial remedy,
each natural or legal person shall have
the right to an effective judicial remedy
against a legally binding decision*

Or. en

Amendment 2777

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 68 a (new)

Text proposed by the Commission

Amendment

Article 68 a

*Right to lodge a complaint with a
supervisory authority*

*1. Every citizen who considers that his or
her right to protection of personal data
has been infringed by the use of a
prohibited AI system or a high-risk AI
system shall have the right to lodge a
complaint with the authority in charge to
handle complaints under Article 77 of
Regulation (EU) 2016/679 in the Member
State of his or her habitual residence,
place of work or place of the alleged
infringement.*

*2. The supervisory authority with which
the complaint has been lodged shall
inform the complainant on the progress
and the outcome of the complaint.*

Or. en

Amendment 2778

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

Proposal for a regulation

Article 68 b (new)

Text proposed by the Commission

Amendment

Article 68 b

Representation of affected persons

1. An affected person shall have the right to mandate a not-for-profit body, organisation or association that has been properly constituted in accordance with the law of a Member State, has statutory objectives which are in the public interest, and is active in the field of the protection of rights and freedoms of affected persons, with regard to the protection of their fundamental rights, to lodge the complaint on their behalf, to exercise the rights referred to in Article 68a on his or her behalf, and to exercise the right to receive compensation referred to in Article 70a and 71 on his or her behalf.

2. Any body, organisation or association referred to in paragraph 1 of this Article, independently of an affected person's mandate, has the right to lodge, in that Member State, a complaint with the national supervisory authority which is competent pursuant to Article 68a, if it considers that the rights of a affected persons under this Regulation have been infringed as a result of them being subject to AI systems.

Or. en

Amendment 2779

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Samira Rafaela, Monica Semedo, Salima Yenbou, Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 68 b (new)

Text proposed by the Commission

Amendment

Article 68 b

*Right to an effective judicial remedy
against a national supervisory authority*

- 1. Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to an effective judicial remedy against a legally binding decision of a national supervisory authority concerning them.*
- 2. Without prejudice to any other administrative or non-judicial remedy, each data subject shall have the right to a an effective judicial remedy where the national supervisory authority does not handle a complaint, does not inform the complainant on the progress or preliminary outcome of the complaint lodged within three months pursuant to Article 68a(3) or does not comply with its obligation to reach a final decision on the complaint within six months pursuant to Article 68a(4) or its obligations under Article 65.*
- 3. Proceedings against a supervisory authority shall be brought before the courts of the Member State where the national supervisory authority is established.*

Or. en

Amendment 2780

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

Proposal for a regulation
Article 68 b (new)

Text proposed by the Commission

Amendment

Article 68 b

*Right to an effective judicial remedy
against an authority*

- 1. Without prejudice to any other administrative or non-judicial remedy, individuals and their representatives shall*

have the right to an effective judicial remedy against any legally binding decision concerning them, whether by a market surveillance authority or a supervisory authority.

2. Without prejudice to any other administrative or non-judicial remedy, individuals shall have the right to an effective judicial remedy where the authority which is competent does not handle a complaint, does not inform the individual on the progress or preliminary outcome of the complaint lodged within three months pursuant to Article 68a (3), does not comply with its obligation to reach a final decision on the complaint within six months pursuant to Article 68a (3) or its obligations under Article 65.

3. Proceedings against a market surveillance authority shall be brought before the courts of the Member State where the authority is established.

Or. en

Amendment 2781

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 68 b (new)

Text proposed by the Commission

Amendment

Article 68 b

Representation of affected persons or groups of persons

1. Without prejudice to Directive 2020/1828/EC, the person or groups of persons harmed by AI systems shall have the right to mandate a not-for-profit body, organisation or association which has been properly constituted in accordance with the law of a Member State, has statutory objectives which are in the

public interest, and is active in the field of the protection of rights and freedoms impacted by AI to lodge the complaint on his, her or their behalf, to exercise the rights referred to in this Regulation on his, her or their behalf.

2. Without prejudice to Directive 2020/1828/EC, the body, organisation or association referred to in paragraph 1 shall have the right to exercise the rights established in this Regulation independently of a mandate by a person or groups of person if it considers that a provider or a user has infringed any of the rights or obligations set out in this Regulation.

Or. en

Amendment 2782

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

Proposal for a regulation

Article 68 c (new)

Text proposed by the Commission

Amendment

Article 68 c

Remedies

1. Without prejudice to any available administrative or non-judicial remedy and the right to lodge a complaint with a supervisory authority pursuant to Article 68a, any natural person shall have the right to an effective judicial remedy against a provider or deployer where they consider that their rights under this Regulation have been infringed or has been subject to an AI system otherwise in non-compliance with this Regulation.

2. Any person who has suffered material or non-material harm, as a result of an infringement of this Regulation shall have the right to receive compensation from the provider or deployer for the damage

suffered. Individuals and their representatives shall be able to seek judicial and non-judicial remedies against providers or deployers of AI systems, including repair, replacement, price reduction, contract termination, reimbursement of the price paid or compensation for material and immaterial damages, for breaches of the rights and obligations set out in this Regulation.

3. Providers and deployers of AI systems which may affect individuals, including AI-subjects, or consumers must provide an effective complaint handling system which enables complaints to be lodged electronically and free of charge, and ensure that complaints submitted through this system are dealt with in an efficient and expedient manner.

4. Providers and deployers of AI systems shall ensure that their internal complaint-handling systems are easy to access, user-friendly and enable and facilitate the submission of sufficiently precise and adequately substantiated complaints.

5. Where an AI system infringes this Regulation, any natural or legal person affected by said AI system may ask the supervisory authority or judicial authorities to stop the use of this system.

6. Member States shall ensure that where infringements of an AI system are imminent or likely, any affected natural or legal person may seek a prohibitory injunction under national law.

Or. en

Amendment 2783

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 68 c (new)

Text proposed by the Commission

Amendment

Article 68 c

Amendment to Directive 2020/1828/EC on Representative Actions for the Protection of the Collective Interests of Consumers

The following is added to Annex I of Directive 2020/1828/EC on Representative actions for the protection of the collective interests of consumers: “Regulation xxxx/yyyy of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (artificial intelligence act) and amending certain union legislative acts”.

Or. en

Amendment 2784

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

Proposal for a regulation

Article 68 d (new)

Text proposed by the Commission

Amendment

Article 68 d

Representation of individuals

1. Without prejudice to Directive 2020/1828/EC, individuals shall have the right to mandate a body, organisation or association to exercise the rights referred to in Articles 68a, 68b and 68c and, where relevant, the rights of AI subjects, on their behalf, provided that the body, organisation or association meets all of the following conditions:

- a) It operates on a not-for-profit basis;***
- b) It has been constituted in accordance of the law of a Member State;***
- c) Its statutory objectives include a legitimate interest in ensuring that this Regulation is complied with.***

2. Without prejudice to Directive 2020/1828/EC, the bodies, organisations or associations referred to in paragraph 1 shall have the right to exercise the rights established in Articles 68a, 68b and 68c independently of an individual's mandate, if they consider that a provider or user of an AI system has infringed any of the rights or obligations set out in this Regulation.

Or. en

Amendment 2785

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 68 d (new)

Text proposed by the Commission

Amendment

Article 68 d

Reporting of breaches and protection of reporting persons

Directive (EU) 2019/1937 of the European Parliament and of the Council shall apply to the reporting of breaches of this Regulation and the protection of persons reporting such breaches.

Or. en

Amendment 2786

Drago Tudorache

Proposal for a regulation

Article 69 – paragraph 1

Text proposed by the Commission

Amendment

1. The Commission and the Member States shall encourage and facilitate the drawing up of codes of conduct intended to

1. The Commission, *AI Office*, and the Member States shall encourage and facilitate the drawing up of codes of

foster the *voluntary application to AI* systems other than high-risk AI systems *of* the requirements set out in Title III, Chapter 2 on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems.

conduct intended to foster the *development and use of safe and trustworthy AI for* AI systems other than high-risk AI systems. *These codes of conduct should be voluntary and should be based on* the requirements set out in Title III, Chapter 2 on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements *but be adapted* in light of the intended purpose of the systems *and of the lower risk involved*

Or. en

Amendment 2787

Svenja Hahn, Drago Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation Article 69 – paragraph 1

Text proposed by the Commission

1. The Commission and the *Member States* shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to AI systems other than high-risk AI systems of the requirements set out in Title III, Chapter 2 on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems.

Amendment

1. The Commission and the *board* shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to AI systems other than high-risk AI systems of the requirements set out in Title III, Chapter 2 on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems.

Or. en

Amendment 2788

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation Article 69 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

I a. The Commission and the Board shall encourage and facilitate the drawing up of Codes of Conduct intended to foster the voluntary application of the concept of trustworthy AI set out in Article 4(a) to AI systems other than high-risk AI systems on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the system.

Or. en

Amendment 2789

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

Proposal for a regulation

Article 69 – paragraph 2

Text proposed by the Commission

2. La Commission et le Comité encouragent et facilitent l’élaboration de codes de conduite destinés à favoriser l’application volontaire aux systèmes d’IA d’exigences liées, par exemple, à la viabilité environnementale, à l’accessibilité pour les personnes handicapées, à la participation des parties prenantes à la conception et au développement des systèmes d’IA *et à la diversité des équipes de développement* sur la base d’objectifs clairs et d’indicateurs de performance clés pour mesurer la réalisation de ces objectifs.

Amendment

2. La Commission et le Comité encouragent et facilitent l’élaboration de codes de conduite destinés à favoriser l’application volontaire aux systèmes d’IA d’exigences liées, par exemple, à la viabilité environnementale, à l’accessibilité pour les personnes handicapées *et* à la participation des parties prenantes à la conception et au développement des systèmes d’IA sur la base d’objectifs clairs et d’indicateurs de performance clés pour mesurer la réalisation de ces objectifs.

Or. fr

Amendment 2790

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nută, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Alin Mituă

Proposal for a regulation

Article 69 – paragraph 2

Text proposed by the Commission

2. The Commission and the **Board** shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to AI systems of requirements related for example to environmental sustainability, accessibility for persons with a disability, stakeholders participation in the design and development of the AI systems and diversity of development teams on the basis of clear objectives and key performance indicators to measure the achievement of those objectives.

Amendment

2. The Commission and the **AI Office** shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to AI systems of requirements related for example to environmental sustainability, accessibility for persons with a disability, stakeholders participation in the design and development of the AI systems and diversity of development teams on the basis of clear objectives and key performance indicators to measure the achievement of those objectives.

Or. en

Amendment 2791

Drago Tudorache

Proposal for a regulation
Article 69 – paragraph 3

Text proposed by the Commission

3. Codes of conduct may be drawn up by individual providers of AI systems or by organisations representing them or by **both**, including with the involvement of users and any interested stakeholders and their representative organisations. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems.

Amendment

3. Codes of conduct may be drawn up by individual providers of AI systems or by organisations representing them or by **the Commission or the AI Office**, including with the involvement of users and any interested stakeholders and their representative organisations. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems.

Or. en

Amendment 2792

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Istrate, Ramona Strugariu, Drago Pîslaru, Lucia Šuriš Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation
Article 69 – paragraph 4

Text proposed by the Commission

4. The Commission and the **Board** shall take into account the specific interests and needs of the small-scale providers and start-ups when encouraging and facilitating the drawing up of codes of conduct.

Amendment

4. The Commission and the **AI Office** shall take into account the specific interests and needs of the small-scale providers and start-ups when encouraging and facilitating the drawing up of codes of conduct.

Or. en

Amendment 2793

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Ondej Kováčik, Jan-Christoph Oetjen

Proposal for a regulation

Article 69 – paragraph 4

Text proposed by the Commission

4. The Commission and the Board shall take into account the specific interests and needs of **the small-scale providers** and start-ups when encouraging and facilitating the drawing up of codes of conduct.

Amendment

4. The Commission and the Board shall take into account the specific interests and needs of **SMEs** and start-ups when encouraging and facilitating the drawing up of codes of conduct.

Or. en

Amendment 2794

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 69 – paragraph 4

Text proposed by the Commission

4. The Commission and the Board shall take into account the specific interests and needs of the **small-scale providers** and start-ups when encouraging and facilitating the drawing up of codes of conduct.

Amendment

4. The Commission and the Board shall take into account the specific interests and needs of the **SMEs** and start-ups when encouraging and facilitating the drawing up of codes of conduct.

Or. en

Amendment 2795

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 70 – paragraph 1 – introductory part

Text proposed by the Commission

1. National competent authorities and notified bodies involved in the application of this Regulation shall *respect* the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:

Amendment

1. National competent **authorities, market surveillance** authorities and notified bodies involved in the application of this Regulation shall *put effective cybersecurity, technical and organisational measures in place to ensure* the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:

Or. en

Amendment 2796

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ondej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 70 – paragraph 1 – introductory part

Text proposed by the Commission

1. National competent authorities **and** notified bodies involved in the application of this Regulation shall *respect* the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:

Amendment

1. National competent authorities, notified bodies, **the Commission, the Board, and any other natural or legal person** involved in the application of this Regulation shall, *in accordance with Union or national law, put appropriate technical and organisational measures in place to ensure* the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:

Or. en

Amendment 2797

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López

Aguilar

Proposal for a regulation

Article 70 – paragraph 1 – introductory part

Text proposed by the Commission

1. National competent authorities and notified bodies involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:

Amendment

1. **National supervisory authorities**, national competent authorities and notified bodies involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:

Or. en

Amendment 2798

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Nută, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation

Article 70 – paragraph 1 – introductory part

Text proposed by the Commission

1. National competent authorities and notified bodies involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:

Amendment

1. **The Commission, the AI Office**, national competent authorities and notified bodies involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:

Or. en

Amendment 2799

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 70 – paragraph 1 – point a

Text proposed by the Commission

(a) intellectual property rights, and

Amendment

(a) intellectual property rights, and

confidential business information or trade secrets of a natural or legal person, including source code, except the cases referred to in Article 5 of Directive 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure apply.

confidential business information or trade secrets of a natural or legal person *in line with the 2016 EU Trade Secrets Directive (Directive 2016/943) as well as the 2004 Directive on the enforcement of intellectual property rights (Directive 2004/48/EC)*, including source code, except the cases referred to in Article 5 of Directive 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure apply.

Or. en

Amendment 2800
Marion Walsmann

Proposal for a regulation
Article 70 – paragraph 1 – point a

Text proposed by the Commission

(a) intellectual property rights, and confidential business information or trade secrets of a natural or legal person, including source code, except the cases referred to in Article 5 of Directive 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure apply.

Amendment

(a) intellectual property rights, and confidential business information *or professional secrecy* or trade secrets of a natural or legal person, including source code, except the cases referred to in Article 5 of Directive 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure apply.

Or. en

Amendment 2801
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 70 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) ***intellectual property rights, and*** confidential business information or trade secrets of a natural or legal person, ***including source code***, except the cases referred to in Article 5 of Directive 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure apply.

(a) confidential business information or trade secrets of a natural or legal person, except the cases referred to in Article 5 of Directive 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure apply.

Or. en

Amendment 2802

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 70 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) the principles of purpose limitation and data minimization, meaning that national competent authorities minimize the quantity of data requested for disclosure in line with what is absolutely necessary for the perceived risk and its assessment, and they must not keep the data for any longer than absolutely necessary.

Or. en

Amendment 2803

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ondej Kováčik, Jan-Christoph Oetjen

Proposal for a regulation

Article 70 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) the principles of purpose limitation and data minimization, meaning that national competent authorities minimize the quantity of data requested for disclosure inline with what is absolutely

necessary for the perceived risk and its assessment, and they must not keep the data for any longer than absolutely necessary;

Or. en

Amendment 2804

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 70 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

I a. In cases where the activity of national competent authorities, market surveillance authorities and notified bodies pursuant to the provisions of this Article results in a breach of intellectual property rights, Member States shall provide for the measures, procedures and remedies necessary to ensure the enforcement of the intellectual property rights in full application of Directive 2004/48/EC on the enforcement of intellectual property rights.

Or. en

Amendment 2805

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 70 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

I a. Where the activities of national competent authorities and bodies notified under the provisions of this Article infringe intellectual property rights, Member States shall provide for the measures, procedures and remedies necessary to ensure the enforcement of intellectual property rights in full

*application of Directive 2004/48/EC on
the enforcement of intellectual property
rights.*

Or. en

Amendment 2806

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

Proposal for a regulation

Article 70 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

*I a. The Commission, the Board,
national supervisory authorities, national
competent authorities and notified bodies
involved in the application of this
Regulation shall put in place adequate
cybersecurity and organisational
measures to protect the security and
confidentiality of the information and
data obtained in carrying out their tasks
and activities.*

Or. en

Amendment 2807

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 70 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

*I b. Information and data collected by
national competent authorities and
notified bodies and referred to in
Paragraph 1 shall be:*

*a) collected for specified, explicit and
legitimate purposes and not further
processed in a way incompatible with
those purposes; further processing for
archiving purposes in the public interest,
for scientific or historical research*

purposes or for statistical purposes shall not be considered incompatible with the original purposes ('purpose limitation');

b) adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation');

Or. en

Amendment 2808

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

Proposal for a regulation

Article 70 – paragraph 2 – introductory part

Text proposed by the Commission

2. Without prejudice to paragraph 1, information exchanged on a confidential basis between the national competent authorities and between national competent authorities and the Commission shall not be disclosed without the prior consultation of the originating national competent authority and the **user** when high-risk AI systems referred to in points 1, 6 and 7 of Annex III are used by law enforcement, immigration or asylum authorities, when such disclosure would jeopardise public **and** national security **interests**.

Amendment

2. Without prejudice to paragraph 1, information exchanged on a confidential basis between the national competent authorities and between national competent authorities and the Commission shall not be disclosed without the prior consultation of the originating national competent authority and the **deployer** when high-risk AI systems referred to in points 1, 6 and 7 of Annex III are used by law enforcement, immigration or asylum authorities, when such disclosure would jeopardise public **or** national security.

Or. en

Amendment 2809

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

Proposal for a regulation

Article 70 – paragraph 2 – introductory part

Text proposed by the Commission

2. Without prejudice to **paragraph 1**, information exchanged on a confidential

Amendment

2. Without prejudice to **paragraphs 1 and 1a**, information exchanged on a

basis ***between*** the national ***competent*** authorities ***and between*** national competent authorities and the Commission shall not be disclosed without the prior consultation of the originating ***national competent*** authority and the user when high-risk AI systems referred to in points 1, 6 and 7 of Annex III are used by law enforcement, immigration or asylum authorities, when such disclosure would jeopardise public and national security interests.

confidential basis ***among*** the national ***supervisory*** authorities, national competent authorities and the Commission shall not be disclosed without the prior consultation of the originating authority and the user when high-risk AI systems referred to in points 1, 6 and 7 of Annex III are used by law enforcement, immigration or asylum authorities, when such disclosure would jeopardise public and national security interests.

Or. en

Amendment 2810

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation Article 70 – paragraph 4

Text proposed by the Commission

4. The Commission and Member States may exchange, where necessary, confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of confidentiality.

Amendment

4. The Commission and Member States may exchange, where necessary ***and in compliance with trade agreements between the EU and third countries that may apply***, confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of confidentiality.

Or. en

Amendment 2811

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation Article 70 – paragraph 4

Text proposed by the Commission

4. The Commission and Member States may exchange, where necessary,

Amendment

4. The Commission and Member States may, ***if consistent with the***

confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of confidentiality.

provisions contained in EU trade agreements with third countries, exchange, where necessary, confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of confidentiality.

Or. en

Amendment 2812

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

Proposal for a regulation

Article 70 a (new)

Text proposed by the Commission

Amendment

Article 70 a

Administrative fines

1. Each national supervisory authority shall ensure that the imposition of administrative fines pursuant to this Article in respect of infringements of this Regulation shall in each individual case be effective, proportionate and dissuasive.

2. When deciding whether to impose an administrative fine and deciding on the amount of the administrative fine in each individual case due regard shall be given to the following:

(a) the nature, gravity and duration of the infringement taking into account the nature, scope or purpose of the processing concerned as well as, where appropriate, the number of affected persons and the level of harm suffered by them;

(b) the intentional or negligent character of the infringement;

(c) any action taken by the operator to mitigate the harm suffered by the users or the affected persons;

(d) the degree of responsibility of the operator taking into account the technical and organisational measures implemented by them;

(e) any relevant previous infringements by the operator;

(f) the degree of cooperation with the national supervisory authority, in order to remedy the infringement and mitigate the possible adverse effects of the infringement, including compliance with any of the measures previously ordered by the national supervisory authority with regard to the same subject matter

(g) the manner in which the infringement became known to the national supervisory authority, in particular whether, and if so to what extent, the operator notified the infringement;

(h) adherence to approved codes of conduct or approved certification mechanisms; and

(i) any other aggravating or mitigating factor applicable to the circumstances of the case, such as financial benefits gained, or losses avoided, directly or indirectly, from the infringement.

3. If an operator, intentionally or negligently, infringes several provisions of this Regulation, the total amount of the administrative fine shall not exceed the amount specified for the gravest infringement.

4. The non-compliance of the AI system with the prohibition of the artificial intelligence practices referred to in Article 5 shall be subject to administrative fines of up to 50 000 000 or, if the offender is a company, up to 10% of its total worldwide annual turnover for the preceding financial year, whichever is higher.

5. The non-compliance of the AI system with the requirements laid down in Article 10 shall be subject to administrative fines of up to 40 000 000 EUR or, if the offender is a company, up to

8 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

6. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to 30 000 000 EUR or, if the offender is a company, up to 6 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

7. The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to 20 000 000 EUR or, if the offender is a company, up to 4 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

8. Without prejudice to the corrective powers of national supervisory authorities, each Member State may lay down the rules on whether and to what extent administrative fines may be imposed on public authorities and bodies established in that Member State.

9. The exercise by the national supervisory authority of its powers under this Article shall be subject to appropriate procedural safeguards in accordance with Union and Member State law, including effective judicial remedy and due process.

10. Where the legal system of the Member State does not provide for administrative fines, this Article may be applied in such a manner that the fine is initiated by the national supervisory authority and imposed by competent national courts, while ensuring that those legal remedies are effective and have an equivalent effect to the administrative fines imposed by national supervisory authorities. In any event, the fines imposed shall be effective, proportionate and dissuasive. Those Member States shall notify to the Commission the provisions of their laws

which they adopt pursuant to this paragraph by [3 months after entry into force] and, without delay, any subsequent amendment law or amendment affecting them.

Or. en

Amendment 2813

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 70 b (new)

Text proposed by the Commission

Amendment

Article 70 b

Right for removal and injunction

1. If an AI system infringes this Regulation each natural or legal person affected by said AI system may require the user of this system to stop the use and to remove the infringement.

2. If further infringements of an AI system are to be feared, each affected natural or legal person may seek a prohibitory injunction.

Or. en

Amendment 2814

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

Proposal for a regulation

Article 71 – paragraph 1

Text proposed by the Commission

Amendment

1. Dans le respect des conditions établies dans le présent règlement, les États membres déterminent le régime des sanctions, y compris les amendes administratives, applicables aux violations des dispositions du présent règlement et

1. Dans le respect des conditions établies dans le présent règlement, les États membres déterminent le régime des sanctions, y compris les amendes administratives, applicables aux violations des dispositions du présent règlement et

prennent toute mesure nécessaire pour assurer la mise en œuvre correcte et effective de ces sanctions. Ces sanctions doivent être effectives, proportionnées et dissuasives. Elles tiennent compte en particulier des intérêts des petits fournisseurs et des jeunes entreprises, ainsi que de leur viabilité économique.

prennent toute mesure nécessaire pour assurer la mise en œuvre correcte et effective de ces sanctions. Ces sanctions doivent être effectives, proportionnées et dissuasives. Elles tiennent compte en particulier des intérêts des petits fournisseurs et des jeunes entreprises, ainsi que de leur viabilité économique, *et de l'intentionnalité de la violation commise ainsi que de l'importance du préjudice résulté.*

Or. fr

Amendment 2815

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 71 – paragraph 1

Text proposed by the Commission

1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests of small-scale providers and start-up and their economic viability.

Amendment

1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented *and aligned with the guidelines issued by the Board, as referred to in Article 58 (c) (iii).* The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests of small-scale providers and start-up and their economic viability.

Or. en

Amendment 2816

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

Proposal for a regulation

Article 71 – paragraph 1

Text proposed by the Commission

1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. ***They shall take into particular account the interests of small-scale providers and start-up and their economic viability.***

Amendment

1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive.

Or. en

Amendment 2817

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

**Proposal for a regulation
Article 71 – paragraph 1**

Text proposed by the Commission

1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests of ***small-scale providers and start-up*** and their economic viability.

Amendment

1. In compliance with the terms and conditions laid down in this Regulation, ***the Commission in consultation with*** Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and ***in cooperation with*** ***Member States*** shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the ***size and the*** interests of ***SME*** providers ***including start-ups*** and their economic viability.

Or. en

Amendment 2818
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 71 – paragraph 1

Text proposed by the Commission

1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests of ***small-scale providers*** and start-up and their economic viability.

Amendment

1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented ***and aligned with the guidelines issued by the Board, as referred to in Article 58 (c) (iii).*** The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests of ***SMEs*** and start-up and their economic viability.

Or. en

Amendment 2819
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation
Article 71 – paragraph 1

Text proposed by the Commission

1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, ***including administrative fines,*** applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. ***They shall take into particular account the interests of small-scale providers and start-up and their economic viability.***

Amendment

1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, applicable to infringements of this Regulation, ***in particular for infringements which are not subject to administrative fines pursuant to Article 70a,*** and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive.

Amendment 2820

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

**Proposal for a regulation
Article 71 – paragraph 1**

Text proposed by the Commission

1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests of small-scale providers and *start-up* and their economic viability.

Amendment

1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests *and size* of small-scale providers and *start-ups* and their economic viability.

Amendment 2821

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Ond ej Kova īk, Jan-Christoph Oetjen

**Proposal for a regulation
Article 71 – paragraph 1**

Text proposed by the Commission

1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties

Amendment

1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties

provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests of ***small-scale providers and start-up*** and their economic viability.

provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the ***size and*** interests of ***SMEs and start-ups*** and their economic viability

Or. en

Amendment 2822

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 71 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

I a. In cases where administrative fines have been imposed under Article 83 of Regulation 2016/679, no further penalties shall be imposed on operators under the AI Act.

Or. en

Amendment 2823

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

Proposal for a regulation

Article 71 – paragraph 2

Text proposed by the Commission

Amendment

2. The Member States shall notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

deleted

Or. en

Amendment 2824

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

Proposal for a regulation
Article 71 – paragraph 2

Text proposed by the Commission

2. The Member States shall notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

Amendment

2. The Member States shall notify [*by 3 months following the date of entry into force of this Regulation*] the Commission **and the Board** of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

Or. en

Amendment 2825

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 71 – paragraph 2

Text proposed by the Commission

2. The Member States shall notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

Amendment

2. *Within [three months following the entry into force of this Regulation],* the Member States shall notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

Or. en

Amendment 2826

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 71 – paragraph 2

Text proposed by the Commission

2. **The** Member States shall notify the Commission of those rules and of those

Amendment

2. Member States shall notify the Commission of those rules and of those

measures and shall notify it, without delay, of any subsequent amendment affecting them.

measures and shall notify it, without delay, of any subsequent amendment affecting them.

Or. en

Amendment 2827

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

Proposal for a regulation

Article 71 – paragraph 2

Text proposed by the Commission

2. The Member States shall notify the Commission of those rules and of those measures and ***shall notify it, without delay,*** of any subsequent amendment affecting them.

Amendment

2. The Member States shall ***without delay*** notify the Commission of those rules and of those measures and of any subsequent amendment affecting them.

Or. en

Amendment 2828

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 71 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The non-compliance of the AI system with the prohibition of the practices referred to in Article 5 shall be subject to administrative fines of up to 50 000 000 EUR or, if the offender is a company, up to 10% of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. en

Justification

Penalties for prohibited practices need to be truly dissuasive and cannot be at the same level as violations of Article 10.

Amendment 2829

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

Proposal for a regulation

Article 71 – paragraph 3

Text proposed by the Commission

Amendment

3. *The following infringements shall be subject to administrative fines of up to 30 000 000 EUR or, if the offender is a company, up to 6 % of its total worldwide annual turnover for the preceding financial year, whichever is higher:*
- (a) *non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;*
- (b) *non-compliance of the AI system with the requirements laid down in Article 10.*
- deleted*

Or. en

Amendment 2830

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ondej Kováč, Jan-Christoph Oetjen

Proposal for a regulation

Article 71 – paragraph 3 – introductory part

Text proposed by the Commission

Amendment

3. *The following infringements shall be subject to administrative fines of up to 30 000 000 EUR or, if the offender is a company, up to 6 % of its total worldwide annual turnover for the preceding financial year, whichever is higher:*

3. *Non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5 shall be subject to administrative fines of up to 20 000 000 EUR or, if the offender is a company, up to 4 % of its total worldwide annual turnover for the preceding financial year, and in case of SMEs and start-ups, up to 3 % of its worldwide*

annual turnover for the preceding financial year, whichever is higher.

.

Or. en

Amendment 2831

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Mituță, Ramona Strugariu, Drago Pîslaru, Lucia Ūriș Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 71 – paragraph 3 – introductory part

Text proposed by the Commission

3. ***The following infringements*** shall be subject to administrative fines of up to 30 000 000 EUR or, if the offender is a company, up to 6 % of its total worldwide annual turnover for the preceding financial year, whichever is higher:

Amendment

3. ***Non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5*** shall be subject to administrative fines of up to 30 000 000 EUR or, if the offender is a company, up to 6 % of its total worldwide annual turnover for the preceding financial year, whichever is higher;

Or. en

Amendment 2832

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 71 – paragraph 3 – introductory part

Text proposed by the Commission

3. ***The following infringements*** shall be subject to administrative fines of up to 30 000 000 EUR or, if the offender is a company, up to 6 % of its total worldwide annual turnover for the preceding financial year, whichever is higher:

Amendment

3. ***The non-compliance of the AI system with the requirements laid down in Article 10*** shall be subject to administrative fines of up to 40 000 000 EUR or, if the offender is a company, up to 8 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. en

Amendment 2833

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 3 – introductory part

Text proposed by the Commission

3. ***The following infringements*** shall be subject to administrative fines of up to ***30 000 000 EUR*** or, if the offender is a company, up to ***6 %*** of its total worldwide annual turnover for the preceding financial year, whichever is higher:

Amendment

3. ***Non-compliance with the prohibition of the AI practices referred to in Article 5*** shall be subject to administrative fines of up to ***20 000 000 EUR*** or, if the offender is a company, up to ***4%*** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. en

Amendment 2834

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

Proposal for a regulation

Article 71 – paragraph 3 – introductory part

Text proposed by the Commission

3. Les infractions suivantes font l'objet d'amendes administratives pouvant aller jusqu'à ***30 000 000 EUR*** ou, si l'auteur de l'infraction est une entreprise, jusqu'à ***6 %*** de son chiffre d'affaires annuel mondial total réalisé au cours de l'exercice précédent, le montant le plus élevé étant retenu:

Amendment

3. Les infractions suivantes font l'objet d'amendes administratives pouvant aller jusqu'à ***1 000 000 000 EUR*** ou, si l'auteur de l'infraction est une entreprise, jusqu'à ***10 %*** de son chiffre d'affaires annuel mondial total réalisé au cours de l'exercice précédent, le montant le plus élevé étant retenu:

Or. fr

Justification

En raison de la gravité des pratiques interdites par l'article 5, il est nécessaire que les sanctions prévues aient un caractère dissuasif.

Amendment 2835

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 71 – paragraph 3 – introductory part

Text proposed by the Commission

3. The following infringements shall be subject to administrative fines of up to 30 000 000 EUR or, if the offender is a company, up to **6 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher:

Amendment

3. The following infringements shall be subject to administrative fines of up to 30 000 000 EUR or, if the offender is a company, up to **10 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher:

Or. en

Amendment 2836

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 71 – paragraph 3 – point a

Text proposed by the Commission

(a) non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;

Amendment

deleted

Or. en

Amendment 2837

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 3 – point a

Text proposed by the Commission

(a) non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;

Amendment

deleted

Or. en

Amendment 2838

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 71 – paragraph 3 – point a

Text proposed by the Commission

Amendment

(a) *non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;* *deleted*

Or. en

Amendment 2839

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituță

Proposal for a regulation

Article 71 – paragraph 3 – point a

Text proposed by the Commission

Amendment

(a) *non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;* *deleted*

Or. en

Amendment 2840

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 71 – paragraph 3 – point b

Text proposed by the Commission

Amendment

(b) *non-compliance of the AI system with the requirements laid down in Article 10.* *deleted*

Or. en

Amendment 2841

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 71 – paragraph 3 – point b

Text proposed by the Commission

Amendment

(b) *non-compliance of the AI system* *deleted*
with the requirements laid down in Article
10.

Or. en

Justification

Such very substantial fines should only be issued for the most serious breaches of the Regulation, for example the putting into service of explicitly prohibited AI systems, not in cases when, for example, a dataset is found to have errors.

Amendment 2842

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituța

Proposal for a regulation

Article 71 – paragraph 3 – point b

Text proposed by the Commission

Amendment

(b) *non-compliance of the AI system* *deleted*
with the requirements laid down in Article
10.

Or. en

Amendment 2843

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 3 – point b

Text proposed by the Commission

Amendment

*(b) non-compliance of the AI system
with the requirements laid down in Article
10.* *deleted*

Or. en

Amendment 2844

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 71 – paragraph 3 – point b

Text proposed by the Commission

Amendment

*(b) non-compliance of the AI system
with the requirements laid down in Article
10.* *deleted*

Or. en

Amendment 2845

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 71 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

*3 a. Non-compliance of the AI system
with the requirements laid down in Article
10 shall be subject to administrative fines
of up to 20 000 000 EUR or, if the
offender is a company, up to 4 % of its
total worldwide annual turnover for the
preceding financial year, whichever is
higher.*

Or. en

Amendment 2846

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

**Proposal for a regulation
Article 71 – paragraph 4**

Text proposed by the Commission

Amendment

4. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to 20 000 000 EUR or, if the offender is a company, up to 4 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

deleted

Or. en

Amendment 2847

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 71 – paragraph 4**

Text proposed by the Commission

Amendment

4. The non-compliance of the AI system with **any requirements or obligations under this Regulation, other than those laid down in Articles 5 **and 10**, shall be subject to administrative fines of up to **20 000 000** EUR or, if the offender is a company, up to **4 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.**

4. The **grossly negligent non-compliance **by the provider or user** of the AI system with **the respective** requirements or obligations under this Regulation, other than those laid down in Articles 5, shall be subject to administrative fines of up to **10 000 000** EUR or, if the offender is a company, up to **2 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher, **and in case of SMEs and start-ups, up to 1% of its worldwide annual turnover for the preceding financial year, whichever is higher.****

Or. en

Amendment 2848

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ondej Kováčik, Jan-Christoph Oetjen

Proposal for a regulation

Article 71 – paragraph 4

Text proposed by the Commission

4. The non-compliance of the **AI system** with any requirements or obligations under this Regulation, other than those laid down in **Articles 5 and 10**, shall be subject to administrative fines of up to **20 000 000 EUR** or, if the offender is a company, up to **4 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Amendment

4. The **grossly negligent** non-compliance **by the provider or the user** of the **AIs system** with any requirements or obligations under this Regulation, other than those laid down in **Article 5**, shall be subject to administrative fines of up to **10 000 000 EUR** or, if the offender is a company, up to **2 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. en

Amendment 2849

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

Proposal for a regulation

Article 71 – paragraph 4

Text proposed by the Commission

4. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to **20 000 000 EUR** or, if the offender is a company, up to **4 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Amendment

4. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to **30 000 000 EUR** or, if the offender is a company, up to **6 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. en

Amendment 2850

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Article 71 – paragraph 4**

Text proposed by the Commission

4. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to 20 000 000 EUR or, if the offender is a company, up to **4 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Amendment

4. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to 20 000 000 EUR or, if the offender is a company, up to **7 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. en

Amendment 2851

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

**Proposal for a regulation
Article 71 – paragraph 4**

Text proposed by the Commission

4. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to 20 000 000 EUR or, if the offender is a company, up to **4 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Amendment

4. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to 20 000 000 EUR or, if the offender is a company, up to **6 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. en

Amendment 2852

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 71 – paragraph 4

Text proposed by the Commission

4. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to **20 000 000** EUR or, if the offender is a company, up to **4 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Amendment

4. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to **1 000 000** EUR or, if the offender is a company, up to **1 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. en

Amendment 2853

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Nută, Ramona Strugariu, Drago Pîslaru, Lucia Ūriș Nicholsonová, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 71 – paragraph 4

Text proposed by the Commission

4. **The** non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to **20 000 000** EUR or, if the offender is a company, up to **4 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Amendment

4. Non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to **10 000 000** EUR or, if the offender is a company, up to **2 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. en

Amendment 2854

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

Proposal for a regulation

Article 71 – paragraph 5

Text proposed by the Commission

Amendment

5. *The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to 10 000 000 EUR or, if the offender is a company, up to 2 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.*

deleted

Or. en

Amendment 2855

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 71 – paragraph 5**

Text proposed by the Commission

Amendment

5. The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to 10 000 000 EUR or, if the offender is a company, up to 2 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

5. The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to 10 000 000 EUR or, if the offender is a company, up to 2 % of its total worldwide annual turnover for the preceding financial year, whichever is higher *and in case of SMEs and start-ups, up to 1% of its worldwide annual turnover for the preceding financial year, whichever is higher.*

Or. en

Amendment 2856

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Article 71 – paragraph 5**

Text proposed by the Commission

Amendment

5. The supply of incorrect, incomplete

5. The supply of incorrect, incomplete

or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to 10 000 000 EUR or, if the offender is a company, up to **2 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to 10 000 000 EUR or, if the offender is a company, up to **4 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. en

Amendment 2857

Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 71 – paragraph 5

Text proposed by the Commission

5. The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to 10 000 000 EUR or, if the offender is a company, up to **2 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Amendment

5. The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to 10 000 000 EUR or, if the offender is a company, up to **4 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. en

Amendment 2858

Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation

Article 71 – paragraph 5

Text proposed by the Commission

5. The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to

Amendment

5. The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to

administrative fines of up to **10 000 000** EUR or, if the offender is a company, up to **2 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

administrative fines of up to **20 000 000** EUR or, if the offender is a company, up to **4 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. en

Amendment 2859

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation Article 71 – paragraph 5

Text proposed by the Commission

5. The supply of incorrect, *incomplete* or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to **10 000 000** EUR or, if the offender is a company, up to **2 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Amendment

5. The supply of incorrect or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to **1 000 000** EUR or, if the offender is a company, up to **1 %** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. en

Amendment 2860

Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation Article 71 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. Where trade secrets, intellectual property rights or data protection rights have been infringed in the development of an AI system, competent authorities may order the definitive deletion of that system and all associated training data and outputs.

Or. en

Amendment 2861

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar

Proposal for a regulation

Article 71 – paragraph 6

Text proposed by the Commission

Amendment

6. When deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:

deleted

- (a) the nature, gravity and duration of the infringement and of its consequences;*
- (b) whether administrative fines have been already applied by other market surveillance authorities to the same operator for the same infringement.*
- (c) the size and market share of the operator committing the infringement;*

Or. en

Amendment 2862

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 6 – introductory part

Text proposed by the Commission

Amendment

6. When deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:

6. Fines may be imposed in addition to or instead of non-monetary measures such as orders or warnings. When deciding on whether to impose a fine or on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:

Or. en

Amendment 2863

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 6 – point a

Text proposed by the Commission

- (a) the nature, gravity and duration of the infringement and of its consequences;

Amendment

- (a) the nature, gravity and duration of the infringement and of its consequences *taking into account the nature, scope or purpose of the AI system concerned, as well as the number of individuals affected, and the level of damage suffered by them;*

Or. en

Amendment 2864

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 71 – paragraph 6 – point b

Text proposed by the Commission

- (b) whether administrative fines have been already applied by other market surveillance authorities to the same operator for the same infringement.

Amendment

- (b) whether administrative fines have been already applied by other market surveillance authorities *of one or more Member States* to the same operator for the same infringement.

Or. en

Amendment 2865

Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation

Article 71 – paragraph 6 – point c

Text proposed by the Commission

Amendment

(c) *the size and market share of the operator committing the infringement;* *deleted*

Or. en

Justification

Even small operators can cause major infringements of this Regulation that impact health, safety, fundamental rights, the environment or the values enshrined in Article 2 TEU, and therefore their size should not be a decisive element when deciding on the fines (even more so as they are calculated as a percentage of a company's turnover).

Amendment 2866

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ondej Kováčik, Jan-Christoph Oetjen

Proposal for a regulation

Article 71 – paragraph 6 – point c

Text proposed by the Commission

(c) the size and market share of the operator committing the infringement;

Amendment

(c) the size, *the annual turnover* and market share of the operator committing the infringement;

Or. en

Amendment 2867

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 6 – point c

Text proposed by the Commission

(c) the size and market share of the operator committing the infringement;

Amendment

(c) the size, *the annual turnover* and market share of the operator committing the infringement;

Or. en

Amendment 2868

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 71 – paragraph 6 – point c a (new)

Text proposed by the Commission

Amendment

(c a) any action taken by the provider to mitigate the harm or damage suffered by the affected persons;

Or. en

Amendment 2869
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 71 – paragraph 6 – point c a (new)

Text proposed by the Commission

Amendment

(c a) the intentional or negligent character of the infringement;

Or. en

Amendment 2870
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 71 – paragraph 6 – point c c (new)

Text proposed by the Commission

Amendment

(c c) the degree of cooperation with the national competent authorities, in order to remedy the infringement and mitigate the possible adverse effects of the infringement;

Or. en

Amendment 2871
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 6 – point c c (new)

Text proposed by the Commission

Amendment

(c c) any relevant previous infringements by the provider;

Or. en

Amendment 2872

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 6 – point c e (new)

Text proposed by the Commission

Amendment

(c e) any other aggravating or mitigating factor applicable to the circumstances of the case, such as financial benefits gained, or losses avoided, directly or indirectly, from the infringement;

Or. en

Amendment 2873

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 6 – point c e (new)

Text proposed by the Commission

Amendment

(c e) the manner in which the infringement became known to the national competent authority, in particular whether, and if so to what extent, the provider notified the infringement;

Or. en

Amendment 2874

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 6 – point c g (new)

Text proposed by the Commission

Amendment

(c g) in the context of paragraph 5 of this Article, the intentional or unintentional nature of the infringement.

Or. en

Amendment 2875

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation

Article 71 – paragraph 7

Text proposed by the Commission

Amendment

7. Each Member State shall lay down rules on whether and to what extent administrative fines may be imposed on public authorities and bodies established in that Member State. *deleted*

Or. en

Amendment 2876

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Mituță, Ramona Strugariu, Drago Pîslaru, Lucia Șuriș Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 71 – paragraph 7

Text proposed by the Commission

Amendment

7. Each Member State shall lay down rules on whether and to what extent administrative fines may be imposed on public authorities and bodies established in that Member State.

7. Each Member State shall lay down rules on administrative fines to be imposed on public authorities and bodies established in that Member State, with a view to ensure compliance with this Regulation.

Amendment 2877

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation

Article 71 – paragraph 8

Text proposed by the Commission

Amendment

8. *Depending on the legal system of the Member States, the rules on administrative fines may be applied in such a manner that the fines are imposed by competent national courts of other bodies as applicable in those Member States. The application of such rules in those Member States shall have an equivalent effect.* *deleted*

Amendment 2878

René Repasi, Marc Angel, Andreas Schieder, Maria-Manuel Leitão-Marques

Proposal for a regulation

Article 71 – paragraph 8

Text proposed by the Commission

Amendment

8. Depending on the legal system of the Member States, the rules on administrative fines may be applied in such a manner that the fines are imposed by competent national courts of other bodies as applicable in those Member States. The application of such rules in those Member States shall have an equivalent effect.

8. Depending on the legal system of the Member States, the rules on administrative fines may be applied in such a manner that the fines are imposed by competent national courts of other bodies as applicable in those Member States. The application of such rules in those Member States shall have an equivalent effect. *In any event, the fines imposed shall be effective, proportionate and dissuasive.*

Amendment 2879

René Repasi, Marc Angel, Andreas Schieder, Maria-Manuel Leitão-Marques

Proposal for a regulation

Article 71 – paragraph 8 a (new)

Text proposed by the Commission

Amendment

8 a. In respect of adopting administrative fines and of deciding on the amount of the administrative fine the procedure as set out in Article 68a, paragraphs 2 to 6, applies mutatis mutandis.

Or. en

Amendment 2880

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 8 a (new)

Text proposed by the Commission

Amendment

8 a. Administrative fines shall not be applied to a participant in a regulatory sandbox, who was acting in line with the recommendation issued by the supervisory authority.

Or. en

Amendment 2881

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Article 71 – paragraph 8 a (new)

Text proposed by the Commission

Amendment

8 a. Administrative fines shall not be applied to a participant in a regulatory sandbox, who was acting in line with the recommendation issued by the supervisory

authority;

Or. en

Amendment 2882
Axel Voss, Deirdre Clune

Proposal for a regulation
Article 71 – paragraph 8 b (new)

Text proposed by the Commission

Amendment

8 b. The penalties referred to in this article as well as the associated litigation costs and indemnification claims may not be the subject of contractual clauses or other form of burden-sharing agreements between the providers and distributors, importers, users, or any other third-parties.

Or. en

Amendment 2883
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 71 – paragraph 8 c (new)

Text proposed by the Commission

Amendment

8 c. The exercise by the market surveillance authority of its powers under this Article shall be subject to appropriate procedural safeguards in accordance with Union and Member State law, including effective judicial remedy and due process.

Or. en

Amendment 2884
Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 72 – paragraph 1 – introductory part

Text proposed by the Commission

1. The European Data Protection Supervisor may impose administrative fines on Union institutions, agencies and bodies ***falling within the scope of this Regulation***. When deciding whether to impose an administrative fine and deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:

Amendment

1. The European Data Protection Supervisor may impose administrative fines on Union institutions, agencies and bodies ***developing, deploying or operating AI systems***. When deciding whether to impose an administrative fine and deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:

Or. en

Amendment 2885

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini, Brando Benifei

Proposal for a regulation

Article 72 – paragraph 1 – point a

Text proposed by the Commission

(a) the nature, gravity and duration of the infringement and of its consequences;

Amendment

(a) the nature, gravity and duration of the infringement and of its consequences, ***including to affected persons***;

Or. en

Amendment 2886

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini, Brando Benifei

Proposal for a regulation

Article 72 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) any action taken by the Union institution, agency or body to mitigate the harm;

Or. en

Amendment 2887

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 72 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) the intentional or negligent character of the infringement;

Or. en

Amendment 2888

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 72 – paragraph 1 – point a b (new)

Text proposed by the Commission

Amendment

(a b) any relevant previous infringement;

Or. en

Amendment 2889

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte

Proposal for a regulation

Article 72 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) la coopération établie avec le Contrôleur européen de la protection des données en vue de remédier à l'infraction et d'en atténuer les éventuels effets négatifs, y compris le respect de toute mesure précédemment ordonnée par le Contrôleur européen de la protection des données à l'encontre de l'institution ou de l'agence ou de l'organe de l'Union

supprimé

concerné pour le même objet;

Or. fr

Justification

Il n'est pas juste ni équitable que les institutions, agences et organes de l'Union, qui ont un devoir d'exemplarité, disposent d'un critère d'établissement des sanctions dont, à violation égale du présent règlement, les autres entités ne bénéficient pas.

Amendment 2890

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 72 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(b a) the degree of cooperation with the supervisory authority, in order to remedy the infringement and mitigate the possible adverse effects of the infringement;

Or. en

Amendment 2891

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 72 – paragraph 1 – point b b (new)

Text proposed by the Commission

Amendment

(b b) any action taken by the provider to mitigate the damage suffered by subjects;

Or. en

Amendment 2892

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini, Brando Benifei

Proposal for a regulation

Article 72 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) the manner in which the infringement became known to the European Data Protection Supervisor, in particular whether, and if so, to what extent, the Union institution, agency or body notified the infringement.

Or. en

Amendment 2893

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 72 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) any other aggravating or mitigating factor applicable to the circumstances of the case, such as financial benefits gained, or losses avoided, directly or indirectly, from the infringement.

Or. en

Amendment 2894

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 72 – paragraph 2 – introductory part

Text proposed by the Commission

Amendment

2. The *following infringements* shall be subject to administrative fines of up to **500 000 EUR**:

2. The *non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5* shall be subject to administrative fines of up to **1 000 000 EUR**;

2a. The non-compliance of the AI system with the requirements laid down in Article

10 shall be subject to administrative fines of up to 700 000 EUR.

Or. en

Amendment 2895

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Malik Azmani, Alin Mituța, Irena Joveva

Proposal for a regulation

Article 72 – paragraph 2 – introductory part

Text proposed by the Commission

2. ***The following infringements*** shall be subject to administrative fines of up to **500 000 EUR:**

Amendment

2. ***Non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5*** shall be subject to administrative fines of up to **1.000 000 EUR;**

Or. en

Amendment 2896

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar

Proposal for a regulation

Article 72 – paragraph 2 – introductory part

Text proposed by the Commission

2. ***The following infringements*** shall be subject to administrative fines of up to **500 000 EUR:**

Amendment

2. ***The non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5*** shall be subject to administrative fines of up to **1 000 000 EUR:**

Or. en

Amendment 2897

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Article 72 – paragraph 2 – introductory part

Text proposed by the Commission

2. Les infractions suivantes font l'objet d'une amende administrative pouvant aller jusqu'à **500 000 EUR**:

Amendment

2. Les infractions suivantes font l'objet d'une amende administrative pouvant aller jusqu'à **30 000 000 EUR**:

Or. fr

Justification

Alignement sur le montant prévu à l'article 70 pour les mêmes faits, aucune raison ne permettant de justifier que les institutions, agences et organes de l'Union soient soumises à des amendes moins sévères que les autres fournisseurs et utilisateurs, y compris les administrations publiques des États membres.

Amendment 2898

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 72 – paragraph 2 – introductory part

Text proposed by the Commission

2. The following infringements shall be subject to administrative fines of up to **500 000 EUR**:

Amendment

2. The following infringements shall be subject to administrative fines of up to **5 000 000 EUR**:

Or. en

Amendment 2899

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 72 – paragraph 2 – point a

Text proposed by the Commission

(a) non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;

Amendment

deleted

Or. en

Amendment 2900

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar

Proposal for a regulation

Article 72 – paragraph 2 – point a

Text proposed by the Commission

Amendment

(a) *non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;* *deleted*

Or. en

Amendment 2901

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia uriaș Nicholsonová, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 72 – paragraph 2 – point a

Text proposed by the Commission

Amendment

(a) *non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;* *deleted*

Or. en

Amendment 2902

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar

Proposal for a regulation

Article 72 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) *non-compliance of the AI system with the requirements laid down in Article 10.* *deleted*

Amendment 2903

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 72 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) *non-compliance of the AI system with the requirements laid down in Article 10.* *deleted*

Amendment 2904

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia uriš Nicholsonová, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 72 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) *non-compliance of the AI system with the requirements laid down in Article 10.* *deleted*

Amendment 2905

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar

Proposal for a regulation

Article 72 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. *The non-compliance of the AI system with the requirements laid down in Article 10 shall be subject to*

administrative fines of up to 700 000 EUR.

Or. en

Amendment 2906

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 72 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. non-compliance of the AI system with the requirements laid down in Article 10 shall be subject to administrative fines of up to 500 000 EUR.

Or. en

Amendment 2907

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 72 – paragraph 3

Text proposed by the Commission

Amendment

3. La non-conformité du système d'IA avec les exigences ou obligations au titre du présent règlement, autres que celles énoncées aux articles 5 et 10, fait l'objet d'une amende administrative pouvant aller jusqu'à **250 000 EUR**.

3. La non-conformité du système d'IA avec les exigences ou obligations au titre du présent règlement, autres que celles énoncées aux articles 5 et 10, fait l'objet d'une amende administrative pouvant aller jusqu'à **20 000 000 EUR**.

Or. fr

Justification

Alignement sur le montant prévu à l'article 70 pour les mêmes faits, aucune raison ne permettant de justifier que les institutions, agences et organes de l'Union soient soumises à des amendes moins sévères que les autres fournisseurs et utilisateurs, y compris les administrations publiques des États membres.

Amendment 2908**Pernando Barrena Arza, Cornelia Ernst****Proposal for a regulation****Article 72 – paragraph 3***Text proposed by the Commission*

3. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to **250 000 EUR**.

Amendment

3. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to **2 500 000 EUR**.

Or. en

Amendment 2909**Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar****Proposal for a regulation****Article 72 – paragraph 3***Text proposed by the Commission*

3. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to **250 000 EUR**.

Amendment

3. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to **500 000 EUR**.

Or. en

Amendment 2910**Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Mituță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță****Proposal for a regulation****Article 72 – paragraph 3***Text proposed by the Commission**Amendment*

3. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to **250 000 EUR**.

3. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to **300 000 EUR**.

Or. en

Amendment 2911

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 72 – paragraph 3

Text proposed by the Commission

3. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to **250 000 EUR**.

Amendment

3. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to **500 000 EUR**.

Or. en

Amendment 2912

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar

Proposal for a regulation

Article 72 – paragraph 5

Text proposed by the Commission

5. The rights of defense of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the European Data Protection Supervisor's file, subject to the legitimate interest of individuals or undertakings in the protection of their personal data *or business secrets*.

Amendment

5. The rights of defense of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the European Data Protection Supervisor's file, subject to the legitimate interest of individuals or undertakings in the protection of their personal data.

Amendment 2913

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 72 – paragraph 5**

Text proposed by the Commission

5. The rights of defense of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the European Data Protection Supervisor's file, subject to the legitimate interest of individuals or undertakings in the protection of their personal data *or business secrets*.

Amendment

5. The rights of defense of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the European Data Protection Supervisor's file, subject to the legitimate interest of individuals or undertakings in the protection of their personal data.

Amendment 2914

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte

**Proposal for a regulation
Article 72 – paragraph 6**

Text proposed by the Commission

6. *Les fonds collectés en imposant des amendes en vertu du présent article font partie des recettes du budget général de l'Union.*

Amendment

supprimé

Amendment 2915

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

**Proposal for a regulation
Article 72 – paragraph 6**

Text proposed by the Commission

6. Funds collected by imposition of fines in this Article shall ***be the income of*** the general budget of the Union.

Amendment

6. Funds collected by imposition of fines in this Article shall ***contribute to*** the general budget of the Union.

Or. en

Amendment 2916

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation

Article 72 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6 a. The European Data Protection Supervisor shall, on an annual basis, notify the Board of the fines it has imposed pursuant to this Article.

Or. en

Amendment 2917

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 73 – paragraph 2

Text proposed by the Commission

Amendment

2. The delegation of power referred to in Article 4, Article 7(1), Article 11(3), Article 43(5) ***and*** (6) ***and*** Article 48(5) shall be conferred on the Commission for an indeterminate period of time from [entering into force of the Regulation].

2. The delegation of power referred to in Article 7(1), Article 11(3), Article 43(5), Article 48(5) ***and Article 68a*** shall be conferred on the Commission for an indeterminate period of time from [entering into force of the Regulation].

Or. en

Justification

consistent with deletion of Annex I and Article 43(6).

Amendment 2918

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 73 – paragraph 2

Text proposed by the Commission

2. The delegation of power referred to in Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) **and** Article 48(5) shall be conferred on the Commission for an indeterminate period of time from [entering into force of the Regulation].

Amendment

2. The delegation of power referred to in Article 4, Article 5a, Article 7(1), Article 11(3), Article 43(5) and (6), Article 48(5) **and Article 52a** shall be conferred on the Commission for an indeterminate period of time from [entering into force of the Regulation].

Or. en

Amendment 2919

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 73 – paragraph 2

Text proposed by the Commission

2. The delegation of power referred to in Article 4, Article 7(1), Article 11(3), Article 43(5) **and** (6) and Article 48(5) shall be conferred on the Commission for an indeterminate period of time from [entering into force of the Regulation].

Amendment

2. The delegation of power referred to in Article 4 and Article 48(5) shall be conferred on the Commission for an indeterminate period of time from [entering into force of the Regulation].

Or. en

Amendment 2920

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 73 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. *The delegation of power referred to in Article 4, Article 7(1), Article 11(3),*

*Article 43(5) and (6) and Article 48(5)
shall undergo due process, be
proportionate and be based on a
permanent and institutionalised exchange
with the relevant stakeholders as well as
the Board and the High Level Expert
Group on AI.*

Or. en

Amendment 2921

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 73 – paragraph 3

Text proposed by the Commission

3. The delegation of power referred to in Article 4, Article 7(1), Article 11(3), Article 43(5) **and (6)** and Article 48(5) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following that of its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Amendment

3. The delegation of power referred to in Article 7(1), Article 11(3), Article 43(5), Article 48(5) **and Article 68a** may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following that of its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Or. en

Justification

same as amendment above.

Amendment 2922

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 73 – paragraph 3

Text proposed by the Commission

3. The delegation of power referred to in Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) **and** Article 48(5) may be revoked at any time by the European Parliament **or by** the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following that of its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Amendment

3. The delegation of power referred to in Article 4, Article **5a**, Article 7(1), Article 11(3), Article 43(5) and (6), Article 48(5) **and Article 52a** may be revoked at any time by **a joint decision from** the European Parliament **and** the Council.. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following that of its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Or. en

Amendment 2923

Jörgen Warborn, Arba Kokalari, Tomas Tobé

**Proposal for a regulation
Article 73 – paragraph 3**

Text proposed by the Commission

3. The delegation of power referred to in Article 4, **Article 7(1)**, **Article 11(3)**, **Article 43(5) and (6)** and Article 48(5) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following that of its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Amendment

3. The delegation of power referred to in Article 4 and Article 48(5) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following that of its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Or. en

Amendment 2924

Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 73 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. Before adopting a delegated act, the Commission shall consult with the relevant institutions and stakeholders in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

Or. en

Amendment 2925

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia urîș Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation
Article 73 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. Prior to adopting a delegated act pursuant to Article 4, Article 7(1), Article 11(3), Article 43(5) and (6), and Article 48(5) the Commission shall consult the AI Office.

Or. en

Amendment 2926

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia urîș Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituță

Proposal for a regulation
Article 73 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3 b. Delegated acts that lead to the modification or the addition of obligations on operators shall foresee an adequate transition period of no less than 24

months before their entry into force.

Or. en

Amendment 2927

Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 73 – paragraph 4

Text proposed by the Commission

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

Amendment

4. *Once the Commission decides to draft a delegated act, it shall notify the European Parliament of this fact. This notification does not place an obligation on the Commission to adopt the said act. I*
As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

Or. en

Amendment 2928

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation
Article 73 – paragraph 4

Text proposed by the Commission

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament **and to** the Council.

Amendment

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament, the Council, **and the AI Office.**

Or. en

Amendment 2929

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Article 73 – paragraph 4**

Text proposed by the Commission

4. *As soon as it adopts* a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

Amendment

4. *In preparation of* a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

Or. en

Amendment 2930

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Article 73 – paragraph 5**

Text proposed by the Commission

5. Any delegated act adopted pursuant to Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) **and** Article 48(5) shall enter into force only if no objection has been expressed by either the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

Amendment

5. Any delegated act adopted pursuant to Article 4, Article **5a**, Article 7(1), Article 11(3), Article 43(5) and (6), Article 48(5) **and Article 52a** shall enter into force only if no objection has been expressed by either the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

Or. en

Amendment 2931

Jörgen Warborn, Arba Kokalari, Tomas Tobé

**Proposal for a regulation
Article 73 – paragraph 5**

Text proposed by the Commission

Amendment

5. Any delegated act adopted pursuant to Article 4, **Article 7(1)**, **Article 11(3)**, **Article 43(5) and (6)** and Article 48(5) shall enter into force only if no objection has been expressed by either the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

5. Any delegated act adopted pursuant to Article 4 and Article 48(5) shall enter into force only if no objection has been expressed by either the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

Or. en

Amendment 2932

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 73 – paragraph 5

Text proposed by the Commission

5. Any delegated act adopted pursuant to Article 4, **Article 7(1)**, Article 11(3), **Article 43(5) and (6) and Article 48(5)** shall enter into force only if no objection has been expressed by either the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

Amendment

5. Any delegated act adopted pursuant to Article 7(1), Article 11(3), Article 43(5), **Article 48(5) and 68d** shall enter into force only if no objection has been expressed by either the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

Or. en

Justification

same as above.

Amendment 2933

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 80 – paragraph 1 – introductory part

Text proposed by the Commission

In Article 5 of Regulation (EU) 2018/858
the following **paragraph is** added:

Amendment

In Article 5 of Regulation (EU) 2018/858
the following **paragraphs are** added:

Or. en

Amendment 2934

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 80 – paragraph 1 – introductory part

Text proposed by the Commission

In Article 5 of Regulation (EU) 2018/858
the following **paragraph is** added:

Amendment

In Article 5 of Regulation (EU) 2018/858
the following **paragraphs are** added:

Or. en

Amendment 2935

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 80 – paragraph 1

Regulation (EU) 2018/858

Article 5

Text proposed by the Commission

Amendment

4 a. The Commission shall, prior to fulfilling the obligation pursuant to paragraph 4, provide a reasonable explanation based on a gap analysis of existing sectoral legislation in the

automotive sector to determine the existence of potential gaps relating to Artificial Intelligence therein, and consult relevant stakeholders, in order to avoid duplications and overregulation, in line with the Better Regulation principles.

Or. en

Amendment 2936

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 80 – paragraph 1

Regulation (EU) 2018/858

Article 5

Text proposed by the Commission

Amendment

4 a. The Commission shall, prior to fulfilling the obligation pursuant to paragraph 4, provide a reasonable explanation based on a gap analysis of existing sectoral legislation in the automotive sector to determine the existence of potential gaps relating to Artificial Intelligence therein, and consult relevant stakeholders, in order to avoid duplications and overregulation, in line with the Better Regulation principle.

Or. en

Amendment 2937

Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 81 a (new)

Text proposed by the Commission

Amendment

Article 81 a

*Amendment to Regulation (EU)
2019/1020*

In Article 14.4 of Regulation (EU) 2019/1020 the following paragraph is added:

“(l) The power to implement the powers provided for in this Article remotely, where applicable.”

Or. en

Justification

In order to permit "on site" inspections to be carried out remotely, where feasible and appropriate.

Amendment 2938

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 82 – paragraph 1 – introductory part

Text proposed by the Commission

In Article 11 of Regulation (EU) 2019/2144, the following *paragraph is* added:

Amendment

In Article 11 of Regulation (EU) 2019/2144, the following *paragraphs are* added:

Or. en

Amendment 2939

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 82 – paragraph 1 – introductory part

Text proposed by the Commission

In Article 11 of Regulation (EU) 2019/2144, the following *paragraph is* added:

Amendment

In Article 11 of Regulation(EU) 2019/2144, the following *paragraphs are* added:

Or. en

Amendment 2940

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 82 – paragraph 1

Regulation (EU) 2019/2144

Article 11

Text proposed by the Commission

Amendment

3 a. The Commission shall, prior to fulfilling the obligation pursuant to paragraph 3, provide a reasonable explanation based on a gap analysis of existing sectoral legislation in the automotive sector to determine the existence of potential gaps relating to Artificial Intelligence therein, and consult relevant stakeholders, in order to avoid duplications and overregulation, in line with the Better Regulation principles.

Or. en

Amendment 2941

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 82 – paragraph 1

Regulation (EU) 2019/2144

Article 11

Text proposed by the Commission

Amendment

3 a. The Commission shall, prior to fulfilling the obligation pursuant to paragraph 3, provide a reasonable explanation based on a gap analysis of existing sectoral legislation in the automotive sector to determine the existence of potential gaps relating to Artificial Intelligence therein, and consult relevant stakeholders, in order to avoid duplications and overregulation, in line with the Better Regulation principle.

Or. en

Amendment 2942

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tefnută, Ramona Strugariu, Drago Pîslaru, Lucia Ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituță

Proposal for a regulation

Article 82 a (new)

Text proposed by the Commission

Amendment

Article 82 a

Sound regulation

In taking into account the requirements of this Regulation pursuant to the Amendments in Articles 75, 76, 77, 78, 79, 80, 81, and 82, the Commission shall conduct an analysis and consult relevant stakeholders to determine potential gaps as well as overlaps between existing sectoral legislation and the provisions of this Regulation in order to avoid duplication, overregulation, and the creation of loopholes.

Or. en

Amendment 2943

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar

Proposal for a regulation

Article 83

Text proposed by the Commission

Amendment

Article 83

deleted

AI systems already placed on the market or put into service

1. This Regulation shall not apply to the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before [12 months after the date of application of this Regulation referred to in Article 85(2)], unless the replacement

or amendment of those legal acts leads to a significant change in the design or intended purpose of the AI system or AI systems concerned.

The requirements laid down in this Regulation shall be taken into account, where applicable, in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts.

2. This Regulation shall apply to the high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], only if, from that date, those systems are subject to significant changes in their design or intended purpose.

Or. en

Amendment 2944

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 83 – paragraph 1 – introductory part

Text proposed by the Commission

1. Le présent règlement *ne* s'applique *pas* aux systèmes d'IA qui sont des composants des systèmes d'information à grande échelle établis par les actes juridiques énumérés à l'annexe IX qui ont été mis sur le marché ou mis en service avant le [12 mois après la date d'application du présent règlement visée à l'article 85, paragraphe 2], *sauf si le remplacement ou la modification de ces actes juridiques entraîne une modification importante de la conception ou de la destination du ou des systèmes d'IA concernés.*

Amendment

1. Le présent règlement s'applique aux systèmes d'IA qui sont des composants des systèmes d'information à grande échelle établis par les actes juridiques énumérés à l'annexe IX qui ont été mis sur le marché ou mis en service avant le [12 mois après la date d'application du présent règlement visée à l'article 85, paragraphe 2].

Amendment 2945

Sophia in 't Veld, Michal Šimek

Proposal for a regulation

Article 83 – paragraph 1 – introductory part

Text proposed by the Commission

1. This Regulation shall **not** apply to the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before [12 months after the *date of application* of this Regulation referred to in Article 85(2)], unless the replacement or amendment of those legal acts leads to a significant change in the design or intended purpose of the AI system or AI systems concerned.

Amendment

1. This Regulation shall apply to the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before, *with a transitional period of two years* after the *entry into force* of this Regulation.

Amendment 2946

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Article 83 – paragraph 1 – introductory part

Text proposed by the Commission

1. **This Regulation shall not apply to** the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before [12 months after the date of application of this Regulation referred to in Article 85(2)], unless the replacement or amendment of those legal acts leads to a significant change in the design or intended purpose of the AI system or AI

Amendment

1. **Operators of** the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before [the date of application of this Regulation referred to in Article 85(2)] **shall take the necessary steps to comply with the requirements of the present Regulation within 4 years of its entry into force.**

systems concerned.

Or. en

Amendment 2947

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 83 – paragraph 1 – introductory part

Text proposed by the Commission

1. This Regulation shall **not** apply to the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before [12 months after the date of application of this Regulation referred to in Article 85(2)], **unless the replacement or amendment of those legal acts leads to a significant change in the design or intended purpose of the AI system or AI systems concerned.**

Amendment

1. This Regulation shall apply to the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before [12 months after the date of application of this Regulation referred to in Article 85(2)] **and the requirements laid down in this Regulation shall be taken into account in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX.**

Or. en

Amendment 2948

Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 83 – paragraph 1 – introductory part

Text proposed by the Commission

1. This Regulation shall **not** apply to the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX **that have been placed on the market or put into service before [12 months after** the date of application of this Regulation referred to in Article 85(2)], **unless the replacement or amendment of those legal acts leads to a significant change in the design or intended**

Amendment

1. This Regulation shall apply to the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX **starting [on** the date of application of this Regulation referred to in Article 85(2)], **or as soon as there is** a significant change in the design or intended purpose of the AI system or AI systems concerned **in which case it shall apply from [the date of application of this**

purpose of the AI system or AI systems concerned.

Regulation]

Or. en

Amendment 2949

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 83 – paragraph 1 – introductory part

Text proposed by the Commission

1. This Regulation shall not apply to the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before [12 months after the date of application of this Regulation referred to in Article 85(2)], unless the replacement or amendment of those legal acts leads to a significant change in the design or intended purpose of the AI system or AI systems concerned.

Amendment

1. This Regulation shall not apply to the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before [24 months after the date of application of this Regulation referred to in Article 85(2)], unless the replacement or amendment of those legal acts leads to a significant change in the design or intended purpose of the AI system or AI systems concerned.

Or. en

Justification

It is important to provide sufficient time for AI developers to adopt to the Regulation before the provisions enter into force.

Amendment 2950

Sophia in 't Veld, Michal Šimečka, Róberta Thun und Hohenstein

Proposal for a regulation

Article 83 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The requirements laid down in this Regulation shall be taken into account, where applicable, in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be

Amendment

deleted

*undertaken as provided for in those
respective acts.*

Or. en

Amendment 2951

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 83 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Amendment

*The requirements laid down in this
Regulation shall be taken into account,
where applicable, in the evaluation of
each large-scale IT systems established by
the legal acts listed in Annex IX to be
undertaken as provided for in those
respective acts.*

deleted

Or. en

Amendment 2952

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituța

Proposal for a regulation

Article 83 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Amendment

The requirements laid down in this
Regulation shall be taken into account,
where applicable, in the evaluation of each
large-scale IT systems established by the
legal acts listed in Annex IX to be
undertaken as provided for in those
respective acts.

The requirements laid down in this
Regulation shall be taken into account,
where applicable, in the evaluation of each
large-scale IT systems established by the
legal acts listed in Annex IX to be
undertaken as provided for in those
respective acts *and whenever those legal
acts are replaced or amended.*

Or. en

Amendment 2953

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 83 – paragraph 1 – subparagraph 1***Text proposed by the Commission*

The requirements laid down in this Regulation shall **be taken into account, where applicable**, in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts.

Amendment

The requirements laid down in this Regulation shall **apply** in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts.

Or. en

Amendment 2954

Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation**Article 83 – paragraph 1 – subparagraph 1***Text proposed by the Commission*

The requirements laid down in this Regulation shall be taken into account, **where applicable**, in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts.

Amendment

The requirements laid down in this Regulation shall be taken into account in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts.

Or. en

Amendment 2955

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation**Article 83 – paragraph 2**

Text proposed by the Commission

2. This Regulation shall apply to the high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], only if, from that date, those systems are subject to significant changes in their design or intended purpose.

Amendment

2. This Regulation shall apply to the high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], only if, from that date, those systems are subject to significant changes *as defined in Article 3(23)* in their design or intended purpose, *and those changes are not needed to comply with applicable existing or new legislation, or to provide security fixes.*

Or. en

Amendment 2956

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Article 83 – paragraph 2**

Text proposed by the Commission

2. This Regulation shall apply to the high-risk AI systems, *other than the ones referred to in paragraph 1*, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], *only if, from that date, those systems are subject to significant changes in their design or intended purpose.*

Amendment

2. This Regulation shall apply to the high-risk AI systems that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)].

Or. en

Amendment 2957

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

**Proposal for a regulation
Article 83 – paragraph 2**

Text proposed by the Commission

2. ***This Regulation shall apply to the*** high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], ***only if, from that date, those*** systems are subject to ***significant changes*** in their design or intended purpose.

Amendment

2. ***Operators of high-risk AI systems,*** other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)] ***shall take the necessary steps to comply with the requirements of the present Regulation within 2 years of its entry into force or at the time when such systems are subject to a substantial modification*** in their design or intended purpose.

Or. en

Amendment 2958

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

**Proposal for a regulation
Article 83 – paragraph 2**

Text proposed by the Commission

2. Le présent règlement s'applique aux systèmes d'IA à haut risque, autres que ceux visés au paragraphe 1, qui ont été mis sur le marché ou mis en service avant le [date d'application du présent règlement visée à l'article 85, paragraphe 2], ***uniquement si, à compter de cette date, ces systèmes subissent d'importantes modifications de leur conception ou de leur destination.***

Amendment

2. Le présent règlement s'applique aux systèmes d'IA à haut risque, autres que ceux visés au paragraphe 1, qui ont été mis sur le marché ou mis en service avant le [date d'application du présent règlement visée à l'article 85, paragraphe 2].

Or. fr

Amendment 2959

Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

**Proposal for a regulation
Article 83 – paragraph 2**

Text proposed by the Commission

2. This Regulation shall apply to the high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service **before** [date of application of this Regulation referred to in Article 85(2)], **only if, from that date, those systems are subject to significant changes in their design or intended purpose.**

Amendment

2. This Regulation shall apply to the high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service **from** [date of application of this Regulation referred to in Article 85(2)].

Or. en

Amendment 2960

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 83 – paragraph 2**

Text proposed by the Commission

2. This Regulation shall apply to the high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], **only if, from that date, those systems are subject to significant changes in their design or intended purpose.**

Amendment

2. This Regulation shall apply to the high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)].

Or. en

Amendment 2961

Sophia in 't Veld, Michal Šimečka, Róza Thun und Hohenstein

**Proposal for a regulation
Article 83 – paragraph 2**

Text proposed by the Commission

2. This Regulation shall apply to the high-risk AI systems, **other than the ones**

Amendment

2. This Regulation shall apply to the high-risk AI systems that have been placed

referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], ***only if, from that date, those systems are subject to significant changes in their design or intended purpose.***

on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], ***with a transitional period of two years after the application of this Regulation.***

Or. en

Amendment 2962

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ondej Kováčik, Jan-Christoph Oetjen

Proposal for a regulation Article 83 – paragraph 2

Text proposed by the Commission

2. This Regulation shall apply to the high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], only if, from that date, those systems are subject to ***significant changes*** in their design or intended purpose.

Amendment

2. This Regulation shall apply to the high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], only if, from that date, those systems are subject to ***substantial modification*** in their design or intended purpose ***as defined in Article 3(23)***.

Or. en

Amendment 2963

Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation Article 83 a (new)

Text proposed by the Commission

Amendment

Article 83 a
AI systems deployed in the context of employment

Member States may, by law or by

collective agreements, decide to prohibit or limit the use of certain AI systems in the employment context or provide for more specific rules for AI systems in employment, in particular for the purposes of the recruitment, the performance of the contract of employment, including discharge of obligations laid down by law or by collective agreements, management, planning and organisation of work, equality and diversity in the workplace, health and safety at work, protection of employer's or customer's property and for the purposes of the exercise and enjoyment, on an individual or collective basis, of rights and benefits related to employment, and for the purpose of the termination of the employment relationship.

Or. en

Amendment 2964

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 84 – paragraph 1

Text proposed by the Commission

1. The Commission shall assess the need for amendment of the list in Annex III once a year following the entry into force of this Regulation.

Amendment

1. The Commission shall assess the need for amendment of the list in Annex III, *including the extension of existing area headings or addition of new area headings; Article 5's list of prohibited AI practices, and Article 52's list of AI systems requiring additional transparency measures*, once a year following the entry into force of this Regulation.

Or. en

Amendment 2965

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 84 – paragraph 1**

Text proposed by the Commission

1. The Commission shall assess the need for amendment of the list in Annex III once a year following the entry into force of this Regulation.

Amendment

1. The Commission shall assess the need for amendment of the list in Annex III, *including the extension of existing area headings or addition of new area headings, the list of prohibited practices in Article 5, and the list of AI systems requiring additional transparency measures*, once a year following the entry into force of this Regulation.

Or. en

Amendment 2966

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

**Proposal for a regulation
Article 84 – paragraph 1**

Text proposed by the Commission

1. The Commission shall assess the need for amendment of the list in Annex III *once a year* following the entry into force of this Regulation.

Amendment

1. The Commission shall assess the need for amendment of the list in Annex III *every 24 months* following the entry into force of this Regulation *and until the end of the period of the delegation of power. The findings of that assessment shall be presented to the European Parliament and the Council.*

Or. en

Amendment 2967

Jörgen Warborn, Arba Kokalari, Tomas Tobé

**Proposal for a regulation
Article 84 – paragraph 1**

Text proposed by the Commission

Amendment

1. The Commission shall assess the need for amendment of the list in Annex III once a year following the entry into force of this Regulation.

1. The Commission shall assess the need for amendment of the list in Annex III once a year following the entry into force of this Regulation, *and when necessary, table to the European Parliament and the Council a legislative proposal in this regard.*

Or. en

Amendment 2968

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 84 – paragraph 1

Text proposed by the Commission

1. The Commission shall assess the need for amendment of the list in Annex *III* once a year following the entry into force of this Regulation.

Amendment

1. The Commission shall assess the need for amendment of the list in Annex *I* once a year following the entry into force of this Regulation. *The findings of that assessment shall be presented to the European Parliament and the Council.*

Or. en

Amendment 2969

Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 84 – paragraph 1

Text proposed by the Commission

1. The Commission shall assess the need for amendment of the list in Annex III once a year following the entry into force of this Regulation.

Amendment

1. The Commission shall assess the need for amendment of the list in Annex III, *including the extension of existing area headings or addition of new area headings*, once a year following the entry into force of this Regulation.

Or. en

Amendment 2970

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Alin Mituța, Malik Azmani

**Proposal for a regulation
Article 84 – paragraph 1***Text proposed by the Commission*

1. ***The Commission*** shall assess the need for amendment of the list in Annex III once a year following the entry into force of this Regulation.

Amendment

1. ***In consultation with the AI Office, the Commissions*** shall assess the need for amendment of the list in Annex III once a year following the entry into force of this Regulation.

Or. en

Amendment 2971

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar

**Proposal for a regulation
Article 84 – paragraph 1***Text proposed by the Commission*

1. The Commission shall assess the need for amendment of the list in Annex III ***once a year*** following the entry into force of this Regulation.

Amendment

1. The Commission shall assess the need for amendment of the list in Annex III ***annually*** following the entry into force of this Regulation ***and following a recommendation of the Board.***

Or. en

Amendment 2972

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

**Proposal for a regulation
Article 84 – paragraph 1 a (new)***Text proposed by the Commission**Amendment*

I a. The Commission shall assess the need for amendment of the list in Annex III once a year following the entry into force of this Regulation. The findings of that assessment shall be presented to the European Parliament and the Council.

Or. en

Amendment 2973

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 84 – paragraph 2

Text proposed by the Commission

2. By [three years after the date of application of this Regulation referred to in Article 85(2)] and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The reports shall be made public.

Amendment

2. By [two years after the date of application of this Regulation referred to in Article 85(2)] and every three years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The reports shall be made public.

Or. en

Amendment 2974

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 84 – paragraph 3 – point a

Text proposed by the Commission

(a) the status of the financial and human resources of the national competent authorities in order to effectively perform the tasks assigned to them under this Regulation;

Amendment

(a) the status of the financial, *technical* and human resources of the national competent authorities in order to effectively perform the tasks assigned to them under this Regulation;

Or. en

Amendment 2975

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation

Article 84 – paragraph 3 – point b

Text proposed by the Commission

(b) the state of penalties, and notably administrative fines as referred to in Article 71(1), applied by Member States to infringements of the provisions of this Regulation.

Amendment

(b) the state of penalties, and notably administrative fines as referred to in Articles 70a and 71 applied by *national supervisory authorities* and Member States to infringements of the provisions of this Regulation.

Or. en

Amendment 2976

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia uríš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation

Article 84 – paragraph 3 – point b

Text proposed by the Commission

(b) the state of penalties, and notably administrative fines as referred to in Article 71(1), applied by Member States to infringements of the provisions of this Regulation.

Amendment

(b) the state of penalties, and notably administrative fines as referred to in Article 71, applied by Member States to infringements of the provisions of this Regulation.

Or. en

Amendment 2977

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia uríš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituța

Proposal for a regulation

Article 84 – paragraph 3 – point b a (new)

Text proposed by the Commission

Amendment

(b a) the state of the development of harmonised standards and common specifications for Artificial Intelligence;

Or. en

Amendment 2978

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 84 – paragraph 3 – point b a (new)

Text proposed by the Commission

Amendment

(b a) the levels of investments in research, development and application of AI systems throughout the Union,

Or. en

Amendment 2979

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 84 – paragraph 3 – point b b (new)

Text proposed by the Commission

Amendment

(b b) the competitiveness of the aggregated European AI ecosystem compared to AI ecosystems in third countries.

Or. en

Amendment 2980

Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 84 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. Within [two years after the date of application of this Regulation referred to in Article 85(2)] and every two years thereafter, the Commission shall evaluate the impact and effectiveness of the Regulation with regards to the resource and energy use, waste production and other environmental impact of AI systems and evaluate the need for proposing legislation to regulate the resource and energy efficiency of AI systems and related ICT systems in order for the sector to contribute to EU climate strategy and targets.

Or. en

Amendment 2981

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Mituță, Ramona Strugariu, Drago Pîslaru, Lucia Šuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

**Proposal for a regulation
Article 84 – paragraph 4**

Text proposed by the Commission

4. Within [*three years* after the date of application of this Regulation referred to in Article 85(2)] and every *four* years thereafter, the Commission shall evaluate the impact and effectiveness of codes of conduct to foster the application of the requirements set out in Title III, Chapter 2 and possibly other additional requirements for AI systems other than high-risk AI systems.

Amendment

4. Within [*one year* after the date of application of this Regulation referred to in Article 85(2)] and every *two* years thereafter, the Commission shall evaluate the impact and effectiveness of codes of conduct to foster the application of the requirements set out in Title III, Chapter 2 and possibly other additional requirements for AI systems other than high-risk AI systems.

Or. en

Amendment 2982

Sophia in 't Veld, Michal Šimečka

**Proposal for a regulation
Article 84 – paragraph 5**

Text proposed by the Commission

5. For the purpose of paragraphs 1 to 4 the Board, the Member States and national competent authorities shall provide the Commission with information on its request.

Amendment

5. For the purpose of paragraphs 1 to 4 the Board, the Member States and national competent authorities shall provide the Commission with information on its request ***without undue delay***.

Or. en

Amendment 2983

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Alin Mituța

Proposal for a regulation

Article 84 – paragraph 5

Text proposed by the Commission

5. For the purpose of paragraphs 1 to 4 the **Board**, the Member States and national competent authorities shall provide the Commission with information on its request.

Amendment

5. For the purpose of paragraphs 1 to 4 the **AI Office**, the Member States and national competent authorities shall provide the Commission with information on its request.

Or. en

Amendment 2984

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 84 – paragraph 6

Text proposed by the Commission

6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions and findings of the Board, of the European Parliament, of the Council, and of other relevant bodies or sources.

Amendment

6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions and findings of the Board, of the European Parliament, of the Council, and of ***equality bodies and*** other relevant bodies or sources, ***and shall consult relevant external stakeholders, in particular those potentially affected by the AI system, as well as stakeholders from academia and civil society.***

Amendment 2985

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 84 – paragraph 6**

Text proposed by the Commission

6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions and findings of the Board, of the European Parliament, of the Council, and of other relevant bodies or sources.

Amendment

6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions and findings of the Board, of the European Parliament, of the Council, and of **equality bodies and** other relevant bodies or sources, **and shall consult relevant external stakeholders, in particular those potentially affected by the AI system, as well as stakeholders from academia and civil society.**

Amendment 2986

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

**Proposal for a regulation
Article 84 – paragraph 6**

Text proposed by the Commission

6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions and findings of the Board, of the European Parliament, of the Council, and of other relevant bodies or sources.

Amendment

6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions and findings of the Board, of the European Parliament, of the Council, and of other relevant bodies or sources, **including stakeholders, and in particular civil society.**

Amendment 2987

Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation**Article 84 – paragraph 6***Text proposed by the Commission*

6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions and findings of the Board, of the European Parliament, of the Council, and of other relevant bodies or sources.

Amendment

6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions and findings of the Board, of the European Parliament, of the Council, and of other relevant bodies or sources, *including from academia and civil society.*

Or. en

Amendment 2988

Sophia in 't Veld, Michal Šimek

Proposal for a regulation**Article 84 – paragraph 6***Text proposed by the Commission*

6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions and findings of the Board, of the European Parliament, of the Council, and of other relevant bodies or sources.

Amendment

6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions and findings of the Board, of the European Parliament, of the Council, and of other relevant bodies or sources, *which shall be attached to the report.*

Or. en

Amendment 2989

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tefnută, Ramona Strugariu, Drago Pîslaru, Lucia Ūriș Nicholsonová, Irena Joveva, Alin Mituță

Proposal for a regulation**Article 84 – paragraph 6***Text proposed by the Commission**Amendment*

6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions and findings of the **Board**, of the European Parliament, of the Council, and of other relevant bodies or sources.

6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions and findings of the **AI Office**, of the European Parliament, of the Council, and of other relevant bodies or sources.

Or. en

Amendment 2990

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 84 – paragraph 7

Text proposed by the Commission

7. The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology and in the light of the state of progress in the information society.

Amendment

7. The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology, ***the effect of AI systems on health and safety, fundamental rights, the environment, equality, and accessibility for persons with disabilities***, and in the light of the state of progress in the information society.

Or. en

Amendment 2991

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 84 – paragraph 7

Text proposed by the Commission

7. The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology and in the light of the state of progress in the information society.

Amendment

7. The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology, ***the effect of AI systems on health and safety, fundamental rights, equality, and***

accessibility for persons with disabilities,
and in the light of the state of progress in
the information society.

Or. en

Amendment 2992

Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 84 – paragraph 7

Text proposed by the Commission

7. The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology and in the light of the state of progress in the information society.

Amendment

7. The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account *the effect of AI systems on fundamental rights, equality, and accessibility for persons with disabilities*, developments in technology and in the light of the state of progress in the information society.

Or. en

Amendment 2993

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Article 84 – paragraph 7

Text proposed by the Commission

7. The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology and in the light of the state of progress in the information society.

Amendment

7. The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology and *new potential or realised risks to fundamental rights, and* in the light of the state of progress in the information society.

Or. en

Amendment 2994

Sophia in 't Veld, Michal Šimek

Proposal for a regulation

Article 84 – paragraph 7

Text proposed by the Commission

7. The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology and in the light of the state of progress in the information society.

Amendment

7. The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account *the impact of this Regulation on fundamental rights*, developments in technology and in the light of the state of progress in the information society.

Or. en

Amendment 2995

Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 84 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

7 a. By three years from the date of application of this Regulation at the latest, the Commission shall carry out an assessment of the enforcement of this Regulation and shall report it to the European Parliament, the Council and the European Economic and Social Committee, taking into account the first years of application of the Regulation. On the basis of the findings that report shall, where appropriate, be accompanied by a proposal for amendment of this Regulation with regard to the structure of enforcement and the need for an EU agency to resolve any identified shortcomings.

Or. en

Amendment 2996

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 84 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

7 a. To guide the evaluations and reviews referred to in paragraphs 1 to 4, the Board shall undertake to develop an objective and participative methodology for the evaluation of risk level based on the criteria outlined in the relevant articles and inclusion of new systems in: the list in Annex III, including the extension of existing area headings or addition of new area headings; Article 5's list of prohibited AI practices; and Article 52's list of AI systems requiring additional transparency measures.

Or. en

Amendment 2997

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 84 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

7 a. To guide the evaluations and reviews referred to in paragraphs 1 to 4, the Board shall undertake to develop an objective and participative methodology for the evaluation of risk level based on the criteria outlined in the relevant articles and inclusion of new systems in: the list in Annex III, including the extension of existing area headings or addition of new area headings; the list of prohibited practices in Article 5; and the list of AI systems requiring additional transparency measures.

Or. en

Amendment 2998

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 84 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

7 a. Any amendment to this Regulation pursuant to paragraph 7, or relevant future delegated or implementing acts, which concern sectoral legislation listed in annex II section B, shall take into account the regulatory specificities of each sector, and should not interfere with existing governance, conformity assessment and enforcement mechanisms and authorities established therein.

Or. en

Amendment 2999

René Repasi, Marc Angel, Andreas Schieder, Maria-Manuel Leitão-Marques

Proposal for a regulation

Article 84 a (new)

Text proposed by the Commission

Amendment

Article 84 a

New Article 84a

Amendments to Directive (EU) 2020/1828 on Representative Actions for the Protection of the Collective Interests of Consumers

The following is added to Annex I:

"(X) Regulation laying down harmonised rules on artificial intelligence (Artificial Intelligence Act). Artificial Intelligence (AI)

Or. en

Amendment 3000
Marion Walsmann

Proposal for a regulation
Article 85 – paragraph 2

Text proposed by the Commission

2. This Regulation shall apply from [24 months following the entering into force of the Regulation].

Amendment

2. This Regulation shall apply from [36 months following the entering into force of the Regulation].

Or. en

Amendment 3001
Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ondej Kováč, Jan-Christoph Oetjen

Proposal for a regulation
Article 85 – paragraph 2

Text proposed by the Commission

2. This Regulation shall apply from [24 months following the entering into force of the Regulation].

Amendment

2. This Regulation shall apply from [48 months following the entering into force of the Regulation].

Or. en

Amendment 3002
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 85 – paragraph 2

Text proposed by the Commission

2. This Regulation shall apply from [24 months following the entering into force of the Regulation].

Amendment

2. This Regulation shall apply from [48 months following the entering into force of the Regulation].

Or. en

Amendment 3003

Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation**Article 85 – paragraph 2***Text proposed by the Commission*

2. This Regulation shall apply from [24 months following the entering into force of the Regulation].

Amendment

2. This Regulation shall apply from [6 months following the entering into force of the Regulation].

Or. en

Amendment 3004

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation**Article 85 – paragraph 3 – point b***Text proposed by the Commission*

(b) Article 71 shall apply from [*twelve* months following the entry into force of this Regulation].

Amendment

(b) Article 71 shall apply from [24 months following the entry into force of this Regulation].

Or. en

Amendment 3005

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation**Article 85 – paragraph 3 – point b a (new)***Text proposed by the Commission**Amendment*

(b a) Title II shall apply from [24 months following the entry into force of this Regulation].

Or. en

Amendment 3006

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 85 – paragraph 3 a (new)**

Text proposed by the Commission

Amendment

***3 a. Member States shall not until ...
[24 months after the date of application of
this Regulation] impede the making
available of AI systems and products
which were placed on the market in
conformity with Union harmonisation
legislation before [the date of application
of this Regulation].***

Or. en

Amendment 3007

**Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner,
Ondej Kováč, Jan-Christoph Oetjen**

**Proposal for a regulation
Article 85 – paragraph 3 a (new)**

Text proposed by the Commission

Amendment

***3 a. Member States shall not until...
[24 months after the date of application of
this Regulation] impede the making
available of AI systems and products
which were placed on the market
inconformity with Union harmonisation
legislation before [the date of application
of this Regulation].***

Or. en

Amendment 3008

**Svenja Hahn, Drago Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Moritz
Körner, Ondej Kováč, Jan-Christoph Oetjen**

**Proposal for a regulation
Article 85 – paragraph 3 b (new)**

Text proposed by the Commission

Amendment

3 b. At the latest by six months after entry into force of this Regulation, the European Commission shall submit a standardization request to the European Standardisation Organisations in order to ensure the timely provision of all relevant harmonised standards that cover the essential requirements of this regulation. Any delay in submitting the standardisation request shall add to the transitional period of 24 months as stipulated in paragraph 3a.

Or. en

Amendment 3009

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 85 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3 b. At the latest by six months after entry into force of this Regulation, the European Commission shall submit a standardization request to the European Standardisation Organisations in order to ensure the timely provision of all relevant harmonised standards that cover the essential requirements of this regulation. Any delay in submitting the standardisation request shall add to the transitional period of 24 months as stipulated in paragraph 4

Or. en

Amendment 3010

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

Annex I

<i>Text proposed by the Commission</i>	<i>Amendment</i>
ARTIFICIAL INTELLIGENCE TECHNIQUES AND APPROACHES referred to in Article 3, point 1	<i>deleted</i>
(a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning;	
(b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;	
(c) Statistical approaches, Bayesian estimation, search and optimization methods.	

Or. en

Justification

*An exhaustive list of techniques risks creating loopholes and having to be updated too often.
Therefore, it is appropriate to delete it.*

Amendment 3011

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Annex I

<i>Text proposed by the Commission</i>	<i>Amendment</i>
ARTIFICIAL INTELLIGENCE TECHNIQUES AND APPROACHES referred to in Article 3, point 1	<i>deleted</i>
(a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep	

learning;

(b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;

(c) Statistical approaches, Bayesian estimation, search and optimization methods.

Or. en

Justification

Our modified definition of AI makes this obsolete.

Amendment 3012

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation

Annex I

Text proposed by the Commission

Amendment

***ARTIFICIAL INTELLIGENCE
TECHNIQUES AND
APPROACHES referred to in Article 3,
point 1***

deleted

(a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning;

(b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;

(c) Statistical approaches, Bayesian estimation, search and optimization methods.

Or. en

Amendment 3013

Carlo Fidanza

Proposal for a regulation

Annex I – point b

Text proposed by the Commission

Amendment

(b) *Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;* *deleted*

Or. en

Justification

To reflect the necessity of a more detailed definition, Annex I should be adjusted and limited to point a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning.

Amendment 3014

Geoffroy Didier

Proposal for a regulation

Annex I – point b

Text proposed by the Commission

Amendment

(b) *Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;* *deleted*

Or. en

Justification

Annex I lists different techniques and approaches that can refer to AI. If some are inherently linked and identified as AI (paragraph a), the others can be used within applications which do not fall under AI (paragraphs b and c).

Amendment 3015
Axel Voss, Deirdre Clune

Proposal for a regulation
Annex I – point b

Text proposed by the Commission

Amendment

(b) *Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;* *deleted*

Or. en

Amendment 3016
Karlo Ressler

Proposal for a regulation
Annex I – point b

Text proposed by the Commission

Amendment

(b) *Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;* *deleted*

Or. en

Amendment 3017
Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation
Annex I – point b

Text proposed by the Commission

Amendment

(b) *Logic- and knowledge-based approaches, including knowledge representation, inductive (logic)* *deleted*

programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;

Or. en

Amendment 3018

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Annex I – point b

Text proposed by the Commission

(b) *Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;*

Amendment

(b) *Other data-driven approaches, including search and optimization methods.*

Or. en

Amendment 3019

Carlo Fidanza

Proposal for a regulation

Annex I – point c

Text proposed by the Commission

(c) *Statistical approaches, Bayesian estimation, search and optimization methods.*

Amendment

deleted

Or. en

Justification

To reflect the necessity of a more detailed definition, Annex I should be adjusted and limited to point a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning.



*Committee on the Internal Market and Consumer Protection
Committee on Civil Liberties, Justice and Home Affairs*

2021/0106(COD)

13.6.2022

AMENDMENTS

3020 - 3312

Draft report
Brando Benifei, Drago 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))

AM_Com_LegReport

Amendment 3020
Axel Voss, Deirdre Clune

Proposal for a regulation
Annex I – point c

Text proposed by the Commission

Amendment

(c) *Statistical approaches, Bayesian estimation, search and optimization methods.* *deleted*

Or. en

Amendment 3021
Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation
Annex I – point c

Text proposed by the Commission

Amendment

(c) *Statistical approaches, Bayesian estimation, search and optimization methods.* *deleted*

Or. en

Justification

The inclusion of (c) under the classification of AI means that simple statistical methods which have been applied to products and services for several decades would also be covered by the AI Regulation. This would lead to immense bureaucracy for actors the Regulation was never meant to target.

Amendment 3022
Karlo Ressler

Proposal for a regulation
Annex I – point c

Text proposed by the Commission

Amendment

(c) *Statistical approaches, Bayesian estimation, search and optimization* *deleted*

methods.

Or. en

Amendment 3023

Geoffroy Didier

Proposal for a regulation

Annex I – point c

Text proposed by the Commission

Amendment

(c) *Statistical approaches, Bayesian estimation, search and optimization methods.* *deleted*

Or. en

Justification

Annex I lists different techniques and approaches that can refer to AI. If some are inherently linked and identified as AI (paragraph a), the others can be used within applications which do not fall under AI (paragraphs b and c).

Amendment 3024

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Annex I – point c

Text proposed by the Commission

Amendment

(c) *Statistical approaches, Bayesian estimation, search and optimization methods.* *deleted*

Or. en

Amendment 3025

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Annex I – point c

Text proposed by the Commission

(c) Statistical approaches, Bayesian estimation, search ***and optimization methods.***

Amendment

(c) Statistical approaches, Bayesian estimation, *if they are used to extract decisions from data in an automated way and search.*

Or. en

Amendment 3026

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Annex I – point c a (new)

Text proposed by the Commission

Amendment 3027

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Annex I – point c b (new)

Text proposed by the Commission

Amendment 3028

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Amendment

(c bis) Approches fondées sur l'imitation de réseaux neuronaux et neuraux et les réseaux neuro-robotiques;

Or. fr

Amendment

(c ter) Tâches d'apprentissage automatique sur les graphiques pour les tâches de répétition ou la reconnaissance des formes;

Or. fr

Proposal for a regulation
Annex I – point c c (new)

Text proposed by the Commission

Amendment

(c quater) Techniques de programmation en langage naturel, y compris mêlée à des systèmes de détection et de reconnaissance des émotions, utilisant des interactions entre le langage humain et le langage informatique;

Or. fr

Amendment 3029

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Annex I – point c d (new)

Text proposed by the Commission

Amendment

(c quinques) Vision artificielle pour la reconnaissance de formes, y compris les analyses graphiques ou l'identification des signatures numériques;

Or. fr

Amendment 3030

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Annex I – point c e (new)

Text proposed by the Commission

Amendment

(c sexies) Systèmes interactifs liés à des systèmes mécatroniques, robotiques et d'automation.

Or. fr

Amendment 3031
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Annex II – Part A – point 6

Text proposed by the Commission

Amendment

6. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62); *deleted*

Or. en

Amendment 3032
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Annex II – Part A – point 11

Text proposed by the Commission

Amendment

11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1); *deleted*

Or. en

Amendment 3033
Deirdre Clune, Axel Voss, Andreas Schwab

Proposal for a regulation
Annex II – Part A – point 11

Text proposed by the Commission

Amendment

11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1;

deleted

Or. en

Amendment 3034

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Annex II – Part A – point 12**

Text proposed by the Commission

Amendment

12. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

deleted

Or. en

Amendment 3035

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

**Proposal for a regulation
Annex II – Part A – point 12 a (new)**

Text proposed by the Commission

Amendment

12 a. Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96/357, 29.3.2014).

Or. en

Amendment 3036

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Annex II – Part A – point 12 a (new)

Text proposed by the Commission

Amendment

***12 bis. [RÈGLEMENT DU
PARLEMENT EUROPÉEN ET DU
CONSEIL relatif à un marché intérieur
des services numériques (Législation sur
les services numériques) et modifiant la
directive 2000/31/CE]***

Or. fr

Amendment 3037

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Annex II – Part A – point 12 b (new)

Text proposed by the Commission

Amendment

***12 ter. [RÈGLEMENT DU
PARLEMENT EUROPÉEN ET DU
CONSEIL relatif aux marchés
contestables et équitables dans le secteur
numérique (législation sur les marchés
numériques)].***

Or. fr

Amendment 3038

Deirdre Clune, Axel Voss, Andreas Schwab

Proposal for a regulation

Annex II – Part B – point 7 a (new)

Text proposed by the Commission

Amendment

7 a. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1;

Or. en

Amendment 3039

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex II – Part B – point 7 a (new)

Text proposed by the Commission

Amendment

7 a. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1;

Or. en

Amendment 3040

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex II – Part B – point 7 a (new)

Text proposed by the Commission

Amendment

7 a. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign

requirements for energy-related products.

Or. en

Amendment 3041

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex II – Part B – point 7 b (new)

Text proposed by the Commission

Amendment

7 b. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

Or. en

Amendment 3042

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Paul Tang, Maria Grapini

Proposal for a regulation

Annex III – title

Text proposed by the Commission

Amendment

HIGH-RISK AI SYSTEMS REFERRED TO IN ARTICLE 6(2)

INDICATIVE LIST OF HIGH-RISK AI SYSTEMS REFERRED TO IN ARTICLE 6(2)

Or. en

Amendment 3043

Geoffroy Didier

Proposal for a regulation

Annex III – title

Text proposed by the Commission

Amendment

HIGH-RISK AI SYSTEMS REFERRED TO IN ARTICLE 6(2)

HIGH-RISK USES OF AI SYSTEMS REFERRED TO IN ARTICLE 6(2)

Or. en

Justification

Some applications of AI must be considered as high-risk systems from the moment some criteria, such as seriousness and probability of occurrence of serious damages for individuals (threats on health, life or fundamental rights), are gathered. It is important to ensure that not all applications of AI in a specific sector are irrelevantly considered as high-risk systems, while the use made of them is not necessarily high-risk. For instance, in human resources field, AI systems should be restricted to the only objective of recruitment or individual selection and decision making for promotions or contract termination. A too broad definition of a high-risk AI system could bring to heavy obligations for numerous economic players and thus hamper technological innovation from French and European players, especially smaller ones.

Amendment 3044

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – title

Text proposed by the Commission

Amendment

HIGH-RISK AI SYSTEMS REFERRED TO IN ARTICLE 6(2)

CRITICAL USE CASES REFERRED TO IN ARTICLE 6(2)

Or. en

Amendment 3045

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ond ej Kova īk, Jan-Christoph Oetjen

Proposal for a regulation

Annex III – title

Text proposed by the Commission

Amendment

HIGH-RISK AI SYSTEMS REFERRED TO IN ARTICLE 6(2)

CRITICAL AREAS REFERRED TO IN ARTICLE 6(2)

Or. en

Amendment 3046

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – introductory part

Text proposed by the Commission

High-risk AI systems pursuant to Article 6(2) **are the AI systems listed in any of the following areas:**

Amendment

The AI systems specifically mentioned under points 1-8 stand for critical use cases and are each considered to be high-risk AI systems pursuant to Article 6(2), when - according to their instructions to use - their intended purpose and specific use pose a significant risk of harm to the health and safety or a risk of adverse impact on fundamental rights:

Or. en

Amendment 3047

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nută, Ramona Strugariu, Drago Pîslaru, Lucia urîș Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation

Annex III – paragraph 1 – point 1 – introductory part

Text proposed by the Commission

1. Biometric identification **and** categorisation of natural persons:

Amendment

1. Biometric and biometrics-based systems:

- (a) **AI systems intended to be used for the ‘real-time’ and ‘post’ remote biometric identification of natural persons;**
- (b) **AI systems intended to be used for the remote biometric categorisation of natural persons in publicly-accessible spaces;**
- (c) **AI systems intended to be used for emotion recognition in natural persons;**

Or. en

Amendment 3048

Axel Voss, Deirdre Clune

Proposal for a regulation
Annex III – paragraph 1 – point 1 – introductory part

Text proposed by the Commission

1. Biometric identification *and* categorisation of natural persons:

Amendment

1. Biometric identification *systems, excluding biometric authentication or verification, intended to be used for the ‘real-time’ and ‘post’ remote biometric identification or categorisation of natural persons (i.e., revealing their identity or tracking their behaviour) without their expressed or implied consent and causing legal effects or discrimination against the affected person;*

Or. en

Amendment 3049

Rob Rooken

on behalf of the ECR Group

Proposal for a regulation

Annex III – paragraph 1 – point 1 – introductory part

Text proposed by the Commission

1. Biometric identification and categorisation of natural persons:

Amendment

1. Biometric *or biometrics-based profiling, including* identification and categorisation of natural persons:

Or. en

Amendment 3050

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 1 – introductory part

Text proposed by the Commission

1. Biometric identification and categorisation of natural persons:

Amendment

1. Biometric identification, *biometrics-based data* and categorisation

of natural persons:

Or. en

Amendment 3051

Kosma Złotowski, Patryk Jaki, Eugen Jurzyca, Adam Bielan

Proposal for a regulation

Annex III – paragraph 1 – point 1 – introductory part

Text proposed by the Commission

1. **Biometric** identification and categorisation of natural persons:

Amendment

1. **Biometrics systems** identification and categorisation of natural persons

Or. en

Amendment 3052

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 1 – introductory part

Text proposed by the Commission

1. Biometric **identification and categorisation of natural persons**:

Amendment

1. **AI systems which use biometric or biometrics-based data**:

Or. en

Amendment 3053

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Paul Tang, Maria Grapini

Proposal for a regulation

Annex III – paragraph 1 – point 1 – introductory part

Text proposed by the Commission

1. Biometric **identification and categorisation of natural persons**:

Amendment

1. **AI systems which use biometric or biometrics-based data**:

Or. en

Amendment 3054

**Krzysztof Hetman, Adam Jarubas, Andrzej Halicki, Jerzy Buzek, Janusz Lewandowski,
Radosław Sikorski**

Proposal for a regulation

Annex III – paragraph 1 – point 1 – introductory part

Text proposed by the Commission

Amendment

1. Biometric identification **and categorisation** of natural persons:

1. Biometric identification of natural persons:

Or. en

Amendment 3055

Axel Voss, Deirdre Clune

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a

Text proposed by the Commission

Amendment

(a) *AI systems intended to be used for the ‘real-time’ and ‘post’ remote biometric identification of natural persons;* *deleted*

Or. en

Amendment 3056

Drago Tudorache

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a

Text proposed by the Commission

Amendment

(a) *AI systems intended to be used for the ‘real-time’ and ‘post’ remote biometric identification of natural persons;* *deleted*

Or. en

Amendment 3057

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a

Text proposed by the Commission

Amendment

(a) *AI systems intended to be used for the ‘real-time’ and ‘post’ remote biometric identification of natural persons;* *deleted*

Or. en

Amendment 3058

Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Marc Angel

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a

Text proposed by the Commission

Amendment

(a) *AI systems intended to be used for the ‘real-time’ and ‘post’ remote biometric identification of natural persons;* *deleted*

Or. en

Amendment 3059

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a

Text proposed by the Commission

Amendment

(a) AI systems intended to be used for the ‘real-time’ and ‘post’ remote biometric

(a) AI systems intended to be used for the ‘real-time’ and ‘post’ remote biometric identification of natural persons, *excluding*

identification of natural persons;

verification/authentification systems whose sole purpose is to confirm that a specific natural person is the person he or she claims to be, and systems that are used to confirm the identity of a natural person for the sole purpose of having access to a service, a device or premises;

Or. en

Amendment 3060

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Paul Tang, Maria Grapini, Brando Benifei

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a

Text proposed by the Commission

(a) AI systems *intended to* be used for the ‘*real-time*’ and ‘*post*’ remote biometric identification of natural persons;

Amendment

(a) AI systems *that are or may* be used for the biometric identification of natural persons, *including in workplaces, in educational settings and in border surveillance, or for the provision of public or essential services*;

Or. en

Amendment 3061

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a

Text proposed by the Commission

(a) les systèmes d’IA destinés à être utilisés pour l’identification biométrique à distance «en temps réel» et «a posteriori» des personnes physiques.

Amendment

(a) les systèmes d’IA destinés à être utilisés pour l’identification biométrique à distance «en temps réel» et «a posteriori» des personnes physiques, *dans la stricte mesure de la dérogation à l’interdiction générale de leur usage prévue par l’article 5*;

Or. fr

Amendment 3062

Krzysztof Hetman, Adam Jarubas, Andrzej Halicki, Jerzy Buzek, Janusz Lewandowski, Radosław Sikorski

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a

Text proposed by the Commission

(a) AI systems intended to be used for the ‘real-time’ and ‘post’ remote biometric identification of natural persons;

Amendment

(a) AI systems intended to be used for the ‘real-time’ and ‘post’ remote biometric identification of natural persons ***without their agreement, including remote biometric identification;***

Or. en

Amendment 3063

Kosma Złotowski, Patryk Jaki, Eugen Jurzyca

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a

Text proposed by the Commission

(a) AI systems intended to be used for the ‘**real-time**’ and ‘post’ remote biometric identification of natural persons;

Amendment

(a) AI ***biometric identification*** systems intended to be used for the ‘**real time**’ and ‘post’ remote biometric identification of natural persons ***without their agreement;***

Or. en

Amendment 3064

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a

Text proposed by the Commission

(a) AI systems ***intended to*** be used for the ‘real-time’ and ‘post’ remote biometric identification of natural persons;

Amendment

(a) AI systems ***that are or may*** be used for the ‘real-time’ and ‘post’ remote biometric identification of natural persons;

Or. en

Amendment 3065

Rob Rooken

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a

Text proposed by the Commission

(a) AI systems *intended to be* used for the ‘real-time’ and ‘post’ *remote* biometric identification of natural persons;

Amendment

(a) AI systems used for the ‘real-time’ and ‘post’ biometric identification of natural persons;

Or. en

Amendment 3066

Svenja Hahn, Nicola Beer, Karen Melchior, Vlad-Marius Boto , Abir Al-Sahlani, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) AI systems intended to be used to make inferences on the basis of biometric data, including emotion recognition systems, or biometrics-based data, including speech patterns, tone of voice, lip-reading and body language analysis, that produces legal effects or affects the rights and freedoms of natural persons.

Or. en

Amendment 3067

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Maria Grapini, Brando Benifei

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) AI systems that are or may be used for the detection of a person's presence, in workplaces, in educational settings, and in border surveillance, including in the virtual / online version of these spaces, on the basis of their biometric or biometrics-based data;

Or. en

Amendment 3068

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) AI systems that are or may be used for the biometric identification of natural persons in publicly accessible spaces, as well as in workplaces, in educational settings and in border surveillance, or in the provision of public or essential services;

Or. en

Amendment 3069

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) AI systems that may be or are intended to be used for the 'real-time' and 'post' non-remote biometric identification of natural persons in publicly accessible spaces, as well as in workplaces, in educational settings and in border surveillance;

Amendment 3070

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a a (new)

Text proposed by the Commission

Amendment

(a bis) les systèmes d'I.A. destinés à être utilisés par des appareils, drones ou véhicules autonomes pour transporter ou prendre en charge des personnes physiques;

Or. fr

Amendment 3071

Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) AI systems that are or may be used for biometric verification in publicly accessible spaces, as well as in workplaces and in educational settings;

Or. en

Amendment 3072

Rob Rooken

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) AI categorisation systems using biometric or biometrics-based data;

Amendment 3073

Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a b (new)

Text proposed by the Commission

Amendment

(a b) AI systems that are or may be used for the detection of a person's presence, in workplaces, in educational settings, and in border surveillance, including in the virtual / online version of these spaces, on the basis of their biometric or biometrics-based data;

Amendment 3074

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a b (new)

Text proposed by the Commission

Amendment

(a b) AI systems that may be or are intended to be used for the 'real-time' and 'post' non-remote biometric identification of natural persons in publicly accessible spaces, as well as in workplaces, in educational settings and in border surveillance;

Amendment 3075

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Maria Grapini, Brando Benifei

Proposal for a regulation
Annex III – paragraph 1 – point 1 – point a b (new)

Text proposed by the Commission

Amendment

(a b) AI systems that are or may be used for monitoring compliance with health and safety measures or inferring alertness /attentiveness for safety purposes, on the basis of biometric or biometrics-based data;

Or. en

Amendment 3076

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a b (new)

Text proposed by the Commission

Amendment

(a b) AI systems that are or may be used for biometric verification in publicly accessible spaces, as well as in workplaces and in educational settings;

Or. en

Amendment 3077

Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a b (new)

Text proposed by the Commission

Amendment

(a b) AI systems that are or may be used for categorisation on the basis of biometric or biometrics-based data;

Or. en

Amendment 3078

Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a c (new)

Text proposed by the Commission

Amendment

(a c) AI systems that are or may be used for monitoring compliance with health and safety measures or inferring alertness / attentiveness for safety purposes, on the basis of biometric or biometrics-based data;

Or. en

Amendment 3079

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a c (new)

Text proposed by the Commission

Amendment

(a c) AI systems that are or may be used for ‘real-time’ and ‘post’ biometric verification in publicly accessible spaces, as well as in workplaces and in educational settings;

Or. en

Amendment 3080

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Maria Grapini, Brando Benifei

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a c (new)

Text proposed by the Commission

Amendment

(a c) AI systems that are or may be used to diagnose or support diagnosis of medical conditions or medical

emergencies on the basis of biometric or biometrics-based data;

Or. en

Amendment 3081

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a c (new)

Text proposed by the Commission

Amendment

(a c) AI systems that are or may be used to diagnose or support diagnosis of medical conditions or medical emergencies on the basis of biometric or biometrics-based data;

Or. en

Amendment 3082

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a c (new)

Text proposed by the Commission

Amendment

(a c) AI systems that are or may be used for categorisation on the basis of biometric or biometrics-based data;

Or. en

Amendment 3083

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä, Tineke Strik

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a d (new)

Text proposed by the Commission

Amendment

(a d) AI systems that are or may be used for the ‘real-time’ and ‘post’ detection of a person’s presence, in workplaces, in educational settings, and in border surveillance, including in the virtual or online version of these spaces, on the basis of their physical, physiological or behavioural data, including biometric data;

Or. en

Amendment 3084

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a d (new)

Text proposed by the Commission

Amendment

(a d) AI systems that are or may be used for the detection of a person’s presence, in workplaces, in educational settings, and in border surveillance, including in the virtual / online version of these spaces, on the basis of their biometric or biometrics-based data;

Or. en

Amendment 3085

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä, Tineke Strik

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a e (new)

Text proposed by the Commission

Amendment

(a e) AI systems intended to be used by or on behalf of competent authorities in ‘real-time’ and ‘post’ migration, asylum and border control management for the

forecasting or prediction of trends related to migration, movement and border crossings.

Or. en

Amendment 3086

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a e (new)

Text proposed by the Commission

Amendment

(a e) AI systems that are or may be used for monitoring compliance with health and safety measures or inferring alertness / attentiveness for safety purposes, on the basis of biometric or biometrics-based data;

Or. en

Amendment 3087

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 2 – introductory part

Text proposed by the Commission

Amendment

2. Management **and** operation of critical infrastructure:

2. Management, operation, **generation and supply** of critical infrastructure, **technology and energy**:

Or. en

Amendment 3088

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Annex III – paragraph 1 – point 2 – introductory part

Text proposed by the Commission

2. ***Management and operation of critical infrastructure:***

Amendment

2. ***Critical infrastructure and protection of environment:***

Or. en

Amendment 3089

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Annex III – paragraph 1 – point 2 – point a

Text proposed by the Commission

(a) AI systems intended to be used as safety ***components*** in the management ***and*** operation ***of road*** traffic and the supply of water, gas, heating and electricity.

Amendment

(a) AI systems intended to be used as ***a component, the failure or malfunctioning of which endangers the health, safety or fundamental rights of persons or the safety of property,*** in the management, operation, ***generation and/or supply of the telecom, internet, and financial infrastructure, road, rail, air and water*** traffic, and the ***operation, management an/or*** supply of water, gas, heating, and electricity ***and energy (including nuclear power).***

Or. en

Amendment 3090

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan, Vincenzo Sofo

Proposal for a regulation

Annex III – paragraph 1 – point 2 – point a

Text proposed by the Commission

(a) AI systems intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity.

Amendment

(a) AI systems intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity, ***whose failure or malfunctioning would directly cause significant harm to the health, natural environment or safety of natural persons.***

Amendment 3091

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 2 – point a

Text proposed by the Commission

(a) AI systems intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity.

Amendment

(a) AI systems ***that may be or are*** intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity ***and entities falling under [Directive XXXX/XXX/EU ('NIS 2 Directive')].***

Amendment 3092

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Annex III – paragraph 1 – point 2 – point a

Text proposed by the Commission

(a) AI systems intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity.

Amendment

(a) AI systems intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity, ***unless these are regulated in harmonisation legislation or sectorial regulation.***

Amendment 3093

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Annex III – paragraph 1 – point 2 – point a

Text proposed by the Commission

(a) AI systems intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity.

Amendment

(a) AI systems intended to be used as safety components in the management and operation of road traffic, ***digital infrastructure*** and the supply of water, gas, heating and electricity.

Or. en

Amendment 3094

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 2 – point a

Text proposed by the Commission

(a) AI systems ***intended to be*** used as safety components in the management and operation of road traffic ***and the supply of water, gas, heating and electricity.***

Amendment

(a) AI systems used as safety ***or security*** components in the management and operation of road traffic ***to the extent that they are not embedded in a vehicle;***

Or. en

Amendment 3095

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 2 – point a a (new)

Text proposed by the Commission

Amendment

(a a) AI systems intended to be used as safety or security components in the management and operation of the supply of water, gas, heating and electricity, provided the failure of the AI system is highly likely to lead to an imminent threat to such supply.

Or. en

Amendment 3096

René Repasi, Marc Angel, Andreas Schieder, Paul Tang, Maria-Manuel Leitão-Marques

**Proposal for a regulation
Annex III – paragraph 1 – point 2 a (new)**

Text proposed by the Commission

Amendment

2 a. Vulnerable groups:

- a) AI systems intended to be used by children in a way that may seriously affect a child's personal development, such as by educating the child in a broad range of areas not limited to areas which parents or guardians can reasonably foresee at the time of the purchase;*
- b) AI systems, such as virtual assistants, intended to be used by natural persons for taking decisions with regard to their private lives that have legal effects or similarly significantly affect the natural persons;*

Or. en

Amendment 3097

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Annex III – paragraph 1 – point 3 – point a**

Text proposed by the Commission

Amendment

- (a) AI systems intended to be used for the purpose of determining *access or assigning* natural persons to educational and vocational training institutions;

- (a) AI systems intended to be used for the purpose of determining *or materially influence decision on the admission of* natural persons to educational and vocational training institutions;

Or. en

Amendment 3098

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation
Annex III – paragraph 1 – point 3 – point a

Text proposed by the Commission

(a) AI systems intended to be used for the purpose of determining access or assigning natural persons to educational and vocational training institutions;

Amendment

(a) AI systems ***that may be or are*** intended to be used for the purpose of determining access or assigning natural persons to educational and vocational training institutions;

Or. en

Amendment 3099

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
Annex III – paragraph 1 – point 3 – point b

Text proposed by the Commission

(b) AI systems intended to be used for the purpose of assessing students in educational and vocational training institutions and for assessing participants in tests commonly required for admission to educational institutions.

Amendment

(b) AI systems intended to be used for the purpose of assessing students in educational and vocational training institutions and for assessing participants in tests commonly required for admission to educational institutions ***or monitoring of students during exams, for determining learning objectives, and for allocating personalised learning tasks to students;***

Or. en

Amendment 3100

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation
Annex III – paragraph 1 – point 3 – point b

Text proposed by the Commission

Amendment

(b) AI systems intended to be used for the purpose of assessing students in educational and vocational training institutions **and** for assessing participants in tests commonly required for admission to educational institutions.

(b) AI systems **that may be or are** intended to be used for the purpose of assessing students in educational and vocational training institutions **or** for assessing participants in tests commonly required for admission to educational institutions.

Or. en

Amendment 3101

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 3 – point b

Text proposed by the Commission

(b) AI systems intended to be used for the purpose of assessing students in educational and vocational training institutions and for assessing participants in tests commonly required for admission to **educational** institutions.

Amendment

(b) AI systems intended to be used for the purpose of assessing **the learning outcome of** students in educational and vocational training institutions and for assessing participants in tests commonly required for admission to **these** institutions.

Or. en

Amendment 3102

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Annex III – paragraph 1 – point 3 – point b

Text proposed by the Commission

(b) AI systems intended to be used for the purpose of assessing students in educational and vocational training institutions and for assessing participants in tests commonly required for admission to **educational** institutions.

Amendment

(b) AI systems intended to be used for the purpose of assessing students in educational and vocational training institutions and for assessing participants in tests commonly required for admission to **those** institutions.

Or. en

Amendment 3103

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 3 – point b a (new)

Text proposed by the Commission

Amendment

(b a) AI systems that may be or are intended to be used for the purpose of assessing the appropriate level of education for an individual with potential effects for the methods or level of education that individual will receive or will be able to access.

Or. en

Amendment 3104

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 3 – point b a (new)

Text proposed by the Commission

Amendment

(b a) AI systems intended to be used for the optimization of individual learning processes based on a student's learning data.

Or. en

Amendment 3105

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 4 – introductory part

Text proposed by the Commission

Amendment

4. Employment, workers management and access to self-employment:

4. Employment *and work-related contractual relationships*

AI systems intended to be used to make or materially influence decisions on:

- (i) recruitment or selection of natural persons, specifically for screening or filtering applications, evaluating candidates in the course of interviews or tests;*
- (ii) promotion and termination of work-related contractual relationships;*
- (iii) task allocation based on individual behaviour or personal traits or characteristics; or*
- (iv) monitoring and evaluating the performance and behaviour of persons.*

where those decisions are likely to pose a significant risk of adversely impacting fundamental rights or threatening harm to health and safety.

Or. en

Amendment 3106

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 4 – point a

Text proposed by the Commission

Amendment

(a) AI systems intended to be used for recruitment or selection of natural persons, notably for advertising vacancies, screening or filtering applications, evaluating candidates in the course of interviews or tests; *deleted*

Or. en

Amendment 3107

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Annex III – paragraph 1 – point 4 – point a

Text proposed by the Commission

- (a) AI systems intended to be used for recruitment or selection of natural persons, **notably for advertising vacancies, screening or filtering applications, evaluating candidates in the course of interviews or tests;**

Amendment

- (a) AI systems intended to be used **to make final decisions** for recruitment or selection of natural persons.

Or. en

Justification

Not all phases of a recruitment or selection process can reasonably be considered as high-risk. Advertising for vacancies and early assessment and filtering of grades and formal competences should not be included, only the phases of a recruitment process where human oversight is important, for example in assessing non-formal skills and overall suitability, leading up to a final decision.

Amendment 3108

Svenja Hahn, Nicola Beer, Karen Melchior, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ej Kova ík, Jan-Christoph Oetjen

Proposal for a regulation

Annex III – paragraph 1 – point 4 – point a

Text proposed by the Commission

- (a) AI systems intended to **be used for** recruitment or selection of natural persons, notably for **advertising vacancies, screening or filtering applications, evaluating candidates in the course of interviews or tests;**

Amendment

- (a) AI systems intended to **make autonomous decisions or materially influence decisions about** recruitment or selection of natural persons, notably for screening or filtering applications, evaluating candidates in the course of interviews or tests;

Or. en

Amendment 3109

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 4 – point a

Text proposed by the Commission

(a) AI systems intended to be used for recruitment or selection of natural persons, notably for advertising vacancies, screening or filtering applications, evaluating candidates in the course of interviews or tests;

Amendment

(a) AI systems ***that may be or are intended*** intended to be used for recruitment or selection of natural persons, notably for advertising vacancies, screening or filtering applications, evaluating candidates in the course of interviews or tests;

Or. en

Amendment 3110

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituță

Proposal for a regulation

Annex III – paragraph 1 – point 4 – point a

Text proposed by the Commission

(a) AI systems intended to be used ***for recruitment or selection of natural persons, notably*** for advertising vacancies, screening or filtering applications, evaluating candidates in the course of interviews or tests;

Amendment

(a) AI systems intended to be used ***in recruitment for advertising vacancies, screening or filtering applications, or evaluating candidates in the course of interviews or tests;***

Or. en

Amendment 3111

Krzysztof Hetman, Adam Jarubas, Andrzej Halicki, Jerzy Buzek, Janusz Lewandowski, Radosław Sikorski

Proposal for a regulation

Annex III – paragraph 1 – point 4 – point a

Text proposed by the Commission

(a) AI systems intended to be used for recruitment or selection of natural persons, ***notably for advertising vacancies,*** screening or filtering applications, evaluating candidates in the course of interviews or tests;

Amendment

(a) AI systems intended to be used for recruitment or selection of natural persons, screening or filtering applications, evaluating candidates in the course of interviews or tests;

Amendment 3112

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 4 – point b

Text proposed by the Commission

Amendment

(b) *AI intended to be used for making decisions on promotion and termination of work-related contractual relationships, for task allocation and for monitoring and evaluating performance and behavior of persons in such relationships.*

deleted

Amendment 3113

Kosma Złotowski, Patryk Jaki, Adam Bielan, Vincenzo Sofo

Proposal for a regulation

Annex III – paragraph 1 – point 4 – point b

Text proposed by the Commission

Amendment

(b) AI intended to be used *for making* decisions on promotion and termination of work-related contractual relationships, *for task allocation* and for monitoring and evaluating performance and *behavior* of persons in such relationships.

(b) *AI systems* intended to be used *to make* decisions on promotion and termination of work-related contractual relationships, *based on individual behaviour or personal traits or characteristics*, and for monitoring and evaluating performance and *behaviour* of persons in such relationships *that have a likelihood of causing harm to the physical health and safety or adversely impact on the fundamental rights or have given rise to significant concerns in relation to the materialisation of such harm or adverse impact.*

Amendment 3114

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 4 – point b

Text proposed by the Commission

(b) AI intended to be used *for making decisions on promotion* and termination of work-related *contractual relationships*, for task allocation and for monitoring and evaluating performance and behavior of persons in such relationships.

Amendment

(b) AI *that may be or are* intended to be used *to assist decision-making affecting the initiation, establishment, implementation* and termination of *an employment relationship, including AI systems intended to support collective legal and regulatory matters, particularly* work-related relationships, for task allocation and for monitoring, *measuring* and evaluating performance and behavior of persons in such relationships.

Or. en

Amendment 3115

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

Annex III – paragraph 1 – point 4 – point b

Text proposed by the Commission

(b) AI intended to be used for making decisions *on* promotion and termination of *work-related contractual relationships*, for task allocation and for monitoring and evaluating performance and behavior of persons in such relationships.

Amendment

(b) AI intended to be used for making decisions *affecting the initiation, establishment, implementation*, promotion and termination of *an employment relationship, including AI systems intended to support collective legal and regulatory matters, particularly* for task allocation and for monitoring and evaluating performance and behavior of persons *or in matters of training or further education* in such relationships.

Or. en

Amendment 3116

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 4 – point b

Text proposed by the Commission

(b) AI intended to be used for making decisions *on promotion* and termination of *work-related contractual relationships*, for task allocation and for monitoring and evaluating performance and behavior of persons in such relationships.

Amendment

(b) AI intended to be used for making decisions *affecting the initiation, establishment, implementation* and termination of *an employment relationship, including AI systems intended to support collective legal and regulatory matters, particularly* for task allocation and for monitoring and evaluating performance and behavior of persons in such relationships

Or. en

Amendment 3117

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation

Annex III – paragraph 1 – point 4 – point b

Text proposed by the Commission

(b) AI intended to be used for making decisions on promotion and termination of work-related contractual relationships, *for* task allocation and for monitoring and evaluating performance and *behavior of* persons in such relationships.

Amendment

(b) *AI systems* intended to be used for *making decisions or to assist in* making decisions on promotion and termination of work-related contractual relationships; *for personalized* task allocation *based on biometrics, biometrics-based, or personal data*; and for monitoring and evaluating performance and *behaviour of natural* persons in such relationships.

Or. en

Amendment 3118

Svenja Hahn, Nicola Beer, Karen Melchior, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ondej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Annex III – paragraph 1 – point 4 – point b

Text proposed by the Commission

(b) AI intended to ***be used for making*** decisions on promotion and termination of work-related contractual relationships, ***for task allocation and*** for monitoring and evaluating performance and behavior of persons in such relationships.

Amendment

(b) AI intended to ***make autonomous decisions or materially influence*** decisions on promotion and termination of work-related contractual relationships, for monitoring and evaluating performance and behavior of persons in such relationships.

Or. en

Amendment 3119

Nathalie Colin-Oesterlé

Proposal for a regulation

Annex III – paragraph 1 – point 4 – point b

Text proposed by the Commission

(b) l'IA destinée à être utilisée pour la prise de décisions de promotion et de licenciement dans le cadre de relations professionnelles contractuelles, ***pour l'attribution des tâches*** et pour le suivi et l'évaluation des performances et du comportement de personnes dans le cadre de telles relations.

Amendment

(b) l'IA destinée à être utilisée pour la prise de décisions de promotion et de licenciement dans le cadre de relations professionnelles contractuelles, et pour le suivi et l'évaluation des performances et du comportement de personnes dans le cadre de telles relations.

Or. fr

Amendment 3120

René Repasi, Marc Angel, Andreas Schieder, Maria-Manuel Leitão-Marques

Proposal for a regulation

Annex III – paragraph 1 – point 5 – introductory part

Text proposed by the Commission

5. Access to and enjoyment of

Amendment

5. Access to and enjoyment of

essential private services and public services and benefits:

essential private services and public services and benefits, *including access to products*:

Or. en

Amendment 3121
Sophia in 't Veld, Michal Šimek

Proposal for a regulation
Annex III – paragraph 1 – point 5 – point a

Text proposed by the Commission

Amendment

(a) *AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for public assistance benefits and services, as well as to grant, reduce, revoke, or reclaim such benefits and services;*

deleted

Or. en

Amendment 3122
Kate iná Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Annex III – paragraph 1 – point 5 – point a

Text proposed by the Commission

Amendment

(a) AI systems intended to be used by public authorities or *on behalf of public authorities* to evaluate the eligibility of natural persons for public assistance benefits and services, as well as to grant, reduce, revoke, or reclaim such benefits and services;

(a) AI systems intended to be used by *or on behalf of (semi-)public authorities or private parties* to evaluate *or predict the lawful use by, or* the eligibility of, natural persons, *including the self employed and micro-enterprises*, for public assistance, benefits and services *and essential private services including but not limited to housing, electricity, heating/cooling, finance, insurance and internet*, as well as to grant, reduce, revoke, or reclaim such benefits and services *or set payment obligations related to these services*;

Amendment 3123

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 5 – point a

Text proposed by the Commission

(a) AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for public assistance benefits and services, as well as to grant, reduce, revoke, or reclaim such benefits and services;

Amendment

(a) AI systems ***that may be or are*** intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for public assistance benefits and services, as well as to grant, reduce, revoke, or reclaim such benefits and services;

Amendment 3124

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 5 – point a

Text proposed by the Commission

(a) AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for public assistance benefits and services, as well as to grant, reduce, revoke, or reclaim such benefits and services;

Amendment

(a) AI systems intended to be used by public authorities or on behalf of public authorities to evaluate ***and decide on*** the eligibility of natural persons for public assistance benefits and services, as well as to grant, reduce, revoke, or reclaim such benefits and services;

Amendment 3125

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituță

Proposal for a regulation
Annex III – paragraph 1 – point 5 – point a

Text proposed by the Commission

(a) AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for public assistance benefits and services, as well as to grant, reduce, revoke, or reclaim such benefits and services;

Amendment

(a) AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for public assistance benefits and services, as well as to grant, reduce, revoke, *increase*, or reclaim such benefits and services;

Or. en

Amendment 3126
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Annex III – paragraph 1 – point 5 – point b

Text proposed by the Commission

(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems put into service by small scale providers for their own use;

Amendment

deleted

Or. en

Amendment 3127
Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Annex III – paragraph 1 – point 5 – point b

Text proposed by the Commission

(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems put into service by small scale providers for their

Amendment

deleted

own use;

Or. en

Amendment 3128

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Annex III – paragraph 1 – point 5 – point b

Text proposed by the Commission

(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, *with the exception of AI systems put into service by small scale providers for their own use;*

Amendment

(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score *in order to determine their access to credit or to other essential services. Ancillary applications such as AI applications used for the acceleration of the credit disbursement process, in the valuation of collateral, or for the internal process efficiency, as well as other subsequent applications based on the credit scoring which do not create high risks for individuals are not included in those systems;*

Or. en

Amendment 3129

René Repasi, Marc Angel, Andreas Schieder, Maria-Manuel Leitão-Marques

Proposal for a regulation

Annex III – paragraph 1 – point 5 – point b

Text proposed by the Commission

(b) AI systems intended to be used *to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems put into service by small scale providers for their own use;*

Amendment

(b) AI systems intended to be used

Or. en

Justification

Moved to next paragraph.

Amendment 3130

Kosma Złotowski, Patryk Jaki

Proposal for a regulation

Annex III – paragraph 1 – point 5 – point b

Text proposed by the Commission

(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or *establish their credit score*, with the exception of AI systems put into service by small scale providers for their own use;

Amendment

(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or *assessment of insurance risk*, with the exception of AI systems put into service by small scale providers for their own use *or AI systems related to low-value credits for the purchase of moveables*;

Or. en

Amendment 3131

Krzysztof Hetman, Adam Jarubas, Andrzej Halicki, Jerzy Buzek, Janusz Lewandowski, Radosław Sikorski

Proposal for a regulation

Annex III – paragraph 1 – point 5 – point b

Text proposed by the Commission

(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems put into service by small scale providers for their own use;

Amendment

(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems put into service by small scale providers for their own use; *or AI systems related to low-value credits for the purchase of moveables*;

Or. en

Amendment 3132

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Annex III – paragraph 1 – point 5 – point b

Text proposed by the Commission

(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, *with the exception of AI systems put into service by small scale providers for their own use*;

Amendment

(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score;

Or. en

Amendment 3133

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation
Annex III – paragraph 1 – point 5 – point b

Text proposed by the Commission

(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems put into service by small scale providers for their own use;

Amendment

(b) AI systems *that may be or are* intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems put into service by small scale providers for their own use;

Or. en

Amendment 3134

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation
Annex III – paragraph 1 – point 5 – point b

Text proposed by the Commission

(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with

Amendment

(b) AI systems *that may be or are* intended to be used to evaluate the creditworthiness of natural persons or

the exception of AI systems put into service by small scale providers for their own use;

establish their credit score, with the exception of AI systems put into service by small scale providers for their own use;

Or. en

Amendment 3135

Maria-Manuel Leitão-Marques, Eva Kaili

Proposal for a regulation

Annex III – paragraph 1 – point 5 – point b

Text proposed by the Commission

(b) AI systems intended to be used to evaluate the creditworthiness of natural persons *or* establish their credit score, *with the exception of AI systems put into service by small scale providers for their own use;*

Amendment

(b) AI systems intended to be used to evaluate the creditworthiness of natural persons, establish their credit score, *or predict human medical conditions and health-related outcomes*

Or. en

Amendment 3136

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Catharina Rinzema, Moritz Körner, Ondřej Kovářík, Jan-Christoph Oetjen

Proposal for a regulation

Annex III – paragraph 1 – point 5 – point b

Text proposed by the Commission

(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems put into service by *small scale providers* for their own use;

Amendment

(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems put into service by *SMEs and start-ups* for their own use;

Or. en

Amendment 3137

René Repasi, Marc Angel, Andreas Schieder, Maria-Manuel Leitão-Marques

Proposal for a regulation

Annex III – paragraph 1 – point 5 – point b – point i (new)

Text proposed by the Commission

Amendment

i) to evaluate the creditworthiness of natural persons or establish their credit score,

Or. en

Amendment 3138

René Repasi, Marc Angel, Andreas Schieder, Maria-Manuel Leitão-Marques

Proposal for a regulation

Annex III – paragraph 1 – point 5 – point b – point ii (new)

Text proposed by the Commission

Amendment

ii) to evaluate the behaviour of natural persons such as with regard to complaints or the exercise of statutory or contractual rights in order to draw conclusions for their future access to private or public services,

Or. en

Amendment 3139

René Repasi, Marc Angel, Andreas Schieder, Maria-Manuel Leitão-Marques

Proposal for a regulation

Annex III – paragraph 1 – point 5 – point b – point iii (new)

Text proposed by the Commission

Amendment

iii) for making individual risk assessments of natural persons in the context of access to essential private and public services, including insurance contracts, or

Or. en

Amendment 3140

René Repasi, Marc Angel, Andreas Schieder, Maria-Manuel Leitão-Marques

Proposal for a regulation

Annex III – paragraph 1 – point 5 – point b – point iv (new)

Text proposed by the Commission

Amendment

iv) for personalized pricing within the meaning of Article 6 (1) (ea) of Directive 2011/83/EU, with the exception of AI systems put into service by small scale providers of AI systems for their own use;

Or. en

Amendment 3141

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Annex III – paragraph 1 – point 5 – point c

Text proposed by the Commission

Amendment

(c) les systèmes d'IA destinés à être utilisés pour envoyer ou établir des priorités dans l'envoi des services d'intervention d'urgence, y compris par les pompiers et les secours.

(c) les systèmes d'IA destinés à être utilisés, *sans prendre de décisions en la matière*, pour envoyer ou établir des priorités dans l'envoi des services d'intervention d'urgence, y compris par les pompiers et les secours.

Or. fr

Amendment 3142

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 5 – point c

Text proposed by the Commission

Amendment

(c) AI systems intended to be used to dispatch, or to establish priority in the

(c) AI systems *that may be or are* intended to be used to dispatch, or to

dispatching of emergency first response services, including by firefighters and medical aid.

establish priority in the dispatching of emergency first response services, including by firefighters and medical aid.

Or. en

Amendment 3143

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 5 – point c a (new)

Text proposed by the Commission

Amendment

(c a) AI systems that may be used or are intended to be used for making individual risk assessments of natural persons in the context of access to private and public services, including determining the amounts of insurance premiums.

Or. en

Amendment 3144

Kosma Złotowski, Patryk Jaki

Proposal for a regulation

Annex III – paragraph 1 – point 5 – point c a (new)

Text proposed by the Commission

Amendment

(c a) AI systems intended to be used for insurance premium setting, underwritings and claims assessments, with the exception of AI systems related to low-value property insurance.

Or. en

Amendment 3145

Krzysztof Hetman, Adam Jarubas, Andrzej Halicki, Jerzy Buzek, Janusz Lewandowski, Radosław Sikorski

Proposal for a regulation
Annex III – paragraph 1 – point 5 – point c a (new)

Text proposed by the Commission

Amendment

(c a) AI systems intended to be used for insurance premium setting, underwritings and claims assessments, with the exception of AI systems related to low-value property insurance.

Or. en

Amendment 3146

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation
Annex III – paragraph 1 – point 5 – point c b (new)

Text proposed by the Commission

Amendment

(c b) AI systems that may be used or are intended to be used in the context of payment and debt collection services.

Or. en

Amendment 3147

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation
Annex III – paragraph 1 – point 5 a (new)

Text proposed by the Commission

Amendment

5 a. Use by vulnerable groups or in situations that imply vulnerability

(a) AI systems intended to be used by children in a way that may seriously affect a child's personal development, such as by educating the child in a broad range of

areas not limited to areas which parents or guardians can reasonably foresee at the time of the purchase;

(b) AI systems, such as virtual assistants, intended to be used by natural persons for taking decisions with regard to their private lives that have legal effects or similarly significantly affect the natural persons;

(c) AI systems intended to be used for personalised pricing within the meaning of Article 6 (1) (ea) of Directive 2011/83/EU.

Or. en

Amendment 3148

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point a

Text proposed by the Commission

Amendment

(a) *les systèmes d'IA destinés à être utilisés par les autorités répressives pour mener des évaluations individuelles des risques visant à déterminer la probabilité qu'une personne physique commette une infraction ou récidive, ou le risque encouru par les victimes potentielles d'infractions pénales;*

supprimé

Or. fr

Justification

Selon un amendement précédent, ces systèmes sont interdits, ils ne relèvent donc pas du régime commun des systèmes d'I.A. à haut risque figurant à l'annexe III.

Amendment 3149

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Maria Grapini

Proposal for a regulation
Annex III – paragraph 1 – point 6 – point a

Text proposed by the Commission

Amendment

(a) *AI systems intended to be used by law enforcement authorities for making individual risk assessments of natural persons in order to assess the risk of a natural person for offending or reoffending or the risk for potential victims of criminal offences;* *deleted*

Or. en

Justification

Moved under prohibited practices in Article 5

Amendment 3150

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation
Annex III – paragraph 1 – point 6 – point a

Text proposed by the Commission

Amendment

(a) *AI systems intended to be used by law enforcement authorities for making individual risk assessments of natural persons in order to assess the risk of a natural person for offending or reoffending or the risk for potential victims of criminal offences;* *deleted*

Or. en

Justification

Moved to Article 5

Amendment 3151

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point a

Text proposed by the Commission

Amendment

(a) *AI systems intended to be used by law enforcement authorities for making individual risk assessments of natural persons in order to assess the risk of a natural person for offending or reoffending or the risk for potential victims of criminal offences;* *deleted*

Or. en

Amendment 3152

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point a

Text proposed by the Commission

Amendment

(a) *AI systems intended to be used by law enforcement authorities for making individual risk assessments of natural persons in order to assess the risk of a natural person for offending or reoffending or the risk for potential victims of criminal offences;* *deleted*

Or. en

Amendment 3153

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point a

Text proposed by the Commission

Amendment

(a) AI systems intended to be used by law enforcement authorities for making individual risk assessments of natural persons in order to assess the risk *of* a natural person for offending or reoffending or the risk for potential *victims* of criminal

(a) AI systems intended to be used by law enforcement authorities *or on their behalf* for making individual risk assessments of natural persons in order to assess the risk *for* a natural person for offending or reoffending or the risk for *a*

offences;

natural person to become a potential victim of criminal offences;

Or. en

Amendment 3154

Svenja Hahn, Drago Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Abir Al-Sahlani, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point a

Text proposed by the Commission

(a) AI systems intended to be used by law enforcement authorities for making individual risk assessments of natural persons in order to assess the risk of a natural person for offending or reoffending or the risk for potential victims of criminal offences;

Amendment

(a) AI systems intended to be used by law enforcement authorities *or on their behalf* for making individual risk assessments of natural persons in order to assess the risk of a natural person for offending or reoffending or the risk for potential victims of criminal offences;

Or. en

Amendment 3155

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point a a (new)

Text proposed by the Commission

Amendment

(a a) AI systems designed for real-time remote biometric identification in publicly accessible locations for law enforcement purposes.

Or. en

Justification

Instead of blanketly banning the law enforcement's use of facial recognition AI, these systems should be incorporated in the list of high-risk AI systems and subject to strict control.

Amendment 3156

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point b

Text proposed by the Commission

Amendment

(b) *les systèmes d'IA destinés à être utilisés par les autorités répressives en tant que polygraphes et outils similaires, ou pour analyser l'état émotionnel d'une personne physique;* *supprimé*

Or. fr

Justification

Selon un amendement précédent, ces systèmes sont interdits, ils ne relèvent donc pas du régime commun des systèmes d'I.A. à haut risque figurant à l'annexe III.

Amendment 3157

Brando Benifei, 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

Annex III – paragraph 1 – point 6 – point b

Text proposed by the Commission

Amendment

(b) *AI systems intended to be used by law enforcement authorities as polygraphs and similar tools or to detect the emotional state of a natural person;* *deleted*

Or. en

Justification

Moved to Article 5.

Amendment 3158

Sophia in 't Veld, Michal Šimečka

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point b

Text proposed by the Commission

Amendment

(b) *AI systems intended to be used by law enforcement authorities as polygraphs and similar tools or to detect the emotional state of a natural person;* *deleted*

Or. en

Amendment 3159

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point b

Text proposed by the Commission

Amendment

(b) *AI systems intended to be used by law enforcement authorities as polygraphs and similar tools or to detect the emotional state of a natural person;* *deleted*

Or. en

Amendment 3160

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Paul Tang

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point b

Text proposed by the Commission

Amendment

(b) *AI systems intended to be used by law enforcement authorities as polygraphs and similar tools or to detect the emotional state of a natural person;* *deleted*

Or. en

Justification

Moved under prohibited practices in Article 5

Amendment 3161

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point b

Text proposed by the Commission

Amendment

(b) *AI systems intended to be used by law enforcement authorities as polygraphs and similar tools or to detect the emotional state of a natural person;* *deleted*

Or. en

Amendment 3162

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point b

Text proposed by the Commission

Amendment

(b) *AI systems intended to be used by law enforcement authorities as polygraphs and similar tools or to detect the emotional state of a natural person;* *deleted*

Or. en

Justification

Moved to Article 5

Amendment 3163

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Ró a Thun und Hohenstein, Alin Mituță

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point b

Text proposed by the Commission

(b) AI systems intended to be used by law enforcement authorities as polygraphs and similar tools or to detect the emotional state of a natural person;

Amendment

(b) AI systems intended to be used by **law enforcement authorities or on behalf of** law enforcement authorities as polygraphs and similar tools or to detect the emotional state of a natural person;

Or. en

Amendment 3164

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point b

Text proposed by the Commission

(b) AI systems intended to be used by law enforcement authorities as polygraphs and similar tools or to detect the emotional state of a natural person;

Amendment

(b) AI systems intended to be used by law enforcement authorities **or on their behalf** as polygraphs and similar tools or to detect the emotional state of a natural person;

Or. en

Amendment 3165

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

Annex III – paragraph 1 – point 6 – point c

Text proposed by the Commission

(c) AI systems intended to be used by law enforcement authorities to detect deep fakes as referred to in article 52(3);

Amendment

(c) AI systems intended to be used by law enforcement authorities **or on their behalf** to detect deep fakes as referred to in article 52(3) **and in point 8a(a) and (b) of this Annex;**

Or. en

Amendment 3166

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nută, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Alin Mitu 

Proposal for a regulation**Annex III – paragraph 1 – point 6 – point c***Text proposed by the Commission*

(c) AI systems intended to be used by law enforcement authorities to detect deep fakes as referred to in article 52(3);

Amendment

(c) AI systems intended to be used by **law enforcement authorities or on behalf of** law enforcement authorities to detect deep fakes as referred to in article 52(3);

Or. en

Amendment 3167

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alamets 

Proposal for a regulation**Annex III – paragraph 1 – point 6 – point c***Text proposed by the Commission*

(c) AI systems intended to be used by law enforcement authorities to detect deep fakes as referred to in article 52(3);

Amendment

(c) AI systems **that may be or are** intended to be used by law enforcement authorities to detect deep fakes as referred to in article 52(3);

Or. en

Amendment 3168

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Sandro Gozi, Vlad-Marius Boto , Moritz K rner, Jan-Christoph Oetjen

Proposal for a regulation**Annex III – paragraph 1 – point 6 – point c***Text proposed by the Commission*

(c) AI systems intended to be used by law enforcement authorities to detect deep fakes as referred to in article 52(3);

Amendment

(c) AI systems intended to be used by law enforcement authorities **or on their behalf** to detect deep fakes as referred to in

article 52(3);

Or. en

Amendment 3169

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Alin Mituța

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point d

Text proposed by the Commission

(d) AI systems intended to be used by law enforcement authorities for evaluation of the reliability of evidence in the course of investigation or prosecution of criminal offences;

Amendment

(d) AI systems intended to be used by **law enforcement authorities or on behalf of** law enforcement authorities for evaluation of the reliability of evidence in the course of investigation or prosecution of criminal offences;

Or. en

Amendment 3170

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

Annex III – paragraph 1 – point 6 – point d

Text proposed by the Commission

(d) AI systems intended to be used by law enforcement authorities for evaluation of the reliability of evidence in the course of investigation or prosecution of criminal offences;

Amendment

(d) AI systems intended to be used by law enforcement authorities **or on their behalf** for evaluation of the reliability of evidence in the course of investigation or prosecution of criminal offences;

Or. en

Amendment 3171

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point d

Text proposed by the Commission

(d) AI systems intended to be used by law enforcement authorities for evaluation of the reliability of evidence in the course of investigation or prosecution of criminal offences;

Amendment

(d) AI systems ***that may be or are*** intended to be used by law enforcement authorities for evaluation of the reliability of evidence in the course of investigation or prosecution of criminal offences;

Or. en

Amendment 3172

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point d

Text proposed by the Commission

(d) AI systems intended to be used by law enforcement authorities for evaluation of the reliability of evidence in the course of investigation or prosecution of criminal offences;

Amendment

(d) AI systems intended to be used by law enforcement authorities ***or on their behalf*** for evaluation of the reliability of evidence in the course of investigation or prosecution of criminal offences;

Or. en

Amendment 3173

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point e

Text proposed by the Commission

(e) *les systèmes d'IA destinés à être utilisés par les autorités répressives pour prédire la survenance ou la réitération d'une infraction pénale réelle ou potentielle sur la base du profilage de*

Amendment

supprimé

personnes physiques tel que visé à l'article 3, paragraphe 4, de la directive (UE) 2016/680, ou pour évaluer les traits de personnalité, les caractéristiques ou les antécédents judiciaires de personnes physiques ou de groupes;

Or. fr

Justification

Selon un amendement précédent, ces systèmes sont interdits, ils ne relèvent donc pas du régime commun des systèmes d'I.A. à haut risque figurant à l'annexe III.

Amendment 3174

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point e

Text proposed by the Commission

Amendment

(e) AI systems intended to be used by law enforcement authorities for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups;

Or. en

Amendment 3175

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point e

Text proposed by the Commission

Amendment

(e) AI systems intended to be used by law enforcement authorities for predicting the occurrence or reoccurrence of an actual or potential criminal offence based

on profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups;

Or. en

Amendment 3176

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point e

Text proposed by the Commission

Amendment

(e) AI systems intended to be used by law enforcement authorities for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups;

Or. en

Justification

Moved to Article 5

Amendment 3177

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Vlad-Marius Boto , Abir Al-Sahlani, Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point e

Text proposed by the Commission

Amendment

(e) AI systems intended to be used by law enforcement authorities for predicting the occurrence or reoccurrence of an

actual or potential criminal offence based on profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups;

Or. en

Justification

Moved to Art. 5 - prohibited AI practices

Amendment 3178

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Maria Grapini

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point e

Text proposed by the Commission

Amendment

(e) AI systems intended to be used by law enforcement authorities for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups; *deleted*

Or. en

Justification

Moved under prohibited practices in Article 5

Amendment 3179

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point e

Text proposed by the Commission

Amendment

(e) AI systems intended to be used by *(e) AI systems intended to be used by*

law enforcement authorities for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups;

law enforcement authorities for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups, *with the exception of AI systems used for compliance with applicable counterterrorism and anti-money laundering legislation*;

Or. en

Amendment 3180

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point f

Text proposed by the Commission

(f) *les systèmes d'IA destinés à être utilisés par les autorités répressives pour le profilage de personnes physiques visé à l'article 3, paragraphe 4, de la directive (UE) 2016/680 dans le cadre d'activités de détection, d'enquête ou de poursuite relatives à des infractions pénales;*

Amendment

supprimé

Or. fr

Justification

Selon un amendement précédent, ces systèmes sont interdits, ils ne relèvent donc pas du régime commun des systèmes d'I.A. à haut risque figurant à l'annexe III.

Amendment 3181

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point f

Text proposed by the Commission

Amendment

(f) *AI systems intended to be used by law enforcement authorities for profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of detection, investigation or prosecution of criminal offences;*

deleted

Or. en

Amendment 3182

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Alin Mituță

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point f

Text proposed by the Commission

Amendment

(f) AI systems intended to be used by law enforcement authorities for profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of detection, investigation or prosecution of criminal offences;

(f) *AI systems intended to be used by law enforcement authorities or on behalf of law enforcement authorities for profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of detection, investigation or prosecution of criminal offences;*

Or. en

Amendment 3183

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point f

Text proposed by the Commission

Amendment

(f) AI systems intended to be used by law enforcement authorities for profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of detection, investigation or

(f) *AI systems that may be or are intended to be used by law enforcement authorities for profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of detection,*

prosecution of criminal offences;

investigation or prosecution of criminal offences;

Or. en

Amendment 3184

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point f

Text proposed by the Commission

(f) AI systems intended to be used by law enforcement authorities for profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of detection, investigation or prosecution of criminal offences;

Amendment

(f) AI systems intended to be used by law enforcement authorities *or on their behalf* for profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of detection, investigation or prosecution of criminal offences;

Or. en

Amendment 3185

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point g

Text proposed by the Commission

(g) AI systems intended to be used for crime analytics regarding natural persons, allowing law enforcement authorities to search complex related and unrelated large data sets available in different data sources or in different data formats in order to identify unknown patterns or discover hidden relationships in the data.

Amendment

deleted

Or. en

Amendment 3186
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Annex III – paragraph 1 – point 6 – point g

Text proposed by the Commission

Amendment

(g) *AI systems intended to be used for crime analytics regarding natural persons, allowing law enforcement authorities to search complex related and unrelated large data sets available in different data sources or in different data formats in order to identify unknown patterns or discover hidden relationships in the data.* *deleted*

Or. en

Amendment 3187
Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation
Annex III – paragraph 1 – point 6 – point g

Text proposed by the Commission

Amendment

(g) *AI systems intended to be used for crime analytics regarding natural persons, allowing law enforcement authorities to search complex related and unrelated large data sets available in different data sources or in different data formats in order to identify unknown patterns or discover hidden relationships in the data.* *deleted*

Or. en

Justification

Covered in Article 5

Amendment 3188

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point g

Text proposed by the Commission

(g) AI systems intended to be used for crime analytics regarding natural persons, allowing *law enforcement authorities* to search complex related and unrelated large data sets available in different data sources or in different data formats in order to identify unknown patterns or discover hidden relationships in the data.

Amendment

(g) AI systems intended to be used *by law enforcement authorities or on their behalf* for crime analytics regarding natural persons, allowing to search complex related and unrelated large data sets available in different data sources or in different data formats in order to identify unknown patterns or discover hidden relationships in the data.

Or. en

Amendment 3189

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä, Tineke Strik

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point a

Text proposed by the Commission

(a) AI systems intended to be used by competent public authorities as polygraphs and similar tools or to detect the emotional state of a natural person;

Amendment

deleted

Or. en

Justification

Covered now by Article 5

Amendment 3190

Sophia in 't Veld, Michal Šimek

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point a

Text proposed by the Commission

Amendment

(a) *AI systems intended to be used by competent public authorities as polygraphs and similar tools or to detect the emotional state of a natural person;* *deleted*

Or. en

Amendment 3191

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point a

Text proposed by the Commission

Amendment

(a) *AI systems intended to be used by competent public authorities as polygraphs and similar tools or to detect the emotional state of a natural person;* *deleted*

Or. en

Amendment 3192

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point a

Text proposed by the Commission

Amendment

(a) *AI systems intended to be used by competent public authorities as polygraphs and similar tools or to detect the emotional state of a natural person;* *deleted*

Or. en

Amendment 3193

Brando Benifei, 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

Annex III – paragraph 1 – point 7 – point a

Text proposed by the Commission

Amendment

(a) *AI systems intended to be used by competent public authorities as polygraphs and similar tools or to detect the emotional state of a natural person;* *deleted*

Or. en

Justification

Moved to Article 5.

Amendment 3194

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Paul Tang

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point a

Text proposed by the Commission

Amendment

(a) *AI systems intended to be used by competent public authorities as polygraphs and similar tools or to detect the emotional state of a natural person;* *deleted*

Or. en

Justification

Moved under prohibited practices in Article 5

Amendment 3195

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point a

Text proposed by the Commission

Amendment

(a) AI systems intended to be used by competent public authorities as polygraphs and similar tools or to detect the emotional state of a natural person;

(a) AI systems intended to be used by competent public authorities **or on their behalf** as polygraphs and similar tools or to detect the emotional state of a natural person;

Or. en

Amendment 3196

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Alin Mituță

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point a

Text proposed by the Commission

(a) AI systems intended to be used by competent public authorities as polygraphs and similar tools or to detect the emotional state of a natural person;

Amendment

(a) AI systems intended to be used by competent public authorities **or on their behalf** as polygraphs and similar tools or to detect the emotional state of a natural person;

Or. en

Amendment 3197

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point b

Text proposed by the Commission

(b) AI systems intended to be used by competent public authorities to assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;

Amendment

deleted

Or. en

Justification

Moved under prohibited practices in Article 5

Amendment 3198

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point b

Text proposed by the Commission

Amendment

(b) *AI systems intended to be used by competent public authorities to assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;* *deleted*

Or. en

Amendment 3199

Sophia in 't Veld, Michal Šime ka

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point b

Text proposed by the Commission

Amendment

(b) *AI systems intended to be used by competent public authorities to assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;* *deleted*

Or. en

Amendment 3200

Brando Benifei, 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
Annex III – paragraph 1 – point 7 – point b**

Text proposed by the Commission

Amendment

(b) *AI systems intended to be used by competent public authorities to assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;* *deleted*

Or. en

Justification

Moved to Article 5.

Amendment 3201

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä, Tineke Strik

**Proposal for a regulation
Annex III – paragraph 1 – point 7 – point b**

Text proposed by the Commission

Amendment

(b) AI systems intended to be used by competent public authorities to assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;

(b) AI systems ***that may be or are*** intended to be used by competent public authorities, ***or third parties on their behalf***, to assess a risk, including, ***but not limited to***, a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;

Or. en

Amendment 3202

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Annex III – paragraph 1 – point 7 – point b**

Text proposed by the Commission

(b) AI systems intended to be used by competent public authorities to assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;

Amendment

(b) AI systems intended to be used by competent public authorities, *or by third parties acting on their behalf*, to assess a risk, including *but not limited to* a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;

Or. en

Amendment 3203

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point b

Text proposed by the Commission

(b) AI systems intended to be used by competent public authorities to assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;

Amendment

(b) AI systems intended to be used by competent public authorities *or by third parties acting on their behalf* to assess a risk, including *but not limited to* a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;

Or. en

Amendment 3204

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia uríš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Alin Mituță

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point b

Text proposed by the Commission

(b) AI systems intended to be used by competent public authorities to assess a risk, including a security risk, a risk of irregular immigration, or a health risk,

Amendment

(b) AI systems intended to be used by competent public authorities *or on their behalf* to assess a risk, including a security risk, a risk of irregular immigration, or a

posed by a natural person who intends to enter or has entered into the territory of a Member State;

health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;

Or. en

Amendment 3205

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Sandro Gozi, Vlad-Marius Boto , Abir Al-Sahlani, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point b

Text proposed by the Commission

(b) AI systems intended to be used by competent public authorities to assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;

Amendment

(b) AI systems intended to be used by competent public authorities ***or on their behalf*** to assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;

Or. en

Amendment 3206

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä, Tineke Strik

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point c

Text proposed by the Commission

(c) AI systems intended to be used by competent public authorities for the verification of the authenticity of travel documents and supporting documentation of natural persons and detect non-authentic documents by checking their security features;

Amendment

(c) AI systems ***that may be or are*** intended to be used by competent public authorities for the verification of the authenticity of travel documents and supporting documentation of natural persons and detect non-authentic documents by checking their security features;

Or. en

Amendment 3207

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point c

Text proposed by the Commission

(c) AI systems intended to be used by competent public authorities for the verification of the authenticity of travel documents and supporting documentation of natural persons and detect non-authentic documents by checking their security features;

Amendment

(c) AI systems intended to be used by competent public authorities **or on their behalf** for the verification of the authenticity of travel documents and supporting documentation of natural persons and detect non-authentic documents by checking their security features;

Or. en

Amendment 3208

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia uriaș Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Alin Mituța

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point c

Text proposed by the Commission

(c) AI systems intended to be used by competent public authorities for the verification of the authenticity of travel documents and supporting documentation of natural persons and detect non-authentic documents by checking their security features;

Amendment

(c) AI systems intended to be used by competent public authorities **or on their behalf** for the verification of the authenticity of travel documents and supporting documentation of natural persons and detect non-authentic documents by checking their security features;

Or. en

Amendment 3209

Brando Benifei, 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

Annex III – paragraph 1 – point 7 – point d

Text proposed by the Commission

Amendment

(d) AI systems intended to assist competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status. *deleted*

Or. en

Justification

Moved to Article 5.

Amendment 3210

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point d

Text proposed by the Commission

Amendment

(d) AI systems intended to assist competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status. *deleted*

Or. en

Justification

Moved under prohibited practices in Article 5

Amendment 3211

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point d

Text proposed by the Commission

(d) AI systems intended to assist competent public authorities for the examination *of* applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.

Amendment

(d) AI systems intended to assist competent public authorities for the examination *and assessment of the veracity of evidence and claims in relation to* applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.

Or. en

Amendment 3212

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point d

Text proposed by the Commission

(d) AI systems intended to assist competent public authorities for the examination *of* applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.

Amendment

(d) AI systems intended to assist competent public authorities for the examination *and assessment of the veracity of evidence and claims in relation to* applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.

Or. en

Amendment 3213

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Alin Mituță

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point d

Text proposed by the Commission

(d) AI systems intended to assist competent public authorities *for* the examination of applications for asylum,

Amendment

(d) AI systems intended *to be used by competent public authorities or on their behalf or* to assist competent public

visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.

authorities *in* the examination of applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.

Or. en

Amendment 3214

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Sandro Gozi, Vlad-Marius Boto , Abir Al-Sahlani, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point d

Text proposed by the Commission

(d) AI systems intended to assist competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.

Amendment

(d) AI systems intended to assist competent public authorities *or on their behalf* for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.

Or. en

Amendment 3215

**Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä, Tineke Strik**

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point d

Text proposed by the Commission

(d) AI systems intended to assist competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.

Amendment

(d) AI systems *that may be or are* intended to assist competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.

Or. en

Amendment 3216

Svenja Hahn, Drago Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Abir Al-Sahlani, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation**Annex III – paragraph 1 – point 7 – point d**

Text proposed by the Commission

(d) AI systems intended to *assist* competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.

Amendment

(d) AI systems intended to ***be used by*** competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.

Or. en

Amendment 3217

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä, Tineke Strik

Proposal for a regulation**Annex III – paragraph 1 – point 7 – point d a (new)**

Text proposed by the Commission

Amendment

(d a) AI systems that may be or are intended to be used by competent public authorities for border management and immigration authorities to monitor, surveil or process data for the purpose of detecting, verifying or identifying natural persons.

Or. en

Amendment 3218

Sophia in 't Veld, Michal Šimek

Proposal for a regulation**Annex III – paragraph 1 – point 7 – point d a (new)**

Text proposed by the Commission

Amendment

(d a) AI systems intended to be used by or on behalf of competent authorities in migration, asylum and border control management for the forecasting or prediction of trends related to migration, movement and border crossings;

Or. en

Amendment 3219

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point d a (new)

Text proposed by the Commission

Amendment

(d a) AI systems intended to be used by or on behalf of competent authorities in migration, asylum and border control management for the forecasting or prediction of trends related to migration, movement and border crossings;

Or. en

Amendment 3220

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point d a (new)

Text proposed by the Commission

Amendment

(d a) AI systems intended to be used by or on behalf of competent authorities in migration, asylum and border control management for the forecasting or prediction of trends related to migration, movement and border crossings;

Or. en

Amendment 3221

Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point d a (new)

Text proposed by the Commission

Amendment

(d a) AI systems that are or may be used by or on behalf of competent authorities in law enforcement, migration, asylum and border control management for the biometric identification of natural persons;

Or. en

Amendment 3222

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä, Tineke Strik

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point d b (new)

Text proposed by the Commission

Amendment

(d b) AI systems that may be or are intended to be used for migration analytics regarding natural persons or groups, allowing immigration authorities or related entities to search complex related and unrelated large data sets available in different data sources or in different data formats in order to identify unknown patterns or discover hidden relationships in the data.

Or. en

Amendment 3223

Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point d b (new)

Text proposed by the Commission

Amendment

(d b) AI systems intended to be used by, or on behalf of, competent authorities in migration, asylum and border control management to monitor, surveil, or process data in the context of border management activities for the purpose of recognizing or detecting objects and natural persons;

Or. en

Amendment 3224

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point d b (new)

Text proposed by the Commission

Amendment

(d b) AI systems that are or may be used by or on behalf of competent authorities in law enforcement, migration, asylum and border control management for the biometric identification of natural persons;

Or. en

Amendment 3225

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point d b (new)

Text proposed by the Commission

Amendment

(d b) AI systems that are or may be used by or on behalf of competent authorities in law enforcement, migration, asylum and border control management for the biometric identification of natural persons;

Or. en

Amendment 3226

Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point d c (new)

Text proposed by the Commission

Amendment

(d c) AI systems intended to be used by, or on behalf of, competent authorities in migration, asylum and border control management to monitor, surveil or process data in the context of border management activities for the purpose of recognising or detecting objects and natural persons;

Or. en

Amendment 3227

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point d c (new)

Text proposed by the Commission

Amendment

(d c) AI systems intended to be used by, or on behalf of, competent authorities in migration, asylum and border control management to monitor, surveil or process data in the context of border management activities for the purpose of recognizing or detecting objects and natural persons;

Or. en

Amendment 3228

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Annex III – paragraph 1 – point 8

Text proposed by the Commission

Amendment

8. *Administration de la justice et processus démocratiques:* *supprimé*

(a) *les systèmes d'IA destinés à aider les autorités judiciaires à rechercher et à interpréter les faits et la loi, et à appliquer la loi à un ensemble concret de faits.*

Or. fr

Justification

Selon un amendement précédent, ces systèmes sont interdits, ils ne relèvent donc pas du régime commun des systèmes d'I.A. à haut risque figurant à l'annexe III.

Amendment 3229

Axel Voss, Deirdre Clune

Proposal for a regulation

Annex III – paragraph 1 – point 8 – introductory part

Text proposed by the Commission

Amendment

8. Administration of justice **and** democratic processes:

8. Administration of justice:

Or. en

Amendment 3230

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nută, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Alin Mituă

Proposal for a regulation

Annex III – paragraph 1 – point 8 – point a

Text proposed by the Commission

Amendment

(a) AI systems intended to assist a judicial authority in researching and interpreting facts **and** the law and in applying the law to a concrete set of facts.

(a) AI systems intended **to be used by a judicial authority or administrative body or on their behalf or** to assist a judicial authority **or administrative body** in researching and interpreting facts **or** the law and in applying the law to a concrete

set of facts.

Or. en

Amendment 3231

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 8 – point a

Text proposed by the Commission

(a) AI systems intended to assist a judicial authority in researching and interpreting facts and the law and in applying the law ***to a concrete set of facts.***

Amendment

(a) AI systems ***which may be or are*** intended to assist a judicial authority in researching and interpreting facts and the law and in applying the law ***or used in a similar way in alternative dispute resolution.***

Or. en

Amendment 3232

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 8 – point a

Text proposed by the Commission

(a) AI systems intended to ***assist*** a judicial authority in researching and interpreting facts and the law and ***in*** applying the law to a concrete set of facts.

Amendment

(a) AI systems intended to ***be used by*** a judicial authority, ***administrative body or on their behalf for*** in researching and interpreting facts and the law and ***for*** applying the law to a concrete set of facts.

Or. en

Amendment 3233

Svenja Hahn, Drago Tudorache, Nicola Beer, Karen Melchior, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Annex III – paragraph 1 – point 8 – point a

Text proposed by the Commission

(a) AI systems intended to *assist a judicial authority in researching and interpreting facts and the law and in applying the law to a concrete set of facts.*

Amendment

(a) AI systems intended to *be used by judicial authorities or on their behalf in interpreting facts or the law for applying the law to a concrete set of facts.*

Or. en

Amendment 3234

Sophia in 't Veld

Proposal for a regulation

Annex III – paragraph 1 – point 8 – point a a (new)

Text proposed by the Commission

Amendment

(a a) AI systems intended to be used by electoral constituencies for the purpose of protecting democracy and predicting the risk of a candidate for political office, in particular the position of head of government, being homophobic, sexist, dictatorial, kleptocratic and/or having other toxic personality traits;

Or. en

Amendment 3235

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Alin Mituă

Proposal for a regulation

Annex III – paragraph 1 – point 8 – point a a (new)

Text proposed by the Commission

Amendment

(a a) AI systems used by political parties, political candidates, public authorities, or on their behalf for influencing natural persons in the exercise of their vote in local, national, or European Parliament elections;

Amendment 3236

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 8 – point a a (new)

Text proposed by the Commission

Amendment

(a a) AI systems that may or are intended to assist in democratic processes, the casting or counting of votes, such as in elections.

Amendment 3237

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae tef nuță, Ramona Strugariu, Drago Pîslaru, Lucia urîș Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation

Annex III – paragraph 1 – point 8 a (new)

Text proposed by the Commission

Amendment

8 a. Other applications:

(a) AI systems intended to be used to generate, on the basis of limited human input, complex text content that would falsely appear to a person to be human generated and authentic, such as news articles, opinion articles, novels, scripts, and scientific articles, with the exception of AI systems used exclusively for content that undergoes human review and for the publication of which a natural or legal person established in the Union is liable or holds editorial responsibility;

(b) AI systems intended to be used to generate or manipulate audio or video content that features existing natural persons appearing to say or do something

they have never said or done, with the exception of AI systems used exclusively for content that forms part of an evidently artistic, creative or fictional cinematographic and analogous work;

(c)AI systems that deploy subliminal techniques for scientific research and for therapeutical purposes;

Or. en

Amendment 3238

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

Annex III – paragraph 1 – point 8 a (new)

Text proposed by the Commission

Amendment

8 a. Other applications:

(a) AI systems intended to be used to generate, on the basis of limited human input, complex text content that would falsely appear to a person to be human-generated and authentic, such as news articles, opinion articles, novels, scripts, and scientific articles, except where the content forms part of an evidently artistic, creative or fictional and analogous work;

(b) AI systems intended to be used to generate or manipulate audio or video content that appreciably resembles existing natural persons, in a manner that significantly distorts or fabricates the original situation, meaning, content, or context and would falsely appear to a person to be authentic, except where the content forms part of an evidently artistic, creative or fictional cinematographic and analogous work.

Or. en

Amendment 3239

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Annex III – paragraph 1 – point 8 a (new)

Text proposed by the Commission

Amendment

8 a. Use in online platforms such as social media and search engines:

- a) AI systems intended to recommend content to users of online intermediaries such as social media platforms and search engines*
- b) AI systems intended to assist the moderation of content produced by users of online intermediaries such as social media platforms.*

Or. en

Amendment 3240

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 8 a (new)

Text proposed by the Commission

Amendment

8 a. Media

(a). Recommender systems, meaning AI systems used by an online platform to suggest in its online interface specific information to recipients of the service, including as a result of a search initiated by the recipient or otherwise determining the relative order or prominence of information displayed.

Or. en

Amendment 3241

Maria-Manuel Leitão-Marques, Paul Tang, Tiemo Wölken, Biljana Borzan, Lina

Gálvez Muñoz, Birgit Sippel, Martin Schirdewan, Christel Schaldemose, Alex Agius
Saliba, Karen Melchior, René Repasi, Eva Kaili, Sylvie Guillaume

Proposal for a regulation

Annex III – paragraph 1 – point 8 a (new)

Text proposed by the Commission

Amendment

8 a. Others

a) AI systems intended to be used for the delivery of online advertising to internet users

Or. en

Justification

As ad delivery algorithms determine who within the potential audiences as defined by the sponsors will actually have the ad presented to them, they pose two types of risks to fundamental rights. First, the use of ad delivery algorithms in general poses serious threats to the rights enshrined in Article 7 and Article 8 (respect of private and family life, protection of personal data) of the Charter of Fundamental Rights of the European Union. Second, the deployment of ad delivery algorithms to optimise (economically) the delivery of ads containing specific content, including working and housing opportunities, constitutes a serious risk to the fundamental right to non-discrimination as established in Article 21 of the Charter. In addition, it could be argued that there are harms to mental health in the presentation of certain advertisements to vulnerable users designed to exploit their vulnerabilities, such as with the case of gambling ads. Lastly, it is clear that, for ad delivery algorithms, there are at present no effective measures of redress in relation to the risks posed by the systems, nor any effective measures to prevent or substantially minimise those risks, provided for in existing Union legislation. Thus, they meet several of the criteria present in Article 7 and should be included in Annex III as high-risk AI systems

Amendment 3242

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex III – paragraph 1 – point 8 b (new)

Text proposed by the Commission

Amendment

8 b. Health and Healthcare

(a) AI systems intended to be used inside or outside of the national healthcare system the outputs of which can influence individuals' health, for example through

impacting health diagnostics, treatments or medical prescriptions.

(b) AI systems intended to be used to facilitate administrative, planning, and health insurance processes within the healthcare system which could influence the distribution of healthcare resources, health insurance or access to healthcare.

(c) AI systems intended to be used by pharmaceutical companies and medical technology companies to facilitate research and development, as well as for pharmacovigilance, market optimisation and pharmaceutical marketing.

Or. en

Amendment 3243

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex IV – paragraph 1 – point 1 – point a

Text proposed by the Commission

(a) its intended purpose, the person/s developing the system the date and the version of the system;

Amendment

(a) its intended purpose, the person/s developing the system the date and the version of the system, *reflecting its relation to previous and, where applicable, more recent, versions in the succession of revisions*;

Or. en

Amendment 3244

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand

Proposal for a regulation

Annex IV – paragraph 1 – point 1 – point a

Text proposed by the Commission

Amendment

(a) its intended purpose, the person/s developing the system the date and the version of the system;

(a) its intended purpose ***or reasonably foreseeable use***, the person/s developing the system, the date and the version of the system;

Or. en

Amendment 3245

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex IV – paragraph 1 – point 1 – point a

Text proposed by the Commission

(a) its intended purpose, the person/s developing the system the date and the version of the system;

Amendment

(a) its intended purpose ***or reasonably foreseeable use***, the person/s developing the system the date and the version of the system;

Or. en

Amendment 3246

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

Annex IV – paragraph 1 – point 1 – point a

Text proposed by the Commission

(a) its intended purpose, the person/s developing the system the date and the version of the system;

Amendment

(a) its intended purpose ***or reasonably foreseeable use***, the person/s developing the system the date and the version of the system;

Or. en

Amendment 3247

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 1 – point a

Text proposed by the Commission

Amendment

(a) its intended purpose, the **person/s developing the system the date** and the version of the system;

(a) its intended purpose, the **name of the provider** and the version of the system;

Or. en

Amendment 3248

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex IV – paragraph 1 – point 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) the categories of natural persons and groups likely or foreseen to be affected;

Or. en

Amendment 3249

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex IV – paragraph 1 – point 1 – point a b (new)

Text proposed by the Commission

Amendment

(a b) the categories and nature of data likely or foreseen to be processed;

Or. en

Amendment 3250

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation
Annex IV – paragraph 1 – point 1 – point b

Text proposed by the Commission

(b) how the AI system interacts or can be used to interact with hardware or software **that is** not part of the AI system itself, where applicable;

Amendment

(b) how the AI system interacts or can be used to interact with hardware or software, **including other AI systems that are** not part of the AI system itself, where applicable;

Or. en

Amendment 3251

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Maria Grapini, Brando Benifei

Proposal for a regulation
Annex IV – paragraph 1 – point 1 – point b

Text proposed by the Commission

(b) how the AI system interacts or can be used to interact with hardware or software **that is** not part of the AI system itself, where applicable;

Amendment

(b) how the AI system interacts or can be used to interact with hardware or software, **including other AI systems, that are** not part of the AI system itself, where applicable;

Or. en

Amendment 3252

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Annex IV – paragraph 1 – point 1 – point b

Text proposed by the Commission

(b) how the AI system **interacts or can be used to interact** with hardware or software that is not part of the AI system itself, where applicable;

Amendment

(b) how the AI system **is intended to be used** with hardware or software that is not part of the AI system itself, where applicable;

Or. en

Amendment 3253

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex IV – paragraph 1 – point 1 – point c

Text proposed by the Commission

- (c) the versions of relevant software or firmware and any requirement related to version update;

Amendment

- (c) the versions of relevant software or firmware and any requirement related to ***development, maintenance and*** version update;

Or. en

Amendment 3254

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 1 – point c

Text proposed by the Commission

- (c) the versions of relevant software or firmware and ***any requirement related to*** version update;

Amendment

- (c) the versions of relevant software or firmware and version update ***information for the user, where applicable;***

Or. en

Amendment 3255

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 1 – point d

Text proposed by the Commission

- (d) the description ***of all forms in which*** the AI system ***is placed*** on the market or put into service;

Amendment

- (d) the description ***or list of the various configurations and variants of*** the AI system ***which are intended to be made available*** on the market or put into service;

Or. en

Amendment 3256

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 1 – point f

Text proposed by the Commission

(f) *where the AI system is a component of products, photographs or illustrations showing external features, marking and internal layout of those products;*

Amendment

(f) *descriptions and, if applicable, photographs or illustrations of the user interface;*

Or. en

Amendment 3257

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex IV – paragraph 1 – point 1 – point g

Text proposed by the Commission

(g) instructions of use for the *user* and, where applicable installation instructions;

Amendment

(g) instructions of use for the *deployer* and, where applicable installation instructions;

Or. en

Amendment 3258

Kim Van Sparrentak, Sergey Lagodinsky

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex IV – paragraph 1 – point 1 – point g a (new)

Text proposed by the Commission

Amendment

(g a) instructions on the intervention in case of emergency, interrupting the system through a “stop” button or a similar procedure that allows the system to come to a halt in a safe state;

Or. en

Justification

To align with proposed Article 14(4)(e)

Amendment 3259

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 2 – introductory part

Text proposed by the Commission

2. A detailed description *of the elements* of the AI system and of the process for its development, including:

Amendment

2. *Provided that no confidential information or trade secrets are disclosed,* a detailed description of the AI system and of the process for its development, including:

Or. en

Amendment 3260

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Annex IV – paragraph 1 – point 2 – point a

Text proposed by the Commission

(a) the methods and steps performed for the development of the AI system, including, where relevant, recourse to pre-trained systems or tools provided by third parties and how these have been used, integrated or modified by the provider;

Amendment

(a) *provided that no confidential information or trade secrets are disclosed,* the methods and steps performed for the development of the AI system, including, where relevant, recourse to pre-trained systems or tools provided by third parties and how these have been used, integrated or modified by the provider;

Or. en

Amendment 3261

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 2 – point b

Text proposed by the Commission

(b) the design specifications of the system, *namely the general logic of the AI system and of the algorithms*; the key design choices including the rationale and assumptions made, also with regard to persons or groups of persons on which the system is intended to be used; the main classification choices; what the system is designed to optimise for and the relevance of the different parameters; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Title III, Chapter 2;

Amendment

(b) the *architecture and* design specifications: *a description of the AI system architecture, with a decomposition of its components and interfaces, how they relate to one another and how they provide for the overall processing or* logic of the AI system; the key design choices including the rationale and assumptions made, also with regard to persons or groups of persons on which the system is intended to be used; the main classification choices; what the system is designed to optimise for and the relevance of the different parameters; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Title III, Chapter 2;

Or. en

Amendment 3262

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Annex IV – paragraph 1 – point 2 – point b

Text proposed by the Commission

(b) the design specifications of the system, namely the general logic of the AI system and of the algorithms; the key design choices including the rationale and assumptions made, also with regard to persons or groups of persons on which the system is intended to be used; the main classification choices; what the system is designed to optimise for and the relevance

Amendment

(b) *provided that no confidential information or trade secrets are disclosed*, the design specifications of the system, namely the general logic of the AI system and of the algorithms; the key design choices including the rationale and assumptions made, also with regard to persons or groups of persons on which the system is intended to be used; the main

of the different parameters; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Title III, Chapter 2;

classification choices; what the system is designed to optimise for and the relevance of the different parameters; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Title III, Chapter 2;

Or. en

Amendment 3263

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex IV – paragraph 1 – point 2 – point b

Text proposed by the Commission

(b) the design specifications of the system, namely the general logic of the AI system **and** of the algorithms; the key design choices including the rationale and assumptions made, also with regard to persons or groups of persons on which the system is intended to be used; the main classification choices; what the system is designed to optimise for and the relevance of the different parameters; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Title III, Chapter 2;

Amendment

(b) the design specifications of the system, namely the general logic of the AI system, of the algorithms **and of data structures**; the key design choices including the rationale and assumptions made, also with regard to persons or groups of persons on which the system is intended to be used; the main classification choices; what the system is designed to optimise for and the relevance of the different parameters; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Title III, Chapter 2;

Or. en

Amendment 3264

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 2 – point c

Text proposed by the Commission

Amendment

(c) the description of the system architecture explaining how software components build on or feed into each other and integrate into the overall processing; the computational resources used to develop, train, test and validate the AI system;

deleted

Or. en

Amendment 3265

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 2 – point d

Text proposed by the Commission

Amendment

(d) where relevant, the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used, including information about the provenance of those data sets, their scope and main characteristics; how the data was obtained and selected; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection);

deleted

Or. en

Amendment 3266

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex IV – paragraph 1 – point 2 – point d

Text proposed by the Commission

Amendment

(d) where relevant, the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used,

(d) where relevant, the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used,

including information about the provenance of those data sets, their scope and main characteristics; how the data was obtained **and** selected; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection);

including information about the provenance of those data sets, their scope and main characteristics; how the data was obtained, selected **and prepared**; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection), **and methods applied to prevent bias**;

Or. en

Amendment 3267

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex IV – paragraph 1 – point 2 – point e

Text proposed by the Commission

(e) assessment of the human oversight measures needed in accordance with Article 14, including an assessment of the technical measures needed to facilitate the interpretation of the outputs of AI systems by the **users**, in accordance with Articles 13(3)(d);

Amendment

(e) assessment of the human oversight measures needed in accordance with Article 14, including an assessment of the technical measures needed to facilitate the interpretation of the outputs of AI systems by the **deployers**, in accordance with Articles 13(3)(d);

Or. en

Amendment 3268

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 2 – point g

Text proposed by the Commission

(g) the validation and testing procedures used, including information about the validation and testing data used and their main characteristics; **metrics** used to measure accuracy, robustness, **cybersecurity** and compliance with other relevant requirements set out in Title III,

Amendment

(g) the validation and testing procedures used, including information about the **machine-learning** validation and testing data used and their main characteristics; **information** used to measure accuracy, robustness, and compliance with other relevant

Chapter 2 as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point (f).

requirements set out in Title III, Chapter 2 as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point (f);

Or. en

Amendment 3269

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini, Brando Benifei

Proposal for a regulation

Annex IV – paragraph 1 – point 2 – point g

Text proposed by the Commission

(g) the validation and testing procedures used, including information about the validation and testing data used and their main characteristics; metrics used to measure **accuracy**, robustness, cybersecurity and compliance with other relevant requirements set out in Title III, Chapter 2 as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point (f).

Amendment

(g) the validation and testing procedures used, including information about the validation and testing data used and their main characteristics; metrics used to measure **performance**, robustness, cybersecurity and compliance with other relevant requirements set out in Title III, Chapter 2 as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point (f).

Or. en

Amendment 3270

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex IV – paragraph 1 – point 2 – point g

Text proposed by the Commission

(g) the validation and testing procedures used, including information about the validation and testing data used and their main characteristics; metrics used

Amendment

(g) the validation and testing procedures used, including information about the validation and testing data used and their main characteristics; metrics used

to measure **accuracy**, robustness, cybersecurity and compliance with other relevant requirements set out in Title III, Chapter 2 as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point (f).

to measure **performance**, robustness, cybersecurity and compliance with other relevant requirements set out in Title III, Chapter 2 as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point (f).

Or. en

Amendment 3271

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 2 – point g a (new)

Text proposed by the Commission

Amendment

(g a) cybersecurity measures put in place.

Or. en

Amendment 3272

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex IV – paragraph 1 – point 3

Text proposed by the Commission

Amendment

3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI

3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose **or reasonably foreseeable use**; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in

system; the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate;

view of the intended purpose *or reasonably foreseeable use* of the AI system; the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate;

Or. en

Amendment 3273

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar

Proposal for a regulation

Annex IV – paragraph 1 – point 3 a (new)

Text proposed by the Commission

Amendment

3 a. A description of the appropriateness of the performance metrics for the specific AI system;

Or. en

Amendment 3274

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

Annex IV – paragraph 1 – point 3 a (new)

Text proposed by the Commission

Amendment

3 a. A description of the appropriateness of the performance metrics for the specific AI system.

Or. en

Amendment 3275

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

Annex IV – paragraph 1 – point 3 b (new)

Text proposed by the Commission

Amendment

3 b. Detailed information about the carbon footprint and the energy efficiency of the AI system, in particular with regard to the development of hardware, computational resources, as well as algorithm design and training processes;

Or. en

Amendment 3276

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

Annex IV – paragraph 1 – point 3 c (new)

Text proposed by the Commission

Amendment

3 c. Information about the computational resources required for the functioning of the AI system and its expected energy consumption during its use;

Or. en

Amendment 3277

**Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä**

Proposal for a regulation

Annex IV – paragraph 1 – point 4 a (new)

Text proposed by the Commission

Amendment

4 a. A detailed description of the

system's environmental impact in accordance with Article 10a.

Or. en

Justification

To align with proposed Article 10a

Amendment 3278

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 5

Text proposed by the Commission

Amendment

5. *A description of any change made deleted to the system through its lifecycle;*

Or. en

Amendment 3279

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Boto , Moritz Körner, Ondej Kovačík, Jan-Christoph Oetjen

Proposal for a regulation

Annex IV – paragraph 1 – point 5

Text proposed by the Commission

Amendment

5. A description of *any change made* to the system through its lifecycle;

5. A description of *relevant changes made by providers* to the system through its lifecycle;

Or. en

Amendment 3280

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Tefnută, Ramona Strugariu, Drago Pîslaru, Lucia Ūriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituță

Proposal for a regulation

Annex IV – paragraph 1 – point 5

Text proposed by the Commission

5. A description of any change made to the system through its lifecycle;

Amendment

5. A description of any **relevant** change made to the system through its lifecycle;

Or. en

Amendment 3281

Svenja Hahn, Drago Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Annex IV – paragraph 1 – point 6

Text proposed by the Commission

6. A list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union; where no such harmonised standards have been applied, a detailed description of the solutions adopted to meet the requirements set out in Title III, Chapter 2, including a list of other relevant standards and technical specifications applied;

Amendment

6. A list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union; where no such harmonised standards have been applied, a detailed description of the solutions adopted to meet the requirements set out in Title III, Chapter 2, including a list of **common specifications or** other relevant standards and technical specifications applied;

Or. en

Amendment 3282

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex IV – paragraph 1 – point 8 a (new)

Text proposed by the Commission

Amendment

8 a. Without prejudice to Article 9(2), a detailed description of the economic and social implications and potential risks for health, and in particular mental health, safety and fundamental rights arising from the hypothetical widespread usage of

the AI system or of similar systems in society, with reference to past incidents that occurred using similar systems and associated mitigating measures.

Or. en

Amendment 3283

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Annex VI

Text proposed by the Commission

Amendment

PROCÉDURE D'ÉVALUATION DE LA CONFORMITÉ FONDÉE SUR LE CONTRÔLE INTERNE

supprimé

- 1. La procédure d'évaluation de la conformité fondée sur le contrôle interne est la procédure d'évaluation de la conformité décrite aux points 2 à 4.*
- 2. Le fournisseur vérifie que le système de gestion de la qualité établi est conforme aux exigences de l'article 17.*
- 3. Le fournisseur examine les informations contenues dans la documentation technique afin d'évaluer la conformité du système d'IA avec les exigences essentielles pertinentes énoncées au titre III, chapitre 2.*
- 4. Le fournisseur vérifie également que le processus de conception et de développement du système d'IA et son système de surveillance après commercialisation prévu à l'article 61 sont cohérents avec la documentation technique.*

Or. fr

Justification

Nous supprimons cette procédure qui ne présente pas à nos yeux assez de fiabilité.

Amendment 3284**Axel Voss, Deirdre Clune, Eva Maydell****Proposal for a regulation****Annex VII – point 4 – point 4.3***Text proposed by the Commission*

4.3. The technical documentation shall be examined by the notified body. To this purpose, the notified body shall be granted full access to the ***training and*** testing datasets used by the provider, including through application programming interfaces (API) or other appropriate means and tools enabling remote access.

Amendment

4.3. The technical documentation shall be examined by the notified body. To this purpose, the notified body shall be granted full access to the testing datasets used by the provider, including through application programming interfaces (API) or other appropriate means and tools enabling remote access.

Or. en

Amendment 3285**Axel Voss, Deirdre Clune, Eva Maydell****Proposal for a regulation****Annex VII – point 4 – point 4.4***Text proposed by the Commission*

4.4. In examining the technical documentation, the notified body may require that the provider supplies further evidence or carries out further tests so as to enable a proper assessment of conformity of the AI system with the requirements set out in Title III, Chapter 2. ***Whenever the notified body is not satisfied with the tests carried out by the provider, the notified body shall directly carry out adequate tests, as appropriate.***

Amendment

4.4. In examining the technical documentation, the notified body may require that the provider supplies further evidence or carries out further tests so as to enable a proper assessment of conformity of the AI system with the requirements set out in Title III, Chapter 2.

Or. en

Amendment 3286**Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan Nută, Ramona Strugariu, Drago Pîslaru, Lucia Šuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin**

Mituța

Proposal for a regulation Annex VII – point 4 – point 4.5

Text proposed by the Commission

4.5. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the notified body shall also be granted access to the source code of the AI system.

Amendment

4.5. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2, *after all other reasonable ways to verify conformity have been exhausted and have proven to be insufficient*, and upon a reasoned request, the notified body shall also be granted access to the source code of the AI system. *Such access shall be subject to existing Union law on the protection of intellectual property and trade secrets.*

Or. en

Amendment 3287

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation Annex VII – point 4 – point 4.7

Text proposed by the Commission

4.7. Any change to the AI system that could affect the compliance of the AI system with the requirements or its intended purpose shall be approved by the notified body which issued the EU technical documentation assessment certificate. The provider shall inform such notified body of its intention to introduce any of the above-mentioned changes or if it becomes otherwise aware of the occurrence of such changes. The intended changes shall be assessed by the notified body which shall decide whether those changes require a new conformity assessment in accordance with Article 43(4) or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In

Amendment

4.7. Any change to the AI system that could affect the compliance of the AI system with the requirements or its intended purpose *or reasonably foreseeable use* shall be approved by the notified body which issued the EU technical documentation assessment certificate. The provider shall inform such notified body of its intention to introduce any of the above-mentioned changes or if it becomes otherwise aware of the occurrence of such changes. The intended changes shall be assessed by the notified body which shall decide whether those changes require a new conformity assessment in accordance with Article 43(4) or whether they could be addressed by means of a supplement to the EU technical

the latter case, the notified body shall assess the changes, notify the provider of its decision and, where the changes are approved, issue to the provider a supplement to the EU technical documentation assessment certificate.

documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the provider of its decision and, where the changes are approved, issue to the provider a supplement to the EU technical documentation assessment certificate.

Or. en

Amendment 3288

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Annex VIII – title**

Text proposed by the Commission

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF HIGH-RISK AI SYSTEMS IN ACCORDANCE WITH ARTICLE 51

Amendment

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF HIGH-RISK AI SYSTEMS **AND OF CERTAIN AI SYSTEMS, USES THEREOF, AND USES OF AI SYSTEMS BY PUBLIC AUTHORITIES** IN ACCORDANCE WITH ARTICLE 51

Or. en

Amendment 3289

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

**Proposal for a regulation
Annex VIII – title**

Text proposed by the Commission

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF **HIGH-RISK** AI SYSTEMS IN ACCORDANCE WITH ARTICLE 51

Amendment

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF AI SYSTEMS IN ACCORDANCE WITH ARTICLE 60

Or. en

Amendment 3290**Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura****Proposal for a regulation****Annex VIII – paragraph 1***Text proposed by the Commission*

The following information shall be provided and thereafter kept up to date with regard to high-risk AI systems to be registered in accordance with Article 51.

Amendment

The following information shall be provided and thereafter kept up to date *by the provider* with regard to high-risk AI systems *referred to in Article 6(2) and to any AI system referred to in Article 52 1(b) and (2)* to be registered in accordance with Article 51(1).

Or. en

Amendment 3291**Kim Van Sparrentak, Sergey Lagodinsky**

on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä**Proposal for a regulation****Annex VIII – paragraph 1***Text proposed by the Commission*

The following information shall be provided and thereafter kept up to date with regard to *high-risk* AI systems to be registered in accordance with Article 51.

Amendment

The following information shall be provided and thereafter kept up to date with regard to AI systems to be registered in accordance with Article 51.

Or. en

Amendment 3292**Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini****Proposal for a regulation****Annex VIII – paragraph 1***Text proposed by the Commission*

The following information shall be provided and thereafter kept up to date

Amendment

The following information shall be provided and thereafter kept up to date

with regard to **high-risk** AI systems to be registered in accordance with Article 51.

with regard to AI systems to be registered in accordance with Article 60.

Or. en

Amendment 3293

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex VIII – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The following information shall be provided and thereafter kept up to date by the user with regard to uses of high-risk AI systems referred to in Article 6(2) and any AI system referred to in Article 52 I(b) and (2) to be registered in accordance with Article 51(2).

- (a) Name, address and contact details of the user;*
- (b) Where submission of information is carried out by another person on behalf of the user, the name, address and contact details of that person;*
- (c) Name, address and contact details of the authorised representative, where applicable;*
- (d) URL of the entry of the AI system in the EU database by its provider, or, where unavailable, AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system;*
- (e) Description of the intended purpose of the intended use of the AI system;*
- (f) Description of the context and the geographical and temporal scope of application, geographic and temporal, of the intended use of the AI system;*
- (g) Basic explanation of design specifications of the system, namely the general logic of the AI system and of the algorithms; the key design choices*

including the rationale and assumptions made, also with regard to categories persons or groups of persons on which the system is intended to be used; the main classification choices; and what the system is designed to optimise for and the relevance of the different parameters.

(h) For high-risk AI systems and for systems referred to in Article 52 1(b) and (2), designation of persons foreseeably impacted by the intended use of the AI system as required by Article X;

(i) For high-risk AI systems, results of the impact assessment on the use of the AI system that is conducted under obligations imposed by Article XX of this Regulation. Where full public disclosure of these results cannot be granted for reasons of privacy and data protection, disclosure must be granted to the national supervisory authority, which in turn must be indicated in the EU database.

(j) A description of how the relevant accessibility requirements set out in Annex I to Directive 2019/882 are met by the use of the AI system.

Or. en

Amendment 3294

Drago Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefan nuță, Ramona Strugariu, Drago Pîslaru, Lucia ūriš Nicholsonová, Irena Joveva, Malik Azmani, Róza Thun und Hohenstein, Alin Mituță

Proposal for a regulation

Annex VIII – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The following information shall be provided and updated with regard to high risk AI systems to be registered in accordance with Article 51(2) by users who are or act on behalf of public authorities or Union institutions, bodies, offices or agencies:

- 1. the name, address and contact details of the user;*
- 2. the name, address and contact details of any person submitting information on behalf of the user;*
- 3. the high-risk AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system used;*
- 4. description of the intended use of the AI system, including the specific outcomes sought through the use of the system;*
- 5. a summary of the findings of the fundamental rights impact assessment conducted in accordance with the obligation of public authorities or Union institutions, agencies, offices or bodies set out in this Regulation;*
- 6. a summary of the data protection impact assessment carried out in accordance with Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680 as specified in paragraph 6 of Article 29 of this Regulation, where applicable; 6. a declaration of conformity with the applicable data protection rules.*

Or. en

Amendment 3295

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex VIII – paragraph 1 b (new)

Text proposed by the Commission

Amendment

The following information shall be provided and thereafter kept up to date by the user with regard to uses of AI systems by public authorities to be registered in accordance with Article 51(3).

(a) Name, address and contact details of the user;(b) Where submission of

information is carried out by another person on behalf of the user, the name, address and contact details of that person;

(c) Name, address and contact details of the authorised representative, where applicable;

(d) For high-risk AI systems, URL of the entry of the AI system in the EU database by its provider, or, for non-high risk systems, AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system;

(e) Description of the intended purpose of the intended use of the AI system;

(f) Description of the context and the geographical and temporal scope of application, geographic and temporal, of the intended use of the AI system;

(g) Basic explanation of design specifications of the system, namely the general logic of the AI system and of the algorithms; the key design choices including the rationale and assumptions made, also with regard to categories persons or groups of persons on which the system is intended to be used; the main classification choices; and what the system is designed to optimise for and the relevance of the different parameters.

(h) Designation of persons foreseeably impacted by the intended use of the AI system;

(i) If available, results of any impact assessment or due diligence process regarding the use of the AI system that the user has conducted;

(j) Assessment of the foreseeable impact on the environment, including but not limited to energy consumption, resulting from the use of the AI system over its entire lifecycle, and of the methods to reduce such impact;

(k) A description of how the relevant accessibility requirements set out in Annex I to Directive 2019/882 are met by

the use of the AI system.

Or. en

Amendment 3296

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex VIII – point 1

Text proposed by the Commission

1. Name, address and contact details of the provider;

Amendment

1. Name, address and contact details of the provider *or deployer*;

Or. en

Amendment 3297

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex VIII – point 2

Text proposed by the Commission

2. Where submission of information is carried out by another person on behalf of the provider, the name, address and contact details of that person;

Amendment

2. Where submission of information is carried out by another person on behalf of the provider *or deployer*, the name, address and contact details of that person;

Or. en

Amendment 3298

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation

Annex VIII – point 3

Text proposed by the Commission

3. Name, address and contact details of the **authorised** representative, where applicable;

Amendment

3. Name, address and contact details of the **legal** representative, where applicable;

Or. en

Amendment 3299

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation
Annex VIII – point 5

Text proposed by the Commission

5. **Description of** the intended purpose of the AI system;

Amendment

5. **Descriptions of:**

- (a) the intended purpose of the AI system;
- (b) **the components and functions supported through AI;**
- (c) **the main parameters the AI system takes into account;**
- (d) **arrangements for human oversight and responsible natural persons for decisions made or influenced by the AI system;**

Or. en

Amendment 3300

Pernando Barrena Arza, Kate ina Kone ná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Annex VIII – point 5

Text proposed by the Commission

5. Description of the intended purpose of the AI system;

Amendment

5. Description of the intended purpose **or reasonably foreseeable use** of the AI system;

Or. en

Amendment 3301

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex VIII – point 5 a (new)

Text proposed by the Commission

Amendment

5 a. Where applicable, the categories of natural persons and groups likely or foreseen to be affected;

Or. en

Amendment 3302

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex VIII – point 5 b (new)

Text proposed by the Commission

Amendment

5 b. Where applicable, the categories and nature of data likely or foreseen to be processed by the AI system;

Or. en

Amendment 3303

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group
Alexandra Geese, Alviina Alametsä

Proposal for a regulation

Annex VIII – point 5 c (new)

Text proposed by the Commission

Amendment

5 c. For each deployment, the deployer's assessments of the assessment of the systems' impact in the context of use throughout the entire lifecycle as conducted by the deployer under Article 9a;

Or. en

Amendment 3304

Sophia in 't Veld, Michal Šimek

Proposal for a regulation

Annex VIII – point 6 a (new)

Text proposed by the Commission

Amendment

6 a. where the user is obliged to register an AI system under Article 29, the human rights impact assessment must also be registered and publicly available;

Or. en

Amendment 3305

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex VIII – point 11

Text proposed by the Commission

Amendment

11. Electronic instructions for use; this information shall not be provided for high-risk AI systems in the areas of law enforcement and migration, asylum and border control management referred to in Annex III, points 1, 6 and 7.

deleted

Or. en

Amendment 3306

Kim Van Sparrentak, Sergey Lagodinsky
on behalf of the Verts/ALE Group

Alexandra Geese, Alviina Alametsä

**Proposal for a regulation
Annex VIII – point 11**

Text proposed by the Commission

11. Electronic instructions for use; *this information shall not be provided for high-risk AI systems in the areas of law enforcement and migration, asylum and border control management referred to in Annex III, points 1, 6 and 7.*

Amendment

11. Electronic instructions for use.

Or. en

Amendment 3307

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Annex VIII – point 11**

Text proposed by the Commission

11. Electronic instructions for use; *this information shall not be provided for high-risk AI systems in the areas of law enforcement and migration, asylum and border control management referred to in Annex III, points 1, 6 and 7.*

Amendment

11. Electronic instructions for use *as listed in Article 13(3) and basic explanation of the general logic and key design as listed in Annex IV point 2(b) and of optimization choices as listed in Annex IV point (3).*

Or. en

Amendment 3308

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

**Proposal for a regulation
Annex VIII – point 11 a (new)**

Text proposed by the Commission

Amendment

11 a. Assessment of the environmental impact, including but not limited to resource consumption, resulting from the design, data management and training, and underlying infrastructures of the AI

system, and of the methods to reduce such impact;

Or. en

Amendment 3309

Kate ina Kone ná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Annex VIII – point 11 b (new)

Text proposed by the Commission

Amendment

11 b. A description of how the system meets the relevant accessibility requirements of Annex I to Directive 2019/882.

Or. en

Amendment 3310

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation

Annex VIII – point 12 a (new)

Text proposed by the Commission

Amendment

12 a. The list of users of the AI systems

Or. en

Amendment 3311

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IX – title

Text proposed by the Commission

Amendment

Union legislation ON large-scale IT systems in the area of Freedom, Security and Justice

ANNEX IXa: MODALITIES FOR AN EU AI REGULATORY SANDBOXING WORK PROGRAMME

1. The AI Regulatory Sandboxes shall be part of the EU AI Regulatory Sandboxing Programme ('sandboxing programme') to be established by the Commission in collaboration with Member States.

2. 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 of these regulatory sandboxes.

3. Participants in the sandboxing programme, in particular small-scale providers, are granted access to pre-deployment services, such as preliminary registration of their AI system, compliance 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 & Experimentation Facilities, Digital Hubs, Centres of Excellence, and EU benchmarking capabilities; and to other value-adding services such as standardisation documents and certification, an online social platform for the community, contact databases, existing portal for tenders and grant making and lists of EU investors.

4. The sandboxing programme shall, in a later development phase, look at helping Member States develop and manage two types of regulatory sandboxes: Physical Regulatory Sandboxes for AI systems embedded in physical products or services and Cyber Regulatory Sandboxes for AI systems operated and used on a stand-alone basis, not embedded in physical products or services.

5. The sandboxing programme shall work with the already established Digital Innovation Hubs in Member States to provide a dedicated point of contact for entrepreneurs to raise enquiries with competent authorities and to seek non-binding guidance on the conformity of innovative products, services or business

models embedding AI technologies.

6. One of the objectives of the sandboxing programme is to enable firms' compliance with this Regulation at the design stage of the AI system ('compliance-by-design'). To do so, the programme shall facilitate the development of software tools and infrastructure for testing, benchmarking, assessing and explaining dimensions of AI systems relevant to sandboxes, such as accuracy, robustness and cybersecurity

7. The sandboxing programme shall be rolled out in a phased fashion, with the various phases launched by the Commission upon success of the previous phase.

8. The sandboxing programme will have a built-in impact assessment procedure to facilitate the review of cost-effectiveness against the agreed-upon objectives. This assessment shall be drafted with input from Member States based on their experiences and shall be included as part of the Annual Report submitted by the Commission to the European Artificial Intelligence Board.

Or. en

Justification

@ LIBE Secretariat: please shift this block behind Annex IX as new ANNEX X! AT4AM is unfortunately not allowing the user to do it.

Amendment 3312

Svenja Hahn, Nicola Beer, Sandro Gozi, Vlad-Marius Boto , Moritz Körner, Ond ěj Ková ík, Jan-Christoph Oetjen

**Proposal for a regulation
Annex IX a (new)**

Text proposed by the Commission

Amendment

**ANNEX IXa:
MODALITIES FOR AN EU AI
REGULATORY SANDBOXING
PROGRAMME**

- 1. The European Commission shall establish the EU AI Regulatory Sandboxing Programme ('sandboxing programme') in collaboration with Member States and other competent entities such as regions or universities.*
- 2. The Commission shall play a complementary role, allowing those entities 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 and regions that seek guidance on the set-up of these regulatory sandboxes.*
- 3. Participants in the sandboxing programme, in particular start-ups and SMEs, are granted access to pre-deployment services, such as preliminary registration of their AI system, compliance 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 &Experimentation Facilities, Digital Hubs, Centres of Excellence, and EU benchmarking capabilities; and to other value-adding services such as standardisation documents and certification, an online social platform for the community, contact databases, existing portal for tenders and grant making and lists of EU investors.*
- 4. Foreign providers, in particular start-ups and SMEs, are eligible to take part in the sandboxes to incubate and refine their products in compliance with this Regulation.*
- 5. Individuals such as researchers, entrepreneurs, innovators and other pre-market ideas owners are eligible to pre-register into the sandboxing programme to incubate and refine their products in compliance with this Regulation.*
- 6. The sandboxing programme and its benefits shall be available from a single portal established by the European*

Commission.

7. The sandboxing programme shall develop and manage two types of regulatory sandboxes: Physical Regulatory Sandboxes for AI systems embedded in physical products or services and Cyber Regulatory Sandboxes for AI systems operated and used on a stand-alone basis, not embedded in physical products or services.

8. The sandboxing programme shall work with the already established Digital Innovation Hubs in Member States to provide a dedicated point of contact for entrepreneurs to raise enquiries with competent authorities and to seek non-binding guidance on the conformity of innovative products, services or business models embedding AI technologies.

9. One of the objectives of the sandboxing programme is to enable firms' compliance with this Regulation at the design stage of the AI system ('compliance-by-design'). To do so, the programme shall facilitate the development of software tools and infrastructure for testing, benchmarking, assessing and explaining dimensions of AI systems relevant to sandboxes, such as accuracy, robustness and cybersecurity.

10. The sandboxing programme shall include a Reg Tech lab, to help authorities experiment and develop enforcement tools and protocols for enforcing this Regulation.

11. The sandboxing programme shall be rolled out in a phased fashion, with the various phases launched by the Commission upon success of the previous phase. The sandboxing programme will have a built-in impact assessment procedure to facilitate the review of cost-effectiveness against the agreed-upon objectives. This assessment shall be drafted with input from Member States based on their experiences and shall be included as part of the Annual Report submitted by the Commission to the

European Artificial Intelligence Board.

Or. en